10 Operations of the Deposit System

The patent microorganism deposit system is intended to ensure that third parties will be able to work biological inventions. An international depositary authority (IDA) as defined under the Budapest Treaty must store deposited microorganisms for at least for thirty years, and also for five years from the latest furnishing. During that period, deposited microorganisms must be available for furnishing. On the other hand, some users say that preparing the quantity of samples required by a depositary institution before patent filing is a heavy burden. Therefore, reduction of burden in depositing is being requested in the field of biotechnology, which is making remarkable progress.

With regard to these issues under consideration, this study has determined the deposit systems of major countries and overseas institutions, the actual conditions of deposit/furnishing by overseas IDAs and the needs of users in Japan, and examined which operations of the deposit system can reduce the burden of deposit at the time of patent filing while maintaining the purpose of the deposit system, in light of consistency with the provisions of the Budapest Treaty.

I Introduction

Under the deposit system for microorganisms(*1) in patent filing, a microorganism pertaining to a microorganism-related invention is deposited to a depositary institution, and is made available for furnishing under certain conditions. Thereby, the system secures the existence of the microorganism pertaining to the relevant invention and enables third parties to work the invention.

In Japan and Europe, there is a requirement to deposit a specified quantity of microorganisms before filing. However, it has been pointed out that preparation for deposit places a burden on applicants, including universities and venture companies, since, for some microorganisms, much time and labor and many facilities are required to assure the quantity of microorganisms required at the time of deposit.

On the other hand, taking the purpose of the deposit system into consideration, it is necessary to pay attention to availability for furnishing and the provisions of the Budapest Treaty when considering the aforementioned reduction of burden, because deposited microorganisms must be available for furnishing to third parties over the entire duration of the patent and because domestic patent microorganism depositary institutions are international depositary authorities (IDAs) under the Budapest Treaty.

From the above points, the deposit systems of major countries and overseas institutions, the actual conditions of deposit/furnishing at overseas IDAs and the needs of Japanese users were determined, and the operations of the deposit system that can reduce the burden of deposit at the time of patent filing while maintaining the purpose of the deposit system was considered in light of consistency with the provisions of the Budapest Treaty. The consideration was conducted by holding a committee consisting of people of learning and experience, etc. who have expert knowledge relating to the microorganism deposit system.

This report summarizes the results of the above.

II Patent Microorganism Deposit System

The patent system is a system to grant

(*1) Microorganisms mean biological materials in general, which are subject to the patent microorganism deposit system, including animal cell cultures (including embryos) and plant cell cultures, in addition to bacteria.

an exclusive right to a person who has developed new technology, in return for publication of the technology. Therefore, a description (specification) of a patent application must disclose the relevant invention as to enable any person ordinarily skilled in the art to which the invention pertains to work the invention. However, for microorganism-related inventions, there are cases where a person skilled in the art cannot work the relevant invention due to such circumstances as not being able to easily obtain the relevant biological materials, no matter how particularly the description states the invention. Under the patent microorganism deposit system, the microorganism pertaining to the invention is deposited to a depositary institution, and the microorganisms are furnished to third parties under certain conditions, so that third parties will be able to work the invention in such a case as mentioned above.

In Japan, a person who intends to file a patent application for an invention pertaining to a microorganism must attach to an application a copy of the certificate of acceptance issued by an IDA as provided by the Budapest Treaty (international deposit) or a document proving that the microorganism has been deposited in an institution designated by the Commissioner of the Japan Patent Office (domestic deposit) with respect to the deposit of the microorganism, except when a person ordinarily skilled in the art to which the invention pertains (a person skilled in the art) can easily obtain the microorganism (Article 27-2(1) of the Ordinance for Enforcement of the Patent Act). In addition, regarding deposited microorganisms, any person intending to work an invention pertaining to a deposited microorganism for experimental or research purposes who falls under any of the following cases may receive the furnishing of the microorganism (Article 27-3(1)):

(i) When registration establishing a patent right for the invention pertaining to the microorganism has been effected;
(ii) When the person has received a warning with documents stating the contents of the invention pertaining to the microorganism pursuant to the provision of Article 65(1) of the Patent Act;
(iii) When the microorganism is necessary to prepare a written opinion set forth in Article 50 of the Patent Act (including cases where it is applied mutatis mutandis pursuant to Article 159(2) of said Act (including cases where it is applied mutatis mutandis pursuant to Article 174(2) of said Act) and Article 163(2) of said Act).

This patent microorganism deposit system has been adopted in many countries, in addition to Japan. However, in the case of filing patent applications pertaining to the same microorganism in multiple countries, if it is necessary to deposit the relevant microorganism to separate depositary institutions designated by each country, the procedures will be very cumbersome. Therefore, the Budapest Treaty was signed mainly in order to make the Contracting States mutually recognize the effects of depositing a microorganism in any IDA for the purpose of patent procedure, with regard to the deposit of microorganism that is required for the purpose of the patent procedure in each country. If an applicant deposits a microorganism in any IDA, the Contracting States of this treaty shall deal with the case as if the microorganism was deposited for the purpose of their own patent procedure. The Contracting States are not allowed to set requirements that are different from those stipulated in this treaty and regulations as well as additional requirements.

Then, furnishing/deposit under the Budapest Treaty is to follow the following procedures.

In depositing, a depositor has to submit a relevant microorganism and a document containing a commitment not to withdraw the deposit during the after-mentioned duration of the storage as well as bibliographic items. In doing so, the relevant

IDA may request the depositor to submit the required quantity of microorganisms in the form that is required to implement the treaty. The IDA conducts a viability test on the deposited microorganism, accepts the microorganism as long as the microorganism has not been clearly lost, and issues a certificate of acceptance to the depositor. If it turns out that the deposited microorganism cannot be furnished during the duration of the storage, the IDA will communicate with the depositor to that effect, and the depositor may make a new deposit of the same microorganism as the one deposited before within the prescribed period. In making a new deposit, the depositor signs a document stating that the newly deposited microorganism is the same as the one pertaining to the original deposit, and submits it to the IDA.

The duration of the storage of microorganisms at IDAs is at least thirty years from the date of deposit, and if a request for furnishing is made, the duration is further extended to five years from the date of receipt of the latest request.

In addition, it is prescribed that, for accepted microorganisms, IDAs shall conduct a viability test (i) immediately after deposit or transfer, (ii) at a reasonable interval or whenever necessary for a technical reason, or (iii) whenever requested by the depositor of the microorganism.

Furnishing is the obligation of IDAs, and IDAs must promptly furnish samples of deposited microorganisms by an appropriate method. It is prescribed that IDAs furnish samples upon request of the interested industrial property office, the depositor itself or the party who has obtained approval to receive furnishing of samples from the depositor, or the party legally entitled (in Japan, a person who falls under any of the items of Article 27-3(1) of the Ordinance for Enforcement of the Patent Act).

The details of the deposit procedure, etc. at IDAs in Japan are provided for by the "Implementation Guidelines for the Deposit, etc. of Microorganisms Conducted by International Depositary Authorities in Japan Based on the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (Public Notice No. 290 of the Ministry of Economy, Trade and Industry of 2002)," while the details of the deposit procedure, etc. at depositary institutions designated by the Commissioner of the Japan Patent Office as prescribed in Article 27-2 of the Ordinance for Enforcement of the Patent Act are provided for by the "Implementation Guidelines for the Patent Microorganism Deposit System, etc. (Public Notice No. 291 of the Ministry of Economy, Trade and Industry of 2002)." In both implementation guidelines, the deposit procedure, etc. conforms to the deposit/furnishing procedures under the aforementioned Budapest Treaty. However, regarding deposit at depositary institutions designated by the Commissioner of the Japan Patent Office (domestic deposit system), the duration of the storage depends on the fee. That is different from deposits at IDAs under the Budapest Treaty (international deposit) in that a depositor can request continuation of deposit according to need (Article 6 of the Implementation Guidelines for the Patent Microorganism Deposit System, etc.).

III Domestic Patent Microorganism Depositary Institutions and Actual Conditions Thereof

1 International Patent Organism Depositary (IPOD), National Institute of Advanced Industrial Science and Technology (AIST)

The IPOD is located in Tsukuba City, Ibaraki Prefecture, which is the central base of the National Institute of Advanced Industrial Science and Technology. It has been carrying out deposit/furnishing business for microorganisms since July 1968.

(1) Operations

Acceptable samples of microorganisms

are microbial cells (bacteria, fungi, yeasts, actinomycetes and plasmids (not in hosts)), animal cell cultures (animal cell cultures and embryos) and plant cell cultures (plant cell cultures, seeds, algae and protozoa) (*2).

The quantity of samples required at the time of deposit is five or more sample tubes in principle for bacteria, actinomycetes, fungi and yeasts (form: freeze-dried, L-dried, slant or frozen), plant cell cultures (form: callus in a test tube), and algae and protozoa (form: slant or liquid medium), 20 or more sample tubes for animal cell cultures (including hybridomas; form: frozen), 25 or more sample tubes for plasmids (not in hosts; form: DNA solution, dried or frozen) and embryos (form: frozen), and 100 or more bags (25 seeds per bag) for seeds (form: dried seeds). (*3)

Regarding bacteria, actinomycetes, fungi, yeasts, plant cell cultures, algae and protozoa, samples are in principle replicated through subculturing, and replicated samples are also used for furnishing. For these microorganisms, replication is conducted in conjunction with a viability test at the time of acceptance of microorganisms, and 16 replicated samples are manufactured. In addition, when the aforementioned replicated samples run short due to furnishing, samples are replicated again. For animal cell cultures (including hybridomas),(*4) embryos and seeds, samples are not replicated through subculturing, and the original samples are furnished.

For bacteria, actinomycetes, fungi, yeasts, plant cell cultures, algae, protozoa and seeds, a secular viability test is conducted in the first, third, fifth, tenth, fifteenth and twentieth year after storage, in addition to a viability test at the time of deposit. For animal cell cultures (including hybridomas) and embryos, a secular viability test is conducted once or twice (the period is not predetermined), in addition to a viability test at the time of deposit, and for plasmids, a viability test is conducted only at the time of deposit. In addition, for all kinds of microorganisms, a viability test is in principle also conducted at the time of furnishing. Therefore, in furnishing, two sample tubes are consumed: one for furnishing and one for a viability test.

(2) Past record of acceptance/furnishing

The number of acceptances between January 1 and December 31, 2006 is 637, including both domestic deposits and international deposits. The total number of stored strains as of December 31, 2006 is 13,780. In addition, the number of cases of furnishing between January 1 and December 31, 2006 is 209 (total of domestic and international cases).

It was estimated that strains for which four or more requests for furnishing are made account for less than 1% of all stored strains, as a result of estimation of the distribution of the number of requests for furnishing in 30 years. This was based on the distribution of the number of requests for furnishing at the IPOD in three years (2004 to 2006) (strains for which one or more requests were made account for 3% of all stored strains) and the average number of stored strains in that three years (13,778), on the following assumption: (i) the probability of receiving requests for furnishing is not biased among deposited strains and (ii) the same distribution of the number of times of furnishing as that between 2004 and 2006 is

(*2) However, the kinds of microorganisms that are not acceptable are provided below.
- Microorganisms that cause harm to health or the environment or have a property that is likely to cause harm thereto (meaning microorganisms that are classified into safety level 3 or 4 in the safety level classification table of the National Institute of Advanced Industrial Science and Technology)
- Microorganisms that require containment measures level P3, P3A or P3P as prescribed in Article 5 of the Ministerial ordinance stipulating containment measures to be taken in type 2 use of LMOs for research and development. (Ordinance No. 1 of the Ministry of Education, Culture, Sports, Science and Technology/Ministry of the Environment of 2004)

(*3) Some of deposited samples are stored without being used for replication of samples through subculturing, furnishing and viability test.

(*4) According to the IPOD, this measure is taken from the perspective of securing authenticity of stored strains since, for animal cell cultures, quality may differ with respect to each subculturing lot.

maintained for 30 years.

Incidentally, at the IPOD, there have been no cases where a new deposit became necessary since many requests for furnishing were made, with respect to the kinds of microorganisms that are not subcultured.

2 National Institute of Technology and Evaluation, Patent Microorganisms Depositary (NPMD)

The NPMD is located in Kisarazu City, Chiba Prefecture, where the Department of Biotechnology of the National Institute of Technology and Evaluation (NITE) is located. It has been carrying out depositing/furnishing for microorganisms since April 2004.

(1) Operations

Acceptable samples of microorganisms are microbial cells (bacteria, fungi, yeasts, actinomycetes, bacteriophages and plasmids (in hosts or not in hosts)) and animal cell cultures (animal cell cultures and embryos).(*5)

The number of sample tubes required at the time of deposit is 20 or more for all kinds of microorganisms.(*6) Acceptable forms are frozen, freeze-dried or L-dried for bacteria, actinomycetes, fungi, yeasts and bacteriophages, dried or frozen or DNA solution for plasmids, and frozen for animal cell cultures (including hybridomas) and embryos.

Regarding furnishing, the original samples deposited by depositors are furnished since the NPMD does not replicate samples through subculturing for any kind of microorganism.

In terms of viability tests, for dried samples, irrespective of the kind of microorganism, an accelerated test designed to see the degradation level of samples under severe storage conditions (temperature, etc.) is conducted once in order to verify whether the samples can endure 30-year storage, in addition to a viability test at the time of deposit. Moreover, for frozen samples, irrespective of the kind of microorganism, a viability test is conducted in the fifth year of storage to verify whether the samples can endure 30-year storage, in addition to a viability test at the time of deposit. Incidentally, since a viability test is also in principle conducted at the time of furnishing, two sample tubes are used in furnishing: one for furnishing and one for a viability test.

(2) Past record of acceptance/furnishing

The number of acceptances between January 1 and December 31, 2006 is 147, including both domestic deposits and international deposits. The total number of stored strains as of December 31, 2006 is 262. In addition, the number of cases of furnishing between January 1 and December 31, 2006 is one (total of domestic and international cases).

IV Actual Conditions of Domestic Users of the System

1 Outline of the Survey

In considering the operations of the patent microorganism deposit system, a questionnaire survey was conducted with domestic users in order to gain a specific understanding of the actual conditions of burden on depositors and the needs of depositors.

(*5) However, the following kinds of microorganisms are not acceptable:
- In the case of genetically modified organisms, microorganisms which require containment measures level P3, P3A or P3P or higher level ("Ministerial ordinance stipulating containment measures to be taken in type 2 use of LMOs for research and development. (Ordinance No. 1 of the Ministry of Education, Culture, Sports, Science and Technology/Ministry of the Environment of 2004)" based on the "Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms").
- Microorganisms which belong to level 3 or higher level of biosafety level (BSL) to human being, which is set by the Department of Biotechnology of NITE.

(*6) Deposited samples are provided for furnishing and viability tests (including accelerated test), and two sample tubes each are stored at the NPMD (Kisarazu City, Chiba Prefecture) and the Tohoku Regional Office (Sendai City, Miyagi Prefecture) without being used for furnishing and viability tests.

The survey targets were 390 applicants (including juridical persons, etc.) who filed applications (only those that have been published) relating to microorganisms that have been deposited to domestic IDAs between 2004 and 2005. Out of the 390 applicants, 115 persons (companies) gave valid responses.

2 Survey Results

About 40% of users consider preparation of the number of samples required at the time of deposit to be a burden. This feeling is common for all categories of respondents (large companies, SMEs/venture companies, etc.). Then, about 80% of those who feel burdened believe that the burden will be reduced through reduction of the number of samples required.

Regarding the time necessary for preparing samples required at the time of deposit, the subculturing process accounts for the large portion of the time for preparing samples. In particular, this tendency is strong for animal cell cultures (including hybridomas). In addition, the major factor that restricts the progress of the subculturing process is the growth rate of microorganisms. However, in some cases, the progress of said process can be delayed due to shortage of processing equipment for manufacturing samples of microorganisms (freeze drier, Tesla coil, etc.).

In addition, the effects of reducing the manufacturing time and the effects of reducing actual working hours that are achieved if the number of samples required for a deposit is reduced tend to be larger for animal cell cultures (including hybridomas).

The rate of the respondents who know the existence of manufacturers of samples for deposit was low at 32%. On the other hand, many of the respondents who answered that they knew the existence of said manufacturers use outsourcing in preparing samples of bacteria. Reasons for using outsourcing are to make up for a shortage of facilities, to manufacture samples appropriately, to divert human resources to other work, and so on.

Though nearly 90% of depositors store deposited microorganisms themselves even after depositing them, the duration of the storage is up in the air in many cases. Moreover, few depositors store microorganisms in consideration of the Budapest Treaty and the duration of patent rights.

V Overseas Patent Microorganism Deposit Systems

1 Outline of the Survey

The overseas system survey(*7) was conducted targeting 13 countries (organizations) – the United States, Canada, Europe, Germany, the United Kingdom, France, the Netherlands, Belgium, Italy, Bulgaria, Russia, China and South Korea – with focus on systems relating to deposit (including new deposit) and furnishing. The aim was to use the survey results not only as a reference for understanding the operations at overseas IDAs but also as basic information in considering the operations of the deposit system in Japan.

2 Survey Results

In the United States and Canada, "being a biological invention" was the only point that was cited as a case where deposit is necessary. However, in other surveyed countries, the unavailability of the relevant microorganism was also cited.

With regard to the time limit for deposit, it is necessary to make a deposit before the filing date (priority date) in the countries other than the United States. (In the United States, the time limit is up to the granting of

(*7) The survey was conducted based on the Guide to the Deposit of Microorganisms under the Budapest Treaty (published by WIPO; fiscal 2007 version) and literature search of patent law, etc. of each country as well as a questionnaire survey to overseas patent offices. (Answers were obtained from seven countries: the United States, Canada, Germany, the United Kingdom, Belgium, Bulgaria and South Korea.)

a patent, but deposit before the filing date is recommended.)

The duration of deposit is "30 years from the date of deposit, or five years from the latest furnishing" in most countries subject to the survey, as prescribed in the provisions of the Budapest Treaty. Seven countries answered that if furnishing becomes unavailable during this duration and a new deposit is not made, in the patent acquisition procedures, the relevant application will be refused, while after acquisition of a patent, the relevant patent will be invalidated.(*8)

Deposited microorganisms become available for furnishing after publication(*9) or granting of a patent. (*10) However, in some countries, deposited microorganisms can be furnished only to experts during the period after publication but before granting of a patent. (*11) Moreover, in most countries, the purpose of furnishing is limited to experiment and research purposes, and transfer to a third party is prohibited. (In the United States, there are no special limitations.)

In some countries, it is necessary to report a new acceptance number that is allocated in a new deposit in cases where a new deposit is made. (*12)

VI Operations at Overseas IDAs

1 Outline of the Survey

In order to use the survey results as a reference in considering the operations of the deposit system in Japan, a survey(*13) was conducted targeting 17 overseas IDAs: the ATCC (United States), the NMLHC (Canada), the DSMZ (Germany), the ECACC (United Kingdom), the NIBSC (United Kingdom), the CNCM (France), the CBS (the Netherlands), the BCCM™ (Belgium), the ABC (Italy), the NBIMCC (Bulgaria), the VKPM (Russia), the NMI (Australia), the CCTCC (China), the CGMCC (China), the KCCM (South Korea), the KCLRF (South Korea) and the KCTC (South Korea). The survey focused on items concerning operations relating to reduction of burden of deposit (the number of sample tubes required at the time of deposit, replication of samples through subculturing, furnishing, viability test, etc.).

2 Survey Results

The literature search revealed that handling methods at IDAs were roughly divided into the method for fungi/yeasts/bacteria/actinomycetes/plasmids, method for animal cell cultures/hybridomas and method for others, and that in the group of fungi, yeasts, bacteria, actinomycetes and plasmids, demand for deposit was highest for bacteria. In consideration of these results, for items for which handling differs depending on the kind of microorganism, handling of bacteria and that of animal cell cultures (including hybridomas) are only summarized.

(1) Number of samples required at the time of deposit

The number of samples required at the time of deposit varies to a great extent among IDAs, specifically, one to 25 sample tubes in depositing bacteria and seven to 25 sample tubes in depositing animal cell cultures. In addition, six IDAs(*14) answered that the

(*8) This is the answer provided by countries from which the questionnaire could be collected, specifically, the United States, Canada, Germany, the United Kingdom, Belgium, Bulgaria and South Korea. However, in the United States, there was also an answer to the effect that even if the relevant microorganism becomes unavailable for furnishing, there will be no problem both in the patent acquisition procedures and after acquisition of a patent if the microorganism is available for commercial use.

(*9) Canada, Europe, Germany, the United Kingdom, France, the Netherlands, Belgium, Italy, Russia, Bulgaria, South Korea and China.

(*10) The United States.

(*11) Canada, Europe, Germany, the United Kingdom, France, the Netherlands, Belgium and Italy.

(*12) The United States, Canada, Europe, the United Kingdom, France, the Netherlands, Belgium and South Korea.

(*13) The survey was conducted based on the Guide to the Deposit of Microorganisms under the Budapest Treaty (published by WIPO; fiscal 2007 version) and literature search by websites, etc. of those IDAs as well as a questionnaire survey to overseas IDAs. (Answers were obtained from 11 IDAs: the ATCC, the NMLHC, the ECACC, the DSMZ, the CNCM, the BCCM™, the ABC, the CBS, the NMI, the KCTC and the NIBSC.)

(*14) The ATCC, the DSMZ, the BCCM, the ABC, the CBS and the NMI.

number of samples required at the time of deposit was set in consideration of the past record of furnishing with respect to the kinds of microorganisms that are not subcultured.

(2) Replication of samples through subculturing

While some IDAs(*15) do not subculture any kind of microorganism in principle, some other IDAs(*16) replicate not only bacteria but also animal cell cultures through subculturing. Whether to replicate samples through subculturing differs depending on the IDA. However, some of IDAs that do not conduct subculturing in principle also conduct subculturing if samples run short due to furnishing, etc. and the relevant depositor requests subculturing. (*17)

Reasons for not subculturing animal cell cultures, etc. include "to avoid lawsuits from being filed against the IDA" and "it is desirable to furnish originally deposited samples since depositors are supposed to deposit relevant microorganisms under optimum conditions to work patented inventions pertaining to the microorganisms."

As far as the survey was conducted, IDAs that replicate samples through subculturing conduct an authenticity check by relevant depositors with respect to replicates made through subculturing.

(3) Furnishing

At 11 IDAs that answered the questionnaire, replicates are furnished with respect to microorganisms for which replication through subculturing is conducted, and originally deposited samples are furnished in cases where replication is not conducted. In addition, it is presumed that similar handling is adopted at six IDAs from which answers to the questionnaire could not be obtained.

(4) Viability test

Regarding viability tests, the number varies among IDAs, specifically, from once to seven times (including a viability test at the time of deposit). In addition, some IDAs do not conduct a viability test even at the time of furnishing. (*18)

VII Consideration of Measures for Reducing Burden on Users of the System

1 Consideration of Reduction of the Number of Samples Required at the Time of Deposit

In order to reduce burden at the time of deposit, it is conceivable to reduce the number of samples required at the time of deposit on the premise of the points cited in (i) to (v) below, taking into account the condition of burden at the time of deposit that was revealed through the user questionnaire survey, consideration of the past record of requests for furnishing when overseas IDAs determine the number of samples required at the time of deposit, and the operations, etc. of replication of samples through subculturing.

(i) For the kinds of microorganisms that particularly require a great deal of labor for replication through subculturing (for example, animal cell cultures), it is, in principle, considered favorable to ensure that deposited microorganisms are furnished wherever possible, since it leads to reduction of burden on depositary institutions and depositors with regard to subculturing and confirmation of authenticity of samples replicated through subculturing.

Incidentally, for the kinds of microorganisms for which subculturing is technically easy and of which authenticity is extremely unlikely to be damaged (for example, bacteria and yeasts), it is not considered necessary to persist in furnishing the original samples.

(*15) The ATCC, the NMLHC and the ECACC.
(*16) The CNCM, the KCTC and the KCLRF.
(*17) The ATCC and the NMLHC.
(*18) The ECACC and the CNCM.

(ii) In deciding on the number of samples required at the time of deposit with respect to the kinds of microorganisms for which replication through subculturing is in principle not conducted, reduction of the number of samples required at the time of deposit is promoted in consideration of the past record of furnishing. In general, requests for furnishing are not supposed to exceed a maximum of three times.

(iii) On the other hand, it is possible to enable a choice between making a new deposit and subculturing by a depositary institution in cases where many requests for furnishing are made and samples stored for furnishing based on the original prediction run short.

(iv) In replicating samples through subculturing, it is considered desirable to ask the relevant depositor to check the authenticity of samples replicated through subculturing, from the perspective of ensuring the authenticity of replicated samples and preventing problems related to authenticity.

(v) Reduction of the number of samples required at the time of deposit is expected to cause an increase in the possibility of occurrence of a new deposit. Therefore, depositors can be informed of the need to store deposited microorganisms in preparation for a new deposit.

Incidentally, before reducing the number of samples required at the time of deposit, there should be a discussion bearing in mind the following points.

(1) Risks arising from reduction of the number of samples required at the time of deposit

Before reducing the number of samples required at the time of deposit, the number of cases of furnishing should be estimated so that considerable new deposits are not required, and the reduction should be considered based on the estimation. In doing so, it is also considered necessary to respond with respect to each kind of microorganism in light of the property of each.

However, since it is true that the possibility of a new deposit increases, the possibility of a new deposit should be specifically publicized in writing or by other means at the time of deposit. (*19) In this regard, it is considered desirable to make clear the conditions for deposit between the depositor and the depositary institution at the time of deposit in order to clarify risk-sharing between the depositor and the depositary institution. However, in doing so, the aforementioned conditions for deposit should be reasonable and satisfying for both the depositor and the depositary institution since the depositor has no choice of depositary institution in some cases.

In addition, regarding costs for a new deposit or replication through subculturing, it is considered necessary to examine the sharing of burden among depositors, those who request furnishing and depositary institutions, including the idea that if such costs arise due to many requests for furnishing, those who request furnishing bear the costs.

(2) Estimation of the number of requests for furnishing

The probability of receiving a request for furnishing is sometimes biased depending on the strain. In addition, it is also necessary to pay attention to the point that there is no guarantee that the probability is the same every year. However, strains for which many requests for furnishing are made are considered to be very few in proportion as the total number of deposited strains.

(3) Authenticity check at the time of replication through subculturing

It is difficult to objectively determine the authenticity of microorganisms replicated through subculturing, and determination is expected to differ depending on the property

(*19) It is conceivable that if the number of samples for furnishing has decreased, the IDA can communicate with the depositor to that effect and promote the depositor to prepare for a new deposit.

of the microorganism that is related to the relevant invention. On the other hand, depositary institutions do not have information about the properties of deposited microorganisms that are related to the relevant inventions. Therefore, it is not depositary institutions but depositors that have to determine the authenticity of replicated microorganisms.

Then, taking into account that furnishing will become impossible if authenticity cannot be guaranteed in replication through subculturing and a new deposit is not made, depositors should maintain the condition in which the authenticity of microorganisms replicated through subculturing can be guaranteed or in which a new deposit of the same microorganism is possible, throughout the duration of storage or the duration of patents.

2 Consideration of Publicizing the Existence of Manufacturers of Samples for Deposit

According to the results of the user questionnaire survey, it can hardly be said that the existence of manufacturers of samples for deposit is widely known. However, outsourcing of sample manufacturing by depositors suffering from shortage of equipment and materials, etc. is expected to have a certain effect for reducing their burden.

Therefore, it is conceivable to publicize the existence of manufactures of samples for deposit to the extent that fairness among the manufactures is not damaged. However, in doing so, the need to clarify the quality of manufacturers, including kinds of microorganisms that can be subcultured, work procedure and costs, in some way should also be taken into consideration.

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