5 Desirable Operations of Patent Microorganism Depositary Institutions (*)

Where a person files a patent application for an invention pertaining to a microorganism in Japan, he/she must deposit the microorganism in a depositary institution except when the microorganism is easily obtainable.

Thus, the Budapest Treaty imposes the obligation of secrecy on international depositary authorities (IDAs) in order to protect the secrets of inventions of microorganisms as claimed in patent applications. On the other hand, institutions engaging in deposit operations are required to improve the efficiency of the operations with the aim of continuing stable operations and enhancing convenience for system users.

In addition, the operations of two patent microorganism depositary institutions in Japan are scheduled to be integrated in fiscal 2012, and those patent microorganism depositary institutions are now required to improve the efficiency of the operations.

Given this factor, we conducted surveys on the status of securing the fulfillment of the obligation of secrecy at microorganism culture collections in Japan and abroad, specific methods for concurrent engagement in different operations and sharing of equipment, backup and safety management of deposited microorganisms, methods of furnishing operations, etc., and examined desirable implementation of operations to run patent microorganism depositary institutions in a stable and efficient manner.

Ⅰ Introduction

Under the Japanese patent system, where a person files a patent application for an invention pertaining to a microorganism, he/she must attach to the application a copy of the certificate of acceptance issued by an IDA as provided by the Budapest Treaty or a document proving that the microorganism has been deposited in a domestic depositary institution designated by the Commissioner of the Japan Patent Office (JPO), except when the microorganism is easily obtainable.

The Budapest Treaty imposes an obligation of secrecy on IDAs, which prohibits them from disclosing information on whether a microorganism has been deposited to any person, with the aim of protecting secrets of inventions of microorganisms as claimed in patent applications. The Treaty provides that IDAs shall not give out any information about deposited microorganisms to any person with certain exceptions.

On the other hand, as long as the patent microorganism deposit system is to enable an applicant who intends to obtain a patent to work the relevant invention, patent microorganism depositary institutions are required to improve the efficiency of their operations with the aim of continuing stable operations and enhancing convenience for system users.

In addition, the operations of two patent microorganism depositary institutions in Japan are scheduled to be integrated after April 2012, and those patent microorganism depositary institutions are now required to improve the efficiency of their operations.

Given this factor, in this study, we conducted surveys on the status of securing the fulfillment of the obligation of secrecy, etc. at IDAs in Japan and abroad, specific methods for concurrent engagement in different operations and sharing of equipment, backup and safety management of deposited microorganisms, methods of furnishing operations, etc., and also conducted surveys on the status of fulfillment of the obligation of secrecy, etc. at microorganism culture collections in Japan which engage in operations similar to those of patent microorganism depositary institutions. Thereby, we examined desirable implementation of operations to run patent microorganism depositary institutions in a stable and efficient manner.

Ⅱ Outline of the Patent Microorganism Deposit System

1 Purpose of the patent microorganism deposit system

The patent system is a system that makes it a principle to grant a person who has created an industrially applicable invention having novelty and inventive step the exclusive right for the

(*) This is an English translation of the summary of the FY2011 JPO-commissioned research study report on the issues related to the industrial property rights system.

working of the invention in return for publication of the invention. Therefore, the description, etc. of a patent application must disclose the invention clearly and sufficiently to the extent that a person ordinarily skilled in the art can work the invention.

However, for microorganism-related inventions, samples of relevant microorganisms are not easily obtainable in some cases. In such a case, the invention cannot be substantively worked and publication of the invention cannot be sufficiently secured; therefore, the invention is not regarded as having been disclosed. Consequently, it is impossible to grant the exclusive right for the invention based on the principle of return for publication.

Given this factor, the patent microorganism deposit system is one that enables a person who has created a microorganism-related invention to secure the confirmation/working of the invention by third parties and fulfill the requirement of disclosure of the description by depositing the microorganism pertaining to the invention, which is hard to obtain, in a patent microorganism depositary institution in advance and thereby making it available for furnishing to third parties under certain requirements.

Specifically, in Japan, Article 27-2 of the Ordinance for Enforcement of the Patent Act provides that an applicant shall attach to an application a document proving that the relevant microorganism has been deposited in an IDA as provided by the Budapest Treaty or an institution designated by the Commissioner of the JPO, except when the microorganism is easily obtainable.

In addition, the Budapest Treaty also provides that if an applicant deposits a microorganism in any IDA, the Contracting States of the Treaty shall deal with the case as if the microorganism was deposited for the purpose of their own patent procedure and the Contracting States shall not require compliance with requirements different from or additional to those which are provided in this Treaty and the Regulations.

2 Regarding the obligation of secrecy

Patent microorganism depositary institutions handle information concerning unpublished patent applications for microorganisms, etc. in the course of implementing deposit operations, etc. Therefore, imposed upon them is the obligation of secrecy, which requires maintenance of secrecy concerning deposited microorganisms, under the Budapest Treaty.

In addition, the Regulations based on said Treaty provide that depositary institutions shall not give out any information about deposited microorganisms to any person. Moreover, the World Intellectual Property Organization (WIPO) has formulated guidelines for the purpose of providing systematic information on the procedures and requirements for depositors and those who receive furnishing and giving practical advice to depositors and those who furnish microorganisms.

However, the Budapest Treaty, the Regulations and the guidelines do not mention at all the specific implementation, etc. for promoting the improvement of the efficiency of operations in compliance with said obligation though they provide for the content of the obligation of secrecy imposed on IDAs and exceptions thereto.

On the other hand, Japanese domestic laws and regulations do not include any special provision on the specific implementation of provisions on the obligation of secrecy though they include such provisions.

3 Regarding the furnishing system

The Budapest Treaty defines "depositary institution" as an "institution which provides for the receipt, acceptance and storage of microorganisms and the furnishing of samples thereof." The Treaty provides for the obligation of IDAs to furnish samples of deposited microorganisms under certain requirements.

The Regulations under the Budapest Treaty provide that IDAs shall furnish samples of microorganisms using a prompt and appropriate method. In addition, the Regulations also provide for the requirements for furnishing to an industrial property office, a depositor or a person who has obtained approval from a depositor, and a person who has been qualified under laws and regulations, respectively. The Regulations provide that one of the conditions for furnishing to a person who has been qualified under laws and regulations shall be certification by an industrial property office that the person has the right to receive furnishing.

Furthermore, the WIPO guidelines describe each country's requirements concerning whether a person who has requested furnishing has been qualified under laws and regulations.

In terms of Japanese domestic laws and regulations, Article 27-3 of the Order for

Enforcement of the Patent Act provides for the requirements for furnishing samples of patent microorganisms and stipulates that the purpose of furnishing a microorganism shall be limited to experiment or research on an invention pertaining to the microorganism and that a person who has received the furnishing of a microorganism shall not have the furnished microorganisms be used by any third party. Moreover, specific requirements which a person who requests furnishing should fulfill are also provided in a public notice.

4 Identification of the problems

As mentioned above, the Budapest Treaty imposes certain obligation of secrecy on IDAs. However, the related regulations and guidelines do not clearly stipulate the specific scope and degree of implementation of the obligation of secrecy which are required to secure the fulfillment of the obligation under the Treaty. The same goes for Japanese domestic laws and regulations. In addition, specific implementation in each country is also unclear with regard to restrictions on use, etc. at the time of furnishing of samples.

For this reason, where a patent microorganism depositary institution belongs to the same organization to which an institution engaging in similar operations such as culture collection belongs, there are unclear points, for example, as follows: to what degree concurrent engagement in different operations and sharing of equipment are permitted, whether facilities should be independent, and what degree of security management is required in terms of the acceptance and storage of microorganisms and furnishing of samples thereof. This becomes a problem in promoting the improvement of the efficiency of operations while fulfilling the obligation of secrecy.

If maintenance of secrecy is excessively thorough, it is supposed that it will affect the setting of fees for deposit and furnishing due to an increase in the operating budget, etc., which will lead to deterioration in safety management and other services due to increase in costs. This will cause concern about hindrance to stable implementation of operations and also result in impairing convenience for system users.

Ⅲ Outline of Patent Microorganism Depositary Institutions in Japan

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

For full-time staff members, the obligation of secrecy is provided in the employment regulations of the AIST. Full-time staff members are given explanations on the content of the obligation when they are employed as staff members, and training is provided to them on a regular basis to confirm the matters to be complied with. In addition, for contract staff members, the obligation is provided in the employment regulations for contract staff members. Contract staff members are obliged to submit a written pledge after hearing explanations of the obligation of secrecy at the time of their employment, and training is provided to them on a regular basis to confirm the matters to be complied with in the same manner as full-time staff members.

No staff member has imposed upon them the obligation of secrecy specialized in patent microorganism deposit operations, and general provisions on the obligation of secrecy which apply to the AIST also apply to staff members. In addition, as no microorganism culture collection is established in the AIST, there is neither concurrent engagement in different operations nor sharing of equipment.

Deposited microorganisms are stored in an independent building within the AIST, and a key card is used for entrance into and exit from the facility as a security measure. Moreover, the IT system for patent microorganism deposit operations is isolated from outside, and data change tracking is automatically recorded. Furthermore, measures such as storing backups on another hard disk are taken.

Regarding the securing of safety, there are biosafety level (BSL) classification regulations by which the IPOD checks the pathogenicity, etc. based on the names, etc. of deposited microorganisms. In addition, the backup is stored in the same building.

When furnishing a sample of a deposited microorganism, the IPOD requires a person who has requested furnishing to submit a "certificate of consent concerning the request for furnishing" and prohibits such person from using a furnished microorganism for purposes other than the

intended purposes.

Incidentally, the IPOD neither provides a service to identify the classification of a deposited microorganism nor take measures to reduce or exempt fees. Moreover, the procedure is available only in the Japanese language, and the IPOD does not accept deposits in foreign languages in principle.

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

For full-time staff members, the obligation of secrecy is provided in the employment regulations of the NITE. Full-time staff members implement operations based on the operation manual of the NPMD. However, they do not have imposed upon them the obligation of secrecy specialized in patent microorganism deposit operations, and the general provisions on the obligation of secrecy which apply to the NITE as a whole also apply to them.

Though a microorganism culture collection (NBRC) is established within the same building, its office and laboratories are separated from those of the NPMD in units of rooms and no equipment is shared between the NBRC and the NPMD. In addition, independency is ensured through management of entrance into and exit from the facilities by using passwords and ID cards. Furthermore, the IT system for patent microorganism deposit operations is a system isolated from outside.

For the securing of safety, the NPMD has biosafety level (BSL) classification regulations, and confirms the safety of cultures by questioning depositors about unclear points after checking documents submitted by the depositors at the time of deposit. In addition, the backup is stored in a separate place within the NPMD, and some samples are stored in a geographically distant place.

When furnishing a sample of a deposited microorganism, the NPMD has a person who has requested furnishing submit a "written acceptance concerning use of the microorganism" and prohibits such person from using a furnished microorganism for purposes other than the intended purposes.

Incidentally, the NPMD neither provides a service to identify the classification of a deposited microorganism nor takes measures to reduce or exempt fees. Moreover, the procedure is available only in the Japanese language, and the NPMD does not accept deposits in foreign languages in principle.

3 Framework in Fiscal 2012 and Thereafter

In the "Basic Policy on the Review of Affairs and Operations of Incorporated Administrative Agencies (decided by the Cabinet on December 7, 2010)," it was decided to integrate the IPOD and the NPMD and to take necessary measures in the order of precedence in fiscal 2011 and thereafter.

The Ministry of Economy, Trade and Industry, etc. has just announced that the NITE will succeed to the IPOD's patent microorganism deposit operations in April 2012 with the aim of integrating patent microorganism deposit operations.

Ⅳ Status of Operations of Microorganism Culture Collections in Japan

1 Outline of the survey

We conducted a questionnaire survey about the outline of the institution, regulations on the obligation of secrecy and the status of implementation thereof, the status of sharing of personnel (full-time engagement in one kind of operation/concurrent engagement in different kinds of operations), facilities, etc. with other departments, regulations on deposited microorganisms and the management system therefor, and furnishing and other operations, targeting 22 institutions engaging in microorganism culture collection operations in Japan (all institutions which belong to the Japan Society for Culture Collections (JSCC), except the IPOD).

The breakdown of 15 institutions which answered the questionnaire is: 10 universities, four research institutes, and one administrative organ. We conducted an additional interview survey targeting nine out of those 15 institutions.

2 Survey results

Differently from patent microorganism depositary institutions, microorganism culture collections do not have imposed upon them the obligation of secrecy with binding power, which is based on a treaty, domestic law or regulation, etc. Therefore, there are no provisions and manuals on the obligation of secrecy of the unified content or level. In reality, microorganism culture

collections apply the general provisions of their parent institutions, such as universities and incorporated administrative agencies, as they are.

However, as microorganism culture collections also engage in operations in which they handle cultures which have not been disclosed to outside, they take certain measures for physical or mechanical resources, such as storage facilities for microorganisms and IT systems for operations, from the perspective of maintaining secrecy. On the other hand, regarding personnel resources (full-time engagement in one kind of operation/concurrent engagement in different kinds of operations), personnel resources are divided depending on the volume of operations from the perspective of efficient allocation of personnel.

Moreover, the main operations of microorganism culture collections are the collection, preservation, and provision of microorganisms; therefore, most collections have an established backup system.

Regarding furnishing, microorganism culture collections do not have imposed upon them the requirements for furnishing based on a treaty, domestic law or regulation, etc., differently from patent microorganism depositary institutions. Therefore, they furnish samples of microorganisms without especially limiting purposes except when there is a safety problem, such as pathogenicity, and when a person who has requested collection of a culture does not desire furnishing.

Incidentally, microorganism culture collections give certain considerations with regard to measures to reduce or exempt fees and acceptance of applications in foreign languages.

Ⅴ Status of Operations of Overseas Patent Microorganism Depositary Institutions

1 Outline of the survey

In order to study the actual conditions of the implementation of operations of overseas patent microorganism depositary institutions, we conducted an interview survey on the outline of the institution, regulations on the obligation of secrecy and the status of implementation thereof, the status of sharing of personnel (full-time engagement in one kind of operation/concurrent engagement in different kinds of operations), facilities, etc. with other departments, regulations on deposited microorganisms and the management system therefor, and furnishing and other operations, targeting nine major IDAs in the United States, the United Kingdom, France, Germany, China, and South Korea.

2 Survey results

Institutions to which major IDAs in other countries belong concurrently engage in patent microorganism deposit operations and culture collection operations. In terms of the form of organization, these institutions are roughly divided into (a) those mainly consisting of an IDA and a culture collection and (b) those which have a parent institution in which an institution engaging in culture collection and other operations is established. In either case, few institutions formulate regulations on the obligation of secrecy unique to patent microorganism deposit operations. In reality, fulfillment of the requirements for the obligation of secrecy required in the Budapest Treaty and the Regulations is secured by regulations on the obligation of secrecy which are shared with the culture collection or the parent institution.

In addition, regarding staff members, the institutions are divided into (a) those in which patent microorganism deposit operations are implemented only by full-time staff members, (b) those in which full-time staff members play a major role but experts support operations (= staff members concurrently engaging in different operations are allocated) depending on the species, etc. of deposited microorganisms, and (c) those in which all staff members concurrently engage in different operations. However, few institutions adopt the form of (a), and many institutions actually allocate staff members concurrently engaging in different operations depending on microbial species and the volume of operations.

Many institutions concurrently engaging in patent microorganism deposit operations and culture collection operations store patent microorganisms and other microorganisms in the same building, and they are roughly divided into (a) those which manage patent microorganisms and other microorganisms in independent storage facilities (refrigerator, freezer, etc.) respectively and (b) those which manage them using independent storage containers, etc. while using the same storage facility. In addition, regarding the IT system, the institutions are roughly divided into (a) those which use a stand-alone IT system and independent database for patent

microorganism deposit operations and (b) those which use the same IT system as the one used for other operations and limits access with the use of a password, etc.

Regarding the securing of safety, major IDAs in other countries set BSL classification based on the guidelines, etc. set by an international organization or the government of their own country. Many IDAs allocate necessary experts according to the BSL classification. Moreover, the IDAs manage the microorganisms of BSL 1 or 2 using facilities for the microorganisms of BSL 2. Furthermore, when furnishing a sample of a microorganism of BSL 2 or higher, IDAs decide on the propriety of sending the sample of the microorganism in consideration of whether the person who has requested furnishing has the necessary facilities and has obtained all necessary permissions. In sending a sample of a microorganism, IDAs use a special preservation container in many cases.

In addition, all IDAs subject to the interview survey make backups of deposited cultures, and they are roughly divided into those which store the backups in a physically distant place and those which store them on the same premises or in the same building.

Regarding restrictions on furnishing, laws and regulations or agreements, etc. often impose certain restrictions in relation to the purposes and acts of use of furnished cultures in other countries in the same manner as in Japan. No regulations imposing criminal punishment were identified. There was an opinion that filing a complaint against a person who has requested furnishing and has committed a violation as well as related authorities through a civil means is one of the remedies.

Hardly any IDAs introduce measures to reduce or exempt fees as a measure to enhance convenience for system users. On the other hand, regarding acceptance of applications in foreign languages, all of the institutions subject to the survey actually accept deposits, etc. in English where the official language is a language other than English.

Ⅵ Desirable Operations of Patent Microorganism Depositary Institutions in Japan

1 Maintenance of secrecy and improvement of efficiency of operations

In order to improve the efficiency of operations, it is considered necessary to examine the fact that patent microorganism depositary institutions in Japan also conduct patent microorganism deposit operations concurrently with operations of other departments, such as culture collection. In doing so, one of the possible rational methods is to establish an operational framework while giving consideration to the volume and specialty of operations and backup personnel, etc. and taking into account the effective utilization of personal resources across multiple departments with respect to individual operations.

In addition, it is necessary to pay proper attention, including adoption of measures to have staff members clearly recognize divisions of operations in which they concurrently engage, in order to prevent the occurrence of situations such as confusion of the obligations under the Treaty (including the obligation of secrecy) and other operational obligations. Moreover, taking into account the importance of the obligation of secrecy in patent microorganism deposit operations, it is considered necessary to examine not only the development of agreements or regulations but also the development of a basic manual specialized in said operations and specific guidelines as well as enrichment of training for staff members.

On the other hand, sharing of buildings, facilities, etc. should also be examined at patent microorganism depositary institutions in Japan from the perspective of improving the efficiency of operations. In doing so, it is considered important to ensure separation at the container level at the very least to the extent that safety can be secured according to the BSL level and to take measures to prevent the occurrence of operational human errors.

Moreover, with regard to information management, including the IT system, one of the possible methods is to formulate and thoroughly implement a code of conduct concerning information management in reference to operations, etc. at other institutions which are required to maintain secrecy of information.

2 Implementation of operations for stable and efficient running

It is ideally desirable to store the backup of a deposited culture in a physically distant place. However, it is considered that geographical isolation is not necessarily required from the perspective of the efficiency of operations at

depositary institutions, taking into account that a depositor has the right to redeposit a microorganism if the microorganism is lost. However, it is also necessary to promote the enrichment of necessary facilities in consideration of circumstances of natural disasters which occur in Japan and expenses for preparing against them. Moreover, one of the possible methods is to store the backup in separate places within the same premise or the same building through effective use of existing facilities.

Regarding the handling of high BSL microorganisms, it is natural to take sufficient safety measures in relation to relevant facilities and management thereof in storing and furnishing such microorganisms. However, from the perspective of preventing increase in costs, it is vital not to take excessive measures. It is considered necessary to continuously examine the detailed and efficient management of deposited microorganisms corresponding to their BSLs.

3 Other Points at Issue

Patent microorganism depositary institutions in Japan have persons who have requested furnishing submit a certificate of consent, etc. to the effect that they comply with the regulations stipulated by laws and regulations, etc. and inform such persons of the risk of being sued in the case of a violation of the regulations, etc. However, as problems concerning requests for furnishing are those that go beyond Japan, it is considered necessary to deepen discussions on measures, which can be additionally taken from the perspective of enhancing the effectiveness of the regulations, from the international perspective through collaboration with other countries.

At the same time, from the perspective of enhancing convenience for the users of the deposit system, it is considered necessary to examine the propriety of introducing reduction and exemption measures while paying attention to the benefit principle and compliance with the Budapest Treaty, on the premise of reconsideration of fees through improvement of the efficiency of operations. In addition, it is also considered necessary to discuss the ideal burden of fees for deposit of patent microorganisms in an integrated manner in discussions on the future biopolicy.

Moreover, it is also important to expand system users in Japan and abroad by promoting enhancement of convenience, including acceptance of applications in foreign languages (English).

Incidentally, some pointed out the following as the problems of the patent microorganism deposit system which are to be discussed in the future: (1) the problem of discrepancy between identification of classification of a new microorganism and identification of classification toward patenting, (2) interlocking of deposit information and patent information, (3) problems arising from both the domestic and international deposit systems, (4) collection of all cultures which have ceased to be deposited and cultures which have been withdrawn, and (5) the propriety of depositing all patented cultures, etc. by gene information. In addition, problems were raised in relation to the Budapest Treaty which has not been revised since its coming into force. Therefore, it is considered necessary to continue to discuss the desirable patent microorganism deposit system for the future not only from the perspective of the Japanese system but also from the international perspective.

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