

12 Ideal Future Structure of the Patent Microorganism Deposit System

When filing a patent application for an invention relating to a microorganism, the applicant is obligated by law to deposit the relevant microorganism at an institution designated by the JPO Commissioner, in principle, in order for the specification to meet the disclosure requirement as well as for third parties to have access to samples of the microorganism. With the recent development of the biotechnological industry, however, the patent microorganism deposit system has been criticized as having not completely responded to the changes in the circumstances of the times, and improvements are required both in terms of the system and its operation.

In this research and study, we conducted the interview survey with domestic companies that used the microorganism deposit system and the questionnaire survey targeting international depositary authorities. Accordingly, based on the analysis of users needs for the deposit system as well as the differences of the Japanese deposit system with the systems in Europe and the United States, this report considers an ideal future structure of the patent microorganism deposit system in Japan.

Microorganism-related Inventions

1 Trends in Microorganism-related Inventions in Japan

(1) Bio-industry trends

Trends in the domestic industry include the successive entry of IT companies into bio-fields, primarily with the development of bio-informatics and DNA chip enterprises. Major pharmaceutical companies in Japan are increasing in spending on genome-related research, in addition to expanding pharmaceutical product development abroad, focused on clinical trials. There has also been a rapid increase in the amount of investment in bio-related fields, including venture capital specifically for bio-fields and investment funds that specialize in the bio-field business.

In comparison, the trend in foreign business is for pharmaceutical makers in Europe and the United States to buy large companies in order to enhance their genome research and development. As a result, there is a growing gap in company scale relative to the Japanese companies. There is also a growing number of alliances between US venture businesses in the bio-informatics field and Japanese pharmaceutical manufacturers.

(2) Trends in the industries relating to fermentation/application microorganisms and bio-process

The fermented drink industry is strongly conservative, but the development of equipment, measurement and control processes has been gradually progressing. Japan's application microorganism industry is included in the top group in the world. This is indicated by the number of patents obtained. 23% of the total patent applications in this field in the United States are filed by Japanese applicants. Representatives of the

application microorganism industry include the amino-acid fermentation industry, the antibiotics production industry, and the enzyme industry.

With regard to the amino-acid fermentation industry, there is an increasing trend in the amount of amino acid produced globally, but as domestic makers have shifted to overseas production for the purpose of cost reduction, the amount of amino acids produced in Japan has been decreasing.

In the antibiotics production industry, it has become possible to produce antibiotics cheaply through the use of gene recombination technology. There are likely to be increases in the future in the use of gene recombination technology.

Many enzymes are produced by Japan's enzyme industry. In recent years, the productivity for target enzymes has improved through the use of gene recombination technology. There are also research results being reported on improvements in enzyme characteristics.

In the field of bio-process industries, the conventional production processes for a variety of products are being replaced by biological processes that utilize microorganisms and enzyme catalysts.

2 Inventions Relating to Microorganisms

Inventions relating to microorganisms can be broadly classified into "inventions of microorganisms themselves" and "inventions of applications of microorganisms." The examples below of inventions relating to microorganisms include some inventions relating to "microorganisms" that are not typically included in the ordinary interpretation of the word "microorganism" but can be deposited in the International Patent Organism Depositary.

(1) Examples of inventions of microorganisms themselves

(a) Bread yeast (Patent Publication No. 52-7477):

A yeast created through a combination of yeasts with different properties, suitable for leavening dough with a sweet flavor.

(b) New fat-soluble microorganism (Patent No. 3,077,975): A new microorganism that is lipolytic in plant or animal fats and oils. (*S.saprophyticus* OD-1 (FERM P17201)) It can be used for processing waste water that contains plant or animal lipids.

(2) Examples of inventions of microorganisms applications

(a) Method for survival improvement for *Lactobacillus bifidus* (Patent No. 3,261,571): A method of survival improvement of *Lactobacillus bifidus* in culture media or cultures with lactitol added, in order to improve the survivability of the *Lactobacillus bifidus* in food and drink.

(b) Formaldehyde decomposition method (Patent No. 3,007,860): A method of formaldehyde decomposition using bacteria of the *Fusarium* genus that can decompose formaldehyde.

(3) Examples of inventions related to “microorganisms” that are not included in the ordinary interpretation of “microorganism” but can be accepted at the patent organism center.

(a) A trophocyte with neo-resistance (Patent No. 3,067,914): A TT2 undifferentiated embryonic cell derivative. Undifferentiated embryonic cells that are FERM P-13200 cells with neo-resistance (expressing neomycin phosphotransferase enzymes and being resistant to neomycin). These cells can be used as good trophocytes on the introduction of genetic material.

3 Technology Trends in Microorganism-related Inventions

The number of publications of patent applications filed for the IPC C12R (indexing scheme relating to microorganisms) of the IPC category C12 (biochemistry; beer; spirits; wine; vinegar; microbiology, etc.) was investigated for each fiscal year. The results from 1993 to 2001 show that there was a peak in 1994 with over 1,700 cases, dropping to a little over 1,000 cases in 2001, indicating that there is a decreasing trend in the number of publications of patent applications for inventions relating to microorganisms. In particular, inventions relating to *Escherichia*, including *E. coli*, and inventions relating to cell lines have decreased significantly since 1998. For most other types of organisms over the long term, there is a decreasing trend or a steady level, but in this 2 or 3 year period there is clearly an increase in the inventions relating to bacteria bacillus.

Outline of the Patent Microorganism Deposit System

1 Protection of Biological Inventions and Objectives of the Patent Microorganism Deposit System

Along with the development of biotechnology, there has been a growing demand for legal protection of the fruits of research, namely biological inventions, and domestic patent laws have globally expanded the scope of biological inventions to be protected on a case-by-case basis. In Japan and the United States, patents have been granted to microorganisms, plants and animals. On the other hand, under the European Patent Convention, microorganisms are included in the scope of protection whereas plant or animal varieties and essentially biological processes for the production of plants and animals are excluded from the scope of protection.

When filing a patent application, the applicant is required to state the invention in the specification in a manner sufficiently clear and complete for the invention to be worked by a person having ordinary skill in the art to which the invention pertains. However, in the case of a biological invention, those skilled in the art may not be able to work the invention unless the relevant biological materials (including microorganisms) are easily available to them, no matter how detailed the invention is described in the specification. The patent microorganism deposit system is intended to furnish deposited biological materials to third parties so that they will be able to work the patented invention.

2 Outline of the Patent Microorganism Deposit/Furnishing System in Japan

(1) Deposit procedures

A person who seeks to file a patent application for an invention relating to a microorganism is required to deposit the relevant microorganism to an institution designated by the JPO Commissioner or an international depositary authority (IDA) and disclose the deposit number in the application document, unless the microorganism is easily available to those skilled in the art. More specifically, such a person shall send by post or deliver in person the relevant microorganism to a depositary institution (in Japan, the “International Patent Organism Depositary (IPOD)”) with the necessary documents. The IPOD annually receives about 500 domestic deposits and about 400 international deposits (including those transferred from domestic deposits).

(2) Furnishing procedures

A request for furnishing of samples of the deposited microorganism may be made when the

establishment of the patent right is registered. A request may also be made under Article 27ter.(1)(ii) and (iii) of the Regulations under the Japanese Patent Law even before the patent right is registered. A request may be made by (i) the Japan Patent Office, (ii) depositor, (iii) a person who has obtained the approval of the depositor or (iv) a person who is legally authorized. These persons may obtain samples of the microorganism by submitting the certificate of conditions and a request for furnishing to the depositary institution. During the period from 1997 to 2000, the IPOD furnished samples in response to about 110-150 requests each year.

3 Outline of the International Deposit/Furnishing System under the Budapest Treaty

The international deposit system under the Budapest Treaty is designed to ensure that a deposit of a microorganism to an international depositary authority in a contracting state will be recognized as an effective deposit in the patent procedures in all contracting states. Currently, 56 countries have become contracting states of the Budapest Treaty and 34 depositary institutions in 21 countries have acquired the status of international depositary authority. In Japan, the International Patent Organism Depositary (IPOD) is the only institution that has acquired the status of international depositary authority. The Budapest Treaty and the Regulations under the treaty provide for duties and obligations imposed on international depositary authorities, but do not indicate specific examples. Responses to individual cases would vary among international depositary authorities as to how they would cope with cases based on their own interpretations of the treaty and the regulations. Under such circumstances, in order to harmonize the rules and procedures of individual international depositary authorities, the "Budapest Treaty: Code of Practice for IDA" was developed in 1998. However, the Code of Practice is not legally binding for individual international depositary authorities.

Little difference exists between the deposit/furnishing procedures under the Budapest Treaty and the domestic procedures in Japan. This report addresses the survey on the deposit/furnishing procedures applied by individual international depositary authorities.

4 Acceptable Biological Materials at Depositary Institutions

The IPOD has expanded the scope of acceptable biological materials. Currently, a total of 11 kinds of organisms can be deposited at the IPOD: fungi, yeasts, bacteria, actinomycetes,

isolated plasmid, animal cells, embryos, protozoa, plant cells, seeds and algae. This report presents the results of the survey targeting international depositary authorities with respect to the kinds of acceptable biological materials, the average number of days required for the viability test, and the modes of depositing biological materials.

5 Domestic Deposit and International Deposit

Japan has both an international deposit system under the Budapest Treaty as its contracting state and a conventional domestic deposit system. There is difference between the domestic and the international deposit systems in terms of fees, permission for withdrawal, etc.

6 Deposit at Depositary Institutions Other Than the IPOD

When filing a patent application in a contracting state of the Budapest Treaty, if the applicant deposits a microorganism at any of the international depositary authorities designated under the Budapest Treaty, that deposit shall be effective in all contracting states. However, when filing a patent application for an invention relating to a microorganism in a country (or region) that has not joined the Budapest Treaty, the applicant should deposit the relevant microorganism at the patent microorganism depositary institution designated by the country under the domestic law of that country.

Recently, the number of Japanese filing patent applications in Taiwan with respect to inventions relating to microorganisms has been increasing. As Taiwan is not a contracting state of the Budapest Treaty, Japanese applicants have to deposit microorganisms at a depositary institution designated in Taiwan. Currently, the Food Industry Research & Development Institute (FIRDI) is the only domestic depositary institution designated in Taiwan. Accordingly, this report addresses the results of the survey on the outline of the deposit system and its operation as well as the kinds of acceptable biological materials at the FIRDI.

7 Self-deposit

In the case where the applicant cannot deposit the biological material concerning his patent application at the patent organism depositary institution for the reason that the material is not included in the scope of acceptable biological materials at the institution, he must store the material by himself and guarantee furnishing of samples of the material. This system, which is called "self-deposit," exists only in Japan and it is rarely used nowadays due to the fact that it is not recognized as a legal system by other countries and

that there is no guarantee that the sample to be furnished to a third party is identical to the deposited material. In addition, the expanded scope of acceptable materials at the IPOD renders this system unnecessary.

8 Current Status of Culture Collections

(1) Culture collections in Japan

Culture collection originally means a strain storage institution. In this report, institutions that collect and store plant cells and animal cells are also treated as culture collections. In Japan, there are 22 culture collections that are registered at the World Data Center for Microorganisms (WDCM), and more than 30 when including those not registered at the WDCM. This report presents the results of the survey targeting these culture collections in terms of the competent ministries and agencies governing them, the kinds of organisms stored and the number of samples furnished.

In addition to the IPOD, the Institute for Fermentation, Osaka (IFO), which is one of the Japanese culture collections dealing with biological materials concerning patent applications, is designated as a patent organism depositary institution by the European Patent Office. Samples of general microorganisms that had been stored at the IFO have been transferred to the NITE Biological Resource Center (NBRC) that was established in April 2002. The Center will enhance its collection of samples with the aim of storing and providing about 100,000 types of biological resources by 2010.

(2) Culture collections abroad

The IPOD only deals with microorganisms that are deposited for patent applications and fails to function as a general culture collection. On the other hand, most European and U.S. depositary institutions that serve as international depositary authorities were first established as culture collections and then have expanded their activities to include patent deposit functions: therefore, these foreign authorities perform both culture collection functions and patent deposit functions. This report provides the number of cultures stored at foreign culture collections.

Problems in the Existing Patent Microorganism Deposit System

1 Problems of the Patent Microorganism Deposit System from the User's Perspective

(1) Interview survey with domestic bio-related companies

In order to identify the current status and problems of the existing patent microorganism

deposit system, interviews were held with 10 major domestic bio-related companies whose deposits of microorganisms and requests for furnishing accounted for the majority of deposits and requests received by the IPOD. The questions and responses are outlined below.

(i) Questions and responses concerning deposit

① What problems do they find when using a foreign depositary institution? : Many respondents stated problems concerning deposits in Taiwan. There was also a complaint that the fees required for an international deposit by the IPOD are higher than those to be paid to foreign depositary institutions.

② Do they think the scope of acceptable biological materials at the IPOD is wide enough? : The 10 companies answered that the current scope is wide enough and there is no necessity to expand it.

③ What problems do they have with the IPOD's operations? : There was an opinion that the relation between the date of the viability test and the date of issuance of the receipt of the deposit should be clarified. Another opinion was that information on the transfer of biological materials from domestic deposit to international deposit should be disclosed, criticizing the present situation in which catalogues of biological materials stored by the IPOD have not been made public.

④ What do they think about increasing the number of domestic depositary institutions? : 7 companies agreed to the increase without conditions, 2 companies agreed but with conditions, and 1 company answered that it was not necessary to increase the number of domestic institutions.

(ii) Questions and responses concerning furnishing

① What problems do they find when furnishing samples to a third party? : Some respondents were concerned that the third party who has obtained furnished samples of biological materials would assign them to another party or use them for industrial purpose instead of research purpose.

② What problems do they find when making a request for furnishing? : There was an opinion that it was difficult to obtain biological materials in the case where a notice of change was not submitted when the materials were transferred from domestic deposit to international deposit and official publications on these materials were issued with the domestic deposit numbers.

(iii) Other questions and responses

① What do they think about depositary institutions also functioning as culture collections? : The majority found no problem and agreed to this idea.

(2) Problems concerning deposits from the user's perspective based on the interviews

Significant problems from the user's perspective include ① the relation between the

time of the viability test and the time of issuance of the receipt of the deposit, ② the amount of the fee required for international deposit, and ③ deposits in Taiwan.

(3) Problems concerning furnishing from the user's perspective based on the survey results

Significant problems from the user's perspective include ① development of rules for furnishing and ② disclosure of information on biological materials that are transferred from domestic deposit to international deposit.

2 Problems of the Patent Microorganism Deposit System from the Perspective of Depository Institutions

According to the investigations of various documents and the questionnaire survey targeting international depository authorities in foreign countries, the problems that are to be found with the Japanese patent microorganism deposit system are as follows: ① budgetary stability; ② handling of biological materials for which the prescribed term of storage has expired; ③ safety measures for personnel engaging in handling deposited biological materials; ④ enhancement of human resources, and ⑤ promotion of interaction with other international depository authorities.

Ideal Future Structure of the Patent Microorganism Deposit System

An ideal future structure of the patent microorganism deposit system is considered based on the survey results.

1 Increasing the Number of Microorganism Depository Institutions

This issue should be positively considered in light of the needs from the industry and advantages to be brought about by the increase.

2 Expanding the Scope of Acceptable Biological Materials at Depository Institutions

In reality, there is no biological material that cannot be accepted at depository institutions in Japan. Therefore, there is no necessity to expand the scope of acceptable biological materials for the present.

3 Reviewing the Mode of Paying Fee

Currently, all fees for domestic and international deposit are paid with patent stamps. It

seems necessary to review the fee payment method in order to make it more convenient for the users.

4 Reviewing the Time of Issuance of the Receipt of the Deposit

According to the results of the interviews, there is not such a strong need for the review of the time of issuance of the receipt of the deposit. However, in light of the Code of Practice under the Budapest Treaty providing that the receipt of the deposit shall be issued after the viability test in the case of a deposit of new material, it seems necessary to review the current system and consider the necessity of introducing the system provided under the Code of Practice.

5 Development of Culture Collections for the Purpose of Developing the Intellectual Foundation for Biological Resources in Japan

Considering that many respondents agreed to make the IPOD also function as a culture collection and that depository institutions in foreign countries carry out culture collection functions as well as patent deposit functions, it seems necessary to consider the possibility of adopting this idea.

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