

17 Patent Applications for Inventions Made by University Researchers in the Field of Biotechnology

The 2006 revision of the Fundamental Law of Education clarified that universities were expected not only to engage in education and research activities but also to contribute to society. Since April 2004, in which national universities were transformed into independent administrative institutions, an increasing number of universities have adopted an intellectual property policy of claiming ownership of intellectual properties created by their researchers in principle (institutional ownership). As a result, patent applications owned by universities have been on the rise.

Despite such an intellectual property policy, some universities still allow their researchers to claim ownership of their inventions (researcher ownership). Furthermore, there are universities that have not adopted any intellectual property policies. Some universities always recognize researcher ownership of an invention and do not recognize institutional ownership thereof. In these cases, it may be presumed that many of the inventions made by university researchers are owned by those researchers or by the companies that conducted the research jointly with those researchers.

The purpose of this report is to outline the characteristics of patent applications for inventions made by university researchers in the field of biotechnology by database analysis and a domestic interview survey and to conduct a comparative analysis on the patent applications' ownership. Based on the analysis results, this report explores how to facilitate transformation of university research findings into intellectual properties and make effective use of those properties for the benefit of society. The goal of this study is to make constructive proposals.

This study was conducted as a part of the JPO's project to promote studies on the intellectual property activities of universities. In view of the increasing importance of biotechnology-related research findings made by universities and other institutions, this study explores how to facilitate transformation of such findings into intellectual properties and make effective use of those properties for the benefit of society. The goal of this study is to make constructive proposals.

I Introduction

The 2006 revision of the Fundamental Law of Education clarified that universities were expected not only to engage in education and research activities but also to contribute to society. Since April 2004, in which national universities were transformed into independent administrative institutions, an increasing number of universities have adopted an intellectual property policy of claiming ownership of intellectual properties created by their researchers in principle (institutional ownership). As a result, patent applications owned by universities have been on the rise.

Despite such an intellectual property policy, some universities still allow their researchers to

claim ownership of their inventions (researcher ownership). Furthermore, there are universities that have not adopted any intellectual property policies. Some universities always recognize researcher ownership of an invention and do not recognize institutional ownership thereof. In these cases, it may be presumed that many of the inventions made by university researchers are owned by those researchers or by the companies that conducted the research jointly with those researchers. Those who work for the intellectual property departments of universities (science) point out that a relatively large number of patent applications are owned by individual researchers in the field of biotechnology.

In order to effectively manage and exploit intellectual properties of universities and other institutions, it is necessary to conduct a multi-perspective study on the researcher ownership of patents at universities and other institutions.

The purpose of this report is to outline the characteristics of patent applications for inventions made by university researchers in the field of biotechnology and to conduct a comparative analysis on the patent applications owned by individual researchers and those owned by universities or other institutions. Based on the analysis results, this report explores how to facilitate transformation of university research

findings into intellectual properties and make effective use of those properties for the benefit of society. The goal of this study is to make constructive proposals.

II Patent Applications for Inventions Made by University Researchers in the Field of Biotechnology

1 Results of database analysis

(1) Analysis method

The Japan Science and Technology Agency (JST) makes available a database, the Directory Database of Research and Development Activities (ReaD), on its website. From the database, data on biotechnology researchers of national, public and private universities was extracted. In addition, from the lists of officers publicized on the websites of biotechnology-related academic societies (The Japanese Biochemical Society, The Pharmaceutical Society of Japan, Japan Society for Bioscience, Biotechnology, and Agrochemistry, and The Molecular Biology Society of Japan), data on university researchers was extracted. In this way, we created a list of 18,224 researchers in total.

Based on this list, the patent applications for the biotechnology-related inventions made by those university researchers were extracted from the publicized patent gazettes issued between 1998 and 2007 (10 years). A total of 7,246 patent applications were extracted and subject to evaluation and analysis for this study. In this study, the “field of biotechnology” means C12 to C14 of the International Patent Classification (IPC).

Based on the extracted patent information, the state of the ownership of inventions made by university researchers was evaluated and analyzed with the focus on such details as whether the ownership of an invention was vested in a university or an individual researcher, whether the ownership of an invention was assigned to another entity such as a company that jointly conducted the research, and whether an invention was jointly owned with another researcher or company, etc.

For the convenience of evaluation and analysis of the extracted patent information, the applicants (the owners of inventions) were divided into four categories, i.e., “university,” “researcher,” “company,” “others.”

The institutions categorized as “others” include the Japan Science and Technology Agency (JST), and its predecessor, the Japan Science and Technology Corporation, and other entities that fall under the category of neither “university,” “researcher,” nor “company.”

In the figures contained in this report, if the indication of an ownership category contains the mark “+,” it means that the applicants stated before and after the mark are joint applicants.

(2) Results of the database analysis

(2)-1 Results of ownership analysis by application year

Thanks to the various measures with regard to intellectual property activities of universities, the number of patent applications for inventions owned by university researchers in the field of biotechnology had been on the rise until 2004 (see [Summary] Fig. 1).

The number of applications owned by universities had also constantly increased from 1996 to 2005. The number of applications jointly owned by universities and companies increased from 2002 as well.

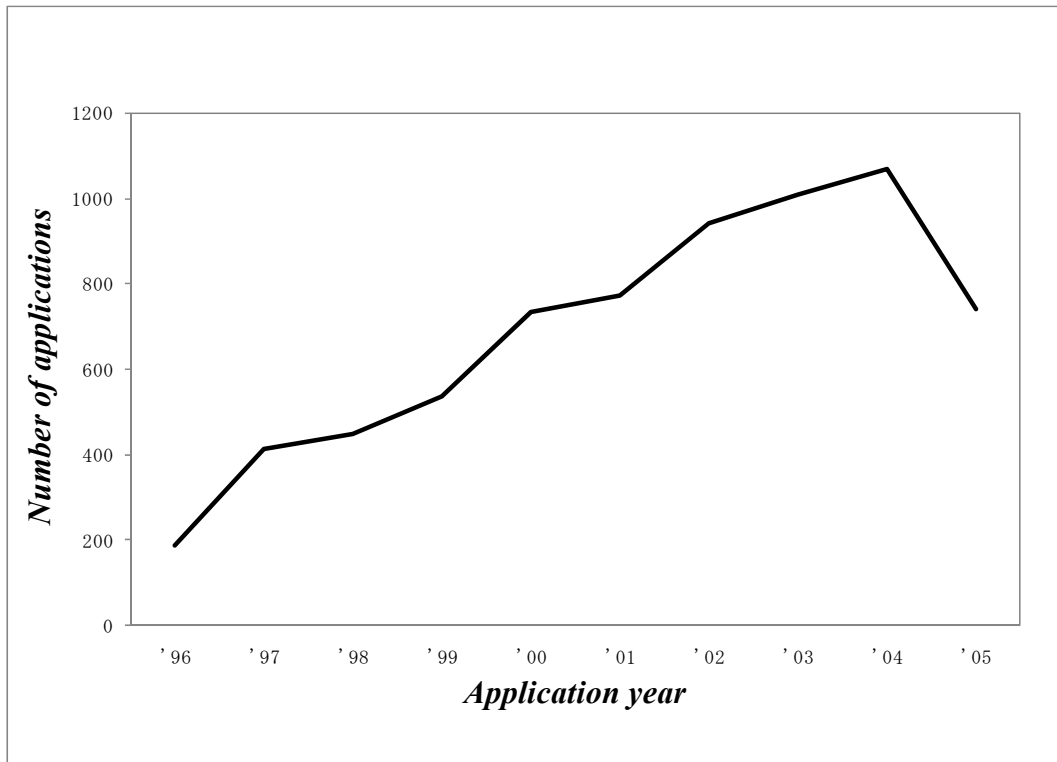
In particular, with regard to the applications filed in 2005 (there is a possibility that many of the national publications^(*1) and re-publications^(*2) were not publicized until the end of 2007), a comparison between the applications filed in 2005 and those filed in or before 2004 shows that the number of patent applications owned by universities exceeded the number of applications owned by companies for the first time. The year 2005 was a milestone for joint applications as well. In that year, the number of applications jointly owned by universities and companies surpassed the number of applications jointly owned by researchers and companies for the first time. (see [Summary] Fig.2 and Fig.3)

The data on the applications filed in 2005 or thereafter and publicized by the end of 2007 shows that the applications owned by researchers accounted for 5.8%, those owned by companies accounted for 27.4%, and those jointly owned by researchers and companies accounted for 6.5%. (see [Summary] Fig. 4)

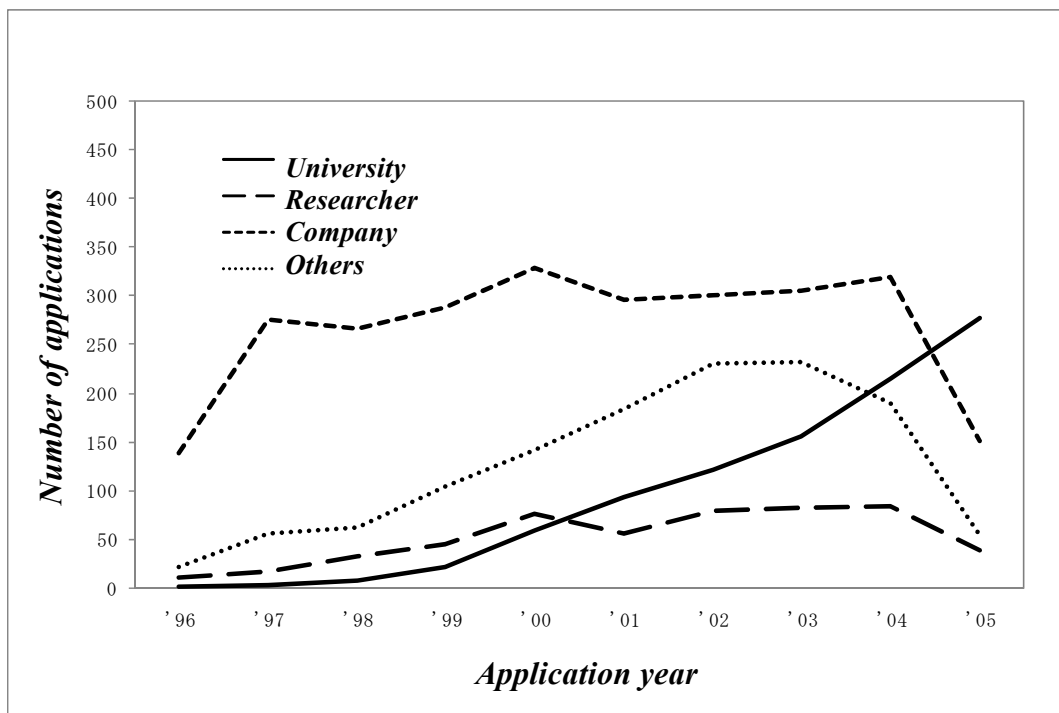
(*1) Japanese translation of PCT international application

(*2) Domestic re-publication of PCT international application

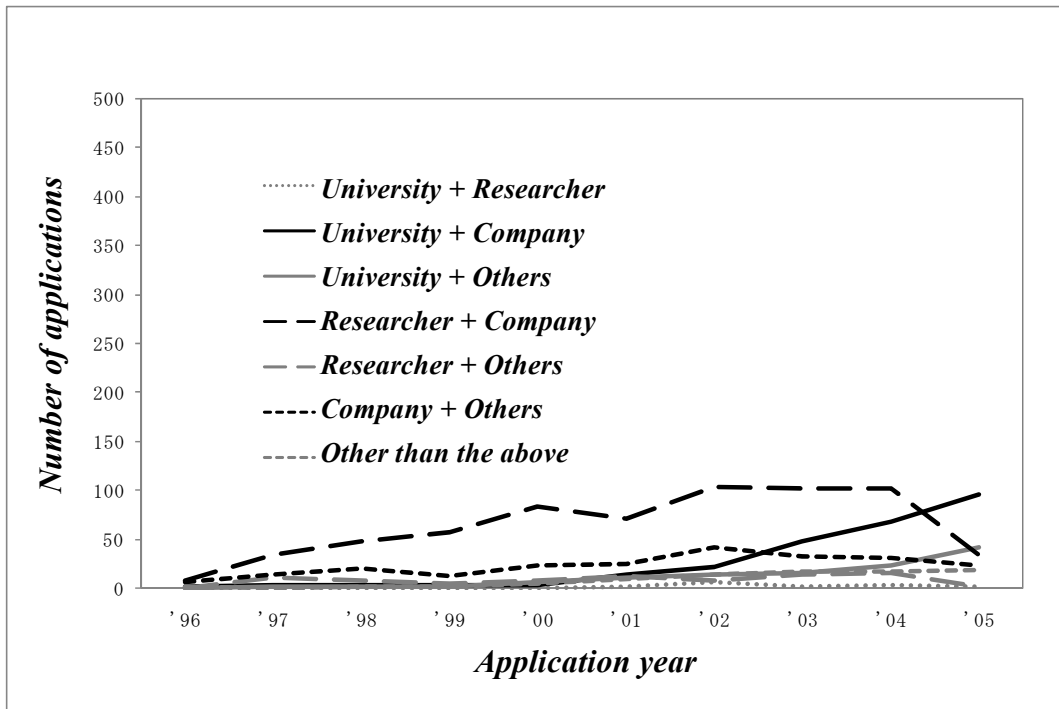
[Summary] Fig. 1. Number of applications (all university inventions)



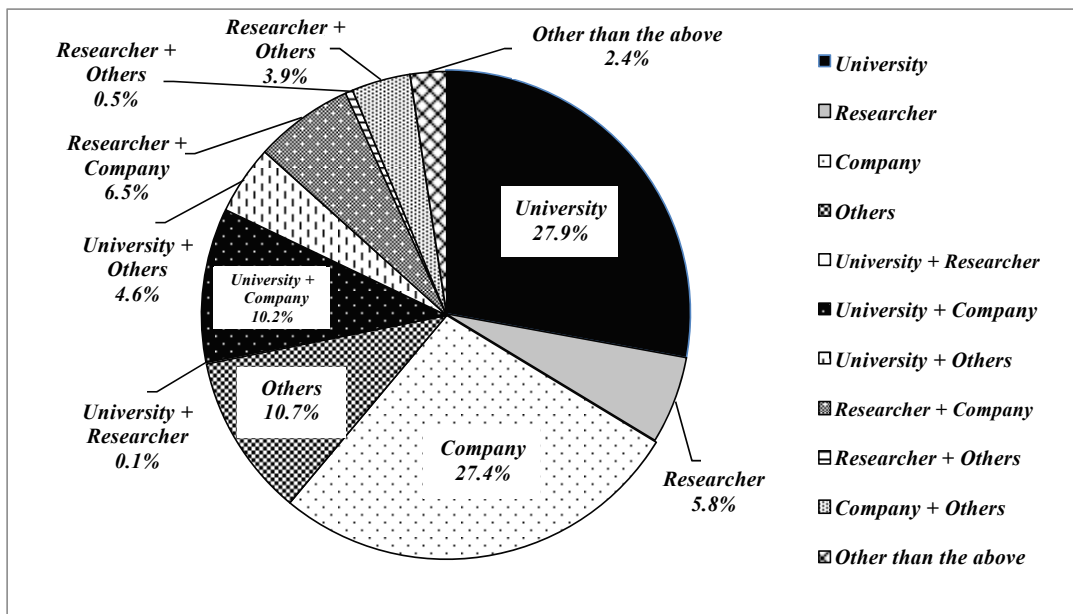
[Summary] Fig. 2. Number of applications owned by applicants who fall under a single ownership category (all university inventions)



[Summary] Fig. 3. Number of applications owned by applicants who fall under multiple ownership categories (all university inventions)



[Summary] Fig. 4. Ownership breakdown of applications filed in or after 2005 and publicized by the end of 2007 (all university inventions)



(2)-2 Results of analysis of ownership by technology classification (the first FI)

The analysis of the patent applications for inventions in the top 10 largest fields in terms of the number of applications filed in the respective fields shows that the proportion of applications

owned by companies was relatively high in all fields except for A01K (animal husbandry) and A01H (new plants) in and before 2004. However, since 2005, the number of applications owned by universities has accounted for a larger proportion than in or before 2004 in every field except for

C12M (apparatus for enzymology or microbiology).

(2)-3 Results of analysis of the ownership of the applications for inventions made by the top 30 researchers in terms of the number of applications they prepared

In and before 2004, the proportion of applications owned by companies was relatively high. Since 2005, the proportions of applications owned by universities and those jointly owned by universities and companies have been on the rise.

However, even after 2005, some patent applications were owned by non-university entities such as companies. As far as the top two researchers in terms of the number of applications are concerned, the proportion of the applications owned by companies has remained high even since 2005. In the case of the top researcher, six of his applications were filed by a research and development-type venture company. With regard to the second researcher, 14 of his applications were filed by five private companies.

In the case of the researchers who have filed a relatively large number of applications since 2005 and ranked 13th, 17th, and 21st in terms of the number of applications (Researchers No.13, No.17, and No.21), all of the applications of Researcher No.13 and Researcher No.21 were owned by their respective universities. In the case of Researcher No.17, ten applications that he prepared were company-owned. The proportion of these company-owned applications was relatively large. All ten applications were filed by a single private company.

2 Results of a domestic interview survey (Universities)

(1) Survey method

In order to conduct a multi-perspective examination of the results of database analysis, an interview survey was conducted with domestic universities (ten national universities, seven private universities, and three public universities). The survey covered such topics as the current state of ownership of patents, etc., and the future direction of patent ownership.

(2) Results of the interview survey

(2)-1 University patent rules

All of the surveyed universities had their respective intellectual property policies and claimed institutional ownership of patents, etc., in principle.

Many of them responded that they made it a

rule to notify an invention as soon as “the invention is made.” However, many of them responded that such a notification is often done before “the invention is presented at an academic meeting” in reality.

(2)-2 Current state of ownership of intellectual properties

(2)-2-1 In the case of research independently conducted by a university

The surveyed universities were asked who owned the inventions made as a result of research independently conducted by a university. Eighteen universities responded that a majority of the inventions were institutionally owned (the assignment rate is 50% or more at those universities). One university responded that a majority of the inventions were owned by researchers. One university responded that it had a different ownership pattern.

All of the surveyed universities attributed the researcher ownership of those inventions to their decision not to request the assignment of the inventions. Some universities mentioned that the decision was made in consideration of the patentability and marketability of the inventions as well as such factors as the “lack of effective embodiments of the inventions due to their early-phase status” and “cost-related issues.”

In response to a question about the merits of institutional ownership, many of the surveyed universities responded, “It promotes joint research and commissioned research,” “It facilitates industry-academia collaboration through central management of inventions,” “It strengthens protection for the rights of universities and inventors,” etc. As demerits, many of them pointed out that “it is costly,” “it is difficult to exploit effectively.”

(2)-2-2 In the case of research jointly conducted by a university and a company

With regard to research jointly conducted by a university and a company, many universities responded that they determined ownership allocation based on the contribution ratio of the inventor (the ownership allocated to the university inventor would be vested in the university). Some universities responded that inventions made through joint research were jointly owned in principle. Some universities responded that they sometimes chose to assign certain patents such as defensive patents for a fee.

Many universities responded that the rate of assignment to universities (i.e., the rate of institutional ownership) was higher in the case of university-company joint research than in the case of university's independent research.

When asked about the reason why a certain invention is owned by a researcher, many universities responded that it was because "The university decided not to request the assignment of the invention." Some universities responded that almost none of the inventions made as a result of joint research were owned by researchers. Other universities responded that researchers rarely file patent applications for their inventions.

To a question about the merits of institutional ownership, many universities responded, "The conclusion of an agreement would not negatively affect the university" and "In general, a company prefers joint application with a university (institution)."

With regard to the reasons why a company prefers joint application with a university (institution), many universities responded that it was because researcher ownership would be difficult to handle due to the different levels of understanding among university inventors about building a contractual relationship. Many universities responded that one of the demerits of institutional ownership was additional procedural burden.

(2)-3 Technology transfer

(2)-3-1 In the case of an application filed independently by a university

Regarding technology transfer of an invention claimed in an application filed independently by a university, nine universities responded that support of their respective internal TLOs was available, while five universities responded that support outside TLOs was available. Some universities responded that technology transfer was conducted by private companies of technology transfer.

When asked about the merits of institutional ownership, many universities pointed out, "The university (TLO) carries out the task of technology transfer," "A company generally prefers negotiations with an institution," etc. As the demerits of institutional ownership, some universities pointed out, "If an invention is made by a university-based venture company established by a university researcher, the institutional ownership of the invention would

cause inconvenience." For example, the universities mentioned, "When the university-based venture company seeks financing from a financial institution such as a bank, the possibility of obtaining financing and the amount of financing depends on whether it owns the right or merely have a license."

As the demerits of researcher ownership, some universities pointed out that the ownership would be subject to general succession in the case of the inventor's death.

(2)-3-2 In the case of an application filed jointly with a company

With regard to technology transfer, many universities have adopted the policy of transferring an invention made as a result of university-company joint research to the company, i.e., a joint patent applicant, on the condition that the company shall exploit the invention. Some universities mentioned that the acquisition of patents would promote further joint research activities.

As the merits of institutional ownership of an invention, some universities pointed out that the exploitation of the invention by the company jointly filing an application would raise revenues for the university. As the demerits of institutional ownership, some universities pointed out that the exploitation of the invention by the company jointly filing an application had not raised any revenues.

(2)-4 Future direction

(2)-4-1 Ownership policy

With regard to the future policy of ownership, all of the surveyed universities mentioned, "Institutional ownership is preferable in principle" and "Institutional ownership is preferable in principle from the perspective of support system and technology transfer." However, many universities responded that, due to budgetary constraints, they planned to shift emphasis from "quantity to quality," "reduce the assignment rate," "lower the rate of examination request," and "decrease the ratio of patents for which patent maintenance fees are continuously paid."

Some universities mentioned that it would be difficult to decide not to request the assignment of an invention even though it might be a reasonable decision to make, given the financial constraints. Some universities pointed out that institutional ownership would be

meaningless if the university lacks negotiation power, contract-making skills, and sufficient funding.

(2)-4-2 Technology transfer

With regard to the future direction of their technology transfer policies, some universities responded, “We need to enhance our marketing ability,” “We plan to put more emphasis on overseas markets,” etc. However, many universities mentioned, “Universities can play only a limited role in technology transfer activities” and “it is difficult to make full use of technology transfer.”

With regard to the field of biotechnology in particular, some universities pointed out that, due to the time lag between the filing of a patent application and the commercialization of the patented invention, an invention cannot be properly evaluated immediately after the filing of the application for the invention. Some universities stated, “Acquisition of patents is a means of inviting corporate participation in joint research,” “We do not adopt a business model in which related costs are covered by license fees. We are trying to use intellectual properties to invite corporate investments in our research activities and thereby make further inventions.”

(2)-4-3 Sample cases of conflicts between a university researcher and the university over the university’s introduction of a patent management system for inventions made by university researchers

Many universities responded that they no longer had major conflicts with their researchers although some researchers were critical of institutional ownership when it was introduced. Some universities reported minor conflicts with a small number of university researchers who refused to assign their inventions to their universities.

3 Results of a domestic interview survey (companies)

(1) Survey method

In order to conduct a multi-perspective study on the results of the database analysis and the domestic interview survey (universities), we conducted an interview survey on companies (ten companies) to which technology had been transferred. The survey covered such topics as the advantages and disadvantages of researcher-owned patents and institutionally

owned patents in transferring technologies to private companies.

(2) Interview survey

(2)-1 University-company joint research

Many companies responded that the ownership of an invention made as a result of joint research would be determined based on the contribution ratio of the inventor (the ownership allocated to the university inventor would be vested in the university). Some companies mentioned that an invention made solely by a university inventor was often jointly owned with the university (institution). Some companies pointed out that, due to the unclear criteria for making a decision between institutional ownership and researcher ownership, such a decision was up to the “university’s policy” and that some universities have even adopted the policy of vesting ownership in individual researchers in principle.

As the merits of institutional ownership, many companies pointed out, “It facilitates explanation to the university inventor and allows efficient establishment of a contractual relationship” and “It gives a sense of security because the consideration for an invention would likely be determined based on the market value.” As the demerits of institutional ownership, many companies pointed out the time-consuming process of concluding a contract, while they admitted, as mentioned above, that institutional ownership had such a merit that it would facilitate explanation to the university inventor. Some companies pointed out the liability for compensatory royalty payment for the jointly owned invention.

As the merits of researcher ownership, many companies pointed out that it would give them a high degree of freedom.

(2)-2 Technology transfer in the field of biotechnology

In response to a question about technology transfer of an invention made as a result of joint research, five companies responded that they had not yet exploited an institutionally owned invention. Some of these companies mentioned that it was because such an invention tends to be a product of basic joint research and therefore takes a long time before commercialization.

As the merits of institutional ownership at the time of technology transfer, other companies pointed out that the consideration for an invention would likely be determined based on

the market value. As the demerits, they pointed out the time-consuming process of concluding a contract and making decisions.

On the other hand, as the merits of researcher ownership, some companies mentioned that it would facilitate negotiations and give them a high degree of freedom and that it would allow the company to lead the negotiations on technology transfer. As the demerits, some companies pointed out the difficulty in predicting the amount of consideration demanded by the university researcher in some cases because the amount of consideration is determined through negotiation with the researcher.

Furthermore, as the demerits of researcher ownership, some companies stated that the ownership would be subject to general succession in the case of the inventor's death and that it would take time to reach the university inventor after his or her retirement from the university.

(2)-3 Future direction

(2)-3-1 Patterns of ownership

In response to a question about future direction, some companies responded that institutional ownership should prevail more widely than researcher ownership. Some companies mentioned that the rights to an invention should be assigned to a company if the invention is going to be commercialized by the company. They explained the reason for their preference for assignment of rights by saying that an exclusive license would not necessarily preclude the right holder from granting a license to a third party if the right holder recognizes that the exclusively licensed invention has not been exploited for a certain period of time. Another reason they presented was that the amount of consideration and other conditions would have room for negotiation. Some companies mentioned that, in the case of a company-university joint invention, the company should be required to pay the university compensatory royalties for the invention only when the invention becomes profitable.

(2)-3-2 Technology transfer

In response to a question about future direction, many companies responded, "Biotechnology-related patents (e.g., research tools), which are often general-purpose, should be treated differently from other patents such as drug-related patents." More specifically, some

companies mentioned, "General-purpose technologies should be transferred in a non-exclusive manner at a reasonable consideration" and "Universities and companies should have specialists who can distinguish general-purpose technologies from the rest."

(2)-3-3 Others

Regarding the contract-making ability of universities, many companies pointed out, "Universities (TLOs) vary greatly in their contract-making policy" and "Some universities have no personnel who can handle contract negotiations" since, as pointed out by many companies, some universities had little experience in building a contractual relationship.

Some companies said that contracts should be made more flexible because "It takes time for a biotechnology-related invention to become profitable," "It also takes time to determine which invention to commercialize," and "Commercialization is costly." For example, some companies requested more flexibility in a contract in terms of the timing of the payment of compensatory royalties and consideration to the university, the timing of concluding a contract, etc. Some companies pointed out that universities had increased the flexibility of joint-research contracts in recent years.

III Study on How to Facilitate Transformation of University Research Findings into Intellectual Properties and Make Effective Use of Those Properties for the Benefit of Society and Proposals

In view of the current state of patent applications for inventions made by university researchers in the field of biotechnology, we studied how to facilitate transformation of university research findings into intellectual properties and make effective use of those properties for the benefit of society. This study was conducted on each of the three major types of research: research independently conducted by a university, research jointly conducted by a university and a company, and research conducted by a university-based venture company. Based on the findings, we presented proposals.

(1) Research independently conducted by a university

- Promotion of further research findings by inviting corporate participation in joint research

The central management of patents by universities has an advantage in the effectiveness in promoting industry-academia collaboration, inviting participation in joint research and offers for commissioned research, and procuring financing from outside the company as well as raising competitive funds. On the other hand, it is difficult to make use of inventions through technology transfer by means of licensing and assignment.

Therefore, universities are expected not only to seek technology transfer by means of licensing and assignment but also to pursue creation of further research findings by promoting corporate participation in joint research conducted based on the basic patents of the universities. Universities' initiative in these activities should be promoted as a means of facilitating transformation of university research findings into intellectual properties and making effective use of those properties for the benefit of society.

- Acquisition of useful basic patents

It is important for universities to obtain useful basic patents. However, these days, only a small number of useful basic patents are created because universities are reluctant to bear the burden of giving a presentation as frequently as once a year and the burden of publicizing an interim report on the relevant projects.

In order to obtain a useful basic patent, a researcher needs to file a patent application containing a sufficient amount of effective data before presenting the invention at an academic meeting, etc. Therefore, as far as the field of biotechnology-related is concerned, political measures should be taken to secure enough time to complete research. Furthermore, it would be necessary to review the current practice of requiring presentation as frequently as once a year and publication of an interim report on the relevant projects.

- Measures to secure financing for the cost of filing patent applications overseas

With regard to inventions related to the projects prioritized in the Japanese science and technology policy, necessary measures must be taken to prevent university's budgetary deficiency or JST's situation from stopping the filing of a patent application overseas.

- Technology transfer of a general-purpose basic patent by means of non-exclusive licensing

In a case where a university obtains a patent in the field of biotechnology, if it is a basic patent for a general-purpose technology such as research tools, such a technology should be made available for technology transfer through non-exclusive licensing at a reasonable license fee in accordance with the principle presented in the Guidelines for Facilitating the Use of Research Tool Patents in the Life Sciences (March 2007: Council for Science and Technology Policy).

(2) Research jointly conducted with a company

- Flexibility of contracts for joint research inventions

As the merits of institutional ownership, many universities pointed out that it would allow a university to participate in contractual negotiations with a company on behalf of a university researcher so as to avoid concluding a contract that is disadvantageous to the university. They also pointed out that it would allow a university to gain revenues from license fees. On the other hand, many companies pointed out that contractual negotiations with a university would be more efficient than negotiations with a university researcher (individual) and that institutional ownership would increase the predictability of the amount of license fee and other costs to a certain extent. They also pointed out that some universities would be reluctant to modify their model contracts.

The way of handling the findings of joint research would differ greatly from one contract to another. In the case of a university's biotechnology-related patent, the patented invention is often a product of basic research. This is why it is difficult to determine how to commercialize such an invention at the time of filing a patent application for the invention. Universities should recognize that the commercialization of a biotechnology-related invention tends to take a long time and a great amount of investments despite a low probability of commercial success. Based on this recognition, universities should increase the flexibility of contracts.

For instance, if a company requests exclusive licensing of an invention, a university should extend the period before starting to consider licensing a third party on the grounds that the company has not exploited the invention for a certain period of time.

- Option for a university to file a patent application independently

If a university and a company file a joint patent application for an invention made as a result of their joint research, non-exploitation of the invention by the company would make it difficult for the university to exploit the invention by means of technology transfer to another company. To prevent such a situation, the university should be given an option to independently file a patent application for a joint research invention that was made mostly by the university and to give the company the first refusal right.

(3) University-based venture companies

- System to ensure the continuation of research activities at universities at the time of the bankruptcy of a university-based venture company or at the time of patent assignment as a result of an M&A

The ownership of a university patent by a university-based venture company would facilitate the procurement of financing from financial institutions, etc. Despite this merit, there is the demerit that an M&A or the bankruptcy of a university-based venture company could lead to a patent assignment to a third party against the will of the university. Such unintended assignment could prevent the inventor from exploiting his own invention.

Therefore, it would be necessary to establish a system to ensure the academic use of inventions by the university inventors. Under the system, a university should own its patents and grant the exclusive licenses to university-based venture companies so that the university can ensure the academic use of the patented inventions as the patentee.

(4) Proposals about the universities' intellectual property activities in general

- Fostering of the awareness of university researchers

Further discussion would be necessary concerning such issues as how to make effective use of universities' research findings as a whole for the benefit of society and how joint research should be. Furthermore, it would be necessary to raise university researchers' awareness that one way of making use of research findings for the benefit of society is to transform those findings into intellectual properties and commercialize them and that one of the roles of university

researchers is to carry out such transformation and commercialization.

For example, it may be a good idea to provide university researchers with information on example cases of successful commercialization in the United States and other countries in order to raise their awareness about the possibility of benefiting society by transforming their research findings into intellectual properties. The purpose of such awareness-raising effort is to make university researchers fully aware what patents could fully exploit, in other words, what intellectual properties could use for the benefit of society.

- Recruiting and nurturing of specialists

In the field of biotechnology in particular, it is important to recruit and nurture specialists who can distinguish profitable inventions from the rest and who can facilitate collaboration and technology transfer between companies and universities. However, it would be unrealistic to expect all of the universities to recruit and nurture all kinds of specialists. Instead, universities could consolidate their intellectual property headquarters and their departments in charge of technology transfer, etc., in order to make efficient use of their human resources.

- Example cases of successful exploitation of inventions in Japan

Some university researchers oppose the current trend of promoting transformation of university research findings into intellectual properties and exploitation of those properties for the benefit of society. Some university researchers have a negative view on the university's central management of patents for inventions made by university researchers. In order to convince them that transformation of their inventions into intellectual properties could benefit society, it would be effective to inform them of example cases of successful exploitation of inventions in Japan. A national project should be launched to establish a research system to promote transformation of research findings into intellectual properties. For instance, it would be recommended to mobilize researchers in a timely and flexible fashion in order to respond to the shortage of manpower to obtain data necessary to transform an invention into a useful intellectual property.

(Resercher: Miki OBI)