9 Measures for Smooth Use of Patented Inventions

The use of patented inventions has been discussed as a general subject, focusing especially on technical standards and upstream technologies in life science. However, it has been pointed out that measures thereof should be further examined based on a more specific understanding of the current situations. In this research, specific cases relating to that subject in question and the current situations in the industry and academic sector are investigated, and studies on measures thereof is developed.

With respect to technical standards, the investigation of the current situations was focused on patent pools that are formed to efficiently conduct the licensing of essential patents, identification of essential patents, and patent statements in international standardization. With respect to upstream technologies in life science, the investigation reveals the current situations that patented inventions are not necessarily used smoothly. For example, a license on another's patent is not obtainable, and thereby, the relevant patented invention is not accessible, and subsequent research is thus blocked.

Possible measures including compulsory licenses should be further discussed based on the current situations and specific cases investigated in this research.

Ⅰ Introduction

Recently, a lot of discussions have been held on use of patented inventions in specific technical and industrial fields. In particular, many of them have been given so far to technical standards and upstream technologies in life science. However, it has been pointed out that more specific understandings of the current situations thereof and further discussion on measures thereto are needed.

Patent licenses essential for a technical standard may be collected at a patent pool. There is concern that the owners of essential patents who do not participate in patent pools may claim or enforce against the users of standards. Participants in standardization, owners of essential patents, patent pools, participants in patent pool, and users of standards may be intricately involved in standards, and their views on standardization with patent licenses are varied. Possible measures to solve issues on patents regarding standards include compulsory license, the Antimonopoly Law and guidelines.

Options for measures to solve issues on patents regarding upstream technologies in life science include compulsory license, guidelines for licensing and the Antimonopoly Law. On the other hand, although no case law has been established with respect to the scope of exceptions for experiment or research, it is generally accepted at the moment that research with the subject matter of the patented invention is outside the scope of that exception and falls into an infringement of the relevant patent, regardless of the entity that uses the invention (university, company, etc.) and the purpose of research.

However, only a few cases concerning the issues in question have been identified, and thus, it can be hardly said that current situations have been studied to the extent necessary and sufficient to consider measures to solve the issues. Therefore, in this reserach, specific examples of relevant issues and the current situations in the industry and academic sector were investigated, and measures for the smooth use of patented inventions were further examined.

The outcomes of the research is summarized as follows.

Ⅱ Issues on Patents Concerning Technical Standards

(General) Major issues on standards and patents have already been considered from various angles. In this research, these issues were arranged in three stages.

With respect to the standardization stage, firstly, the major issues include the development of patent policies of standardization bodies/ organizations, patent statements, patent search, outflow of technical information, adequacy of royalty-free patent licenses and preference of standardization bodies/organizations in anticipation of a prompt and smooth formulation of a standard.

With respect to the stage of establishing

patent/license pools after standardization, secondly, major issues include location and operating entity suitable for the management of patent/license pools, evaluation of essential patents, divisions or amendments of patent applications, nonparticipation of patentees in patent pools, situations where several patent pools exist separately for one standardized technology, income distribution of patent pools, Antimonopoly Act-related guidelines recently published, capping of license fees to be paid to patent pools, and cumulative license fees due to the use of many standardized technologies for one product to be on market.

Major "holdup" issues after standardization include the possibility to apply compulsory license to solve, the possibility to apply the Antimonopoly Act-related guidelines, reasonable license fees for parties concerned, and procedures for restarting standardization after holdup occurs.

(Specifics) Firstly, this report introduces the following as specific cases in the standardization stage: attempts to seek ways to establish a patent pool covering a hypothetical standard; the current trends in China of their own standardization; a case where a concern has arisen in the smooth use of standardized technology due to an unexpected patent statement made at the final stage of standardization; the situation where a patent search cannot be officially performed despite concern about unidentified essential patents; and royalty-free patent licensing and backgrounds thereof.

Next, the following are introduced as the current situations in the stage of establishing patent pools after standardization: the actual circumstances and problems relating to frameworks for collective licensing (such as patent pools) in terms of major standards in the information and communications or electrical fields, especially, standards relating to third-generation mobile communications, DVD and MPEG; bodies or organizations for the evaluation of essential patents, processes to evaluate essential patent, and problems thereof to be solved; and the recognition of the present essential patents evaluation from companies' viewpoints.

Subsequently, the following are introduced as cases in relation to holdup issues after standardization: a case where a licensing conditions offered by a patent pool was reconsidered taking into account public interest; and a case where a licensee complained against licensing conditions fixed by owners of essential patents, as well as the classification of "outsiders" and examples thereof.

As a reference material, this report includes comments and opinions by practitioners from various fields on some issues in these three stages.

Ⅲ Issues on Patents Concerning Upstream Technologies in Life Science

(General) Upstream technologies in life science include materials such as genes, multi-purpose equipments, processes such as drug screening, the process of manufacturing biological macromolecules, and databases and programs relating to gene sequence information. These technologies can be generally divided into three categories: multi-purpose technologies used irrespective of the research subject; those specific to a particular research subject and used only in R&D stage; and those specific to a particular research subject and related to relevant end products.

General issues include: the current situations where distribution of experimental materials and patent licensing are not necessarily smooth; difficulty in detection of patent infringement; difficulty in judging the patentability of inventions; low predictability of final commercialization; non-substitutability; cumulative license fees; and difference in the position between patentee/licensors and licensees. In particular, specific issues have arisen in relation to: licenses solely for research purposes; reach-through royalties; label licensing; ambiguous boundary between commercial purpose and research purpose; market prices of license fees; license agreement; industry-academia cooperation; and R&D particularly relating to pharmaceuticals.

According to an accepted theory on exception of "experiments or research," furthermore, one of the requirements for the exception is that a patented invention itself is the object of experiment or research. However, it is difficult to distinguish "research on" the subject matter of the patented invention with "research with" the subject matter of that invention in the relevant field.

(Specifics) On upstream technologies with low or no substitutability, in particular, genetic inventions including genes, proteins encoded

thereby and various processes using them, this report reveals the characteristics of patent examination in the relevant field in comparison to the chemical field; backgrounds for difficulty in obtaining licenses in the relevant field; a case where a patent license was not obtainable and the downstream R&D was inhibited; a case regarding R&D for gene therapy and enforcements by patentee of inventions crossly relating to the R&D; a non-substitutable technology essential for R&D of antibody medicines; and the viewpoints of patentees/inventors of genetic inventions. Through these, it may be possible to see a portion of the current situations where the use of patented inventions is not necessarily smooth and the subsequent research is blocked, and backgrounds thereof.

Moreover, regarding multi-purpose upstream technologies, cases in relation to: R&D and patent strategies for ES cell-related technologies; multi-purpose technologies used for gene engineering including vectors; a license wasn't obtainable on a gene expression-regulating tool, and research using that tool was significantly delayed; an experimental animal and the use thereof in research, a basic invention essential for the production of recombinant monoclonal antibodies; R&D and litigations regarding system tools such as DNA chips and real time PCR; and computer programs for bioinformatics are reported as well as viewpoints of a biotechnological venture company. These reveal a portion of the current situations in the relevant research field, in which some of multi-purpose technologies can be hardly accessed, regardless of whether or not they can be substituted by the others.

Furthermore, the current situations regarding upstream technologies at universities and companies are reported herein. They may reveal various issues which researchers face with and have to deal with.

As a reference material, comments/opinions on some regulations and guidelines in relation to those issues are provided.

Ⅳ Measures for Smooth Use of Patented Inventions

1 Possibility to Grant Compulsory License

This consideration is premised on provisions on compulsory licenses under the current Patent Law, Implementing Guidelines for Compulsory License, the Paris Convention, and the TRIPS Agreement. In Japan, nine requests have been filed for arbitration decision on grant a compulsory license in case of non-working while fourteen have been filed for that in case of dependent patent. However, no arbitration decision has been rendered yet.

On the grant of a compulsory license, in generally, there is a concern about the issue of balance with patent protection, impacts on developing countries and industries other than life science or technical standard-related fields.

When one asks to be licensed on a research tool patent, the patentee may refuse to license for the reasons that the patentee wants to exclusively conduct R&D, or that parties concerned do not agree on license conditions. Even though the patentee does not refuse to license, the basis to calculate license fees may be unreasonable, or unfair conditions may be set. Whether conditions are "unreasonable" and how they are judged should be carefully considered. Since research tools are used for R&D, compulsory licenses would be meaningless if procedures would demand a long time. Further, as companies now become global and tend to concentrate R&D on particular countries among all the countries concerned, compulsory license in case of no-working should be cautiously examined, taking into account possible impacts on developing countries. Concerning compulsory license for public interest, as what "the public interest" means is not very clear now, careful consideration would be needed.

Considering the applicable provisions on technical standards, there is a question of which is appropriate, a compulsory license in case of non-working or one for public interest. In the former case, as what the patentee requests is presumably royalty in many cases, the sole purpose of arbitration decision is to determine a reasonable royalty. However, there would be a *prima facie* question as to whether granting compulsory license in case of non-working for the purpose of determining a reasonable royalty meets the originally designed purpose of the Patent Act. With respect to compulsory license for public interest, whether a compulsory license is especially necessary for public interest" would be a certain subject to be examined. If a standard has been established for a technology that is an infrastructure in the world, an idea that it could be safely said that a compulsory license on the standardized technology is "especially necessary for public interest" seems to be *prima facie* persuasive. In addition, what is a reasonable royalty would be questioned. Furthermore, there

is another question as to who should be involved in the procedures for the grant of compulsory license on technical standards.

2 Problems in the Antimonopoly Law

(i) As a base for free competition, companies retain the freedom to choose their trading partners, and refusal to trade becomes a problem under the Antimonopoly Law only in exceptional cases. On the other hand, it has been pointed out that in dealings in relation to intellectual property rights, refusal to license (refusal to trade) may have a significant impact on the formulation of technical standards and in the field of research tools.

However, the current situations of such refusal to license are not yet necessarily clarified in Japan. Consequently, it is urgently necessary to firstly collect cases of refusal to license when discussing the issue of refusal to license with the Antimonopoly Law.

(ii) Moreover, it is necessary to define the market where an anticompetitive effect arises when considering the issue of refusal to license with the Antimonopoly Law. In terms of technical standards (in particular, those that are not directly connected to products) or research tools, where a patented invention is a basic technology and subsequent research of the related field cannot be carried out without using the relevant patented invention, it is necessary to define the market, which incurs adverse effect due to refusal to license, from the standpoint of whether or not subsequent R&D are inhibited.

Until now, application of the Antimonopoly Law in technology-related cases has covered "product market" or "technology market." However, in order to deal with cases in which subsequent R&D are inhibited, it is necessary to consider whether the "technology market" includes subsequent R&D, or whether a new concept of a "technology development market" should be introduced into Japan.

(iii) Furthermore, in considering the issue of refusal to license with the Antimonopoly Law, there is the question of substitutability of a relevant patented invention. That is, it is necessary to determine the impact of refusal to license, the existence of alternative technology, the impact of refusal to license on subsequent R&D, and the possibility of alternative R&D in order to decide whether the refusal to license becomes a problem under the Antimonopoly Law. And high-level technological knowledge is required to determine any of these. Consequently, it may be useful for participants in standardization to improve predictability and ensure transparency if the Fair Trade Commission of Japan prepares frameworks for obtaining an objective and neutral evaluation.

(iv) Acts of forcing participants in standardization to disclose their patents or agree on the RAND terms, or acts by technical standardization bodies of negotiating license fees or other conditions with those who refused to license may fall into the category of cartel under the Antimonopoly Law (unfair restraint of trade). On that basis, voluntary pre-agreement on the disclosure of patents among participants, to an extent not conflicting with the Antimonopoly Law, seems to be useful in formulating and implementing technical standards.

(v) In the case where refusal to license was determined to constitute a violation of the Antimonopoly Law, an order for one who violates the Antimonopoly Law to license is within the scope of necessary measures to eliminate violating acts. On this occasion, it would be appropriate to give a moderate order like one to grant a nonexclusive license to who wants to obtain that under reasonable conditions.

3 Recommendations to Companies on Standardization and Licensing Activities

Standardization activities have been intensifying in industrial fields such as information and communications as well as electric appliances and electronics since businesses have come to be run on the layer structure.

Not exclusively using a patented invention but allowing other companies to use has strategic value. First of all, in a market with network externality, utility on both the supply side and demand one will rise through an increase in the variety of products in cooperation with other companies, and the market will expand. Secondly, if a company constantly outputs new products into the market ahead of others and allows others to ship alternative products subsequently after undermining the others' willingness to develop a substitutable technology by promising them the granting of patent licenses, the company can control the market. Thirdly, in the information and communications, and electric appliances and electronics fields, as many companies carry forward R&D in parallel on a global basis to create inventions, they possess many patents separately. In addition, these fields are

characterized by the point that many components and subsystems using patented inventions integrated and then constitute one product or service. Thus, cross-licensing is indispensable. Therefore, Japanese companies should lead the market by utilizing their patents through licensing.

In international standardization activities, it is necessary for companies to increase partners and actively work to incorporate their own technologies but patents into standards. International standardization activities are political negotiations but are not opportunities to determine the superiority of technologies. Companies should let employees who are good at negotiation participate in relevant activities.

It is risky to expect patent pools too much since high costs are required in negotiation to form patent pools. However, if a common understanding that "there is a possibility of organizing a patent pool in the future" is shared by participants of the standardization in the process of their activities, negotiations may become easier. Japanese companies should actively encourage foreign companies to form patent pools, while looking into future, if necessary.

4 Trends toward Improving Standardization Procedures at International Standardization Bodies or Organizations

Among the major international standardization bodies, ISO, IEC and ITU-T, ITU-T has the finest procedures for handling intellectual property. Specifically, ITU-T has established IPR policy guidelines, and patents for which patent statements have to be submitted to declare are restricted to essential ones according to the guidelines. Contrary to this, ISO/IEC is behind ITU-T in the development of IPR policy. However, Japanese Industrial Standards Committee: JISC) continued active proposal at ISO/IEC Joint Technical Committee 1 (JTC1), and then SC29 of JTC1 adopted submission of a proposal to use a common format for patent statements to the JTC1 in 2004. With this as a turning point, the discussions have been expanded into entire ISO/IEC. Consequently, in February 2005, discussions on patent policy started at the WSC, which was established as a organization for collaborative activities among the ISO, IEC and ITU.

The JISC decided to actively provide input to these activities through the secretariats of the standardization bodies. It set up a committee on establishment of standards including patent rights within Japanese Standards Association, and presented concrete opinions on IPR issues and draft guidelines to the ISO and IEC in December 2005. In this, the JISC sorted out various issues regarding relationships between standardization and intellectual property in a comprehensive manner and made some proposals as immediate tasks while noting that there remain many problems that standardization bodies should consider.

The outcomes of the WSC, which were discussed at the TMB in February 2006, include a draft code of conduct for a patent policy shared by those three bodies, and draft guidelines for implementation of patent policy. ISO and IEC agreed to handle royalty-free and RAND as separate patent licensing methods for the first time, marking a significant step toward the adoption of a common patent policy with the ITU-T. Moreover, Japan's proposals were positively incorporated in the draft guidelines for implementation of patent policy, and these new patent policy and guidelines are highly likely to be adopted soon.

As described above, standardization procedures at international standardization bodies have been significantly improved in the last year. This can be considered to be the outcome of the active approach to the secretariats of the bodies by Japan and other technologically advanced countries where many licensors operate. However, since the previous consideration has been somewhat in a bit favor of licensors, it is necessary to continue consideration from the licensees' viewpoint.

5 Possibility to Apply Exception of Experiment or Research

According to an accepted theory up in Japan, the scope of experiment or research should be determined on the object and purpose of research. The object of experiment or research shall be limited to a patented invention itself in question, and the purpose of experiment or research shall be limited to "advance of technology" The report of the Working Group of Issues Related to Patent Strategic Plan (within the Patent System Subcommittee of the Intellectual Property Policy Committee of the Industrial Structure Council), titled "Issues Concerning Smooth Use of Patented Inventions" (November 2004), concluded that the view of the accepted theory is

not inappropriate. According to the view of the theory, in many cases on patents claiming upstream technologies in life science, it seems that research in question does not fall into exceptions for experiment or research. In addition, the scope of a patented invention does not differ depending on whether research is for commercial purpose, or whether the entity that uses the invention is a company. However, no case law has been established for a relevant provision, and there are a variety of opinions thereon.

In the United States, the Supreme Court held in June 2005 that Section 271(e)(1) of the U.S. Patent Law, which stipulates immunity from research relating to application for regulatory approval for the production of medicines, shall apply to all uses reasonably related to the development and submission of various types of information under U. S. Federal laws which regulates pharmaceuticals, etc., and apply to research even in the preclinical stage. On the other hand, with respect to the point of view on the use of patented inventions for research tools, the Supreme Court did not provide any general principle.

In Belgium, the revision of the Patent Act was issued in April 2005; thereby the scope of application of exceptions for use of patented inventions for research purposes was expanded. Article 28(1)(b) of the revised Belgium Patent Law stipulates that the right of the patentee shall not extend to research on or with the subject matter of the patented invention for scientific purpose.

6 Recent Movements to Formulate Guidelines

In Japan, various guidelines relating to the smooth use of patented inventions have been in development. In June 2005, the Fair Trade Commission of Japan published guidelines on standardization and patent pool arrangements. In addition, the Council for Science and Technology Policy is carrying forward the formulation of guidelines for the licensing the intellectual property rights derived from R&D funded by the Government for the purpose of research use.

In industry, the Japan Pharmaceutical Manufactures Association published in January 2006 the "Guideline for Research Tool Patent Licensing (proposal)."

In the world, the Organisation for Economic Co-operation and Development published "Guidelines for the Licensing of Genetic Inventions," which would be applied for human healthcare, as the recommendation of the OECD Council at the end of February 2006.

Ⅴ Conclusion

In this research, current situations were investigated and analyzed with respect to issues on technical standards with patents, particularly focusing on issues concerning patent pools which are organized to license efficiently on patents essential for technical standards. Since R&D is carried out in advance of the standardization of technologies, a time lag often arises between grants or issues of essential patents and standardizations. Seeking to organize a patent pool based on a hypothetically presumed technical standard could be useful as an attempt to bridge such a temporal gap. Moreover, if the object of a technical standard is too broad when organizing a framework for collective licensing (such as a patent pool), the number of essential patents thereof will increase accordingly, that may lead to a problem under the Antimonopoly Law. On the other hand, the problem of escalating cumulative license fees should also be avoided. Therefore, it is necessary to continue trying to organize frameworks for collective licensing in more preferable manner. Regarding the evaluation of essential patents, it is important to try to achieve prompt and precise evaluation procedures through further encouragement of training candidates who evaluate patents and fixing the procedures. Furthermore, for the capping of license fees paid in using standardized technologies, adequacy of the capping tends to be a problem, so it is necessary to cap taking into account manufactures and sales. A complaint about the license conditions set by the owner of an essential patent becomes a problem particularly in the case where the patentee is a R&D-based company but does not manufacture or sell products. If a market expands, however, the income from license fees increases, which is also advantageous to R&D companies. Therefore, it is expected for parties concerned to hold positive discussions.

With respect to upstream technologies in life science, so far as investigated in this study, no one denied the necessity of patent protection. However, there have been cases where the use of upstream technology was inevitably abandoned due to the difficulty in obtaining a relevant patent license, and it has become clear through the

present research that R&D is and could be disturbed actually. In terms of exceptions for experiment or research, the majority of uses on upstream technologies patented in life science are not considered to fall into such exceptions, according to an accepted theory. However, a case law thereon has not yet been established, and a variety of opinions have been provided. For example, some point out that the exceptions are not sufficiently based on natures specific to the relevant field since the accepted theory had been established before those issues became obvious. Therefore, it would be necessary to continue consideration from the viewpoint of globalization of R&D, taking into account international scene such as the U.S. Supreme Court decision and the revision of the Patent Act in Belgium.

As for the adequacy of granting a compulsory license by an arbitration decision for smooth use of patented inventions, the first institutional problem is which one can be applied to uses of patented inventions relating to technical standards and upstream technologies in life science. "Non-working of patented invention," "dependent patent" or "public interest"? Of these, "non-working of patented inventions" should be carefully examined taking into account possible impacts on developing countries, since companies now become global and tends to concentrate their R&D on particular countries among all the countries concerned. As "dependent patent" is applied to only the cases in which a patented invention cannot be practiced without using another patented invention that the former depends, a request for an arbitration decision can be filed if the requirements are fulfilled. Consequently, there seems to be no other way but to use "public interest." However, the "Implementing Guidelines for the Compulsory License" illustrates only two occasions where a "compulsory license is especially necessary for public interest." One of them is the following: "where proper development of the relevant industry is inhibited without granting non-exclusive license on the relevant patent, and consequently, substantial adverse effect on people's livings is observed." However, no concrete directions has been provided with respect to the requirements of "inhibition of proper development of the industry" and "substantial adverse effect on people's livings." Therefore, it is not clear what should be proven when a request for an arbitration decision is filed. For these requirements, a more specific and concrete directions should be given in the "Implementing Guidelines for the Compulsory License." Moreover, some have pointed out concerns as to how the compulsory license is operated. Patentees may refuse to license when they want to exclusively conduct R&D or when they cannot agree on license conditions. Since standards on which arbitration decisions are made have not been established at all in Japan, it have to be said that how adequacy of arbitration decision is judged and how license fees are determined are totally unpredictable. There has arisen concern that the grant of compulsory license by arbitration decision will become meaningless if arbitration decision procedures demand a long time or if the license fee determined is too expensive. It's very important to secure prompt decision procedures and adequacy of judgment or determination.

(Senior Researcher: Toru WATANABE)