8 Trends of Licensing Agreements in the Industrial Sector and Subsequent Economic Problems

With the current serious economic conditions surrounding Japanese companies, intellectual property strategy including licensing activities has become, and will continue to be, one of the important business strategies for such companies.

In this report, the actual conditions and the certain problems of companies' licensing activities were investigated and studied, while taking a look at the background of and the problems in the strengthened Japanese patent system, the licensing regulations, and the relationship between the patent system and licensing agreements.

Specifically, licenses in life science, biotechnological, and pharmaceutical industries as well as the electric and electronic industries and the research of the actual patent pool system and problems for such system were analyzed.

In addition to the above, the necessity for economic analysis, such as the evaluation and study of technological innovations and spread of the technology based on patent data, and the expected patent data for performing such purpose, were also examined.

Ⅰ Introduction

1 Background and Outline of This Report

The following are cited as revisions for strengthening the patent system in Japan: (1) expansion of the scope of patentable inventions, (2) extension of the term of patent, (3) expansion of the range of patent, (4) change in execution, and (5) limitation on compulsory license. Two points are cited as reasons for these revisions for strengthening the patent system. The first is external pressure. This is the strengthening of patent protection, which the United States has been carrying out as one of the means for restoring its industrial competitiveness since the 1980s, that is, adopting a pro-patent policy. The United States tried to restore its industrial competitiveness through strong protection of its advantages, namely, science and technology, by using the patent system, and also requested Japan to strengthen its patent system.

The second is that the technical level of Japanese industry rose and the idea that strong patent protection is necessary for Japanese industry has expanded in Japan. On the other hand, the negative effect of the strengthened patent system on research and development has been increasingly discussed, and it is thus now necessary to get back to and examine the basics—how the patent system should be to promote technological innovation.

In addition, the possibility that patent inhibits technological innovation has been pointed out, and problems known as "patent thicket" and "tragedy of the anticommons" have been discussed. The former problem is that it is necessary to negotiate with many patentees to develop one product and labor for the negotiations and the payment of royalties becomes a burden, obstructing actual product development, like a thicket. The latter refers to the situation where too many private property rights (patents) exist in the biotechnological field and they end up making it impossible to develop pharmaceuticals. This situation is contrary to the "tragedy of the commons," which means that overexploitation is likely to happen in such places as common land and high seas where private property rights have not been established.

Similar problems have been pointed out at places of academic and scientific research, such as universities. Even if they are conducting purely academic research through public funds, they may be required to pay license fees depending on the experimental method.(*1) Requiring universities and hospitals to pay patent royalties should not be categorically denied, but the speedy, free publication of research results and the free exchange of opinions are essential for advance in science. Therefore, it has become necessary to examine the issue of how the patent system should be for advance in science. This is a very important issue for advance in science itself, but to maintain an environment that promotes advance in science is also extremely important for advance in industrial technology since academic research and science have come to play a more important role in industrial technology. In the United States, the National Research Council has been working on this issue for several years, and the NIH(*2) has also

(*1) As a case in Japan, there is the *model mouse case of Hamamatsu University School of Medicine,* which is introduced in Chapter 4 in this report.

(*2) National Institutes of Health.

examined the issue and has been carrying out measures. Japan should also immediately examine desirable public research and desirable limits of the patent right (Section 69 of the Japanese Patent Law) for testing and research.

2 Patent System and Licensing Agreements

Elements that should be examined in considering the relationship between the patent system and licensing agreements are discussed in this chapter. First mentioned is knowledge and information as public goods. When dealing with knowledge that has not been embodied in a product in the market, a trade-off arises between ex-ante efficiency and ex-post efficiency. The patent system exists to create a balance between them. The effect of the patent system on incentive for innovation is composite. Second mentioned is the asymmetry of information. If a licensee cannot clearly know technical information that is the subject of a deal in advance, and there is the situation that information is uncertain between a licensor and a licensee in concluding an agreement and such knowledge is asymmetric between them, the license agreement in question will be incomplete (hold-up problem). Third mentioned is the impossibility of exclusive possession. The possibility of exclusive possession of research and development results is imperfect. Under the patent system, the users of the relevant technology market bear R&D costs, but general taxpayers bear a small part of the costs for research and development conducted by the government and public institutions. The possibility of ex-post observation of costs and benefits, the costs of lawsuits, and the easiness of finding infringements determine a good part of the desirability of the patent system. Fourth mentioned is the factor of how much binding power the intellectual property system has.

On the other hand, from the viewpoint of theory and analysis, examination from the following points is considered necessary: (1) strategic aspect of licensing, (2) strategic selection of technology and licensing, (3) scope of patent protection and licensing, (4) cumulative innovation and licensing, and (5) bilateral character of research and development.

In addition, it is also necessary to focus attention on intellectual property right and spillover effect. For example, the movement of labor accompanies the transfer of knowledge and makes it difficult to exclusively possess knowledge. The effect on capacity to receive technology and spillover effect within and out of a country, region or corporate organization must not be neglected.

In the last place, for pro-patent policy, a system should be carefully designed from the following multifaceted viewpoints: (1) incentive toward innovation, (2) incentive toward disclosure of information, (3) effect on licensing, and (4) risk of lawsuit. In a small part of technical fields, strengthened patent right seems to be activating innovation, but this is not always true through the entire economy. In particular, sufficient attention must be paid to the effect of cumulative property of technology on incentive toward invention, the effect of the functions and characteristics of the technology licensing market on the commercialization of technology, and the degree of social costs including costs for patent litigations. Careful consideration should be given to the economic consequences of the fact that results achieved by universities, etc. in the basic research fields, which have not been subject to patent in the past, become out of the public domain. In particular, from the viewpoint of benefits from diversity, careful attention should be given to the adverse effect of the exclusive possession of basic technology based on an exclusive right.

3 Examination of the Antimonopoly Law

Among regulations based on the Antimonopoly Law, licensing regulations mean regulations for licensing under the competition law, and are regulations under public law and functioning as the outer frame of licensing agreements that cannot be crossed over even by an agreement between the parties concerned. In the United States, judicial precedents under the Antitrust Act were cumulated in terms of licensing regulations by around 1970, and the current case law was established. Licensing practices are carried out in line with the licensing regulations established as case law. The “Antitrust Guidelines for the Licensing of Intellectual Property,” which presents the competition authority’s policy on application of law, was published in 1995. However, since the provisions of the guidelines are looser than those of case law, the guidelines do not have much influence on licensing practices. Although the “Guidelines for Patent and Know-How Licensing Agreements under the Antimonopoly Act” (hereinafter referred to as these guidelines) were published in 1999 in Japan, the effectiveness of these guidelines is not clear because the Fair Trade Commission has not instituted any lawsuits since the publication of these guidelines. The EC stipulates highly detailed rules on the basis of the structure and technology transfer block exemption regulation as provided in Article 81 of the EC Competition Law. In the EC, companies create licensing agreements within limits that do not require notification based on the block exemption regulation, in order to avoid sending a notification to the European Commission. This is the function of binding agreements by the block exemption regulation, and companies tend to create somewhat rigid licensing agreements (referred to as the strait jacket effect). The

"Technology Transfer Block Exemption Regulation" was published in 1996.

Secondly, there are five major restrictions in licensing agreements: (1) sales price restriction and quantitative restriction, (2) restriction on dealing with competing goods, (3) grant back, (4) tie-in, and (5) obligation of not contesting the validity of the relevant patent. These restrictions are applicable to licensing agreements concluded in the United States, Japan and EC countries, but all of these countries are oriented toward considering these restrictions to cause big problems and thus be illegal under competition law.

With the establishment of the global market that focuses on developed countries' markets, international licensing agreements that cover the whole world have been concluded in all fields. These agreements are casting a large doubt over the effectiveness of each country's licensing regulations, but it is almost impossible, in practice, to create a licensing agreement that surely clears all competition laws in the world. To bring it all down to earth, the competition authority in a country other than countries to which parties concerned belong has difficulty in examining licensing agreements that cover the whole world and ordering measures.

Finally, the "Study Report on Patents in New Fields from the Viewpoint of Competition Policy" published on June 26, 2002 brought out refusals to license on the back of use relations in the biotechnological industry fields, which may become problems under the Antimonopoly Law. However, refusals of this kind are considered not to actually exist in license deals between leading companies.

Ⅱ Actual Conditions and Problems of Licenses in the Life Science, Pharmaceutical and Biotechnological Industries

4 Investigation of Examples and Problems

The actual conditions of licensing agreements in the life science, pharmaceutical and biotechnological industries are made clear with specific examples, and certain problems are explained in this chapter. Firstly, the following can be cited as the characteristics of the pharmaceutical and biotechnological industries: (1) manufacturing approval system and long development period that is 10 to 15 years from research and development to placement on the market, (2) large development costs of ¥10 billion to ¥90 billion, and (3) large risk due to low performance up to supply to patients after going through approval examination.

Secondly, the following can be cited in terms of the importance of life science-related technology in the pharmaceutical field: (1) business structure in the life science-related industries, (2) increase in developments of biotechnology-related pharmaceuticals, (3) steep rise of counter value for licensing agreements due to enclosure of tools and genes, (4) intensification of research institutes' pursuit of returning profits, and (5) increase in licenses of a new type that uses gene information and research tools. Thirdly, as for the specialty and problems of the exercise of patent rights in the life science field, gene patents, etc. are patents for substance and the circumvention of such patents is often difficult, while research tool patents are highly versatile since they are tools used in performing research in the life science field and their targets are thus not limited. Fourthly, the following cases are cited as examples used in examining the characteristics of licensing agreements on life science patents: (1) research tool patents that can be used for a wide range of purposes and gene patents, (2) cases where two or more similar patents were established in the same technical field and contest a patent right, (3) sharp rise of cumulated license fees due to obtainment of many licenses. There are examples such as the strategy of dominating the DNA array market (Affymetrix), patent license for laboratory animals in testing and research in the United States (problem of licensing of OncoMouse patent), setting of licensing fees to the total R&D costs and reach-through royalty license (patent license by Housey Pharmaceuticals).

In particular, 23 Japanese companies have been licensed by Housey Pharmaceuticals, and this issue has a large influence. One remarkable characteristic in the mode of licensing in the life science field which is found from specific cases is that the number of licenses from biotechnological venture companies that have received technology transfer from a public institution has been increasing. The excessive exercise of such rights as patents for research tools will bear down on researchers and thereby hinder the progress of research. Japan should also examine the method seen in the United States cases in which a public institution mediates and arbitrates between researchers and patentees with social norm, limits patentees' rights, eliminates the necessity of obtaining a license for non-commercial research, and makes researchers be burdened with test sample transfer agreements. In addition, research tools are to be used just at the research and development stage, and they are not methods for producing end products that are on sale in the market.

Attention should also be paid to measures against research-through licensing agreements, such as those by Housey Pharmaceuticals, and the sharp rise of cumulative royalties due to obtainment of many licenses.

It is necessary to allocate upstream research and downstream research in the life science field in

a balanced manner, and it is considered necessary to set the industrial policy that creates a balance between respect for basic patents and limitations on them through design of a system that does not inhibit continuing technological innovation.

5 Examination Based on Interviews with Companies

This chapter makes clear problems in licensing agreements between companies on the basis of the results of interviews with major Japanese pharmaceutical companies, biotechnological venture companies, and electric and electronic companies, and examines the problems based on personal views. Many Japanese companies now require the introduction of licenses from European and U.S. venture companies in order to put forward the research and development of biotechnological pharmaceuticals. This fact revealed that Japanese companies were in a vulnerable position in licensing negotiations for screening methods and gene information. In addition, it was recognized that there were cases where they were required to obtain licenses for testing and research and pay counter value. Pharmaceutical companies have been strongly based on the "principle of self-sustaining," and to say nothing of the introduction of licenses from competitors, there has been scarcely any joint development or partnership. However, with an increase in the burden of research and development costs, pharmaceutical companies have been activating joint research and development in cooperation with venture companies and competing manufacturers, both in and out of Japan.

It was also revealed that in the electric and electronic industries (interview was conducted for comparison) that are based on a horizontally-divided business structure, a cross-licensing agreement scheme has become less available between companies specialized in development due to the development of digital and network technology, and that the conventional framework has thus been collapsing. In the future, standard technologies are expected to increase due to the spread and advance of network technology, and the utilization of patent pool is also expected to intensify.

On the other hand, it is considered necessary to examine the utilization of the patent pool mechanism in relation to gene chips in the biotechnological industry.

6 Examination from the Economic Viewpoint

On the basis of the contents of Chapters 4 and 5, this chapter brings together the characteristics of the pharmaceutical industry, explains these characteristics from economic viewpoints, and then discusses the effect of the characteristics on licensing. First described is the process of pharmaceutical research and development and licensing. Enormous costs and period are required to develop new drugs as stated in Chapter 4. If capital costs are included, more than ¥10 billion is required. In addition, most of the costs are "sunk" costs, and a problem called "hold-up" is likely to occur in deals that involve investment in which costs are sunk. When a pharmaceutical company that has succeeded in developing a new drug is sued for injunction by a third party due to patent infringement, if the company can make gross profit of even ¥1, it will grant a license under the hold-up condition and sell the new drug. Because of the fear of such situation, pharmaceutical companies have incentive to conclude licensing agreements at the early development stage. However, the counter value payment method of the licensor and licensee differs depending on the degree of probability of successful placement on the market.

The second point is the existence of venture companies in the biotechnological field. Due to the absence of vertical integration, venture companies that are carrying out upstream development are in the environment where they can demand high patent royalties from major pharmaceutical companies, and licensing fees are the only source of income for venture companies that do not manufacture and sell. Therefore, venture companies tend to set an aggressive price in order to maximize their income. However, these venture companies are in danger of being acquired by major pharmaceutical companies.

Thirdly, the boundary between academic research and commercial research has been getting ambiguous. In the United States, there are examples in which the NIH concludes an arrangement with patentees in which patentees do not require the obtainment of a license in relation to use of the relevant technology in research for noncommercial use by the NIH's funds. However, in Japan, there is no organization corresponding to the NIH. Fourthly, the possibility that a patent pool mechanism for DNA chips is formed is considered low due to absence of network externality.

Finally, regarding effect on the product market, the price elasticity of demand for a new drug is low. In addition, when the price elasticity of demand is low, even if the price is raised, the demanded amount will not largely decrease, so income will increase. For this reason, licensors have incentive to demand high royalties without caring about decrease in demand due to a sharp price rise.

Ⅲ Actual Conditions, Problems and Economic Effects of the Patent Pool System

7 Technical Standards and Patent Pools: Actual Conditions and Problems

This chapter discusses technical standards and the actual conditions and problems of patent pools. In relation to the problem of patent license that is essential for technical standards, patent pools have been bought to attention, and they have been more actively utilized mainly in the information and communications fields. However, patent pools do not completely solve the problems, and there remain problems to be solved for the industrial sector. This chapter first reviews the actual conditions of patent pools in operation or those suggested, and then extracts future important tasks and proposes possible solutions.

First of all, the following are considered to be the causes of generation of patent pools: (1) compatibility of information and communications technology, (2) network externality of technical standards, and (3) prevention of a sharp rise of cumulated royalties.

Secondly, the process of establishment of patent pools consists of (1) ascertainment of technical standards, (2) evaluation and selection of essential patents, (3) decision of licensing conditions, and (4) selection or establishment of a license management company.

Thirdly, as for patent pool mechanisms, there are (1) the lump-sum sublicense method which is typified by MPEG2 and (2) the mutual license method.

Fourthly, regarding legal infrastructure for implementing patent pools, it is necessary to make clear (1) the relationship with the Antimonopoly Law, (2) the relationship with the principle of territoriality, and (3) self-protection means of patentees.

In the last place, for problems with patent pools and their solutions, the following is considered necessary: (1) fostering a common understanding in the industrial sector, (2) reviewing the patent policy of technical standardization bodies, (3) government involvement, and (4) attracting companies specialized in development.

Patent pools in the information and communications technology field are expected to be further sophisticated. Particularly, in order to apply patent pools in the biotechnological field, the evaluation of subject patents and the creation of an appropriate counter value allocation system are essential. In addition, in order to encourage companies specialized in development to participate in patent pools, it is necessary to consider RAND plus approach in relation to the patent policy of technical standardization bodies. Therefore, a mechanism for government involvement should not be considered to be a taboo for technical standards that have a large influence on the society.

8 Economic Effects

This chapter explains the economic effects of patent pools.

First of all, as the complementary economic effects of patent pools are (1) the advantage of avoiding excessive licensing fees, (2) diffusion to third parties, (3) one stop shopping of essential patents, and (4) more effective deterrence of the possibility of hold-up by patentees who hold essential patents.

Secondly, as for constraint in patent pools, there are (1) the generation of outsiders of patent pools and (2) the problem of breakup of patent pools. One of the reasons for this is the conflict of basic interests between vertical integration-based companies and companies specialized in research and development.

In short, since there is the conflict of basic interests concerning prices of patent pools in vertical relations, research and development-based companies may have difficulty in participating in patent pools that were set up on the initiative of vertical integration-based companies. Such a basic confrontational structure is anticipated to exist in the background of Qualcomm's showing no inclination to participate at the present moment. Another reason is a free ride on demand due to low prices of patent pools. The pools of complementary patents include internal uncertainty arising from a free ride, and unless this problem is solved, a single patent pool will not be actually realized even if it is beneficial to both companies and society.

Thirdly, regarding patent pools and competition, consideration must be made (1) from the aspect of the substitutability and complementarity of patents (in the case of bi-directional blocking between patent pools of patents, both of which are individually exploitable and are in a substitutive relation) and (2) from the viewpoint of incidental constraint and openness to third parties.

Fourthly, the following are considered in terms of the management of patent pools and future policy issues: (1) fair distribution according to technical contribution, (2) utilization of a reciprocity clause for preventing free rides, (3) strengthening of standard policy, and (4) compulsory license to outsiders. In particular, careful examination is required for the propriety of (4).

Ⅳ Patent Database

9 Necessity of Economic Analysis of Patents and Desirable Patent Data

First of all, the necessity and problems of economic analysis of patents are discussed.

Empirical analysis from various aspects of patent has been required, including analysis from research and development, filing applications, licensing, technological evolution process, process of spread of technology, and lawsuit. However, the actual condition in the past was that the aggregation of patent data by the unit of company, which serves as a basis for economic analysis, could not be conducted at a low price. This is one of the reasons for no progress of empirical analysis of patents in Japan. In addition, for the economic analysis of patents, easy access to only patent data is not sufficient, and it is necessary to combine aggregated patent data with other databases and study their relationships.

Secondly, the patent database of the NBER(*3) in the United States is for free, and it is easy to understand and analyze companies' patent portfolio data using the database. In addition, it is easy to combine the patent database with financial data, corporate ownership-related data, or financial market data. However, data from other aspects, such as concordance with products/industry and licensing, have not been prepared.

Therefore, a patent database for the economic analysis of patents in Japan is proposed, and this database is expected to be a better information source than NBER patent data in terms of the understanding of extinction of rights and disputed relations such as trial for invalidation. The future problems with a Japanese patent database are the weakness of quoted information and the necessity of efforts to combine it with other databases for understanding the patent portfolio of concatenated data and conducting an analysis in combination with financial or fiscal databases. In the future, combination with other survey data and international patent family data is desired.

10 Development of Patent Statistics by the OECD

This chapter introduces the development of patent statistics by the OECD. The OECD(*4) is an international organization based on the OECD Convention and a collection of developed countries that have a policy of market economy (30 members).

Among the OECD's activities, various statistics are especially cited as reliable data throughout the world, and they are also utilized in Japan as vital source materials for legislation at the Diet, policymaking by ministries and agencies, and research activities by such research institutes as universities. In terms of science and technology-related statistics, the OECD has traditionally led the rulemaking for R&D (research and development) statistics and has devoted its efforts to transmit reliable results.

In recent years, there has been increasingly more request especially for more multifaced analysis of policy. In order to meet such request, the OECD is expanding the scope of its activities for science and technology statistics and is also active in the development of new science and technology statistics. Among new science and technology statistics, patent statistics that include an abundant volume of information and have the potential for various forms of analysis are especially a focus of attention, and the development of such statistics is an important task of the OECD. Although the OECD's patent project is an unspectacular activity, it holds the potential to impact on researchers and government officials in Japan in the sense of the creation of a research environment and the provision of a specific, simple patent indicator for policymaking. Therefore, relevant ministries and agencies as well as researchers are asked to pay particular attention to the trend of the OECD patent project and to actively get involved in it.

11 Survey on Intellectual Property Activity

This chapter introduces the survey on intellectual property activity conducted last year (October 2002).

This survey was implemented in response to the "development of intellectual property-related statistics" which was indicated as a specific action plan of the "Intellectual Property Policy Outline" that was decided by the Strategic Council on Intellectual Property hosted by the Prime Minister on July 3, 2002. The result will be published at the end of FY 2003, and it is expected to serve as an extremely important material for promoting the understanding and analysis of corporate intellectual property activities.

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(*3) National Bureau of Economic Research
(*4) The Organization for Economic Cooperation and Development