

5 Exceptions to and Limitation of the Effect of Patent Right

This study investigated and examined the current situations in twelve countries regarding exceptions to and limitations of exclusive rights based on a patent right, especially focusing on the exception of "experiment or research" and the compulsory licensing system (equivalent to arbitrary license in Japan). The primary purpose of this study is to study how these countries cope with the situations where patent rights granted for inventions of upstream technology that is highly versatile and less substitutable are likely to cause adverse effect on commercial activities of others or R&D activities of the next generation, and where the owner of a patent right for the technology indispensable to standardization, without participating in the standardization process, claims excessive royalties or alleges patent infringement. From an international perspective, revision of the TRIPS Agreement is being discussed, because, even if a WTO Member allows a patented product that is necessary for the protection of public health in other countries to be used without the authorization of the patent owner, the provisions of the TRIPS Agreement prevent the use or export of the patented product. This study focused on the progress in discussion and measures taken by WTO Members on this issue.

I Introduction

In recent years, there has been an issue as to what extent inventions of upstream technology that is highly versatile and less substitutable, such as gene-related technology and research tools in the life science fields, should be protected under patent rights. In such fields that are characterized by the cumulative nature of technology innovation and the broad range of applications of individual patented inventions, abuse of intellectual property rights is likely to have a significant adverse effect on R&D of the next generation (in this report, issues concerning such significant adverse effects of patents granted for inventions of upstream technology shall be collectively referred to as "blocking patent / research tool patent issues," or "research tool patent issues" when specifically addressing the issues concerning research tool patents).

In the course of promoting technical standardization through the formation of patent pools, as seen in more and more industrial fields led by the electronics industry, concerns are being raised about the situation in which the owner of a patent right for the technology that is indispensable to the formation of a patent pool, as an outsider who does not participate in the standardization process, claims excessive royalties or alleges patent infringement (hereinafter referred to as the "outsider issue"). In most cases, it is difficult to cope with such exercising of a patent right, for it has reasonable grounds. While some people call for discussion about responding to this issue by the granting of an arbitrary license under the Patent Law, others point out the possibility of alleging such action to be in

violation of the competition law.

Regarding these issues, various legal theories on exceptions to and limitations of the effect of a patent right are being studied at home and abroad, in particular, the exception of "experiment or research," the compulsory license, and the application of the competition law.

In FY2003, the Institute of Intellectual Property (IIP), commissioned by the JPO, conducted a study under the title of "Issues Affecting Smooth Use of Intellectual Property" with the objective of finding solutions to the issues concerning the exception of "experiment or research." The FY2004 study examined and analyzed the situations in foreign countries based on the information obtained from the overseas survey conducted in FY2003 targeting major European countries and the United States, and the follow-up survey thereof, as well as the overseas survey conducted in FY2004 targeting five Asian countries, aiming to consider what measures Japan should take.

From an international perspective, it has been pointed out that even if a WTO Member allows a patented product that is necessary for the protection of public health in other countries to be used without the authorization of the patent owner, the requirements for such use as provided in the TRIPS Agreement Article 31 prevent the use or export of the patented product. On this argument, the IIP also conducted a study under the title of "Desirable Form of Rights in the Pro-Patent Era" in FY2001. The FY2004 study also investigated the subsequent progress in the circumstances and the responses of WTO Members.

II Exception of "Experiment or Research"

Firstly examined was the international legal frameworks concerning the exception of "experiment or research" under the Paris Convention and the TRIPS Agreement, and then reviewed the trends in laws and regulations, case laws, academic theories, practices, legal revisions, and government policies in foreign countries, focusing on: (1) general exception of "experiment or research"; (2) exception of "experiment or research" that is only applicable to clinical experiments of generic drugs; (3) exception of "experiment or research" at universities and research institutes.

The trends regarding these exceptions can be summarized as follows.

As for the general exception of "experiment or research," the major countries in Europe have adopted the provision on experiment or research exception under the Community Patent Convention (CPC), although the convention has yet to be put into force, aiming at equalizing the relevant provisions of national laws in these countries with the provision of the CPC. With respect to the interpretation of this provision, the theory presented by German Federal Supreme Court in two cases in the 1990s is being widely accepted, which argues that the experiment or research shall be exempted from liability for patent infringement if it contributes to an improvement of the patented invention *per se* or some other technical progress, whereas it shall not be exempted if it does not contribute to any special technical progress, for instance, it is conducted only for the purpose of obtaining information to be submitted to the regulatory authorities in order to obtain approval for the production or sale of the patented invention. In this theory, whether or not the experiment or research is conducted by a profit-making entity and whether or not it is conducted for commercial purpose are no longer questioned. The core of this theory is technical progress and industrial development, which is the primary purpose of the patent law. If this theory is applied when determining whether the clinical experiment of a generic drug constitutes patent infringement, the experiment shall be deemed to be patent infringement if it is conducted only for the purpose of obtaining approval for the production or sale of the generic drug. For this reason, in Europe, a special exemption of clinical experiments of generic drugs has been included in the European Community (EC) Directive 2004/27/EC, with the intention of achieving the objective of increasing the competitiveness of European companies in the development of generic drugs.

In Japan, on the other hand, according to the theory advocated by Professor Someno, the scope of "experiment or research" should be distinguished in line with the object and purpose, and exception should be allowed only when the experiment or research is conducted targeting the patented invention *per se* for the purpose of contributing to "technical progress." Also in this theory, whether or not the experiment or research is conducted by a profit-making entity and whether or not it is conducted for commercial purpose shall not be questioned. In 1999, the Supreme Court judged the working of the patented invention conducted in the course of the clinical test necessary for applying for approval of the production of a pharmaceutical product, to fall under the category of "experiment or research" provided in Section 69(1) of the Patent Law, on the grounds that, should it not be allowable to conduct, during the term of the patent right, any clinical experiment necessary for applying for approval of the production of a generic drug, it would in effect prevent a third party from using the patented invention freely even after the expiration of the term of the patent right, whereas the patent owner would have been able to acquire economic benefit by exclusively working the patented invention even if such experiment were allowed. This theory presented by the Supreme Court, which compares, in light of the purport of the Patent Law, the interest of the patent owner and that of the third party who works the patented invention, has also been adopted in the report by the panel on the Canadian case on the patent protection of pharmaceutical products in the WTO dispute settlement procedure (WT/DS114).

In the United States, there is no statute law that limits the scope of effect of a patent right to acts conducted "commercially," and case laws have established the theory that exempts experiment or research from liability for patent infringement as an "exception of experimental use" only if it is conducted merely for the purpose of solving a philosophical issue or ascertaining the truthfulness and correctness of the patent description. Thus, the United States differs from Japan and Europe in that the concept of the exception of "experimental use" is understood very narrowly in the United States. In the *Madey vs. Duke University Case*, the CAFC, while confirming the existence of the theory of "exception of experimental use," pointed out that where the university worked the patented invention in the course of conducting experimental research as its justifiable duty, such work should not be regarded as falling under the exception of "experimental use" and therefore should not be exempted from liability if it was not conducted "for amusement, to satisfy idle

curiosity, or for strictly philosophical inquiry." Thus, due to the very narrow concept of the exception of "experimental use," the United States took legislative measures earlier than other countries to allow clinical experiments of generic drugs, in the form of the Bolar provision (35 U.S.C. §271(e)(1)).

In Asia, all countries targeted in this study have provisions on the exception of "experiment or research," and they are also developing provisions exempting clinical test of generic drugs from liability of patent infringement. However, as there are very few case laws or academic theories relating to these provisions, the development of the interpretation of these provisions will depend on the future progress in this field.

Under such circumstances, the question is whether or not the exception of "experiment or research" can be a solution to the blocking patent / research tool patent issues. In the first place, there is significant difference between countries including Japan, the United States, and European countries, both in industries and academia, in terms of the understanding as to whether or not these issues exist or are likely to occur. Should these issues be recognized at all, the parties concerned including those engaging in research activities have different understandings of the concept of the exception of "experiment or research" in their countries. For instance, some people regard experiment or research conducted at the universities or research institutes as being exempted from liability for patent infringement, and patent practices are being conducted based on such understanding. Furthermore, the concept of the exception of "experiment or research" *per se* differs among countries. For these reasons, we should say that it is very unlikely under the current circumstances that the parties involved in the blocking patent / research tool patent issues will predict, in particular before they launch research and development on a global scale, the consequence of the application of the concept of the exception of "experiment or research." Now is the time for us to promote discussion so as to fill in the gaps of each country and between countries in the understanding and the concept of the exception of research and experiment.

III "Other Use Without Authorization of the Right Holder" Including Arbitrary (Compulsory) License

The scope of Article 31 of the TRIPS Agreement entitled "Other Use Without Authorization of the Right Holder" includes various ways of using a patented invention, such as the use under compulsory (arbitrary) license and the use by the government. After presenting

international legal frameworks under the Paris Convention and the TRIPS Agreement, first of all, reviewed the trends in twelve countries regarding legal grounds and procedures for granting license to a third party for "other use," as well as case laws, academic theories, practices, and legal revisions on this issue. Next, it examined whether or not reference was made to "other use" when solving the blocking patent / research tool patent issues, and outlined such reference, if any. Lastly, it indicated characteristic arguments and cases addressing basic understandings of the relationship between competition law and intellectual property law as well as the connection with technical standardization.

The trends in the foreign countries can be summarized as follows.

As for the types of and requirements for "other use without authorization of the right holder," although many countries still adopt the provisions of Article 5(A) of the Paris Convention as they are, harmonization is going on toward establishing an international framework based on the TRIPS Agreement as a result of the efforts to strongly promote compliance of the TRIPS Agreement. However, some countries appear to be developing national laws according to a false understanding of the purport of the TRIPS Agreement. For instance, the Republic of Korea is criticized as having overlooked the fact that Article 31 of the TRIPS Agreement adopts "conditional approach" instead of "grounds approach," and introduced in its national law a false understanding that Article 31(b) specifically mentions the case of a national emergency or other circumstance of extreme urgency or cases of public non-commercial use, as cases in which some requirements may be waived including the requirement of efforts to obtain authorization from the right holder prior to use, with the intention of allowing the waiver only in the cases listed in this article. On the other hand, Singapore has moved in the direction of narrowing the scope of acceptable grounds, through conclusion of FTA with the United States, compared with the scope under the TRIPS Agreement. Also, according to the provision of Article 28 of the TRIPS Agreement, the act of importing the patented product or the product manufactured by the patented process can be understood as the working of the patented invention. In India, consistency with this understanding is uncertain.

As for the operation, it was rare, except in several countries, that compulsory license was applied for or granted or the use by the government of the patented invention was publicly announced or notified to the patent owner, and after the conclusion of the TRIPS Agreement, it became even rarer. This trend is also seen in countries where compulsory license or use by the

government is seen rather frequently, such as France and India.

On the other hand, as a measure to cope with new problems that have arisen in the pro-patent age when global protection and enforcement of patents promote business activities, we can also see recently movements toward using the compulsory licensing system and other mechanisms of "other use," or establishing a new framework based on what is learnt from such mechanisms.

The following movements are seen toward solving the blocking patent / research tool patent issues. With respect to biotechnology inventions, Germany and France comprehensively reviewed eligibility as the subject-matter of patent protection, exclusive rights based on a patent right, and exceptions to and limitations of exclusive rights, while taking into consideration the consistency with the TRIPS Agreement and the EU law. As a result of the national review, these countries revised the patent laws in an attempt to strictly define the subject-matter of patent protection and the scope of exclusive rights based on a patent right. Furthermore, in order to solve the blocking patent issues while taking into consideration the adverse effect of patents already granted, they revised patent laws with the aim of facilitating the use of patented inventions in the private sector by deleting the requirement of public interest from the grounds for granting compulsory license in case of dependant inventions. Switzerland is currently considering revising the patent law for the purpose of establishing a system for granting compulsory license for patents relating to diagnosis and research tool.

Amongst academia, scholars suggest not only a scheme in which a third party shall be granted compulsory non-exclusive license, but also a scheme in which a third party shall also be allowed to use know-how necessary for the use of a patent right, which has not been covered by compulsory license, or a scheme in which the patent owner shall be allowed to exercise exclusive rights for a certain period of time, and then after the expiration of that period, he shall be obliged to accept an application for the granting of license, which appears to be similar to the conventional license-of-right system. These schemes are intended to solve issues concerning both compulsory license and exclusive rights based on a patent right, by revising the conventional structure of rights based on a patent right.

Furthermore, it is also frequently argued in EU and other countries that the provisions of competition law on abuse of the dominant position shall also be applicable. Based on this argument, Taiwan, India and the Republic of

Korea revised the competition law and developed guidelines for the purpose of increasing the practical applicability of the competition law, or revised both the patent law and the competition law for the purpose of strengthening the linkage between these laws in terms of the objects of regulation and the regulatory authorities concerned.

The outsider issue in technical standardization is being discussed as an issue of competition policy arising from the enforcement of a patent right, in the context of remedying anticompetitive practice. For this reason, stronger orientation is seen for this issue than for the blocking patent / research tool patent issues, towards a solution by granting substantive compulsory license or eliminating anticompetitive practices through the application of the provisions of competition law. Not only in Europe and the United States but also in Asian countries where this issue has yet to become obvious, some people point out the possibility of solving this issue by granting compulsory license for the purpose of remedying anticompetitive practices under the patent laws, but objection to this view is also strong. It is necessary, first of all, to examine and clarify the relationship between competition law and intellectual property laws including patent law in terms of the interest to be protected by law.

Lastly, as for the use by the government, there were no special arguments concerning the blocking patent / research tool patent issues or the outsider issue in technical standardization.

These trends shown above have arisen as a result of the examination of individual issues in response to the demand for the change of "other use" as a measure to cope with the adverse effect of the exclusivity of a patent right, under the pro-patent policy aimed at affording universal protection to intellectual property rights as private rights.

IV WTO Decision on the TRIPS Agreement and Public Health and Compulsory License Systems throughout the World

As shown in Chapter III above, WTO Members have been developing national laws in accordance with their obligations under the TRIPS Agreement, including the grounds for granting compulsory license and allowing "other use without authorization of the right holder." The Doha Declaration on the TRIPS Agreement and Public Health adopted at WTO Ministerial Conference in 20 November 2001 (WT/MIN (01)/DEC/2) and the WTO Decision "Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" adopted at WTO General Council in 30

August 2003 (WT/L/540) have provided WTO Members with the opportunity to call for necessary legislative measures to cope with public health crisis in other countries. WTO Members including Japan have agreed to revise Article 31(f) of the TRIPS Agreement so as to avoid legal instability of such legislative measures, and the TRIPS Council is currently discussing a specific revision method. The WTO General Council Decision indicates tentative measures for the period until the revision of the TRIPS Agreement is effective, so that the Members will, while complying with the provisions of the TRIPS Agreement except for Article 31(f), be able to revise their national laws in order to grant compulsory license and allow "other use without authorization of the right holder" based on new grounds, i.e. to cope with public health crises in other countries.

It is necessary first to examine the history of the adoption of the "WTO Decision on the TRIPS Agreement and Public Health," and clarified the problems of the existing TRIPS Agreement. Next, to review the progress in tentative revision of national laws conducted in line with the WTO Decision in WTO Members, namely, Canada, Norway and India where legal revision was completed, EU and the Republic of Korea where revision bill was submitted to the parliament, and Switzerland, etc. where revision bill was reportedly under preparation. All legal revisions in these countries were intended to improve the grounds and procedures for granting compulsory license for the use of the patented invention with the aim of solving public health problems in other countries.

In the revision discussion at the TRIPS Council, there is a sharp division of opinion over the two revision methods, i.e. addition of a footnote and addition of a new article. Furthermore, even if consensus were reached about how to revise the provisions of the TRIPS Agreement, the revision of Article 31(f) would take effect only for the Members that have accepted the revision upon acceptance by two thirds of the Members, because it is of a nature that would alter the rights and obligations of the Members (Article 10 of the WTO Agreement). Therefore, a great deal of time will be required until the actual enforcement of the revision, and during such time, individual Members will need to take steps to revise national laws as tentative measures in line with the WTO Decision.

Taking such steps is not an obligation of the WTO Members. However, the Doha Declaration and the WTO Decision are based on the consensus reached through lengthy negotiations at the Ministerial Conference, General Council and TRIPS Council. It is necessary to present the outline of the steps to revise national laws taken

by some Members such as Canada and Norway as tentative measures in line with the WTO Decision, and common points of these steps. These Members have started taking such steps with the objective of achieving their own national policy, i.e. respecting decisions made at the WTO and providing international cooperation in coping with global public health issues.

Contrary to these movements abroad, no particular progress has been made in Japan in discussing the revision of Article 31(f) of the TRIPS Agreement or taking steps in line with the WTO Decision. In future discussion, which is expected to be focused on these issues, we should make our intention clear by taking legislative measures with reference to the common points above-mentioned or demonstrating the reason for not taking such measures.

V Conclusion: Significance of Limitation of Patent in the Pro-Patent Era

Chapters II to IV reviewed international agreements and foreign systems in relation to exceptions to and limitations of the effect of a patent, especially the exception of "experiment or research," and "use of the patented invention without authorization of the patent owner," such as compulsory licenses, and examined how these systems would contribute to solving the blocking patent / research tool patent issues and the outsider issue in technical standardization, while presenting characteristic arguments and legal revisions regarding these issues.

When we review the overall trends in foreign countries involving such legal revisions and arguments, we must not overlook the fact that, with respect to biotechnology inventions, comprehensive discussion is underway in accordance with the current technical achievements, as seen in the recent legal revision in Germany or France and the revision bill in Switzerland, focusing on eligibility as the subject-matter of patent protection, appropriateness of the contents of exclusive rights based on a patent right, and appropriateness of the applicability of various exceptions to and limitations of exclusive rights based on a patent right. These countries have taken a stance, particularly in the discussion on the eligibility as the subject-matter of patent protection, to review the existing frameworks of intellectual property laws, including not only the laws themselves but also various views and interests concerned such as morality and ethics and promotion of academic research. Over a period ranging from several years, to ten years or more of comprehensive review on conventional systems under intellectual property laws, these

countries have chosen to establish a compulsory licensing system as a measure to solve the blocking patent / research tool patent issues. In this respect, the compulsory licensing system no longer gives negative incentives to patent owners in working patented inventions by themselves or granting third parties license thereon, but it can be deemed to have become a scheme under which the grounds and requirements for granting license are specified and license will be used to remove obstacles to the actual industrial activities. Also, some countries such as Germany, while making every effort to avoid conflict between national laws and EU law, seem to be ready to propose a discussion on reviewing or revising international agreements if conflict cannot be avoided. How new systems established through such revisions will be operated, is very worthy of note.

Currently, in Japan it is also desired to examine precise needs and consider specific measures to cope with the blocking patent / research tool patent issues. In this process, if we take a comprehensive approach to consider appropriateness of individual ideas, such as the improvement of the compulsory licensing system, while taking into account the approaches taken in foreign countries, it would enhance the use of biotechnology inventions. We can also consider, in light of the trends in international discussion and the circumstances in particular industries and fields, the possibility of granting compulsory license or allowing a particular structure of rights under the patent law, or ascertaining the applicability of the competition law.

On the other hand, with respect to technical standardization, foreign countries do not question the eligibility of the technology indispensable to standardization as the subject-matter of patent protection, and they discuss this issue as an issue of competition policy arising from the enforcement of a patent, in the context of remedying anticompetitive practice. For this reason, while the applicability of the compulsory licensing system for the purpose of remedying anticompetitive practice under the patent law is pointed out, an approach to directly apply the competition law is, of course, also frequently advocated. Especially in Europe, there was noteworthy cases in which the Doctrine of Essential Facility was applied to the act conducted by the intellectual property right holder that could have been regarded as an abuse of right even if it were duly enforced. In Asian countries, there is also a movement toward taking administrative steps to stipulate by law the cooperation between the authorities in charge of intellectual property and those in charge of competition, which has yet to reach a substantive argument.

When we study these issues in Japan, we should consider the relevance with the grounds for granting arbitrary license, such as public interest under Section 93 of the Japanese Patent Law, and also promote concrete discussion on the applicability of the competition law, the strengthening of the cooperation between the authorities under the patent law and those under the competition law, and the measures that can be taken by technical standardization organizations.

The TRIPS Agreement, which provides for the requirements for "other use without authorization of the right holder," is not sacrosanct. WTO Members have agreed to revise Article 31(f) of the TRIPS Agreement, and are currently taking steps as tentative measures to improve their compulsory licensing systems, while discussing how to revise that section.

In light of the purport of the patent law, the balance between the interest of the patent owner and that of society arising from the patented invention, things are coming to a situation in which the "interest of the user of the patented invention" can be deemed to include the public health interest of people in other countries, or at least the interest of people in each country who intend to protect the public health interest of people in other countries. Although taking tentative measures is not an obligation for the Members, the Doha Declaration and the WTO Decision are based on consensus reached through lengthy negotiations at the Ministerial Conference, General Council and TRIPS Council. Now is the time Japan should discuss such measures widely while taking this fact into account.

The trends shown above indicate, when viewed from a different perspective, the current situation in which harmonization is going on under the TRIPS Agreement and other international agreements on patent right, and at the same time, legal revisions are being carried out or discussed in order to establish national provisions in response to national, regional or global needs within these international frameworks. In the pro-patent era, issues are always raised, from social needs of the times, regarding the establishment of exceptions to and limitations of exclusive rights based on a patent right. Also, we should always question whether such exceptions and limitations are acceptable in society in terms of the meaning and grounds thereof.

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