# 10 Issues Affecting Smooth Use of Intellectual Property: Applicability of the Statutory Exception for "Experiment or Research"

*If the smooth use of an upstream technology is hampered in the case where a patent is granted to an invention covering an upstream technology that has a wide range of uses, has little or no substitute, and is difficult to be designed around, and the owner of such a patent refuses to give license at all or requests overly excessive royalty, it is feared that it may cause a significant negative impact on research and development (R&D) of downstream technologies or other related R&D. In this study, in order to contribute to promotion of smooth use of intellectual property as required by the Strategic Program for the Creation, Protection and Exploitation of Intellectual Property, a government-sponsored program, we examine various possible measures to be taken for enabling smooth use of a patented invention that is difficult to be designed around including "research tool" patents in the life science field. Although Article 69 (1) of the Patent Law stipulates the exemption of "experiment or research" from infringement and it has not been formally defined what acts cannot be exempted as "experiment or research," it seems that, in most cases, this exemption cannot apply to an act that is conducted in the course of trade. Accordingly, as an attempt to contribute to the smooth use of such patented inventions, we have examined the possibility of resorting to compulsory licensing, application of the Antimonopoly Law, formulation of license guidelines, and introduction of patent pools.*

## Ⅰ Background and Objectives

In technological fields that are characterized by cumulative innovation, many discussions have been made regarding problems that have arisen and may arise from basic patents that cannot be designed around. However, in recent years, such problems have emerged with regard to not only patents that cover final commodities but also patents that are to be used mainly in the stage of experiment and development, and thus we decided to examine this particular subject in this article. Problems involved with the latter kind of patent may be viewed as a serious problem because they may affect not only industries but also universities and public research institutions.

In the field of life science, these problems have mainly occurred in relation to what is known as "research tool patents" (i.e. patents that cover research tools that are used in the phase of R&D). There is concern that, if the owner of a patent that covers an upstream technology, when requested by others who want to use the technology by entering into a licensing agreement with the owner, rejects granting a license or requests a very high royalty, which is tantamount to a refusal, such a refusal or royalty request would precluded the wide use of such patents and therefore hamper progress of technology and development of industries. Based on this concern, the Government-sponsored *Strategic Program for the Creation, Protection and Exploitation of Intellectual Property* (hereinafter called "IP Strategic Program") states that "the smooth use of patented inventions in research activities by persons other than patentees" should be promoted in order to realize an appropriate "balance between smooth research activities and protection of intellectual property," and "the use of intellectual property concerning upstream technology (e.g. gene-related technology and research tools in the life science field) also should be promoted.

The goal of this study is to discuss various issues concerning smooth use of intellectual property, including specific measures to be taken for this purpose, focusing on the life science field and aiming at contribution to discussions to be conducted in response to the IP Strategic Program.

## Ⅱ Various Issues Concerning Smooth Use of Patented Invention

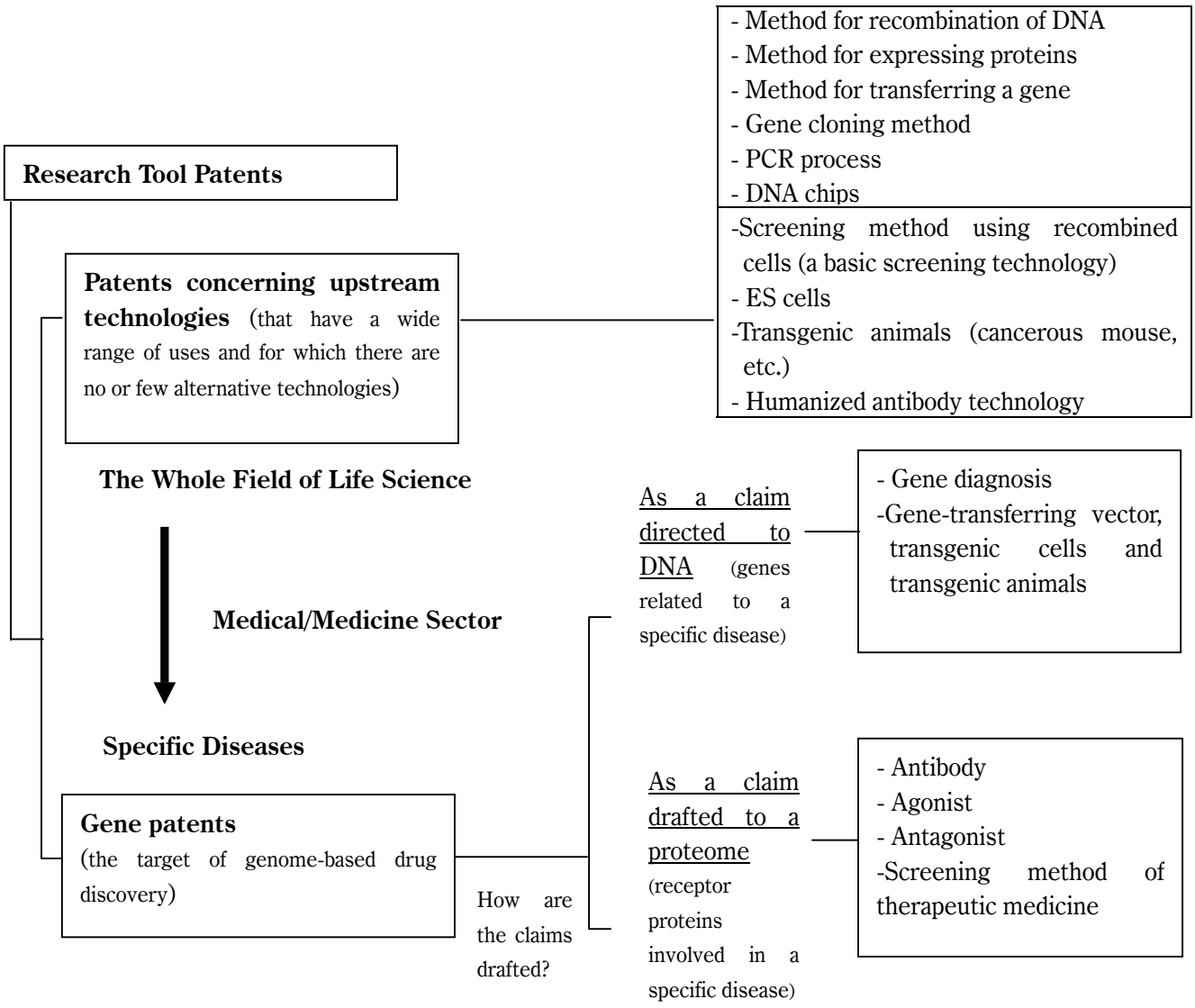
### 1 Research Tool Patents

In this chapter, with a focus on research tool patents (the most notable example being gene patents used in the life science field), we try to classify such patents and examine various issues that may arise from them.

A research tool can be defined as any resource that a scientist may use as an experimental tool in his laboratory. It is used only as a means to achieve particular purposes and cannot be regarded as a final product. Among research tool patents, especially controversial are patents related to the so-called upstream technology, which is a basic technology that have a wide range of uses and cannot be easily replaced by other technologies (alternative technologies). These types of patents can become

very powerful and extensive, significantly blocking future R&D and R&D in downstream areas. In the field of life science, we can identify gene patents and related patents as such controversial patents. A patent on a gene related to a particular disease and its proteome can cover both gene diagnostic methods for the disease and screening methods for its curative medicines.

Research tool patents can be divided into two categories: (i) those directed to upstream technology that have a wide range of uses and have little or no substitute, thereby affecting the whole field of life science and (ii) those directed to a narrower aspect of technology that are directly linked to a certain final product (e.g. a medicine for a specific disease). For example, in efforts to make genome-based drug discovery, various research tool patents are involved at every stage of research (see the figure below).



As a situation that hampers the smooth use of research tool patents, there is the well-known theory of the "tragedy of the anticommons."(*1) However, even when there is only one patent in a particular technological field (the tragedy of anticommons is caused by the existence of multiple patents), if that patent is related to upstream technology and cannot be replaced by another technology, it may give overwhelming power of influence to a patent owner and thereby may hamper the smooth use of research tool patents. When such a patent is one that covers a research tool, the problem may become more serious, because it may hamper not only development of new products by businesses but also all research activity including that conducted by universities or research institutes. Since the subject matter of a research tool patent is not a product but a "tool to be used in research," the kind of act that may be prohibited by its owner is an "act of a researcher in his/her laboratory," and therefore this type of patent may have an extensive effect over various research activities conducted by researchers.

In this chapter, we have examined the following four anecdotal evidences as examples that depicted issues regarding research tool patents: (i) the Cohen-Boyer patent (an example in which development of the related technology was accelerated due to its moderate licensing conditions), (ii) the Patent for the PCR process (an example in which stringent licensing conditions set by a patent owner caused various problems), (iii) the OncoMouse patent (an example where the patent owner attempted to enforce the patent even against nonprofit organizations including universities, thereby resulting in intervention from the U.S. National Institute of Health (NIH) to solve a licensing problem), and (iv) the *Hamamatsu University School of Medicine* case (which is Japan's first patent infringement litigation involving a research tool patent on experimental model animals).(*2) The first two cases are related to research tools concerning upstream basic technology, and the last two cases are related to research tools concerning experimental animals.

## 2 Recent Cases Where Problems Related to Utilization of Research Tool Patents Were Observed

We have examined details of problems related to use of patents concerning research tools, by making distinction between (i) problems arising out of attempts of a patent owner to make the most out of his/her patent, and (ii) those inherent in the biology field in which analysis of a biological reaction in its entirety cannot be achieved without using two or more patents. A representative example of problems falling under category (i) is the increase of market prices arising due to the monopoly on gene information or use of genes, as exemplified by controversies concerning the Myriad Genetics patents on breast-cancer genes BRCA1 and BRCA2 and its monopoly over BRCA 1/2 diagnosis business. As an example of category (ii), we can take notice of the effective patent strategy Genentech employed to overcome conflicts with another party's monoclonal antibody medicine related patents.

As recent examples of problems involving unreasonable licensing conditions and request for a reach-through royalty imposed by a patent owner, we have taken notice of the following opinions or cases: (a) the opinion that the BRCA1/2 gene patents should be made freely available for public welfare and science development, (b) a case where a U.S. district court held that Housey Pharmaceuticals' patents on a screening process for animal cells cannot be regarded as covering final products that were discovered by the screening process (and CAFC affirmed this holding), (c) a plan of Eli Lilly and its partner universities for filing hundreds of litigations for a patent that is getting closer to expiration, (d) an attempt of Columbia University to extend the term of license agreements on a patent for an invention of a process to introduce a gene into an animal cell by obtaining a new patent that covers virtually the same invention as the already licensed patent covers, and (e) a case where CAFC decided that Rochester University's basic patent concerning the COX2 inhibitor screening process should be invalidated because it did not identify chemical compounds that would be inhibited or promoted by the process, and therefore Celebrex, a curative medicine for rheumatoid arthritis provided by Pharmacia and Pfizer, did not infringe the patent.

## 3 Actual States of Utilization of Research Tool Patents in the Biotechnology and Pharmaceutical Industry

Based on published questionnaire survey results, we have studied actual states of utilization of research tool patents in Japan's biotechnology and pharmaceutical industry.

It is difficult to reasonably assess the value of a research tool patent, because this type of patent is primarily used at a research stage and has no direct influence on a product. The most serious problem that may arise in a licensing negotiation is the patentee's request of unreasonable royalty.

(*1) M.A. Heller and R.S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, Science 280, 698-701 (1998).

(*2) Tokyo District Court Decision of December 20, 2001 (Tokyo District Court 1999 (wa) No.15238), *Hanrei Jiho* vol. 1787, 145

Businesses using a research tool patent do not want to reject payment of a royalty for the research tool patent, and are willing to pay for it as long as they find it reasonable.

In the U.S., according to the Walsh Report(*3) (a survey as to whether research tool patents are actually causing a problem such as the one indicated in "the Tragedy of the Anticommons"), most respondents answered that there were no cases in which an important project was cancelled due to existence of a blocking patent, though there were some worrying problems like restriction imposed on use of a gene patent in relation to a target protein needed in the study of a certain disease. It also reports a case in which a university that committed a patent infringement in its research was forgiven by the patentee under the condition that the university conducted the research for nonprofit purposes. This may be regarded as an informal "research exemption."

## Ⅲ Measures to Facilitate the Smooth Use of Patented Inventions

### 1 Background of Discussion

Regarding a situation where smooth use of a research tool (upstream technology) that has a wide range of uses or a gene critical for drug discovery is hampered due to existence of a patent that covers the technology or the gene, we examined some possible measures to be taken to cope with such a situation, by following the discussion made in the IP Strategic Program.

### 2 Applicability of Article 69 (1) of the Patent Law

Article 69 (1) of the Patent Law states that "the effects of the patent right shall not extend to the working of the patent right for the purposes of experiment or research." According to the prevailing theory, the scope of "experiment or research" of Article 69 (1) should be considered as being limited to acts aimed at "progress of technology" (experiments for examining whether the patented invention actually has patentability or not, for ascertaining functions the patented invention is intended to play, or for improving, innovating or designing around the patented invention). Regarding research tool patents, it is considered that application of Article 69 (1) is likely to be denied except in the case that the patented invention itself becomes the subject of "research". In addition, although Article 68 stipulates that the scope of exclusive right granted to a patent does not extend to an act that does not amount to an act of "commercially" working the patented invention, it is highly possible that experimentation or research conducted in a university or other research institution would be regarded as "commercial" working of a patented invention. Therefore, if a research institution needs to work a patented invention owned by another, it is necessary for the institution to be granted license by the patent owner.

There was another question as to whether clinical research needed for regulatory approval for a generic drug falls under the category of "experiment or research" against which a patent right cannot be enforced. In the past, academic theories and rulings on this question were divided into two groups: one that favored the inclusion of clinical research into the category and another that denied it. Recently, however, the Supreme Court, in its decision on a litigation involving a generic drug,(*4) held that such clinical research falls under the category of "experiment or research" exempt from liability of patent infringement under Article 69 (1), putting an end to the controversy over this issue. In addition, it should be noted that, in Japan, there has been only one case so far in which it was disputed whether academic activities in a university or other research institution fall under the category of "experiment or research" for the purpose of applying Article 69 (1) (i.e. the above-mentioned *Hamamatsu University School of Medicine* case). In this case, however, the district court did not provide any opinion on the issue of whether the working of the patented invention could be regarded as "experiment or research."

In the U.S., although the Patent Act does not provide general "experimental use exception," it has been recognized that an act conducted for the mere purpose of philosophical experiment, or to ascertain the verity and exactness of the specification is exempted from the liability of infringement under the common law. This doctrine of "experimental use exception," however, is construed very narrowly as only applicable to conduct undertaken "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry," and courts have rigorously followed this narrow construction. In 2002, existence of the doctrine of "experimental use exception" was confirmed by the CAFC's *Madey v.*

(*3) John P. Walsh, Ashish Arora and Wesley M. Cohen, *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, 285-340, Patents in the Knowledge-Based Economy (W.M. Cohen and S. Merrill, editors, The National Academies Press, 2003)
http://www.nap.edu/books/0309086361/html/285.html

(*4) The Supreme Court Decision of April 16, 1999 (the Second Petty Bench) (1998 (ju) No. 153), Minshu, Vol.53, No.4, at 627

*Duke University*(*5) decision, but the CAFC also held in the same decision that its applicable scope should be very narrow. This decision turned out to be an epoch-making one in U.S. patent law because before *Madey v. Duke University*, use of a patented technology for experiment was regarded as being exempted when conducted for a nonprofit purpose. In addition, the CAFC, in its decision on *Roche Products, Inc. v. Bolar Pharmaceutical Co.*(*6) in 1984, held that experiment for applying for regulatory approval for a generic drug constitutes an infringement. In response to this decision, the Congress passed legislation to exempt from patent infringement the working of a patented invention for the purpose of regulatory approval for medicine (Bolar provision(*7)). In the U.K., Germany, and France, it is currently provided that patent rights cannot be enforced against (a) any acts conducted privately and non-commercially, or (b) any activities conducted for experiment on the subject of the patent concerned.

## 3 Possibility of Resorting to Compulsory Licensing System

The compulsory licensing system allows a third party to obtain a right (compulsory license) to work a patented invention owned by another without his permission or despite his refusal, through arbitration decision by the Commissioner of the JPO or the Minister of Economy, Trade and Industry. The Patent Law has the following provisions related to arbitration: Article 83 (Arbitration decision on grant of non-exclusive license in case of non-working), Article 92 (Arbitration decision on grant of non-exclusive license on one's own patented invention that uses another party's patented invention or other right) and Article 93 (Arbitration decision on grant of non-exclusive license in public interest).

Concerning Article 92, such a relation with another party's right is usually not found in working of a research tool patent. Regarding Article 93, development of medical technology might serve public interest; however, there is no saying that use of a research tool patent in general research activities is particularly needed for public interest. Therefore, it is unrealistic to apply this article to approving use of a research tool patent in ordinary research activities.

## 4 Antimonopoly Law's Implication in License Agreements

Article 21 of the Antimonopoly Law provided that the provisions of this Law shall not apply to such acts recognizable as the exercise of rights under the Patent Law. It is widely accepted, however, that there is an exceptional case in which even a license agreement on a patent conflicts with the Antimonopoly Law, when such an agreement is not judged to amount to the "exercise of rights" stipulated in the article. On the other hand, the Japan Fair Trade Commission published *Guidelines for Patent and Know-how Licensing Agreements under the Antimonopoly Law* in 1999 and the *Report of the Study Group Examining Issues on Patents in New Fields from the Viewpoint of the Competition Policy* in 2002. In these documents, the Commission presents its views on, and provides some examples of, the relationship between the Antimonopoly Law and licensing agreements concerning gene-related inventions as well as research tool patents. The Study Group Report states that the so-called "reach-through license agreement" might fall under the category of unfair trade practice as a dealing on restrictive terms. Now, it is expected that results of discussions in the Study Group Report may be included in the guidelines under the Antimonopoly Law in the near feature.

## 5 License Guidelines

For a party who wishes to use a patented research tool owned by another, the only option it can take at present is to obtain license from the owner by conducting negotiation for it. Under such a situation, it is desired to prepare appropriate guidelines that would enable solving various issues involved in the exercise of research tool patents. This chapter has introduced NIH guidelines as a possible model for such guidelines and the various efforts being made in Japan and other OECD countries.

The U.S. National Institute of Health (NIH) formulated the NIH Guidelines for recipients of NIH funds under and within the legal framework of the Bayh-Dole Act.(*8) The NIH Guidelines are intended to support recipients of the NIH funds who are going to transfer a research tool by enabling them to secure reasonable transfer conditions, and also to further bring forward research in biology and

(*5) *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002)

(*6) *Roche Prods., Inc. v. Bolar Pharmaceutical Co.,* 733 F.2d 858 (Fed. Cir. 1984)

(*7) 35 U.S.C. §271(e)(1)

(*8) Department of Health and Human Services, *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources*: Final Notice, 64 FEDERAL REGISTER 72090 (1999) (Federal Register Notice published on Thursday, December 23, 1999 [64 FR 72090]) (http://ott.od.nih.gov/NewPages/RTguide_final.html)

medical science, which makes the Guidelines consistent with the requirements set by the Bayh-Dole Act.

The Guidelines lists the following four principles: (1) to ensure academic freedom and publication, (2) to ensure appropriate implementation of the Bayh-Dole act, (3) to minimize administrative impediments to academic research, and (4) to ensure dissemination of research resources developed with NIH funds. Recipients are required to take every reasonable measure to simplify the process of transferring their own research tools to other research bodies. An example of such a measure is to adopt a Simple Letter Agreement. The Guidelines for Implementation provide specific information, strategies, and model language for patent and license professionals and sponsored research administrators at Recipient institutions to assist in implementing the above-mentioned principles.

The NIH Guidelines have no binding force over tools that have been developed by using only funds in the private sector and without using any government funds. Nonetheless, there have been several cases in which NIH intervened, though there was no funding by NIH, for the reason that they were regarded as very important cases since they might affect advancement of science in academic fields. For example, regarding the license on OncoMouse patents, a memorandum of understanding (MOU) was entered between the U.S. Public Health Service and the right holder to agree that a license agreement is not required for use of the patents in non-profit research activities.(*9)

In Japan, the Ministry of Education, Culture, Sports, Science and Technology issued the "Report of the Study Group on Handling of Results of Research and Development" that presents fundamental ideas on the handling of results of R&D from the viewpoint of a public agency as is the case with the NIH Guidelines. The report states that facilitating use of results of R&D requires enhancement of administrative systems in public research institutions so as to provide appropriate protection for intellectual property contained in R&D results they have generated. And, when a third party wants to use R&D results covered by an intellectual property right of a public research institution, it should obtain license from, or should be assigned the right by, the research institution, and then the third party should pay to it a remuneration appropriate to such license or assignment.

OECD countries are also currently considering guidelines on licensing of gene-related inventions including research tools. Basic principles of guidelines were already agreed upon at an OECD expert meeting called the "Expert Meeting on Best Practice Guidelines for the Licensing of Genetic Invention" (held in Munich, Germany, 17-18 November 2003). It is expected that such efforts will result in adoption of effective guidelines supported by globally shared understanding.

In the United States, the National Academy of Sciences, mainly in its Board of Science, Technology, and Economic Policy (STEP Board), has already started related work by establishing a "Committee on IP in Genomic and Protein Research and Innovation."

Such discussion is also in progress in Japan. For example, a working group established within a council that provides advices to the Ministry of Economy, Trade and Industry (Working Group of Issues Related to Patent Strategic Plan, Patent System Subcommittee, Intellectual Property Policy Committee of Industrial Structure Council) has held several meetings in order to clarify what could be exempted from patent infringement liability as "experiment or research." In addition, study on how to revitalize use of intellectual property that belongs to universities is also going on in the Special Research Committee on Management of Intellectual Properties (a section of the Council for Science and Technology Policy, Cabinet Office). Moreover, discussions on smooth use by universities or similar research institutions of patented inventions owned by other parties have been conducted in the Committee on Industry-Academia-Public Partnership of the Technology and Research Infrastructure section in the Council for Science and Technology under the Ministry of Education, Culture, Sports, Science and Technology.

## 6 Recommendations on Measures to Promote Use of Biotechnology-related Patents

In this chapter, we have worked out our recommendations on how to solve problems for promoting more use of biotechnology-related patents. From the viewpoint of facilitating development of science and human welfare, we have discussed mainly the possibility of introducing a free license scheme, fair use exemption and patent pool scheme for that purpose. In other words, we proposed the following three concepts: (1) free license of a research tool patent would protect the commons, (2) as a solution based on efforts of private businesses, use of something that is not other than mere gene information should be treated as in the case of copyright (including fair use exemption), and (3) as a possible form of collective

(*9) Memorandum of Understanding between E. I. duPont de Nemours and Company and Public Health Service U.S. Department of Health and Human Services, http://ott.od.nih.gov/textonly/oncomous.htm

management, attention should be given to introduction of a platform-type patent pool that is established based on concepts of RAND (reasonable and non-discriminatory licensing) and MCR (maximum cumulative royalty). Specifically, we have offered recommendations on "what fields in biotechnology and pharmaceutical sectors would allow for introduction of a patent pool or are appropriate for introducing a patent pool therein" and "what methods or frameworks could and should be taken if a patent pool can be introduced." We have also discussed in detail a possible framework of a gene patent pool.

### 7 Approach to Facilitate Smooth Use of Research Tool Patents: By Using Methods Employed in the Electronics Industry for Solving Issues Related to Standard Technology as a Reference Model

In this chapter, we have explored what approach would be effective for facilitating smooth use of research tools in the field of life science, by comparing the situation in the life science field with that in the electronics industry. Private remarks have been also included in the discussion. More specifically, we compared the industrial structure of the electronics industry and the pharmaceutical industry and examined whether licensing through a patent pool or a consortium could also be used for the purpose of promoting smooth use of research tools. We have also proposed establishing an open market for transactions in the biotechnology-related market.

## Ⅳ Conclusions

Use of another party's patented research tool in research activities is unlikely to be regarded as falling under the category of "experiment or research" that is exempted from infringement liability under Article 69 (1) of the Patent Law. Even when such a patent is used in a university or other research institution, such use will be regarded as "commercial" working of the patent under Article 68 of the Patent Law, and accordingly will be held as constituting patent infringement.

Therefore, in order for a researcher to use another party's patented research tool patents in his or her research activities, it is necessary for him or her to secure a licensing agreement on the patent that has little or no terms that might hamper the intended research activities. For enabling it, it is necessary, for example, to establish specific guidelines that would make clear distinction between research for academic purposes and that for commercial purposes and that would take into account whether the patentee/licensee is a university or other public institution or a private business. Moreover such guidelines should cover issues related to sources of finance and management of the research results.

Finally, as a subject of future study, further examination should be made on the possibility of using a compulsory licensing system for the purpose of achieving the smooth use of research tool patents. Also, administrative structure and systems suitable for the same purpose should be established.

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