Enforcement of Patents in the Field of Life Science

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Abstract

There are main two issues about the enforcement of patents in the field of life science. The first one is appropriate enforcement of research tool patents which has no alternative, as typified by biological resources like gene. The other is how to ensure the appropriate patent term. With regard to those issues, recent developments have been studied.

1. Introduction

Recently there has been active discussion regarding protection of patents in the field of the life sciences. A report[1] issued by the Industrial Structure Council in 2004 shows how to understand the limitation of exercise of the patent right to the action for experimental or research purpose, especially regarding research tool patents, as upstream technology which has no alternative. In the report, possible solutions of the problem by use of compulsory licenses are also discussed. In 2007, a report[2] issued by the Intellectual Property Strategy Headquarters provided proposals for the improvement of an environment proceeding utilization of research tools under rational conditions and proposals for a legal measure to admit an extension of registration term for the sustained-release system preparation patent related to nano-biotechnologies[3].

On the other hand, there has been quite a few number of litigation regarding such patents. For example, the chemokine receptor case (Decision of Osaka District Court, October 6, 2008[4]) was a patent infringement suit regarding a typical research tool patent, and in addition there are currently other cases before the courts regarding similar types of patents.

Taking into the consideration the current state of the above issues, this paper will analyze the current state of enforcement of patent rights in this field.

2. Nature of the Problem

The first point regarding the enforcement of patent rights in the life sciences is an issue regarding the appropriate enforcement of research tool patents which has no alternative, as typified by biological resources like gene.

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Patents related to these types of technologies belong to upstream technologies and such rights are very broad in scope. If such upstream technologies can not be smoothly utilized, development of all downstream technologies therein may be impeded. To take an example of a patent for a gene, possible applied areas for such a patent are pharmaceuticals, environmental and chemical products, foods and agriculture, genetic therapies and diagnosis. If those types of patents can not be smoothly utilized, it may bring harmful effects. Furthermore, even if license is intended for a patent, sometimes license negotiation is broken down due to disagreement over conditions. It is far from the smooth utilization of those patents.

The second point regarding the enforcement of patent rights in the life sciences is related to ensuring the appropriate patent term. Over the last few years, the number of litigation regarding the extension of patent term has been increased together with the appearance of pharmaceuticals having revolutionary action and effect as represented for example by the sustained-release system preparation.[5] This is due to the fact that the patent term is eroded because it takes long time to obtain manufacturing approval in order to bring such highly effective formulations to market. Notwithstanding this reduction of term, according to the examination and board of appeal practice of Japan Patent Office based on the current interpretation of Article 67(2), 67 *ter* and 68 *bis*, there was almost no room for extending the patent term for these types of formulation patents. However, as introduced in (6) below, in relation to the extension of patent term, a judgment including comments overturning the conventional legal interpretation was rendered in the end of May 2009 Discussion over the current legal interpretation has attracted considerable attention.

3. Discussion regarding Enforcement of Research Tool Patents which has no Alternative (Point 1)

(1) Experimental or Research Use Exemption

(i) Introduction

There is an opinion that the enforcement of research tool patents which has no alternative should be subject to a partial limitation based on the legal principle of an exemption for Experimental or Research use as prescribed by Article 69(1) of the Patent Law. The following points form the background of the opinion for applying an exemption for Experimental or Research use: (a) various applications which were not conceived when acquiring the patent can be imagined for research tools and therefore the rights are overly broad, and (b) since the final acquisition of pharmaceuticals and the like from experiment or research using a research tool requires success in and securing of not only upstream technologies but also mid-stream and downstream technologies, and screening with an upstream technique does not promise the final success. From this background and from the point of view of the recently popular open innovation, there is an idea gaining ground that a certain level of limitation on private rights may be unavoidable.

(ii) Traditional Interpretation of Experimental or Research Use Exemption

Article 69(1) of the Patent Law states that "the patent right shall not be effective against the working of the patented invention for experimental or research purposes". The Someno theory is commonly accepted interpretation related to the above provision. The Someno theory[6] expresses, as a fundamental idea[7] in defining the permitted scope of experiment or research capable of being conducted as a "business", that "the definition is determined by a scope within which the requirement for the development and progress of technologies as well as respect for private rights and the requirement for freedom in academic research may be rationally harmonized". Furthermore, concrete limitations are

stated, invoking a German theory, to be specified by using the concepts of "limitation by the subject" and "limitation by the purpose".

The "limitation by the subject" is an approach in which the exemption is only applied to experiment or research "for the subject of the patented invention itself" and not to when the experiment or the research is performed as "a means for performing another invention". The reason for applying this limitation is that, in the absence of such a limitation, research and development would be conducted on a large scale and the patented invention would be used in gratuity for developing new technologies without reference to the patented invention. Consequently, the value of patent rights would be seriously damaged. (More specifically, possible examples of the above include use of analytical precision equipment without payment).

Furthermore, with respect to "limitation by the purpose", a limitation should be provided from the point of view of advance in technology based on the gist of Article 69(1) of the Patent Law. The experiment or research for the purpose of the advance in technology may be divided into the three categories of (a) search for patentability, (b) experiment for function and (c) experiment for improvement and development.

(iii) Recent Court Decisions

Litigation regarding the application of the experimental or research use exemption in recent years has resulted from the two different points of view that (a) justification of use of research tool patent for experiment or research and (b) justification of clinical trials for generic pharmaceuticals during the term of patent rights. With respect to the former, there still is no judicial pronouncement regarding the interpretation of the scope of the experimental or research use exemption. Furthermore, for the latter issue, although justification thereof has been the subject of several proceedings in the lower courts[8], a decision of the Supreme Court discussed in (b) below has determined that clinical trials for generic pharmaceuticals during the term of patent rights corresponds to " the experimental or research use exemption" within the meaning of Article 69(1) of the Patent Law and the interpretation of "the experimental or research use exemption" of this issue is seen as determinative. However, the idea of "limitation by the purpose" indicated at in the Supreme Court's judgment has led to the result of invoking new discussion with respect to the interpretation of Article 69(1) of the Patent Law.

Representative recent judgments will be discussed below.

(a) Nude Mouse Case (Decision of Tokyo District Court, December 12, 2001[9]).

The plaintiff was the holder of patent rights relating to an animal model related to human diseases with tumor tissue block obtained from a human organ and sought injunction on the use of the nude mouse against defendants including the Government based on infringement of patent rights due to research performed by Hamamatsu University using athymic mice into which cancerous tissue was transplanted. The defendant insisted of non-infringement and asked for application of Article 69(1) of the Patent Law stating that "in contrast to the research activities of a pharmaceutical manufacturer, the present activities relate to the elucidation of disease mechanisms and research into the development of treatments and as such cannot adversely affect the economic interests of the patent holder".[10]

The court dismissed the claim of the plaintiff in that the nude mouse did not form part of the technical scope of the patented invention and did not make a judgment with respect to the assertion regarding Article 69(1) of the Patent Law.

The plaintiff appealed but the appellate court upheld the decision at first instance.[11]

(b) Camostat Mesylate Case (Decision of Supreme Court, The Second Petty Bench, April 16, 1999[12])

The plaintiff had a patent relating to guanidinobenzoic acid derivative (including generally called "Camostat Mesylate") and asked for an injunction and other remedies regarding alleged offending products with respect to experiments conducted by the defendant during the term of the patent for the purpose of application for a manufacturing approval of a camostat mesylate formulation which is a generic pharmaceutical. At first instance[13], the court noted that, although "the working of the patented invention for experimental or research purposes" specified in Article 69(1) of the Patent Law must finally make a broad contribution to the development of science and technology, or be for that purpose, the above definition is not limited only to a situation in which the result is come out in a direct and concrete form, and dismissed the plaintiff's claim on this basis.

The Supreme Court upheld the decision at first instance albeit for a completely different reason. In other words, since the application for a manufacturing approval of a pharmaceutical under the Pharmaceutical Affairs Law requires conducting a predetermined trials over a fixed period of time in advance. If such trials (experiments) do not fall under the scope of Article 69(1) of the Patent Law, even after the expiration of the term of the patent right, a third party would not be able to freely use the invention for a considerable period. This result would be contrary to the basis of the patent system in that "after the expiration of the term of the patent right, any person may use the invention freely for the general benefit of society". Thus, it was held that trials required for the application for a manufacturing approval of a generic pharmaceutical correspond to "the working of the patented invention for experimental or research purposes" provided by Article 69(1) of the Patent Law.

Although the Supreme Court decision did not touch upon the point of "advance in technology", there is an interpretation for this point, suggesting that it is "an indication that there is no requirement for at least 'advance in technology to a next stage'"[14].

(iv) Recent Discussion

Considering that, at the time when the Someno theory was formulated, there were almost no patents related to technologies which has no alternative such as patents for genes, it has been pointed out that there may be a limit to the unmodified application of the conventional Someno theory to modern technologies since the theory had not been premised on these technologies[15,16]. For example, taking an example of a research tool such as a gene, there may be difficulties in distinguishing objectively whether it is a subject of research or a means for research. That is to say, when this is expressed as "research using A for screening B", there is a strong possibility that A is used as a means. However, when this is expressed as "research to elucidate the interaction between A and B", there is a possibility that this is research for the purpose of elucidating the properties of A. Furthermore, by taking into account of inventions for research tools in biotech areas and in particular, screening methods, it has been noted with respect to the relationship between 'limitation by the subject' and 'the limitation by the purpose' in the Someno theory that "as far as considered as an experiment or research performed for a purpose corresponding to the three classified types described in Someno theory for patented inventions, there may be a room for applying the exemption even if there is an aspect which can be evaluated as a research means".[17]

In contrast, there has still been a strong caution expressing that the exemption for experiment or research should not be unnecessarily expanded from the point of view that Article 69(1) of the Patent Law is not meant to be directed to a specific field of technology.[18] A representative example of such opinions is that, even if it is considered that there is no reason to introduce a theory of interpretation which mitigates the application of Article 69(1) of the Patent Law with respect to the field of biotechnology, in the event of such a mitigation in interpretation, not only the right for injunctions but also the right for compensation for damages will be denied and there is the possibility that there will be a failure to provide an appropriate incentive for inventions relating to a means of experiment or research.[19] Furthermore, in a report[20] entitled "Regarding various problems related to facilitating the use of patented inventions", a view is expressed that is negative to the expansion or the modification of the current interpretation on the following grounds, namely, that a research using research tools does not correspond to the research for the purpose of studying the research tools themselves considered by the Someno theory, and that the interpretation of "the experimental or research use exemption" in Japan is not particularly overly limited when compared to the position in other countries. However thereafter, the Belgium Patent Law has been amended to expand the scope of exemption for research so that the patent rights do not extend to "acts carried out for scientific purposes on or with the subject matter of the invention".[21] The change in the circumstances of foreign countries means that there may yet be a room for discussion on the interpretation of Article 69(1) of the Patent Law.

(2) Compulsory License

(i) Introduction

The reason that the possibility of compulsory license has been considered as a solution for patents which has no alternative such as research tools originating in biological materials is somewhat different from the background for seeking a solution via the experimental or the research exemption. Although there are opinions considering a background similar to the discussion referring to the experimental or the research exemption, the emphasis is on a situation in which the licensor refuses the grant of a license or demands exorbitant license fees so that the license contract is not concluded and the research tool cannot be used, although there is an intent for concluding a license with respect to research tool patents (that is to say, the user-to-be is ready for the payment of royalties). The compulsory licenses is expected to be a solution in this situation. In other words, in problems surrounding the enforcement of the research tool patents, a solution regarding an "application of the experimental or research exemption" and a solution regarding "compulsory license" seem not to be simply mutually exclusive.

(ii) Discussions regarding Compulsory License (Article 92) on Dependent Patent

Japanese Patent Law provides a compulsory license where invention is not worked (Article 83), a compulsory license on dependent patent (Article 92) and a compulsory license for public interest (Article 93). Considering that the discussion surrounding compulsory licenses for research tool patents stems from the background discussed in the problem in (1) above, with respect to legislative intent, the possibility of a solution may be sought in terms of the compulsory license on dependent patent provided for by Article 92 of the Patent Law.

A compulsory license on dependent patent provided for by Article 92 of the Patent Law is based on Article 38(1) of the 1909 law instituted for a reason of public interest to promote improvements and progress in invention.[22]

Article 92 of the Patent Law was said to have been expected to serve as a coordinating measure in order to cope with the potent patentability of substance patents resulting from the introduction of the substance patent system in 1975.[23] Based on this background, there is also the expectation that Article 92 of the Patent Law will be a measure for the coordination of rights of biotechnology patents.[24]

However, the majority of opinions are either negative or cautious regarding a solution using Article 92 of the Patent Law for the problems associated with research tool patents.[25] One important reason is that subsection (1) of Article 92 of the Patent Law states that "where a patented invention falls under any of the cases as provided in Article 72, the patentee or exclusive licensee…" and thus is instituted for the purpose of coordinating rights when working a "patented invention". Considering that the problems associated with the use of research tools occur at the initial stage of a research and there is almost no chance that a patented invention would be present at this stage. Therefore it is doubtful whether Article 92 of the Patent Law will serve as a coordinating rule corresponding to the current situations of research tool patents. Another reason is the effect of the Japan/U.S. Comprehensive Agreement of August 1994.[26] Although doubt has been cast on the legal basis of this agreement, as an actual problems it was agreed that other than (1) to remedy a practice determined after judicial or administrative process to be anti-competitive and (2) to permit public non-commercial use, the JPO is not to render an arbitration decision ordering a dependent patent compulsory license to be granted.

Consistency with Article 31 of the TRIPS Agreement is also poses a problem. In Article 31 of the TRIPS Agreement, it is stated that compulsory license will be granted only when "the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent". However, at the stage of using a research tool patent, since it is often the case that it is not always clear to which dependent invention the patent will be applied, it is thought that this type of provision would be an impediment to the application of Article 92 of the Patent Law.

(iii) Discussions regarding Compulsory License (Art. 93) for Public Interest

With respect to the possibility for the solution of Article 93 of the Patent Law in this issue, Japan Pharmaceutical Manufacturers Association and Japan Bioindustry Association have jointly proposed in a submission entitled "Proposals for amendment of the Operation Guidelines for the Compulsory License System" to extend the target of the compulsory license taking into account with research tool patents which has no alternative.[27] Also, while making reference to the details of "the Operation Guidelines for the Compulsory License System" instituted in connection with the introduction of the substance patent system, there is an opinion that the level of "public interest" is to be set to a lower level than the current level, and Article 93 be allowed to be applied to the upstream research in pharmaceuticals, based on an understanding that the compulsory license system of Article 93 is considered as a coordinating means to make patents which has no alternative work effectively.[28]

On the other hand, many dissenting opinions are insisted. It has been suggested that the wording of "particularly necessary for…" in Article 93 of the Patent Law can actually be understood to constitute a high hurdle for the application of the article.[29] In addition, a cautious standpoint has been expressed that such an application of Article 93 is out of step with developed countries and that a domestic consensus from industry has not been obtained.[30]

However, when international trends are examined, the compulsory license for "public interest" can be seen as a

possible logic. In Belgium, in the process of the discussion on the amendments in 2005, the concern was raised for stagnation of genetic research related to diseases, if gene patents that are useful as research tools were asserted monopolistically.[31] As a result, a compulsory license system for public health was introduced.

(3) Possibility of Limitation to Enforcement through Other Legal Principles

The experimental or research use exemption as discussed in (1) above and the compulsory licenses discussed in (2) above are relatively frequently discussed as a means for enabling a limitation on the enforcement in relation to research tool patents which have no alternative. However, other opinions have examined the possibility of limiting the enforcement through other legal principles.

One example is an approach to limiting the scope of protection by use.[32] This opinion is comparatively new. The reason of the powerfulness of the research tool patents which have no alternative is that, in the same manner as patents for chemical substances, once patented, the rights can be enforced with respect to all uses. In contrast, given the present situation in which isolation of a specific useful gene has become simple and knowledge on the functions of each gene is being integrated, in view of the fundamental difference in the essence of the invention between an invention for a synthetic compound and an invention related to a naturally occurring gene, the idea of limitation by use proposes the possibility of varying the scope of the rights. The underlying idea for this approach is that, since the essence of the gene-related inventions is not identification or isolation of a substance, but lies in the elucidation of the function of the isolated substance, the scope of protection should be limited based the essence of the invention. Namely, there is an idea based on the essence of an invention.

Another example is a limitation based on the Anti-monopoly Law or the Competition Law.[33] The exemption to application with respect to acts recognizable as the exercise of rights pursuant to the Patent Law for example is prescribed by Article 21 of the Anti-monopoly Law. However, it is not generally understood that the provisions of the Anti-monopoly Law do not apply to the exercise of patent rights. For example, according to the "Guidelines Concerning Use of Intellectual Property"[34] even if an act is seen as an "exercise of the patent right" pursuant to the Patent Law, if such act is recognized as deviating from the purpose of the intellectual property system in letting interested parties exhibit originality and creativeness to promote the utilization of technologies, or as being contrary to the objective of the system, the act is not evaluated as "an act deemed to be the exercise of rights" and the Anti-monopoly Law is applied thereto. That is to say, the Anti-monopoly Law under the certain conditions may be a useful means for obtaining a balance with the Patent Law. As for an approach based on the Anti-monopoly Law or the Competition Law it is widely expected to provide a means for solving problems surrounding the refusal of licenses.[35, 36]

Furthermore, in relation to the enforcement of research tool patents, the application of the legal principle of abuse of rights in Civil Code (Civil Code, Article 1(3)), particularly the interpretation rendered in the decision[37] in the Unazuki Onsen Case to counterpoise the objective interest of the other party with subjective circumstances for the rights holder is considered[38] In conclusion, however, for the application of a legal principle of abuse of rights, a cautious opinion is expressed that the applicable scope should be examined with reference to the limitation on the enforcement by other legal principle existing in Patent Law such as the experimental or research use exemption or compulsory license.

(4) Discussion

As stated above, a variety of approaches has been suggested as a solution to providing a limitation with a certain scope to the enforcement of patents related to biological resources which have no alternative. Since various circumstances and situations are envisaged in the enforcement, there is no necessity to limit the means of solution to a single approach. Consequently, a plurality of measures may be implemented corresponding to the available means in order to maintain a balance between facilitating use of research tools covered by patents and the enforcement.

From the standpoint of emphasizing an incentive for the development of industry and from the view point of harmonizing the enforcement with respect to patents on upstream technologies, an approach using the experimental or research use exemption is thought to be the optimal approach when considering the facilitation of use of patents related to biological resources which have no alternative. However, the Supreme Court in the Camostat Mesylate Case as discussed above has ruled that the advance in technology may not play an important role in judging whether or not to apply Article 69(1) of the Patent Law, although it does not mentioned expressly . If this interpretation is correct, it may have become difficult to make a breakthrough based on the experimental or research use exemption in the use of patents related to biological resources which has no alternative. The reason for this difficulty is the following. The opinion underlying the suggestion for a limit on the predetermined enforcement with respect to patents related to biological resources which has no alternative is motivated by the desire to expand the possible applications by emphasizing the concepts of "improvement and development" in "limitation by purpose" in the Someno theory by placing emphasis on the fact that such patents enable the development of various downstream technologies. However, the ground for the possibility of broadened application disappears when the viewpoint of the advance in technology is not viewed as important in the judgment of whether or not to apply Article 69(1) of the Patent Law.

At a same time, there is a room for another approach.

The Supreme Court decision mentioned above stated that "the purpose of the patent system is, through encouraging inventions by granting a monopoly right for a predetermined period to a person making an invention open to the public and giving the third parties the opportunity to utilize the invention, and thereby to contribute to the development of industry. In the light of this view, after the period of a patent right has expired, any person may utilize the invention freely and in this manner, society in general may benefit. This can be said to be a basis of the patent system". The Court further noted that "on the other hand, during the term of the patent right, a third party is not permitted to infringe the patent right by producing a generic pharmaceutical to be sold after the expiration of the patent right, or producing or using a chemical substance related to the patented invention to prepare a component thereof in the manner of exceeding the scope required for a experiment for application for manufacturing approval based on the Pharmaceutical Affairs Law. When understood in this manner, the patent holder conserves the benefit of the monopolistic exploitation of the patented invention during the term of the patent right". These comments may be understood to demonstrate that the Supreme Court is suggesting a comparison of the importance of "a broad benefit to general society" with "conserving the benefit of the monopolistic exploitation of the patent holder", and therefore is determining the justification of the application of the experimental or research use exemption from a different viewpoint to the conventional Someno theory. If this interpretation is correct, the possibility may not be denied that the experimental or research use exemption is applicable to circumstances in which the broad-based benefit to general society from research or experiment using research tools which has no alternative is judged to have priority over the preservation of the benefits arising from monopolistic exploitation by the patent holder.

As an alternative opinion, it has been noted[39] that the range of the Supreme Court's decision is not clear, and the emphasis of the purpose of the advance in technology should be maintained as the commonly accepted theory even after the Supreme Court's decision. In either case, there would appear to be sufficient room for examining the application of the experimental or research use exemption as a possible approach.

An approach employing a concept of use to limit the scope of protection is consistent with the approach of granting patents for biological inventions and attracts considerable attention. Utility is emphasized by nature as a condition for obtaining a patent in a biological invention. This point is clear also from the statement that "an invention for which utility is not described and for which utility would not be easily inferred" is a type of invention which is not industrially applicable as stated in the part of biological invention in the Examination Guidelines for Patent and Utility Model.[40] In contrast, although inventions related to any novel compound require a description defining the compound's use as a condition for exploitation, in fact a high level of detail in such a description is not required.[41] The reason for this is that the creation of a novel compound itself entails the essence of invention in the case of an invention of a new compound. Consequently, since gene-related inventions use substances that are already present within the living body, and even when a procedure for isolating and removing them corresponds to creation, the level of creation is low, and hence such a patent is really not different from a patent granted in relation to discovery of utility, that is to say, a patent granted for the discovery of a use. Although this is the case, once patented, the situation in which all acts of manufacturing and using the invention constitute patent infringement in the same manner as a novel compound created by organic synthesis, etc. must be said to lack a balance between the requirement for obtaining the patent and the scope of the enforcement. This point can truly be said to be the cause of the current problems. When viewed in this manner, a limited interpretation in terms of use should be subjected to further examination in the future.

A policy for relieving the current situation with respect to the difficulty of getting licenses seems to be most consistent with the compulsory license (Article 92) on dependent Patent in terms of the legislative intent. However, high expectation cannot be placed on the compulsory license, since, as described above, Article 92 is premised on "exploiting the patented invention" and therefore is inconsistent with situations in which the use of research tools is the problem (that is to say, the initial stage of research), and also from the situation surrounding the Japan/U.S. Comprehensive Agreement or Article 31 of the TRIPS Agreement. Although there has been a suggestion for a compulsory license system differing from the system of licenses pursuant to Article 92 of the Patent Law[42], in the current situation where there is no application of a compulsory license system, there are doubts whether a compulsory license system would be rapidly provided and be efficiently facilitated. In view of the current circumstances, a certain degree of expectation may be placed on a solution through the provision of a framework for licenses. In particular, there is an urgent need for measures to solve the most pressing current problems including problems surrounding reach-through licenses or license fees. Furthermore, a certain degree of expectation may be placed on a solution based on the Anti-Monopoly Law or abuse of rights in Civil Law. Consequently, there is a need to promote discussion in this area.

4. Ensuring Appropriate Term of Rights (Point 2)

(1) Introduction

The current discussion surrounding problems related to the extension of term of patent rights is focused from two perspectives. The first point is the discussion related to the expansion of the subject of extension (the conditions for the

legal system forming the field of the extension system) and the other point is the discussion surrounding the extension of term of formulation patents characterized by formulation, dose or dosage of which the sustained-release system preparation patent is a typical example. Since the former has been discussed in the "Interim Report (Draft)"[43] prepared by the "Working Group of the System for Extension of Term of Patent Rights" published on July 17, 2009, this paper will only treat issues associated with the latter point.

(2) Conventional Legal Interpretation and Practice

The term of a patent right is 20 years from the filling date of the patent application (Article 67(1) of the Patent Law). The existence of an upper limit to the patent term is for the purpose of balancing the interests of third parties with the exclusive monopoly of the patent holder. An exception to this system is embodied in Article 67(2) of the Patent Law which enables the extension of the patent term. The legislative intent of Article 67(2) of the Patent Law originates in the problem that, for a patent in certain fields, a considerable period of time is required for the collection of required experimental data and examination of the data for approvals pursuant to regulations by government to ensure public safety. Therefore even though a patent right may exist in that period, the benefits of an exclusive right cannot be enjoyed thereby eroding the patent term by the time required for those procedures.[44] For this reason, the conditions for extension require accepting the disposition designated by Cabinet Order prescribed by Article 67(2) of the Patent Law. When it is deemed unnecessary to accept such disposition, no extension of registration is allowed (Article 67(3)(1)).

The relevant problem is the requirement to accept the disposition designated by the Cabinet Order. When an disposition designated by the Cabinet Order is designated by the Pharmaceutical Affairs Law, the scope specified by a number of matters including active component, use, method of manufacture, etc. as required for an disposition under the Pharmaceutical Affairs Law forms the scope which is removed from the prohibition of exploitation of the patent by the patent holder. Firstly, this scope must overlap the patented invention. Although this point is not really a problem, when seeking an extension of term based on a second disposition for the same active component and efficacy and effectiveness, the judgment of "necessity for accepting a disposition" becomes somewhat complicated. That is to say, the effect of extension prescribed by Article 68 *bis* of the Patent Law is specified with reference to "product (active component)" and "use (efficacy and effectiveness)". Therefore on this basis, when there is a previous approval for the same active component and the corresponding efficacy and effectiveness, the practice has been based the judgment that the exploitation of the patent does not require the receipt of the second approval (for example, approval which differs only with respect to formulations, method of manufacture, etc.). In other words, it has been practiced that the necessity to accept dispositions prescribed by Cabinet Order in the judgment of whether or not extension of registration is possible is explained with reference to the effect of extension prescribed by Article 68 *bis* of the Patent Law, and that the decision of whether or not to extend is judged based on a comparison of the scope of "product and use" prescribed by Article 68 *bis* of the Patent Law in the previous disposition.[45]

This legal interpretation has been supported by decisions of both the Tokyo High Court and the Intellectual Property High Court. In a decision[46] of the Intellectual Property High Court handed down on November 16, 2005, the Court stated that "in the system for extension of term of patent rights pursuant to the Patent Law, when dealing with a pharmaceutical substance, since a concept of "disposition" is defined with reference to "product (active component)" and "use (efficacy and effectiveness)" which differs from the provisions of the Pharmaceutical Affairs Law. Thus the

requirement that patented invention is unable to be exploited because of the necessity for accepting dispositions prescribed by Cabinet Order within the meaning of Article 67(2) or the requirement that the disposition designated by Cabinet Order under Article 67(2) is needed to exploit the patented invention within the meaning of Article 67 *ter* (1)-1 should be understood as a problem of whether or not there was a necessity to accept the disposition from the point of view of "product (active component)" and "use (efficacy and effectiveness)" for the exploitation of a patented invention related to a pharmaceutical being the object of an approval pursuant to Article 14(1) of the Pharmaceutical Affairs Law. Thus, this type of interpretation enables a consistent interpretation of the system for extension of term of patent rights as a whole." Furthermore, a decision[47] of the Intellectual Property High Court handed down on October 11, 2005 states that the fact that the necessity for accepting disposition prescribed by Cabinet Order within the meaning of Article 67(2) of the Patent Law must be explained in relation to Article 68 *bis* of the Patent Law is due to an inconsistency in the law, and that "the interpretation of this court is not directly explained based on the provision on the requirements for extension or reasons for refusal. Rather, the fact that one is forced to provide an explanation based on the provisions of Article 68 *bis* in relation to the effect of patent rights resulting from extension is due to the fact that the important matters in relation to pharmaceutical that are the subject of an approval pursuant to Article 14(1) of the Pharmaceutical Affairs Law are found only in the expression of provisions in Article 68 *bis*. Consequently, in spite of the fact that this point is an important determinative rule forming a basis of overall interpretation of provision regarding extension of patent term in relation to pharmaceuticals, there is no doubt that the problem arises due to the fact that this is wholly entrusted to the operational level of the enforcement ordinance of the Patent Law Enforcement Order, the Patent Law Enforcement Regulations and the Q&A of the Japan Patent Office, and legal provisions continue to contain ambiguous sections".[48]

The decision of the Intellectual Property High Court handed down on November 16, 2005 further noted that the provisions related to the extension of term of a patent right are ambiguous in relation to the pharmaceuticals and commented that a clarification of related provisions would be desirable. These decisions were influential in forming a prevailing view that the extension of term of pharmaceutical patents characterized by a formulation, dose or dosage such as the sustained-release system preparation patent would be difficult in the absence of a revision to the law.[49]

(3) Decision dated May 29, 2009 (2008 (GyoKe) No. 10458)[50]

In the above circumstances, a decision was handed down on May 29, 2009 for the first time recognizing an extension of term for the sustained-release system preparation patent. The relevant patent (claim 1) in this case was stated in the following terms.

> "A pharmaceutical comprising combining:
> (A) a quick-release composition containing a pharmaceutical agent reaching a maximum blood concentration within 60 minutes, and
> (B) a release-control composition formed by covering a nucleus containing a pharmaceutical agent with a covering agent, the covering agent containing (1) a water-insoluble substance, (2) a hydrophilic substance selected from a polysaccharide optionally having a sulfate group, a polysaccharide having a hydroxyalkyl group or carboxyalkyl group, methylcellulose, polyvinylpyrrolidone, polyvinyl alcohol and polyethylene glycol, and (3) a cross-linked acrylic acid polymer having an acidic dissociable group and displaying

pH-dependent swelling".

The court in this decision firstly stated that the conventional interpretation of Article 67 *ter* (1)-1 of the Patent Law as adopted in examination (appeal) by the Japan Patent Office with respect to applications for extension of term was in error. In other words, the legal basis does not reside in a judgment of whether or not to extend the term of patent rights by considering the scope of the enforcement of the patent right extended by the previous disposition as stated in (2) above, but rather the justification of extension should be directly determined from compliance with the requirements in Article 67 *ter* (1)-1 of the Patent Law which is the basic provision for examination (appeal) with respect to refusal.

Since Article 67 *ter* (1)-1 of the Patent Law in relation to conditions for an examiner (appeal examiner) to reject an application for extension of registration states that "where the disposition designated by Cabinet Order… is not deemed to have been necessary to obtain for the working of the patented invention", an examiner (or appeal examiner) in refusing such an application must demonstrate that (1) the prohibition is not removed by accepting "a disposition prescribed by Cabinet Order" or (2) "acts by which the prohibition is removed due to accepting 'an disposition prescribed by Cabinet Order' is not contained in the act corresponding to the 'exploitation of the patented invention'". In the present case, these requirements were judged not satisfied.

In the decision, the judgment of "the scope of effect of the extended registration in relation to the previous disposition" in the appeal was also held to be in error. The legal interpretation of the decision states that the judgment of justification of extension is derived from the compliance with the requirements stated in Article 67 *ter* (1)-1 of the Patent Law, and thus the decision in relation to the effect of extension as prescribed by Article 68 *bis* of the Patent Law may be viewed as an *obiter dictum*. However, although the appeal may be viewed as based on a judgment of the justification of extension based on a conventional explanation in accordance with Article 68 *bis* of the Patent Law, the present decision points out that the error in the judgment on this point extends to the conclusion of the appeal.

This decision states that, when "an disposition prescribed by Cabinet Order" is an approval under the Pharmaceutical Affairs Law, the effect of extension pursuant to Article 68 *bis* does not extend to "products" specified by "active component (products)" or "efficacy and effectiveness (use)", but to "products" specified by the "components", "quantity" and "structure" of the pharmaceutical obtained by the relevant approval, and that "components" are not limited to components (active component) displaying a pharmaceutical effect.[51]

(4) Perspective for the Future

As described above, justification of the conventional legal interpretation has become a point of active discussion with respect to the system for extension of term of patent rights. If the legal interpretation displayed in the decision of the Intellectual Property High Court as described in (3) above were adopted in future practice, the effect on related corporations and members of industry would be extremely large.[52] Since the decision is currently under appeal, the decision by the Supreme Court in this matter will be awaited with great interest.

5. Conclusion

An overview has been provided of the current situation and existing challenges facing the enforcement of patent rights in the life sciences centering on two points. Although both those points are important from the point of view of

stimulating corporate and research activities, there is no definitive decision covering those points other than the decision of the Supreme Court in relation to clinical trials for generic pharmaceuticals stated above. Consequently, accumulation of case laws and the evolution of discussion in this area are keenly anticipated. Since active discussion is expected to continue in this area, emerging trends will be watched with considerable interest.

Notes

1 Working Group on Issues related to Patent Strategy Planning of Sub-Committee for Intellectual Property Policy, Industrial Structure Council, *Problems associated with Facilitating Use of Patented Inventions* (November 2004).

2 Life Sciences Project Team, Competition Enhancement Investigation Committee for Intellectual Property, Intellectual Property Headquarters , *Report on Survey of Project Team in Life Sciences* (October 30, 2007).

3 This suggestion is discussed in turn by the Intellectual Property Headquarters, Intellectual Property Administrative Section Patent System Sub-Committee, Working Group for Examination of System for Extension of Term of Patent Rights, started on October 30, 2008.

4 Osaka District Court, 2006 (Wa) No. 7760.

5 Intellectual Property Institute, *Second Period IIP Intellectual Property Seminar Achievement Report* (2007 - 2008) (May, 2009). Examples of recent case laws are listed on p. 87.

6 Keiko Someno, "Exploitation of patented inventions in experiment or research" *AIPPI* Vol. 33, No. 3 (1988), p. 2 ff., Vol. 33, No. 4 (1988), p. 2 ff.

7 Experiment or research not performed as a business are excluded from the scope of the patent right according to Art. 68. See, Someno, *supra* note (6), p. 4. The same interpretation is stated in Tamotsu Shoji, "Exploitation of patented inventions for experiment or research", in Toshiaki Makino *et. al.* (eds.), *Principles and Practice of Intellectual Property Law*, Vol. 1 (Patent Law [1]), (Shinnihonhoki Shuppan, 2007), on p. 241 ff.

8 A list of decisions is given in the report of Working Group on Issues related to Patent Strategy Planning, *supra* note (1), p. 11.

9 Tokyo District Court, 1999, (Wa), No. 15238, *Hanreijiho*, No. 1787, p. 145 ff.

10 However, from the details of the defendant's submissions in the text of the decision, the defendant actually appears to have submitted that "there was no exploitation as a business".

11 Tokyo High Court, October 10, 2002, (Tokyo High Court, 2002 (Ne) No. 675, Hanta, No. 1119, p. 215 ff.).

12 Supreme Court, 1998, (Ju) No. 153, *Minshu*, Vol. 53, No. 4, p. 627.

13 Osaka High Court, May 13, 1998, *Chitekisaishu*, Vol. 30, No. 2, p. 271.

14 Makiko Takabe, " Important Decision Explanatory Note: An Experiment required for application for approval prescribed by Article 14 of Pharmaceutical Affairs Law for generic pharmaceuticals and 'exploitation of patented inventions for experiment or research' within the meaning of Article 69(1) of the Patent Law", *Soji*, Vol. 57, No. 8, p. 177 ff.

15 Intellectual Property Research Institute, *Report on Survey and Research on Facilitating Use of Patented Inventions*, Report on survey and research for issues on industrial property right system committed by JPO, 2006. This report states that, "when considering the handling of whether or not such research corresponds to exploitation for the purpose of experiment or research of the patented invention in relation to A, to the degree that the purpose of research is the promotion of technology in relation to A, specification of the subject of the research should be broadly interpreted. In the example given above, as long as A is not an established versatile technology or means, A and B should be considered as subjects of the research".

16 Hiroshi Ishikawa, "Use of Patented Inventions for Research and Development in the Field of Life Science from Industrial Side: Expectation for the Guidelines of Council for Science and Technology Policy", *Tokkyokenkyu*, Vol. 43 (2007), p. 32 ff.

17 Ichiro Nakayama, "Relationship between 'research freedom' and patent rights seen from a Japan and U.S. comparison: Developments and issues in ' the experimental or research use exemption"', *AIPPI*, Vol. 48, No. 6, (2003), p. 2 ff.

18 First Sub-Committee of Biotechnology Committee, "State of the Compulsory License System for Inventions related to Biotechnology: Observations on the State of Intellectual Property Rights in This Field", *Chizaikanri*, Vol. 54, No. 5 (2004), p. 751 ff.

19 Yoshiyuki Tamura, "Biotechnology undergoing Abstraction and the State of Patent System (3. completed)", *Chitekizaisanhoseisakugakukenkyu*, Vol. 12 (2006), p. 91 ff.

[20] Working Group on Issues related to Patent Strategy Planning, *supra* note (1).

[21] The Institute for Future Technology, *Report on Survey and Research Related to Handling of Patent Rights Used in Research*, Report on survey and research for issues on industrial property right system committed by JPO, 2007, p. 82.

[22] Working Group on Issues related to Patent Strategy Planning, *supra* note (1), p. 41; Masami Hanabusa (ed), *Overview of academic interpretations of decisions in industrial property* (Tokyo: TeikokuChihoGyoseiGakkai, 1956), p. 430.

[23] Biotechnology Committee "Compulsory licenses under Article 93 of the Patent Law for biological invention", *Chizaikanri*, Vol. 52, No. 10 (2002), p. 1511 ff.

[24] Biotechnology Committee, *supra* note (23), p. 1518.

[25] Working Group on Issues related to Patent Strategy Planning, *supra* note (1), p. 87; Naho Ebata, "Possible Solution by Compulsory License for Problems Associated with Research Tool Patents", *Jurist*, Vol. 1321, October 15, 2006, p. 134 ff;, Toshifumi Hienuki, "Biotechnology Industry in Japan and Competition Policy: Licensing Problems Associated with Research Tool Patents", *Chitekizaisanhoseisakugakukenkyu*, Vol. 9 (2005), p. 6 ff.

[26] Working Group on Issues related to Patent Strategy Planning, *supra* note (1), p. 43.

[27] Working Group on Issues related to Patent Strategy Planning, *supra* note (1), reference materials 9.

[28] Biotechnology Committee, *supra* note (18), p. 754.

[29] Ebata, *supra* note (25), p. 78.

[30] Working Group on Issues related to Patent Strategy Planning, *supra* note (1), p. 86.

[31] The Institute for Future Technology, *supra* note (21), p. 78.

[32] Tamura, *supra* note (19), p. 95; Yoshiyuki Tamura, "Biotechnology and the State of Patent System - Third: Principle of Limitation of the Enforcement in Biotech Patents Associated with Information Technology", *Johokanri*, Vol. 50, No. 7, p. 403 ff.

[33] Details on this point, see The Intellectual Property Institute, *supra* note (15).

[34] Japan Fair Trade Commission, "Guidelines on Anti-Monopoly Law in Relation to Use of Intellectual Property", (September 28, 2007) http://www.jftc.go.jp/dk/chitekizaisan.html

[35] Nobuhiro Nakayama, "Pharmaceuticals as an Intellectual Property for Society: Protection and Exploitation of Intellectual Property in a Pro-patent era ", *Capsule*, Vol. 82 (March 2006), p. 2 ff.

[36] Tamura, *supra* note (19), p. 98.

[37] Decision of the former Supreme Court (Taishinin), October 5, 1935, *Minshu*, Vol. 14, p. 1965.

[38] Intellectual Property Research Institute, *supra* note (15), p. 136 ff.

[39] Naohiko Tatsumi, "An Experiment required for application for approval prescribed by Article 14 of Pharmaceutical Affairs Law for generic pharmaceuticals and 'exploitation of patented inventions for experiment or research' within the meaning of Article 69(1) of the Patent Law", *Minshoho Zasshi*, Vol. 122, No. 6, p. 66 ff.

[40] Japan Patent Office, "Examination Guidelines for Patent and Utility Model" Part VII, Chapter 2, biological invention, see 3.2.1.

[41] Tokyo High Court, March 22, 1994, (1990 (GyoKe) No. 243, *ChitekizaisankenKankeiMinji-GyoseiSaibanreishu*, Vol. 26, No. 1, p. 199, *Hanreijiho*, No. 1501, p. 132 ff.). In this decision, the court seems to indicate as if utility is also important in an invention of a chemical compound. In this decision, the level of disclosure (endorsement) of a use required for an invention of a chemical compound is of the same level as that required for a use invention. However, there is an impression that a slight deviation from the actual practice exists in this area. These above decisions may have been made because the claims were too comprehensive.

[42] Ebata, *supra* note (25). However, this suggestion has been made in the form of tentatively setting aside Article 31 of TRIPS Agreement or the Japan/U.S. Comprehensive Agreement.

[43] In the "Interim Report (Draft)", the conditions for extension are (1) a premise based on the intent of the system" and (2) an administrative point of view. Conditions in (1) above include conditions such as (i) a disposition prescribed by law prohibits the exploitation of the patented invention as a business, (ii) as the entire field covered by the provision, there is an unavoidable examination period for regulation, and moreover there is naturally a limit to the reduction of that period from the point of view of securing safety, and (iii) the period for examination for the purpose of safety is of a similar extent to that for agricultural chemicals or pharmaceuticals. Conditions in (2) above include conditions such as (i) a consideration of a balance between the patentee and third parties with respect to the disposition, (ii) a consideration of whether or not to contribute to the progress of innovation, and (iii) relevance to international trends. When these conditions are considered, it is concluded that

reconsideration should be made at a stage at which the actual situation of the approval period has been clear, because there are conditions for which at the current stage it is unclear whether these conditions are satisfied or not, although part of the conditions are satisfied with respect to genetically recombinant living things based on the Cartagena Protocol, medical treatment devices, external pharmaceutical agents, and food additives. However, it is concluded that specified health foods are not included in a field covered by the extension since such foods do not comply with the conditions.

[44] Japan Patent Office, *Article-by-article Explanation of Existing Industrial Property Law* (Hatsumei Kyokai, 16th Edition), p. 198 ff.

[45] Koji Hirayama *et. al.* (eds.), *Detailed Description of Revisions: The System for Extension of the Term of Patent Rights* (Hatsumei Kyokai, 1988), p. 175 ff.

[46] Intellectual Property High Court, 2005, (Gyo-Ke) No. 10184, *HanreiTimes*, No. 1208, p. 292 ff.

[47] Intellectual Property High Court, 2005, (Gyo-Ke) No. 10345.

[48] This decision has been criticized by Kazufumi Doi in "Manufacturing and Approval for Pharmaceuticals and the System for Extension of Term of Patent Right" *AIPPI*, Vol. 51, No. 11 (2006), p. 2 ff. The logical structure stated in this decision is that, in the presence of a patent of a chemical compound having a certain efficacy and effectiveness, after a disposition is made for an approval of manufacturing a pharmaceutical having the chemical compound as an effective component, the decision is valid for the case where a disposition is sought for modifying formulation, etc., however, the decision is clearly inconsistent in the case where the patented invention is not a pharmaceutical itself that is "the substance". One reason for this is that even in the event that a pioneer patented invention is made for the formulation, the recovery of the term cannot be achieved under this logical structure.

[49] In the Working Group of Note (3) above, although the extension of the sustained-release system preparation patent was the subject of debate, it is affected by the broad intent of this type of decision.

[50] Also see a decision 2008 (Gyo-Ke) No. 10459 containing similar statements which was handed down on the same day.

[51] However, according to this decision, those things that are evaluated to be substantially similar or equivalent are also included.

[52] Intellectual Property High Court HP. http://www.ip.courts.go.jp/