4 The System for Registration of Extension of the Duration of Patent Rights of Pharmaceuticals or the like and the Appropriate Operation Thereof (*)

In Japan, there is the system to register for an extension of the duration of a patent right, in which the duration of a patent right may be extended by an application for the registration of extension and according to the Examination Guidelines for Patent and Utility Model in Japan, the examinations of applications for the registration of extension have been carried out. However, on May 30, 2014, the Grand Panel of the Intellectual Property High Court rendered the opinion with respect to the interpretation in the current Examination Guidelines. While this judgment has not become final and binding, the current operation of the system to register for an extension of the duration of a patent right is called into question. The state of approvals and licenses based on the provisions of laws enacted for the purpose of securing safety or the like, which is the ground of the extension, is affected by the globalization of businesses and the complications and advancements of technology. Considering the intensified race to develop novel pharmaceuticals with expanding development of new forms or new dosages and means of administration, and emerging of regenerative medical products, this research was conducted aiming to prepare such basic materials that contribute in studying the system to register an extension of the duration and the appropriate operation thereof in the future, such as the Japanese users' evaluation on the current system and the operation thereof as well as the survey of similar systems in foreign countries and the status and actual circumstances of the operation thereof.

I Introduction

Article 67(1) of the Japanese Patent Act[1] provides that "the duration of a patent right shall expire after a period of 20 years from the filing date of the patent application." The system to register for an extension of the duration of a patent right under paragraph (2) of said Article[2] is provided as an exception to such duration. Currently, the types of the disposition prescribed in said paragraph, which are set forth under Article 2, items (i) and (ii) of the Order for Enforcement of the Patent Act, are (a) registration of agricultural chemicals under the Agricultural Chemicals Control Act; and (b) approval and certification of pharmaceuticals, in-vitro diagnostic pharmaceuticals and regenerative, cellular-therapy and gene-therapy products (including veterinary medicines) under the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, etc. (hereinafter referred to as the "Pharmaceuticals and Medical Devices Act").

With respect to a litigation seeking rescission of a trial decision rendered by the Japan Patent Office (JPO) for an application for registration of extension of the duration of a patent right, the Intellectual Property High Court ("IP High Court") rendered a judgment to rescind the JPO decision on May 29, 2009, and the Supreme Court dismissed the appeal filed by the JPO. In response to these judgments, the examination guidelines were examined for revision in the Working Group Studying the System for Extending the Duration of a Patent Right under the Patent System Subcommittee of the Intellectual Property Committee of the Industrial Structure Council and were revised to avoid any inconsistencies with respect to the judgment of the Supreme Court. However, on May 30, 2014, the trial decision rendered by the JPO based on the revised examination guidelines was rescinded by the judgment of the Grand Panel of the IP High Court. The Grand Panel denied the operations made by the JPO with respect to the interpretation of the revised examination guidelines. While a petition for acceptance for final appeal has been filed with respect to the abovementioned judgment and such judgment has not become final and binding, the operation of the system to register for an extension of the duration of a patent right is called into question.

The state of approvals and licenses based on laws enacted for the purpose of securing safety, etc. is affected by the globalization of businesses

(*) This is an English summary by Institute of Intellectual Property based on the FY2014 JPO-commissioned research study report on the issues related to the industrial property rights system.

and the complications and advancements of technology. In particular, in the field of pharmaceuticals, the system to register for an extension of the duration of a patent right has become increasingly important due to the intensified race to develop pharmaceuticals made of novel active ingredients, pharmaceuticals with new forms or new dosages and means of administration, and regenerative medical products. Amidst this situation, the users' increasing interests in the system to register for an extension of the duration of a patent right and the operation thereof require basic materials that contribute to their study of the system to register an extension of the duration of a patent right and the appropriate operation thereof in the future, such as the Japanese users' evaluation on the current system and the operation thereof as well as the study of similar systems in foreign countries and the status and actual circumstances of the operation thereof.

Ⅱ Japanese system of application for the registration of extension of the duration of a patent right

1 Intent and purpose of the system for the registration of extension of the duration of a patent right

The purpose of the Japanese patent system is to seek development of industry by allowing a monopoly of rights for an art covered by an invention for a certain period of time to compensate for the disclosure of such art, thereby protecting the invention while offering it for use by the public. However, in some fields, a considerably long period of time is required to collect data, due to the necessary experiments to obtain approvals and licenses based on government laws and safety regulations as well as the examination thereof. Consequently, there was an issue that, although the patent right is effective during such period of time, the patentee cannot fully enjoy the benefits of the monopoly of rights and suffers encroachment of the patent term for such period of time.

Although such laws and regulations themselves are essential in terms of their purpose, as a result of the enforcement thereof, in the entire field subject to the abovementioned laws and regulations, the patentees are inevitably unable to enjoy the patent term, which could have originally been enjoyed for the abovementioned period of time. In addition, there were limitations on the reduction in the examination period under such laws and regulations due to security of safety, etc.

Since this situation concerns the basis of the patent system, the system to register for an extension of the duration of a patent right was created upon the revision of the Patent Act in 1987.

The system to register for an extension of the duration of a patent right was created for the purpose of seeking balance between the protection and use of inventions. The system extends the duration of a patent right and fully protects inventions in light of the fact that, in the fields where patent inventions cannot be immediately worked due to the long period of time required for experiments and examinations that are necessary for receiving dispositions under laws and regulations stipulated for securing safety, etc., inventions were protected in a considerably insufficient manner and third parties that only use patented inventions were in an overly advantageous position.

2 Outlines of the system for the registration of extension the duration of a patent right

The current Japanese system to register for an extension of the duration of a patent right was created by the revision of the Patent Act in 1999.

The outline of the system is as follows.

(1) Dispositions that serve as grounds for the registration of extension

The dispositions that serve as grounds for the registration of extension are listed in Article 2 of the Order for Enforcement of the Patent Act mentioned in I. above.

(2) Period to be extended

The period to be extended is provided for in Article 67(2) of the Patent Act. While various tests are conducted according to the purpose, gist and contents of the regulatory law, it is prescribed that only the period for carrying out the test that satisfies all of the requirements mentioned in (i) through (iii) below may be included in the "period during which the patented invention is unable to be worked."

(i) The test is essential to receive the disposition;

(ii) Companies are limited in their freedom to carry out the test since it must be carried out in line with the standards prescribed by government ministries and agencies with respect to the method and contents, etc.; and

(iii) The test is closely related to the receipt of disposition.

More specifically, in the case of pharmaceuticals, in-vitro diagnostic medicines and regenerative, cellular-therapy and gene-therapy products, the abovementioned period is prescribed to begin on the day that the clinical test has commenced or the registration of a patent right has been established, whichever comes later, and to end on the day immediately prior to the day of arrival of the notice of approval to the applicant (the day on which the applicant is placed in a situation in which he/she actually knows or is able to know the grant of such approval). In the case of agricultural chemicals, the abovementioned period is prescribed to begin on the day of commencement of the entrusted field test, which is carried out by clearly stating the name of the compound (the request date, etc.) or the day on which registration of a patent right has been established, whichever comes later, and to end on the day immediately prior to the day of arrival of the notice of approval to the registered applicant (the day on which the applicant is placed in a situation in which he/she actually knows or is able to know the grant of such approval).

(3) Application for the registration of extension

The application requesting the registration of extension of the duration of a patent right shall be filed by the patentee within the time limit prescribed by Cabinet Order (3 months) after the disposition prescribed by Cabinet Order under Article 67(2) is obtained in Article 67(1). The application requesting the registration of extension of the duration of a patent right may not be filed after the expiration of the duration of a patent right (Article 67-2(3) Patent Act).

Where a patent right is jointly owned, none of the joint owners may file an application for the registration of extension of the duration of a patent right unless jointly with all the other joint owners (Art. 67-2(4)).

(4) Effects of application for the registration of extension

Where an application for the registration of extension of the duration of a patent right is filed, the duration shall be deemed to have been extended; provided, however, that this shall not apply where the examiner's decision to the effect that the application is to be refused has become final and binding or where the extension of the duration of a patent right has been registered (Art. 67-2(5)).

(5) Examination of application for the registration of extension

Where an application for the registration of extension of the duration of a patent right falls under any of the items listed in Article 67-3(1), the examiner shall render the examiner's decision to the effect that the application is to be refused. Where the examiner intends to render an examiner's decision to the effect that an application is to be refused, the examiner shall notify the applicant of the reasons therefor and give the said applicant an opportunity to submit a written opinion, designating an adequate time limit for such purpose.

An applicant who has received an examiner's decision to the effect that an application is to be refused and is dissatisfied may file a request for a trial against the examiner's decision of refusal.

Where no reasons for refusal are found for the application for the registration of extension of the duration of a patent right, the examiner shall render an examiner's decision to the effect that the extension is to be registered.

(6) Effects of patent right for which duration is extended

Where the duration of a patent right is extended, such patent right shall not be effective against any act other than the working of the patented invention for the product which was the subject of the disposition designated by Cabinet Order under Article 67(2) which constituted the reason for the registration of extension (where the specific usage of the product is prescribed by the disposition, the product used for that usage)(Article 68-2).

Ⅲ Outcome from questionnaire survey and interview survey

In the entire field of pharmaceuticals, both new drug manufacturers and generic drug manufacturers tend to appreciate the operations that the JPO conducted prior to the rendition of the judgment of the IP High Court on May 29, 2009. While they regarded conventional operations to have been carried out based on certain balance for cases other than those for which the judgment of the Supreme Court was rendered on April 28, 2011, they also appreciated to a certain degree the operations conducted by the JPO based on the revised examination guidelines after the abovementioned judgment of

the Supreme Court was rendered.

With respect to the judgment of the Grand Panel of the IP High Court rendered on May 20, 2014, many of both new drug manufacturers and generic drug manufacturers answered that the interpretation of the effect of a patent right whose duration has been extended presented in the obiter dictum of the judgment of the Grand Panel of the IP High Court destabilizes the scope of effect of a patent right whose duration has been extended. Notably, some new drug manufacturers presented their opinions that a system revision must be made if the effect of a patent right whose duration has been extended would be interpreted as in the judgment of the Grand Panel of the IP High Court.

However, companies have shown different levels of understanding with respect to the impact on practices to be caused by the effect of a patent right whose duration has been extended, which has been presented in the judgment of the Grand Panel of the IP High Court. Moreover, companies have different levels of understanding with respect to the revision of the system, such as the actual revision to be made and the practical revision.

Since the field of agricultural chemicals is subject to conditions different from those of pharmaceuticals, such as the high safety required of agricultural medicines and long data protection period, in some cases, the needs of agricultural chemical manufacturers do not correspond to those of pharmaceutical manufacturers.

In the field of agricultural chemicals, while more importance is placed on the patent right until the agricultural chemical has been registered, once the agricultural chemical has been registered, substantial protection of such agricultural chemical is secured by the Agricultural Chemicals Regulation Act and the system for registration of agricultural chemicals and the operation thereof.

The field of regenerative medicine has only recently been covered by the system to register for an extension of the duration of a patent right and, thus, there are no cases in which the registration of extension of the duration of a patent right has become an issue. However, various cases are expected to occur in the future.

Ⅳ Systems for the registration of extension of the duration of a patent right and related systems in major foreign countries

1 United States

In September 1984, the Drug Price Competition and Patent Term Restoration Act of 1984 came into force. This law is generally called the Hatch-Waxman Act after Representative Waxman, who promoted "competition of drug prices," and Representative Hatch, who promoted "restoration of patent term." The Act contains the Abbreviated New Drug Application (ANDA) approval supported by the generic industry and the method of restoration of patent term supported by research-and-development-oriented companies.

The system to register for an extension of the duration of a patent right in the U.S. is prescribed in Section 156 of the Patent Law and Sections 1.710 through 1.791 of the Patent Rules (37 C.F.R.), "Adjustment and Extension of Patent Terms," as well as in Section 2710 of the Manual of Patent Examining Procedure (MPEP). The outline of the system is as follows.

(1) Products that serve as grounds for registration of an extension

Human drugs, animal drugs, medical devices, food additives and coloring agents are products that serve as grounds for registration of an extension.

(2) Period to be extended

With respect to pharmaceuticals, the total of half of the period starting from the day of Investigational New Drug (IND) Application until the day of New Drug Application (NDA) and the period from the day of NDA until the day of approval (Section 156(c) and (g)(1) of the Patent Law) will be extended for a maximum of 5 years.

However, the period of extension will be reduced for the period during which the applicant did not act with due diligence (Section 156(c)(1) of said Law), and the period from the day of permission (the day of approval in the case of pharmaceuticals) until the date of expiration of the patent term (if the patent term has been extended) shall not exceed 14 years (Section 156(c)(3) of said Law).

The patent term is extended form the first date of expiration of the patent term (the day of expiration when the patent term is not extended) (Section 156(a) of said Law). (The detailed

method for calculating the extension of patent term is provided in Sections 1.775 through 1.779 of the Patent Rules.)

(3) Patents eligible for extension

Patents eligible for extension are those related to products, those related to the process of using products and those related to a process for manufacturing products. The patent term can only be extended for one patent selected by the patentee (this is not necessarily the first patent granted) for one product in relation to the one-time approval of a New Drug Application (NDA) granted for the first time.

(4) Application

The owner of record of the patent or its agent must submit an application within 60 days from the day on which the product received permission, based on the provision of law (the day of acquisition of approval of NDA in the case of pharmaceuticals) (Section 156(d)(1) of the Patent Law).

There is a system where, if the owner of record of the patent or its agent reasonably expects that the review period may extend beyond the expiration of the patent term in effect, the owner or its agent may submit an application to the Director of the United States Patent and Trademark Office (USPTO) for an interim extension. Therefore, for example, the patent term may be allowed an extension even if the patent term were to expire prior to the grant of approval of NDA.

(5) Review

The USPTO decides the extension period after the regulatory review period has been decided by the notification to the Food and Drug Administration (FDA) by the USPTO.

(6) Effects of patent right for which duration is extended

The effect of a patent right whose duration has been extended only extends to approved products that have the same scope of protection as that of the basic patent. However, with respect to use, such effect extends to the use subject to subsequent new approvals. (In this part, the term products refer to the active ingredients of the approved product.)

2 Europe

In Europe, movements requiring the creation of a system similar to the systems to register for an extension of the duration of a patent right used in the United States, Japan and the Republic of Korea were increasing due to the loss of term of use of exclusive right based on patents, decline in the share of pharmaceuticals originated in Europe, deterioration in the quality of pharmaceutical research activities caused by an insufficient source of revenue and concerns over movement of research base to non-member countries of the EU that give better protection to patents. Consequently, the amendment of Art.63EPC was adopted on 17 December 1991 (Official Journal EPO 1992, 1ff.) but did not come into force until 4 July 1997.

Art.63EPC1973 was taken over by Art.63EPC2000, of which Art. 63(2) and(b) states that nothing shall limit the right of a Contracting State to extend the term of a European patent, or to grant corresponding protection that follows immediately on expiry of the term of the patent, under the same conditions as those applying to national patents, if the subject-matter of the European patent is a product or a process for manufacturing a product or a use of a product that has to undergo an administrative authorization procedure required by law before it can be put on the market in that State.

Meanwhile in the EEC (European Economic Community), after the European Commission's proposal of 8 May 1990 (Com 90/0101 Final) designated to the introduction of an institution of SPC (Supplementary Protection Certificate) corresponding to the system for the registration of extension of the duration of a patent right in Japan or the U.S. was deliberated in the European Parliament, the Council Regulation (EEC) No. 1768/92 of 18 June 1992 was promulgated and came into force on 2 January 1993 for the Member States. Meanwhile, non-EU member states such as Switzerland, Iceland, Lichtenstein, and Norway also provided similar national regulations on obtaining extensions of patent rights for medical products.

In the preamble of Council Regulation (EEC) No. 1768/92, it is stated that medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research; and consideration has already been made to the fact that the manufacturers of generic products would suffer delay with respect to the market entry for such products.

The Council Regulation (EEC) No. 1768/92

was revised and superseded by the Council Regulation (EEC) No. 469/2009 of 6 July 2009.

In addition, in order to apply the system of supplementary protection certificate (SPC) to plant protection products, on July 23, 1996, the European Parliament and the European Council of Ministers adopted the Council Regulation (EC) 1610/96, which came into force in 1997, in response to the proposal made by the European Commission in 1994 and 1995 (Com 94/0597 Final and Com 95/0456 Final).

While the SPC system of EU applies to the EU member countries, the applicant must apply for and obtain SPC for each member country.

(1) Products covered by the SPC system

Human medicines, veterinary pharmaceuticals and plant protection products are covered by the SPC system.

(2) Period to be extended

The effective period for SPC is determined by deducting five years from the date of patent application until the date of issuance of first approval for the distribution of pharmaceuticals (the period of extension is not more than five years and the period from the day of approval until the day of expiration is a maximum of 15 years). The date of registration of the patent has no impact on the period to be extended.

(3) Patents eligible for extension

With respect to pharmaceuticals, the patent term may be extended for patents granted for the protection of products as well as methods of production of products and use of products and that have been designated by the owner in the procedures to obtain SPC (hereinafter referred to as the "basic patent").

With respect to agricultural chemicals, the patent term may be extended for patents granted for products, drug formulations, manufacturing method, and use of products and that have been designated by the owner in the procedures to obtain SPC (hereinafter referred to as the "basic patent").

(4) Application

The patentee or its successor must file an application. The patentee or its successor shall apply with the competent office for industrial property rights of the member country after the basic patent has been granted and approval and license for distribution of the product have been obtained.

(5) Scope of protection of SPC

The scope of protection of SPC is prescribed in Articles 4 and 5 of the Regulation (EC) No. 469/2009 of the European Parliament of the Council of 6 May 2009, Articles 4 and 5 of the Regulation (EC) of No. 1610/96 of the European Parliament and of the Council of 23 July 1996 and the respective case laws.

SPC protects the use of pharmaceuticals or agricultural chemicals of a "product" that has been approved to be sold within the scope of protection of the basic patent. The use protected by SPC is not limited to the use referred to in the first approval for sale (which serves as the basis of the SPC), and it includes every use protected and approved by the patent that serves as the basis during the applicable period of SPC. This system is also applicable to the case where the person who obtained approval for sale for a subsequent use is a third party.

In the Novartis; C-574/11 case, the Court of Justice of the European Union (ECJ) held that, in cases where the SPC has been granted for a single active ingredient (A), the effect of protection under the SPC extends to the combination of two active ingredients (A+B) that cover active ingredient (A), as in the case where the effect of a patent that serves as the basis for a single active ingredient (A) also extends to the protection of the use of the active ingredient (A), which is covered by the combination of two active ingredients (A+B).

Only one certificate is granted to each product and a product is construed to be a single active ingredient in a strict sense. Accordingly, an SPC will not be newly granted for any change in the product, such as a new dosage of an active ingredient or its different salt or ester, and thus the scope of protection of an SPC extends to the salt and ester of the relevant active ingredient in addition to its major medicinal benefits. If an extension of the period is allowed for an SPC that protects pediatric medicines, the scope of protection would not be limited to the pediatric use of the relevant medicine.

3 Republic of Korea

In the Republic of Korea, in cases where a long period of time is required for tests confirming effectiveness and safety, etc. that are necessary for permission or registration of pharmaceuticals and agricultural chemicals, the period during which the patentee can enjoy a monopoly would be substantially shorter. Thus in order to achieve balance between

pharmaceuticals and agricultural chemicals and other products in terms of the patent term by extending the patent term of the patent right of the relevant pharmaceuticals and agricultural chemicals within the scope of five years, the system for the registration of extension of the duration of a patent right was introduced by the revision of law on December 31, 1986 (Article 53, paragraph (2) of the former Patent Act). At that time, the system was one wherein the Commissioner of the Korean Intellectual Property Office examined the application for extension and approved the extension in accordance with the subject matter of the patented invention and other relevant requirements prescribed by the President Decree, which is equivalent to the Cabinet Order in Japan.

As a result of subsequent revisions, a new procedure was introduced wherein the patentee files an application for the registration of extension of a patent term and then the examiner examines the application and renders a decision of registration or refusal. Moreover, a system for a trial for invalidation of the registration of extension was provided.

Later, in connection with the conclusion of the Free Trade Agreement (FTA) between the Republic of Korea and the United States, the revised Korean Patent Act was enacted on March 15, 2012, the day on which the U.S.-Korea FTA came into effect.

The past system for the extension of the patent term used in Korea was more similar to the Japanese system than those of the United States and Europe. However, after the revision of the Enforcement Decree of the Patent Act in 2013, the Korean system became more similar to those of the United States and Europe and started to show some difference with the Japanese system. For example, unlike the opinions presented by the Japanese Supreme Court on April 28, 2011, even if permission were additionally granted for a new form of the pharmaceutical product within the Republic of Korea, if the active ingredient were the same as those of the previously permitted product, an additional extension of the patent term would not be allowed.

(1) Products that may serve as grounds for the registration of extension (Article 7 of the Enforcement Decree of the Patent Act)

These products include human or animal pharmaceuticals (Article 31, paragraphs (2) and (3) or Article 42, paragraph (1) of the Pharmaceutical Affairs Act) and agrochemicals (Article 8, paragraph (1), Article 16, paragraph (1) or Article 17, paragraph (1) of the Agrochemicals Control Act).

(2) Period to be extended

Extension of a patent term is allowed for the total of the period of clinical test or test necessary for registration of agrochemicals and the period for administrative disposition up to five years (Article 89 of the Patent Act).

Moreover, the waiting period prior to the test will not be included in the extended period, and only the period during which the test was actually carried out will be included in the extended period. In cases where clinical tests are carried out in foreign countries, only the period for administrative review in the Republic of Korea is approved.

The extension of a patent term following delayed registration (Articles 92-2 through 92-5 of the Patent Act) and the extension of a patent term based on permission, etc. will not be aggregated.

(3) Patents eligible for extension (Article 7 of the Enforcement Decree of the Patent Act)

Patents eligible for extension are all of the patents related to the pharmaceutical or agrochemical (or intermediate) whose active ingredient is a new substance (a substance whose chemical structure of the active part that presents medicinal benefits is new) for which the first permission was granted (e.g., inventions of compounds, composition whose use is limited, manufacturing method and form).

(4) Application

If any disposition including permission and registration has been granted pursuant to the provision of other laws and regulations to work a patented invention, the patentee must file an application for extension of the term of the patent right within three months from the day on which such permission or registration was granted and six months prior to the expiration of the patent right. In addition, in cases where a patent right is owned by joint owners, an application must be jointly filed (Article 90 of the Patent Act).

(5) Examination

An examiner examines the application (Article 91 of the Patent Act). Any person who has received a decision to reject an application to

register extension of the term of a patent right and has an objection to such decision may file a request for a trial against the decision to reject the application (Article 132-3 of the Patent Act).

(6) Effects of the patent right in cases where its term has been extended

The effect of a patent right whose term has been extended only extends to the act of working the patent invention that covers the approved product and use (Article 95 of the Patent Act).

In terms of the legal wording used in Article 95 of the Patent Act, it is construed that such effect does not extend to additionally approved use or approval obtained by a third party. In this section, the term "use" refers to the "function and effect of the active ingredient for which permission has been obtained." If such use is identical, the effect of a patent right whose term has been extended extends to the form of working of the patented invention using different dosage and administration or manufacturing method.

Ⅴ Conclusion

When the system to register for an extension of the duration of a patent right was introduced, importance was placed on the incentives for development of novel active ingredients and efficacy or effects; much weight was placed on the protection of substance patent and use patent as an outcome of the research and development. However, it is true that the art related to Drug Delivery System (DDS) has become one of the major pillars for research activities in the pharmaceutical field with the advancement of social technology, and, thus, it is also important to increase incentives for research and development activities for DDS. Based on this viewpoint, if approval has been granted to a pharmaceutical whose active ingredient and efficacy of effect is identical to those approved but that has a different form, etc., it would be appropriate to allow the registration of extension of the duration of a patent right with respect to patented invention related to DDS in light of the purpose of the system to register for an extension of the duration of a patent right. The examination guidelines revised in response to the judgment of the Supreme Court rendered on April 28, 2011 complies with the abovementioned purpose.

In the judgment rendered on May 30, 2014, the Grand Panel of the IP High Court allowed the registration of extension of the duration of the patent right of a substance patent and use patent in cases where approval has been granted to a pharmaceutical whose effective ingredient and efficacy or effect is identical to those approved but that has a different form, etc. This judgment is essentially different from allowing the registration of extension of a patent right of a patented invention related to DDS. The judgment of the Grand Panel of the IP High Court should not have an adverse effect on the incentives for research activities carried out for the discovery of a novel active ingredient or efficacy or effect, which are the main pillars of research activities in the pharmaceutical field. In fact, many users raised questions about the judgment of the Grand Panel of the IP High Court concerning adverse effects over incentives for research activities carried out for the discovery of novel effective ingredients or efficacy or effect in the survey conducted in this research study and interviews as well as in expert committees.

Among the requirements for the registration of extension, with respect to the requirement of "where the disposition designated by Cabinet Order under Article 67(2) of the Patent Act is not deemed to have been necessary to obtain for the working of the patented invention," it is prescribed in the revised examination guidelines that the JPO makes determination on the relationship with the prior disposition based on the patented invention (matters specifying the invention) stated in the scope of claims.

As long as the purpose of the system to register for an extension of the duration of a patent right is to restore "the period during which the patented invention could not be worked," it is appropriate to determine the patented invention the working of which became possible by a prior disposition based on the matters specifying the invention in interpreting the phrase "working of a patented invention" under the Patent Act.

Even if such interpretation were made, if an approval were granted to a pharmaceutical whose effective ingredient and efficacy or effect is identical to those previously approved but which has a different form, etc., it would be obvious from the revised examination guidelines that a patented invention related to DDS would be covered in the scope of patents eligible for registration of extension of the duration of a patent right. The appropriateness of including a substance patent or use patent in the scope of patents eligible for registration of extension of the duration of a patent right in cases where an approval has been granted to a pharmaceutical

whose effective ingredient and efficacy or effect is identical to those previously approved but that has a different form, etc., should be discussed separately from the inclusion of the patented invention related to DDS in the scope of patents eligible for the registration of extension of the duration of a patent right from the standpoint of incentives for research and development activities carried out for discovery of novel effective ingredients and efficacy or effects.

With respect to the interpretation of the effect of a patent right whose duration has been extended, the Supreme Court made no reference in its judgment rendered on April 28, 2011. Since there is no other case of infringement litigation where the effect of a patent right whose extension of duration has been registered became an issue, the court's opinion on the interpretation of such effect is yet to be fixed. However, since the scope of monopoly of the working of the patented invention after the registration of extension of the duration of the patent right is defined by the scope to which the effect of a patent right whose extension of duration has been registered extends, it is appropriate to make interpretations based on the patented invention stated in the scope of claims (matters specifying the invention) as an interpretation of the Patent Act. Even if such interpretation were made, the scope to which the effect of a patent right related to DDS for which extension of the duration has been registered extends would not be unjustly limited (although it is possible that some parts may overlap with the effect of another patent right whose extension of duration has been registered). However, if interpretation has been made in line with the opinions presented in the obiter dictum of the judgment of the Grand Panel of the IP High Court and the effect of a patent right whose duration has been extended by prior disposition is limited, there is concern that the incentives for research activities for novel effective ingredient and efficacy or effect, which is the purpose of the system to register an extension of the duration of a patent right, may be negatively affected.

In the expert committee held in relation to this research study, some members of the Japan Pharmaceutical Manufacturers Association stated their opinions such that "it is unacceptable to agree to the idea of dividing the effect of a substance patent by the dosage or administration that is subject to the disposition for extension of the duration of the patent right."

The interpretation of the effect of a patent right whose duration has been extended made in the judgment of the Grand Panel of the IP High Court is different from the interpretation made with respect to the effect of the patent right whose duration has been extended under the system to register for an extension of the duration of patent rights of other countries. There are opinions that the effect of a substance patent or use patent whose duration of the patent right has been extended should be interpreted in a conventional manner. These opinions are based on the fact that the purpose of the system to register for an extension of the duration of a patent right is to increase incentives for discovering novel efficacy or effects to novel effective ingredients and introducing pharmaceuticals with secured quality, effectiveness and safety to the world.

As such, the interpretation of the effect of a patent right whose duration has been extended should be considered from the standpoint of balance between the protection and use of inventions (considerations to the protection of the invention and the parties who use the outcome of the research activities made by other companies).

Moreover, since the effect of the patent right whose duration has been extended by a prior disposition is limited and the interpretation of "equivalents or those which may be evaluated as substantially identical" as mentioned in the judgment of the Grand Panel of the IP High Court remains unclear, if an approval has been granted to a pharmaceutical whose effective ingredient and efficacy and effect is identical to those approved but that has a different form, etc., the patentee must file an application for registration of extension of the duration of the patent right for the substance patent or use patent for which the duration of the patent right has already been extended. In this case, attention should be paid to the fact that not only would the burden to manage patents increase (increase in the costs required for filing an application for registration of extension of the duration of a patent right and increase in the burden to manage to file an application during the period in which the application for registration of extension of the duration of a patent right may be filed) for the patentee who files an application for the registration of extension of the duration of a patent right, but so would the burden of monitoring, which is borne by those who intend to join the market upon the expiration of the duration of the patent right. While it may be necessary for those who intend to join the market

upon the expiration of the duration of the patent right to fix as early as possible the possible time of market entry and to make necessary preparations, if operations and interpretation of the scope of effect were made in line with the determinations made in the judgment of the Grand Panel of the IP High Court, this would cause problems to both the patentee who intends to register the extension of the duration of the patent right and those who intend to join the market upon expiration of the duration of the patent right.

Since a petition for acceptance of final appeal has been filed with respect to the judgment of the Grand Panel of the IP High Court, the determination of the Supreme Court is anticipated. The registration of extension of the duration of a patent right should be examined from the standpoints of balance between the patentee and third party relevant to the disposition and contribution to the development of innovation based on the purpose of the Patent Act, and it is expected that the Supreme Court makes determinations from such standpoint.

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[1] http://www.japaneselawtranslation.go.jp/law/detail/?ft=2&re=01&dn=1&yo=&ia=03&x=15&y=15&kn[]=%E3%81%A8&ky=&page=43

[2] "Where there is a period during which the patented invention is unable to be worked because approvals prescribed by relevant Acts that are intended to ensure the safely, etc. or any other disposition designated by Cabinet Order as requiring considerable time for the proper execution of the disposition in light of the purpose, procedures, etc., of such a disposition is necessary to obtain for the working of the patented invention, the duration of the patent right may be extended, upon the filing of a request for the registration of extension of the duration, by a period not exceeding 5 years."