Note: When any ambiguity of interpretation is found in this provisional translation, the Japanese text shall prevail.

(Applied to any applications to register a patent term extension filed on or after November 25, 2014.)

1. Purport of the System for Patent Term Extensions

One of the purposes of the patent system is to protect and encourage inventions by granting exclusive rights to inventors for a certain period of time in exchange for disclosure of the arts used in their inventions, and thereby to contribute to the development of industry.

However, in particular fields, such as drug products, it takes a long time to conduct the testing and examinations etc. that are necessary for gaining the legally-mandated approvals etc. prescribed by the laws that are intended to ensure the safety of those products, which gives rise to the problem that while such testing and examinations are being conducted inventors cannot enjoy the benefits of the exclusive rights that they hold.

Such legal regulations themselves are indispensable due to the importance of their role. However, these regulations have prevented inventors in the particular fields, such as drug products, from enjoying the benefits of their patent rights during the period required for approval. Moreover, from a perspective such as that of drug safety, shorting the period required for pharmaceutical examinations, etc. has its own limitations.

In order to solve this problem, which undermines the fundamental principle of the patent system, it would be necessary to extend the term of such patents.

Therefore, if there is a period during which a patented invention is unable to be worked because it is necessary to obtain approvals or any other dispositions under a law intended to ensure the safety that are designated by the Cabinet Order as requiring considerable time for the proper execution in light of the purpose, procedures, etc., of such dispositions, the term of the patent right may be extended, upon application to register a patent term extension, by a period not exceeding five years.(Article 67(2) of the Patent Act)

Thus, the purpose of the system for patent term extensions is to restore the period during which the patented invention was unable to be worked because it was necessary to obtain a disposition designated by the Cabinet Order under Article 67(2). (hereinafter sometimes referred to simply as “the disposition designated by Cabinet Order” or “the disposition”). (Judgment of the First Petty Bench of the Supreme Court, April 28, 2011, 2009 (Gyo-Hi) No. 324 to 326).

The following dispositions are designated by the Cabinet Order: the registration of agricultural chemicals under the Agricultural Chemicals Regulation Law and the approval and certification of drug products, in vitro diagnostics and regenerative medicine products (hereinafter, "a drug product, an in vitro diagnostic and a regenerative medicine product" are referred to as a "DRUG PRODUCT") under the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics(hereinafter referred to as “Pharmaceuticals, Medical devices and Other Therapeutic Products Act”)(Article 3 of the Order for Enforcement of the Patent Act).

2. Application

2.1 Applicant Eligibility

An application to register a patent term extension may not be filed by any person other than the patentee (67-3(1)(iv) of the Patent Act).

If a patent right is jointly owned, none of the joint owners may file an application to register a patent term extension unless they do so jointly with all the other owners (67-2(4) of the Patent

Act). In addition, the patentee, the exclusive licensee or the non-exclusive licensee of the patent is required to have obtained the disposition designated by the Cabinet Order under Article 67(2) (67-3(1)(ii) of the Patent Act).

2.2 Filing Date Requirements

An application to register a patent term extension must be filed within three months of the date of the disposition designated by the Cabinet Order under Article 67(2) (Note). However, such an application may not be filed after the expiration of the original term of the patent right (Article 67-2(3) of the Patent Act, Article 4 of the Order for Enforcement of the Patent Act). If an application to register a patent term extension cannot be filed within three months after the date of the disposition for any reason not attributable to the applicant, the applicant must file the application within 14 days after the reason ceases to exist (or within nine months after the date of the disposition, whichever period expires earlier) (Article 4 of the Order for Enforcement of the Patent Act).

When a disposition designated by the Cabinet Order is unlikely to be obtained by six months prior to the expiration of the term of a patent right, the applicant must submit a document providing the following information on or before that day (Article 67-2-2(1) of the Patent Act, Article 38-15-2 of the Ordinance for Enforcement of the Patent Act):

(i) the name and domicile or residence of the person filing the application;
(ii) the patent number; and
(iii) the disposition designated by the Cabinet Order under Article 67(2).

If this document is not submitted, no application to register a patent term extension may be filed within the six months prior to the expiration of the term of the patent right (Article 67-2-2(2) of the Patent Act).

(Note) “The date of the disposition designated by the Cabinet Order” means the date on which the applicant is notified of the approval or registration, or in other words, the date on which the applicant learns or could have learned of it. The date of the disposition does not necessarily mean the date on which the applicant receives an approval certificate or registration card; if the applicant learns of the approval or registration before receiving this certificate or card, the date on which the applicant actually learns of it is considered to be the date of the disposition.

2.3 Patents Eligible for Application

Patent rights for patented inventions that were unable to be worked because it was necessary to obtain the dispositions designated by the Cabinet Order under Article 67(2) are eligible as the subject of applications to register a patent term extension.

2.4 Information That Must Be Included in an Application

Any person filing an application to register a patent term extension must submit a written application that includes the following information to the Commissioner of the Patent Office (Article 67-2(1) of the Patent Act, Article 38-15 of the Ordinance for Enforcement of the Patent Act):

(i) the name and domicile or residence of the applicant;
(ii) the patent number;
(iii) the period for which the extension is requested (not exceeding five years);
(iv) the details of the disposition designated by the Cabinet Order under Article 67(2); and

(v) the date of the disposition designated by the Cabinet Order under Article 67(2).

Regarding the details of the disposition designated by the Cabinet Order under Article 67(2) that is listed in item (iv) above, the applicant is required to state the disposition that provides the grounds for the registration of a patent term extension (e.g., the approval specified in Article 14(1) of Pharmaceuticals, Medical devices and Other Therapeutic Products Act granted for a drug product specified in that provision), the reference number identifying the disposition (e.g., the approval number), the product that was the subject of the disposition (*1), and, if a specific use of the product is prescribed by the disposition, its use (*2).

With regard to the date of the disposition designated by the Cabinet Order under Article 67(2) that is listed in item (v) above, please refer to 2.2 (Note).

(*1) In principle, in the case of a drug product, this means the name (product name, etc.) and active ingredients of the product specified in the approval certificate. In the case of an in vitro diagnostic, this means the name (product name, etc.) and component involved in reaction system specified in the approval certificate. In the case of a regenerative medicine product, this means the name (product name, etc.) and component cell or transgene specified in the approval certificate. In the case of an agricultural chemical, this means the name and active ingredients of the agricultural chemical specified in the registration card.
(*2) In principle, in the case of a drug product, this means the indications specified for it in the approval certificate. In the case of an in vitro diagnostic, this means purpose of use specified for it in the approval certificate. In the case of a regenerative medicine product, this means indications or performance specified for it in the approval certificate. In the case of an agricultural chemical, this means the names of crops and the applicable diseases or insects pests, the names of the applicable weeds, or the purpose of use specified in the registration card.

2.5 Information That Must Be Included in Materials Specifying the Reasons for the Extension

The written application must be accompanied by materials specifying the reasons for the extension (Article 67-2(2) of the Patent Act).

The materials that must accompany the written application are as follows (Article 38-16 of the Ordinance for Enforcement of the Patent Act):

(1) Materials necessary for certifying that it was necessary to obtain a disposition designated by the Cabinet Order under Article 67(2) in order to work the patented invention to which the application to register a patent term extension pertains (item 1);
(2) Materials stating the period during which the patented invention to which the application to register a patent term extension pertains was unable to be worked because it was necessary to obtain the disposition specified in the preceding item (item 2); and
(3) Materials necessary for certifying that the person who obtained the disposition specified in item 1 is the patentee, the exclusive licensee or the non-exclusive licensee of the patent right to which the application to register a patent term extension pertains (item 3).

The materials listed in (1) to (3) must contain the information listed in (1) to (3) below and materials supporting such information (see (4) below).

(1) Materials necessary for certifying that it was necessary to obtain a disposition designated by the Cabinet Order in order to work the patented invention

These materials must indicate:

(i) that the subject of the application to register a patent term extension is the patented invention;

In order to certify that the patent right that is the subject of the application to register a patent term extension is valid, the applicant is required to give the date of patent registration, the expiration date of the term of the patent, the record of patent fee payments, etc.

(ii) that a disposition designated by the Cabinet Order has been obtained;

The applicant is required to give the information that is necessary to identify the disposition designated by the Cabinet Order (the disposition that provides the grounds for the registration of a patent term extension (hereinafter sometimes referred to simply as “the present disposition”), the reference number identifying the disposition, and the date of disposition), the product that was the subject of the disposition, and, if the specific use of the product is prescribed by the disposition, its use (see 2.4).

(iii) that manufacturing and marketing the DRUG PRODUCT or manufacturing or importing the agricultural chemical that was the subject of the present disposition constitutes working the patented invention to which the application to register a patent term extension pertains;

The applicant is required to identify the claim that covers the DRUG PRODUCT or the agricultural chemical that was the subject of the present disposition, to compare the matters to define the invention described in that claim with the details specified in the approval certificate for the DRUG PRODUCT (see (4) (ii) below), or in the registration card, etc. (Note) for the agricultural chemical, and to explain that the DRUG PRODUCT or agricultural chemical that was the subject of the present disposition satisfies all of the matters to define the invention described in the claim (see 3.1.1 (2) (i)). If multiple claims cover the DRUG PRODUCT or agricultural chemical that was the subject of the present disposition, the applicant is usually required to provide an explanation about the claim that uses the fewest matters to define the invention (see 3.1.1 (2) (ii)).

(Note) Since the registration card of an agricultural chemical does not specify the manufacturing method, the applicant is required to explain that the agricultural chemical that was the subject of the present disposition satisfies all of the matters to define the invention that are related to the manufacturing method, by using the materials submitted at the time of the application for the registration.

(iv) that the present disposition is the first disposition within the scope determined by the “matters falling under the matters to define the invention (and the use)” of the DRUG PRODUCT or agricultural chemical that was the subject of the present disposition.

The “matters falling under the matters to define the invention (and the use)” means all matters specified in the approval certificate (see (4) (ii) below) or the registration card, etc., falling under the matters to define the patented invention (if the matters to define the patented invention does not include any matters specifying use, this means all matters specified in the approval certificate or the registration card, etc., falling under the matters to define the patented invention and falling under the use (see 3.1.1 (1)).

The applicant is required to compare the present disposition with any prior dispositions of which he or she has knowledge and explain that the present disposition is the first disposition within the scope determined by the “matters falling under the matters to define the invention (and the use)” of the DRUG PRODUCT or agricultural chemical that was the subject of the present disposition (see 3.1.1 (2) (ii)).

(2) Materials stating the period during which the patented invention to which the application to register a patent term extension pertains was unable to be worked because it was necessary to obtain a disposition designated by the Cabinet Order

These materials must indicate:

(i) the history up to the date of the present disposition;

The applicant is required to give summaries and the dates of major events.

(ii) the period during which the patented invention was unable to be worked.

The applicant is required to explain that the grounds for the period during which the patented invention to which the application to register a patent term extension pertains was unable to be worked because it was necessary to obtain the present disposition (see 3.1.3).

(3) Materials necessary for certifying that the person who obtained the disposition designated by the Cabinet Order is the patentee or the exclusive licensee or the non-exclusive licensee of the patent right

These materials must indicate:

(i) that the person who obtained the present disposition is the patentee; or

(ii) that the person who obtained the present disposition is the exclusive licensee or the non-exclusive licensee of the patent right.

(4) Materials supporting this information

(i) Patent gazettes

(ii) In the case of a DRUG PRODUCT, the applicant is required to submit a copy of the approval certificate (including the written application for approval; same below). In order to confirm the period specified in (2) above, the applicant is required to submit materials indicating the date on which the testing necessary for obtaining the present disposition commenced (see 3.1.3 (2)), such as a copy of the notification of a clinical trial plan. If the applicant failed to learn of the approval on the date of approval, the applicant is required to submit materials that objectively indicate the earliest date on which the applicant leaned of the approval or could have learned of it.

(iii) In the case of an agricultural chemical, the applicant is required to submit a copy of the registration card. In order to confirm the period specified in (2) above, the applicant is required to submit materials indicating the date on which the testing necessary for obtaining the present disposition commenced (see 3.1.3 (2)), such as a copy of the written request for a commissioned field trial. If the applicant failed to learn of the registration on the date of registration, the applicant is required to submit materials that objectively indicate the earliest date on which the applicant learned of the registration or could have learned of it.

Regarding materials listed in (ii) and (iii) above, the applicant is required to disclose the parts of the materials that are necessary to support the information.

2.6 Effect of the Application

When an application to register a patent term extension has been filed, the patent term will be deemed to be extended up to the date on which a decision of refusal becomes final and binding or on which the extension is registered (Article 67-2(5) of the Patent Act).

2.7 Publication in the Patent Gazette

When an application to register a patent term extension has been filed, the information

specified in the items of Article 67-2(1), the application number, and the filing date will be published in the Patent Gazette (Article 67-2(6) of the Patent Act).

When the document under Article 67-2-2(1) has been submitted, the information specified in that paragraph will be published in the Patent Gazette (Article 67-2-2(3) of the Patent Act).

3. Examination

3.1 Decision of Refusal

When an application to register a patent term extension falls under any of the items of Article 67-3(1), the examiner will render a decision to refuse the application (Article 67-3(1) of the Patent Act).

Before an examiner seeks to render a decision to refuse an application, he or she will notify the applicant of the reasons for the decision and give him or her an opportunity to submit a written opinion, designating an adequate time limit for the purpose (Article 50 applied mutatis mutandis under Article 67-4 of the Patent Act).

In any of the following cases, the examiner must issue a notice of the reasons for refusal.

3.1.1 Where It Is Not Deemed That Obtaining a Disposition Designated by the Cabinet Order under Article 67(2) Was Necessary in Order to Work the Patented Invention (Article 67-3(1)(i) of the Patent Act)

(1) The interpretation of the phrase “obtaining a disposition designated by the Cabinet Order was necessary in order to work the patented invention”

In making a judgment as to whether “obtaining a disposition designated by the Cabinet Order was necessary in order to work the patented invention as is specified in Article 67-3(1)(i), the examiner will interpret the definition of “to work the patented invention” as follows and judge whether “obtaining a disposition designated by the Cabinet Order was necessary.”

A DRUG PRODUCT or an agricultural chemical that is the subject of approval or registration is defined by the details that are stated in the approval certificate or the registration card, etc. On the other hand, a patented invention is the creation of technical ideas expressed by the “matters to define the invention” (the matters that an applicant considers necessary for defining the invention for which the applicant has requested to be granted a patent).

Therefore, in a judgment pursuant to Article 67-3(1)(i), the phrase “to work the patented invention” should not be interpreted as an act of manufacturing and marketing or otherwise handling the DRUG PRODUCT per se that was the subject of the disposition, nor should it be interpreted as an act of manufacturing, importing, or otherwise handling the agricultural chemical per se that was the subject of the disposition. Instead, it should be interpreted as an act of manufacturing and marketing or otherwise handling such DRUG PRODUCT or as an act of manufacturing, importing, or otherwise handling such agricultural chemical that is defined by the "matters falling under the matters to define the invention" of the DRUG PRODUCT or the agricultural chemical that was the subject of the disposition. The "matters falling under the matters to define the invention" means all matters specified in the approval certificate or the

registration card, etc. falling under the matters to define the patented invention.

Article 68-2 of the Patent Act specifies that, when the term of a patent right is extended, that patent right will not be effective for any act other than “the working of the patented invention for the product that was the subject of the disposition (where the specific use of the product is prescribed by the disposition, the product used for that use),” and the matters falling under the use are prescribed in the approval certificate for a DRUG PRODUCT or the registration card of an agricultural chemical. Because of this if the matters to define the patented invention does not include any matters specifying use, it is appropriate to interpret “to work of the patented invention” as an act of manufacturing and marketing or otherwise handling such DRUG PRODUCT or as an act of manufacturing, importing, or otherwise handling such agricultural chemical that is defined by the “matters falling under the matters to define the patented invention and the use” of the DRUG PRODUCT or the agricultural chemical that was the subject of the disposition. The “matters falling under the matters to define the invention and the use” means all matters specified in the approval certificate or the registration card, etc. falling under the matters to define the patented invention and falling under the use .

(2) Cases in which it is not deemed that obtaining a disposition designated by the Cabinet Order was necessary in order to work the patented invention

(i) When the act of manufacturing and marketing the DRUG PRODUCT or the act of manufacturing or importing the agricultural chemical that was the subject of the present disposition does not constitute an act of working the patented invention to which the application to register a patent term extension pertains

A reason for refusal arises if the examiner finds, through a comparison of the matters to define the patented invention and the details specified in the approval certificate for the DRUG PRODUCT or in the registration card, etc. of the agricultural chemical, that the DRUG PRODUCT or agricultural chemical that was the subject of the present disposition does not satisfy all of the matters to define the patented invention in any of the claims.

Example:

If the patented invention is a “pesticide containing an active ingredient A and a surface-active agent B,” a reason for refusal will arise unless the examiner finds, based on the details specified in the registration card, etc. of the agricultural chemical, that the registered agricultural chemical is a pesticide containing both the active ingredient A or any active ingredient that corresponds to a subordinate concept of active ingredient A, and the surface-active agent B or any surface-active agent that corresponds to a subordinate concept of surface-active agent B.

(ii) When such part of the patented invention to which the application to register a patent term extension pertains that is defined by the “matters falling under the matters to define the invention (and the use)” (see 2.5(4) and 3.1.1 (1)) of the DRUG PRODUCT or agricultural chemical that was the subject of the present disposition has been able to be worked by a prior disposition

If a person has obtained a disposition for a prior DRUG PRODUCT or a prior agricultural chemical (a “prior disposition”) that satisfies the “matters falling under the matters to define the invention (and the use)” of the DRUG PRODUCT or the agricultural chemical that was the subject of the present disposition, such part of the patented invention that is defined by the “matters falling under the matters to define the invention (and the use)” of the DRUG PRODUCT or

agricultural chemical that was the subject of the present disposition has been able to be worked by a prior disposition. Therefore a reason for refusal arises.

Example 1:
In this example, the patented invention is “substance A” and the present disposition was obtained for an agricultural chemical listed as having “active ingredient: Substance a_1, name of crop and name of applicable disease and insect pest: Cabbage and aphid.”

If a person has obtained a Prior Disposition 1 for an agricultural chemical listed as having “active ingredient: Substance a_1, name of crop and name of applicable disease and insect pest: Cabbage and aphid,” even if the Prior Disposition 1 is different from the present disposition in terms of dosage form, etc., such part of the patented invention that is defined by “active ingredient: Substance a_1, name of crop and name of applicable disease and insect pest: Cabbage and aphid,” which are the “matters falling under the matters to define the invention and the use” of the agricultural chemical that was the subject of the present disposition, has been able to be worked by the Prior Disposition 1.

On the other hand, for example, even if a person has obtained a Prior Disposition 2 for an agricultural chemical listed as having “active ingredient: Substance a_1, name of crop and name of applicable disease and insect pest: Rose and aphid,” the aforementioned part of the patented invention has not been able to be worked by the Prior Disposition 2.

(Substance a_1 meaning an ingredient that corresponds to a subordinate concept of Substance A.)

Example 2:
In this example, the patented invention is “a pesticide containing an active ingredient A” and the present disposition was obtained for an agricultural chemical listed as having “active ingredient: Substance a_1, name of crop and name of the applicable disease and insect pest: Chinese cabbage and cabbageworm.”

If a person has obtained a Prior Disposition 1 for an agricultural chemical listed as having “active ingredient: Substance a_1, name of crop and name of applicable disease and insect pest: Chinese cabbage and cabbageworm,” even if the Prior Disposition 1 is different from the present disposition in terms of dosage form, etc., such part of the patented invention that is defined by “the active ingredient: Substance a_1, name of crop and name of applicable disease and insect pest: Chinese cabbage and cabbageworm,” which are the “matters falling under the matters to define the invention” of the agricultural chemical that was the subject of the present disposition, has been able to be worked by the Prior Disposition 1.

On the other hand, for example, even if a person has obtained a Prior Disposition 2 for an agricultural chemical listed as having “active ingredient: Substance a_2, name of crop and the name of applicable disease and insect pest: Chinese cabbage and cabbageworm,” the aforementioned part of the patented invention has not been able to be worked by the Prior Disposition 2.

(Both Substance a_1 and Substance a_2 meaning ingredients that correspond to subordinate concepts of the active ingredient A.)

Example 3:
In this example, the patented invention is “an analgesic injectable drug containing active ingredient A” and the present disposition was obtained for a drug product listed as having “active

ingredient: Substance a_1, indication: analgesia, dosage form: injection."

If a person has obtained a Prior Disposition 1 for a drug product listed as having "active ingredient: Substance a_1, indication: analgesia, dosage form: injection," even if the Prior Disposition 1 is different from the present disposition in terms of dosage amount, etc., such part of the patented invention that is defined by "active ingredient: Substance a_1, indication: analgesia, dosage form: injection," which are the "matters falling under the matters to define the invention" of the drug product that was the subject of the present disposition, has been able to be worked by the Prior Disposition 1.

On the other hand, for example, even if a person has obtained a Prior Disposition 2 for a drug product listed as having "active ingredient: Substance a_1, indication: analgesia, dosage form: pills," the aforementioned part of the patented invention has not been able to be worked by the Prior Disposition 2.

(Substance a_1 meaning an ingredient that corresponds to a subordinate concept of the active ingredient A.)

Example 4:
In this example, the patented invention is "an analgesic drug containing Substance A as an active ingredient and polymer B as a stabilizing agent" as described in Claim 1 and "an analgesic drug containing Substance A as an active ingredient and polymer C as a stabilizing agent" as described in Claim 2, and the present disposition was obtained for a drug product listed as having "active ingredient: Substance a_1, stabilizing agent: polymer c_1, indication: analgesia."

If a person has obtained a Prior Disposition 1 for a drug product listed as having "active ingredient: Substance a_1, stabilizing agent: polymer c_1, indication: analgesia," even if the Prior Disposition 1 is different from the present disposition in terms of dosage form, etc., such part of the patented invention that is defined by "active ingredient: Substance a_1, stabilizing agent: polymer c_1, indication: analgesia," which are the "matters falling under the matters to define the invention" of the drug product that was the subject of the present disposition, has been able to be worked by the Prior Disposition 1.

On the other hand, for example, even if a person has obtained a Prior Disposition 2 for a drug product listed as having "active ingredient: Substance a_1, stabilizing agent: only polymer b_1, indication: analgesia," the aforementioned part of the patented invention has not been able to be worked by the Prior Disposition 2.

(Substance a_1, Polymer b_1, and Polymer c_1 meaning ingredients that correspond to subordinate concepts of Substance A, Polymer B, and Polymer C respectively. Claim 1 and Claim 2 satisfy the requirement of unity of invention.)

The applicant is required to compare the present disposition with any prior dispositions of which he or she has knowledge and explain that the present disposition is the first disposition within the scope determined by the "matters falling under the matters to define the invention (and the use)" of the DRUG PRODUCT or agricultural chemical that was the subject of the present disposition (see 2.5 (1) (iv)).

[If the DRUG PRODUCT or agricultural chemical that was the subject of the present disposition simultaneously satisfies all of the matters to define the patented inventions that are described in multiple claims under the patent to which the application to register a patent term extension pertains]

If the DRUG PRODUCT or agricultural chemical that was the subject of the present disposition simultaneously satisfies all of the matters to define patented inventions that are described in multiple claims under the relevant patent right, it means that there are multiple "parts of the patented invention that are defined by the 'matters falling under the matters to define the invention (and the use)' of the DRUG PRODUCT or agricultural chemical that was the subject of the present disposition."

Since the patent term extension is registered not for each claim but for the patent right, whether obtaining the present disposition was necessary in order to work the patented invention under that patent right is determined based on the following construction.

If such part of the patented invention described in a certain claim that is defined by the "matters falling under the matters to define the invention (and the use)" of the DRUG PRODUCT or agricultural chemical that was the subject of the present disposition has been able to be worked by a prior disposition, it should be interpreted that another part that is included in this part (such part of the patented invention described in another claim containing all of the matters to define the invention described in the aforementioned claim that is defined by the "matters falling under the matters to define the invention and the use" of the DRUG PRODUCT or agricultural chemical that was the subject of the present disposition) has been also able to be worked by the prior disposition as well.

If it is concluded, based on the above-described interpretation, that all of the aforementioned multiple parts of the patented invention have been able to be worked by a prior disposition, it is not deemed that obtaining the present disposition was necessary in order to work the patented invention under that patent right (see Example 5 below).

On the other hand, if it is concluded, based on the above-described interpretation, that at least one of the aforementioned multiple parts of the patented invention have not been able to be worked by any prior disposition, it is deemed that obtaining the present disposition was necessary in order to work the patented invention under that patent right.

Because of the above-described construction, when examining whether multiple parts have been able to be worked by a prior disposition, examiners usually start with whichever of the claim that uses the fewest matters to define the invention.

Example 5:
In this example, the patented invention is "an analgesic drug containing Substance A as an active ingredient" as described in Claim 1 and "an injectable analgesic drug described in Claim 1" as described in Claim 2, and the present disposition was obtained for a drug product listed as having "active ingredient: Substance a_1, indication: analgesia, dosage form: injection."

The drug product subject to the present disposition simultaneously satisfies all of the matters to define the patented inventions as described in Claim 1 and Claim 2.

Claim 2 contains all of the matters to define the invention described in Claim 1. Such part of the patented invention as described in Claim 2 that is defined by "the active ingredient: Substance a_1, indication: analgesia, dosage form: injection" (Part 2), which are the "matters falling under the matters to define the invention" of the drug product subject to the present disposition, is included in such part of the patented invention described in Claim 1 that is defined by "active ingredient:

Substance a_1, indication: analgesia"(Part 1), which are the "matters falling under the matters to define the invention" of the drug product subject to the present disposition.

If a person has obtained a prior disposition for a drug product listed as having "active ingredient: Substance a_1, indication: analgesia, dosage form: pill", Part 1 has been able to be worked by the prior disposition. Therefore Part 2, which is included in Part 1, has been able to be worked by the prior disposition as well.

Consequently, it is not deemed that obtaining the present disposition was necessary in order to work the invention of the relevant patent right.

(Substance a_1 meaning an ingredient that corresponds to a subordinate concept of Substance A.)

(3) When multiple patents correspond to a single disposition

When multiple patents correspond to a single disposition, if it is deemed that obtaining the disposition was necessary in order to work the invention protected by each of those patents, a patent term extension will be registered for each of the patents.

For example, when the applicant has a substance patent for the active ingredient of an approved drug product, a pharmaceutical patent for the use of the active ingredient for an approved pharmaceutical use, and a manufacturing process patent for the manufacturing process of the active ingredient, if it is deemed that obtaining the approval was necessary in order to work the invention protected by all of these patents, a patent term extension will be registered for each of the patents.

(4) When multiple dispositions correspond to a single patent right

When multiple dispositions were issued for a single patent right, if it is deemed that obtaining each of those dispositions was necessary in order to work the patented invention, a patent term extension will be registered for each of the dispositions (see 3.1.1 (2)),

(5) When uses of multiple dispositions partially overlap each other.

If a part of the use of a DRUG PRODUCT or an agricultural chemical that was the subject of the present disposition overlaps the use of a DRUG PRODUCT or an agricultural chemical that was the subject of a prior disposition (for example, where the indication of a drug product that was the subject of the present disposition is a generic concept and the indication of a drug product that was the subject of the prior disposition is a subordinate concept), it is deemed that obtaining the present disposition was necessary in order to work the patented invention for any use other than the overlapped use.

For instance, if the patented invention is "Substance A" and the present disposition was obtained for a drug product listed as having "active ingredient: Substance A, indication: allergic rhinitis," even if a prior disposition has been obtained for a drug product listed as having "active ingredient: Substance A, indication: chronic allergic rhinitis," it is deemed that obtaining the disposition was necessary in order to work the patented invention.

(6) Pharmaceutical-related patent rights excluded from patent term extensions

Any patent right related to intermediates, catalysts, or manufacturing equipment used in the manufacturing process of any DRUG PRODUCT or agricultural chemical is excluded from patent term extensions.

Intermediates, catalysts, and manufacturing equipment are not contained in the DRUG

PRODUCT or agricultural chemical, which is the final product. Pharmaceuticals, Medical devices and Other Therapeutic Products Act and the Agricultural Chemicals Regulation Law aim to regulate the manufacturing and marketing of DRUG PRODUCTs, which are the final products, and the manufacturing or importing of agricultural chemicals, which are the final products, respectively and do not aim to regulate the acts of using intermediates, catalysts, or manufacturing equipment, per se. Because of this, such patent rights are excluded from patent term extensions, as stated above.

3.1.2 Where the Patentee, the Exclusive Licensee, or the Non-exclusive Licensee of the Patent Has Not Obtained a Disposition Designated by the Cabinet Order under Article 67(2) (Article 67-3(1)(ii))

Even if only some of the multiple persons who jointly obtained a disposition hold an exclusive license or a non-exclusive license to the patent, it does not change the fact that the patentee, the exclusive licensee, or the non-exclusive licensee of the patent right has obtained the disposition. As such, this would not fall under Article 67-3(1)(ii).

3.1.3 Where the Period for Which the Extension Is Requested Exceeds the Period During Which the Patented Invention Was Unable to Be Worked (Article 67-3(1)(iii) of the Patent Act)

(1) Interpretation of the phrase “the period during which the patented invention was unable to be worked”

The phrase “the period during which the patented invention was unable to be worked” means a period during which the patented invention was unable to be worked because it was necessary to obtain a disposition designated by the Cabinet Order (Article 67(2)).

This period begins on the date on which the testing necessary for obtaining the disposition designated by the Cabinet Order commenced or on which the relevant patent was registered, whichever comes later. This period ends on the date before the date on which the applicant is notified of the approval or registration, or in other words, the date before the date on which the applicant actually learns of the approval or registration or could have learned of it (Note) (Judgment of the Second Petty Bench of the Supreme Court of October 22, 1999, 1998(Gyo-Hi) No. 43 and No. 44).

(Note) “The date on which the applicant is notified of the approval or registration, or in other words, the date on which the applicant actually learns of the approval or registration or could have learned of it” does not necessarily mean the date on which the applicant receives an approval certificate or a registration card. If the applicant learns of the approval or registration before receiving this certificate or card, the date on which the applicant actually learns of it is considered to be the date of the disposition.

Pharmaceuticals, Medical devices and Other Therapeutic Products Act and the Agricultural Chemicals Regulation Law specify that any person who seeks approval for a DRUG PRODUCT or registration of an agricultural chemical must include materials on the results of testing when filing for the disposition. In order to have test results, it is necessary to conduct testing. Since a “patented invention” means an invention for which a patent has been granted (Article 2(2) of the Patent Act), “the period during which the patented invention was unable to be worked” must be a

period that comes after the registration of the patent right. Therefore, the “period during which the patented invention was unable to be worked” means either “the period of time spent conducting the testing necessary to obtain a disposition plus the period between the date on which the disposition was filed for and the date of the disposition”, or “the period between the date of patent registration and the date of the disposition”, whichever is shorter.

Any part of either “the period of time spent conducting the testing necessary to obtain a disposition plus the period between the date on which the disposition was filed for and the date of the disposition” or “the period between the date of patent registration and the date of the disposition” that is found to have been unnecessary for obtaining the disposition will not be included in the period during which the patented invention was unable to be worked.

While various testings are usually conducted in compliance with the purpose, objective, and regulatory requirements of regulatory laws, the period during which a testing is conducted cannot be regarded as the period during which the patented invention was unable to be worked unless the testing satisfies all of the requirements listed in (i) to (iii) below:

(i) The testing is indispensable for obtaining the disposition;
(ii) The enterprises have little discretion in conducting the testing because the testing needed to be conducted in line with the standards for testing methods, contents of testing, etc., set by administrative agencies; and
(iii) The testing is closely related to obtaining the disposition.

(Note) The period during which preclinical testing was conducted should be regarded as a research and development period to study the utility of the chemical substance that is the active ingredient of the drug product, which is similar to a product development period in general fields of industry. Such period is not necessarily regarded as a testing period that is closely related to obtaining approval. Because of this, the period during which preclinical testing was conducted might not be included in the period during which the patented invention was unable to be worked.

(2) The commencement date of the period during which the patented invention was unable to be worked

The date on which the testing necessary for obtaining the disposition commenced means, in the case of a DRUG PRODUCT, the commencement date of clinical testing (the date on which notification of the clinical trial plan, etc. is submitted) or, in the case of an agricultural chemical, the commencement date of commissioned field trials conducted for the relevant chemical substance whose name is specified (the date on which the request for the commissioned field trial, etc. is submitted).

(3) The end date of the period during which the patented invention was unable to be worked

The period during which the patented invention was unable to be worked is considered to end on the date before the date on which the applicant is notified of the approval or registration, or in other words, on the date before the date on which the applicant actually learns of the approval or registration or could have learned of it. This is because the prohibition under regulatory laws is removed on the date on which the applicant is notified of the approval or registration.

(4) Notes

In determining the period during which the patented invention was unable to be worked referred to in Article 67-3(1)(iii), not only the materials submitted by the applicant but also the conventional process by which the disposition designated by the Cabinet Order is delivered are considered. Based on the consideration of the materials submitted by the applicant and the conventional process by which the disposition designated by the Cabinet Order is delivered, if it is found that the extension period sought by the applicant is longer than the period during which the patented invention was unable to be worked, the application will be refused under Article 67-3(1)(iii).

The extension period sought by the applicant will be acceptable unless the period is longer than that during which the patented invention was unable to be worked. The two periods are not required to be the same in length.

If the date on which the applicant is notified of the approval or registration is prior to the registration date of the patent right, the application will be refused pursuant to Article 67-3(1)(iii), because there was no period during which the patented invention was unable to be worked.

3.1.4 Where the Person Filing the Application Is Not the Patentee (Article 67-3(1)(iv))

3.1.5 Where the Application Does Not Meet the Requirements under Article 67-2(4) (Article 67-3(1)(v) of the Patent Act)

In the case of a jointly owned patent, if only some of the joint patentees file an application to register a patent term extension, the application will be refused.

3.2 Decision of Registration

If no reasons for refusal are found for the application to register a patent term extension, the examiner will render a decision to register the extension (Article 67-3(2) of the Patent Act).

3.3 Publication of Registration in the Patent Gazette

When a patent term extension is registered, the following information will be published in the Patent Gazette (Article 67-3(4) of the Patent Act):

(i) the name and domicile or residence of the patentee;
(ii) the patent number;
(iii) the number and filing date of the application to register a patent term extension;
(iv) the date the patent term extension was registered;
(v) the period of extension; and
(vi) the details of the disposition designated by the Cabinet Order under Article 67(2).

3.4 Amendments

3.4.1 Period During Which Amendments May Be Made

Since a person undertaking procedures with the Patent Office may make amendments only while the case is pending (Article 17(1) of the Patent Act), a person who files an application for a patent term extension is permitted to make amendments when necessary only while the application is pending at the Patent Office.

3.4.2 Allowable Scope of Amendment

In the examination of an application to register a patent term extension, the most important information is which patent right the applicant seeks to extend based on what disposition. Therefore, as long as information identifying the patent right and the disposition (e.g., patent number and the details of the disposition) are given in the written application or in the materials specifying the reasons for the extension that are submitted on the filing date, the applicant is permitted to make amendments to these documents within the scope of the patent right and the disposition.