

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

## Chapter 2 Extension of Patent Term for Pharmaceutical Inventions (Patent Act Article 67(4))

### 1. Overview

The objective of the Patent System is to protect and encourage an invention by granting, as a compensation for publishing a technology related to the invention, an inventor the exclusive right of the invention for a fixed period of time, and, by doing so, to contribute development of the industry.

However, in some fields of such as pharmaceutical products, etc., there is a problem that, because a considerably long time period is needed for required tests and examinations, etc. on occasions when obtaining permission etc. provided in laws that is aimed at securing safety, etc., a profit according to the exclusive right cannot be enjoyed during that period even if the patent right is continuing.

Such laws and regulations themselves are indispensable from their purposes. However, as a result of that, in a field of such as pharmaceutical products, a patent term that could be enjoyed essentially cannot be enjoyed for a time period corresponding to a regulation concerned in the field as a whole. Furthermore, there is a limit naturally in reducing a period of pharmaceutical screenings, etc. from a viewpoint of such as securing safety.

Such situation is a problem which undermines the fundamental principle of the Patent System, and, therefore, in order to solve this, measures for extending a patent term is required.

Therefore, on occasions when there has been a period during which the patented invention was not able to be worked because it is necessary to obtain a disposition designated in Cabinet Order, which is a disposition of permission or others provided in a law aiming at securing safety, etc. and which may take a considerable period to pursue said disposition in an appropriate manner in view of its objective and procedures etc., it has been made possible to extend the period of duration of patent right (Note) by an application for registration of extension concerned with limits of five years (Article 67(4)).

In this way, the objective of the system of patent term extension is to restore the period during which a patented invention was unable to be worked because it was necessary to obtain an disposition designated in Cabinet Order under Article 67(4) (hereinafter, simply referred to as "the disposition designated in Cabinet Order" or "the disposition" in this chapter.) (Determination of the First Petty Bench of the Supreme Court,

Apr. 28, 2011 (2009 (Gyo-Hi) No. 326, Law Reports of Civil Judgments of the Supreme Court Vol. 65 No. 7 pp. 1654) and Determination of the Third Petty Bench of the Supreme Court, Nov. 17 2015 (2014 (Gyo-Hi) No. 356, Law Reports of Civil Judgments of the Supreme Court Vol. 69 No. 7 pp. 1912).

The following two are designated in Cabinet Order as a disposition (Article 2 of the Patent Act Enforcement Order).

- (i) Registration related to agricultural chemicals based on the provisions of the Agricultural Chemicals Regulation Law
- (ii) Approval and certification based on the provisions of the Law for Ensuring the Quality, Efficacy, and Safety of Drugs and Medical Devices (hereinafter, referred to as "Pharmaceutical and Medical Device Law") concerning pharmaceutical products, in vitro diagnostics, products for regeneration medicine, etc. (hereinafter, pharmaceutical products, in vitro diagnostics and products for regeneration medicine, etc. are collectively referred to as "drug products" in this chapter).

(Note) According to Article 67(4), the proviso of Article 67quinquies (3), Article 68bis, and Article 107(1), the period of duration of patent right is 20 years from the date of filing without an application for registration of extension for compensation under Article 67(2), but the period is extended correspondingly under Article 67(4) when the application for registration of extension is made. In this chapter, such period of duration is simply referred to as "duration." Meanwhile, according to the other provisions, the period of duration of patent right is 20 years from the date of filing regardless of whether an application for registration of extension for compensation is made, and stated differently from the former as "duration (except for the period due to the extension of patent term for compensation)."

## 2. Application for Registration of Extension of Patent Term for Pharmaceutical Inventions (Patent Act Article 67(4))

### 2.1 Applicant

An applicant of an application for registration of patent term extension for pharmaceutical inventions (hereinafter, simply referred to as an "application for registration of extension for pharmaceutical inventions" in this chapter) shall be limited to the patent holder (patentee) (Article 67septies (1) (iv)).

On occasions when a patent right is relating to joint ownership, each co-owner

is unable to make an application for registration of extension for pharmaceutical inventions unless the application is made jointly with all other co-owners (Article 67bis (4) which is applied mutatis mutandis in Article 67quinquies (4)). Meanwhile, the patentee or a person who has the exclusive license or non-exclusive license of that patent right shall need to obtain a disposition designated in Cabinet Order under Article 67(4) (article 67septies (1) (ii)).

## 2.2 Filing period for the application

An application for registration of extension for pharmaceutical inventions must be filed within three months after the date (See Note) of obtaining the disposition designated in Cabinet Order under Article 67(4). However, an application may not be filed after the expiration of the original patent term (20 years from the filing date), (Article 67quinquies (3), and Article 3 of the Patent Act Enforcement Order). In addition, on occasions when a person to file an application for registration of extension for pharmaceutical inventions cannot file that application within three months after the date of obtaining the disposition designated in Cabinet Order for any reason not attributable to the applicant, said application must be filed within 14 days (within two months for a foreign resident) after the reason ceases to exist (or within nine months when the period in question exceeds nine months) (Article 3 of the Patent Act Enforcement Order).

When a disposition designated in Cabinet Order is unlikely to be obtained by six months prior to the expiration of the term of a patent right (except for the period due to the extension of patent term for compensation), a person who intends to file an application for registration of extension for pharmaceutical inventions needs to submit a document providing the following matters on or before that date. (Article 67sexies (1) and Article 38sedecies (2) of the Regulations under the Patent Act):

- (i) Surname or entity name and the domicile or residence of the person or entity seeking to make the application;
- (ii) Patent number; and
- (iii) Disposition designated in Cabinet Order under Article 67(4)

When the above-mentioned document is not submitted, an application for registration of extension for pharmaceutical inventions is not able to be made after the day six months before the expiration of the patent term (except for the period due to the extension of patent term for compensation) (Article 67sexies (2)).

(Note) "The date of obtaining the disposition designated in Cabinet Order" is a date on which notification of the approval or registration reached the applicant, that is, a date on which the applicant was put in a state where the applicant learned this or could have learned this. This does not necessarily mean the date of arrival of the "written approval" or "registration card", and, if the applicant knew about the approval or registration in advance of the arrival of the "written approval" or "registration card", it is the date on which the applicant knew this actually.

### 2.3 Patent right eligible for the application

A patent right, for which a patented invention was unable to be worked because it was needed to obtain the disposition designated in Cabinet Order under Article 67(4), becomes the subject of an application for registration of extension for pharmaceutical inventions.

### 2.4 Information which should be included in a request of the application

A person or an entity to seek application for registration of extension for pharmaceutical inventions must submit a request including the following matters to the JPO Commissioner (Article 67quinquies (1) and Article 38quindecies of the Regulations under the Patent Act):

- (i) Surname or entity name and domicile or residence of the applicant;
- (ii) Patent number;
- (iii) Period for which the extension is requested (not exceeding five years);
- (iv) Details of disposition designated in Cabinet Order under the Article 67(4); and
- (v) The date of obtaining a disposition designated in Cabinet Order under Article 67(4).

In the above-mentioned (iv) details of disposition designated in Cabinet Order under Article 67(4), there shall be stated: a disposition to be the reason of the registration of extension for pharmaceutical inventions (for example, "approval based on Article 14(1) of the Pharmaceutical and Medical Device Law related to pharmaceutical product prescribed in the paragraph"); the number for identifying the disposition (the approval number, for example); a product that became the subject of the disposition (Note 1); and, in a case where a particular use in which the product is used is defined in the disposition, said particular use (Note 2).

Regarding (v) the date of obtaining a disposition designated in Cabinet Order

under Article 67(4), see 2.2 (Note).

(Note 1) In principle, as "a product that became the subject of the disposition", the following matters shall be stated:

- (i) In the case of a pharmaceutical product, the name (product name etc.) and the active ingredients stated in the written approval;
- (ii) In the case of a pharmaceutical product for in vitro diagnosis, the name (product name etc.) and ingredients involved in the reaction system stated in the written approval;
- (iii) In the case of a product of regeneration medicine etc., the name (product name etc.) and constituent cells or transgenes stated in the written approval; or
- (iv) In the case of an agricultural chemical, the names of the agricultural chemical and active ingredients stated in the registration card.

(Note 2) In principle, as a "use", the following matters shall be stated:

- (i) In the case of a pharmaceutical product, the efficacy and effect stated in the written approval;
- (ii) In the case of a pharmaceutical product for in vitro diagnosis, the use objective stated in the written approval;
- (iii) In the case of a product of regeneration medicine etc., the efficacy, effect and capability stated in the written approval; or
- (iv) In the case of an agricultural chemical, the names of crops, the names of applicable diseases and pests, the names of applicable weeds or the use objective stated in the registration card.

Where there are more than one disposition corresponding to an act of working of the patented invention pertaining to the application for registration of extension for pharmaceutical inventions (see 3.1.1(1)(ii)) and where the difference between the dispositions needs to be clarified, such difference can be clarified by matters to be stated in the application. For example, in case of a pharmaceutical product, if an applicant intends to clarify the difference by stating dosage and administration, he/she can state them in a column of use in the application.

## 2.5 Information which should be included in materials stating a reason for extension

Materials stating the reason of extension must be attached to the request (Article 67quinquies (2)).

The materials stating the reason of extension, which must be attached to the request, are as follows (Article 38<sup>sedecies</sup> of the Regulations under the Patent Act).

- (i) Materials necessary for certifying that a disposition designated in Cabinet Order under Article 67(4) was necessary to obtain for the working of the patented invention concerning the application for registration of extension for pharmaceutical inventions (the first item);
- (ii) Materials stating the period during which the patented invention concerning the application for registration of extension for pharmaceutical inventions was unable to be worked because it was necessary to obtain the disposition of the previous item (the second item); and
- (iii) Materials necessary for certifying that a person who obtained the disposition of the first item is the exclusive licensee or the non-exclusive licensee of the patent right concerning the application for registration of extension for pharmaceutical inventions, or the owner of said patent (the third item).

Each of the above-mentioned materials listed in (i)-(iii) includes the information listed in (1)-(3) below and also materials supporting such information (see (4) below).

- (1) Materials necessary for certifying that a disposition designated in Cabinet Order was necessary to obtain for the working of the patented invention:

- (i) The invention concerned is a patented invention;

In order to explain that the patent right to be the subject of the application for registration of extension for pharmaceutical inventions is lasting, the date of registration of establishment of patent right, the expiration date of the patent term and a payment situation of patent fees etc. shall be stated.

- (ii) A disposition designated in Cabinet Order has been obtained;

Matters necessary for identifying a disposition designated in Cabinet Order (a disposition to be a reason for registration of extension (hereinafter, it may be called the "present disposition" in this chapter.), a number for identifying the disposition and the date of the disposition), a product that became the subject of the disposition, and, in the case where a particular use in which the product is used is defined in that disposition, said use shall be stated (see 2.4).

- (iii) An act of manufacturing and distribution of drug products or an act of

manufacturing and import of agricultural chemicals that was the subject of the present disposition corresponds to an act of working of the patented invention claimed in an application for registration of extension **for pharmaceutical inventions**;

The applicant shall identify a claims that is thought to include the drug products or agricultural chemicals that became the subject of the present disposition, compare matters specifying the invention in the claim in question and matters stated in the written approval (see (4)(ii) below) of the drug products or in the registration card etc. of the agricultural chemicals (Note), and describe that the drug products or agricultural chemicals that became the subject of the present disposition have all of the matters specifying the invention of the claimed invention in question (see 3.1.1(2)(i)).

(Note) In a registration card for agricultural chemicals, there is no statement concerning a manufacturing method. Therefore, it shall be described using a material submitted on the occasion of the registration request that an agricultural chemical that became the subject of the present disposition is provided with matters specifying the invention pertinent to a manufacturing method.

(iv) Manufacturing and distribution of drug products or manufacturing and import of agricultural chemicals subject to the disposition regarding the prior drug products or the prior agricultural chemicals (the prior disposition) shall not include manufacturing and distribution of drug products or manufacturing and import of agricultural chemicals subject to the present disposition.

The applicant is required to compare the present disposition with any prior dispositions which he/she has known and explain that manufacturing and distribution of drug products or manufacturing and import of agricultural chemicals subject to the prior disposition(s) does not include those subject to the present disposition (see 3.1.1.(1)(ii)d).

(2) Materials stating the period during which the patented invention was unable to be worked because it was necessary to obtain the disposition designated in Cabinet Order

(i) History leading to the present disposition

The applicant is required to explain major facts and dates on which the facts occurred.

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

The applicant is required to explain the grounds for the period during which the patented invention was unable to be worked because it was necessary to obtain the present disposition (see 3.1.3).

- (3) Materials necessary for certifying that a person who obtained the disposition designated in Cabinet Order is the exclusive licensee or the non-exclusive licensee of the patent right, or the owner of a patent in question;

- (i) That the patent owner is a person who obtained the present disposition, or

- (ii) That a person who has the exclusive license or non-exclusive license of the patent right is a person who obtained the present disposition

- (4) Materials supporting the contents of statements

- (i) Patent gazettes

- (ii) In the case of drug products, a copy of the written approval (including the approval request form part (the same shall apply below)).

As a material that indicates a period of the above-mentioned (2), a material that can show the commencement date of a test needed in order to obtain the present disposition, such as a copy of a submission form of a clinical trial plan, for example (see 3.1.3(2)). When the approval was unable to be learned on the approval date, a material that can show a date on which the approval was learned or a date on which the approval was placed in a state being able to be learned, whichever the earliest, objectively.

- (iii) In the case of agricultural chemicals, a copy of the registration card.

As a material that indicates a period of the above-mentioned (2), a material that can show the commencement date of a test needed in order to obtain the present disposition, such as a copy of the request form of a commissioned field trial etc., for example (see 3.1.3(2)). When the registration was unable to be learned on the registration date, a material that can show a date on which the registration was learned or a date on which the registration was placed in a state being able to be learned, whichever the earliest, objectively.

Meanwhile, in the materials of (ii) and (iii) above, a part needed to support the contents is disclosed.



## 2.6 Effects of the application

When an application for registration of extension for pharmaceutical inventions is filed, the duration is deemed to be extended until a decision of refusal is determined or a registration of extension for pharmaceutical inventions is admitted (Article 67bis (5) which is applied mutatis mutandis in Article 67quinquies (4)).

## 2.7 Publication of patent gazette

When an application for registration of extension for pharmaceutical inventions is filed, matters listed in Article 67quinquies (1) and the number and the year, month and date of the application are published in a patent gazette (Article 67bis (6) which is applied mutatis mutandis in Article 67quinquies (4)).

Moreover, a document as provided in Article 67sexies (1) is filed, matters listed in each item in Article 67bis-bis (1) are published in a patent gazette (Article 67sexies (3)).

# 3. Examination of Application for Registration of Extension for Pharmaceutical Inventions

## 3.1 Determination on requirements pertaining to examination of an application for registration of extension for pharmaceutical inventions

In examining an application under registration of extension for pharmaceutical inventions, an examiner determines whether the application applies to any of each item of Article 67ter (1) shown below as (1) to (5). The reason for refusal exists when the application applies to any of (1) to (5) below.

- (1) where the disposition designated by Cabinet Order under Article 67(4) is not deemed to have been necessary to obtain for the working of the patented invention (Article 67septies (1)(i)).
- (2) where the patentee, or the exclusive licensee(s) or registered non-exclusive licensee(s) of the patent have not obtained the disposition designated by Cabinet Order under Article 67(4) (Article 67septies (1)(ii)).

- (3) where the period for which the extension is requested exceeds the period during which the patented invention was unable to be worked (Article 67septies (1)(iii)).
- (4) where the person filing the application is not the patentee (Article 67septies (1)(iv)).
- (5) where the application does not meet the requirements under Article 67bis (4) which is applied mutatis mutandis in Article 67quinquies(4) (Article 67septies (1)(v)).

3.1.1 Where the disposition designated by Cabinet Order under Article 67(4) is not deemed to have been necessary to obtain for the working of the patented invention (Article 67septies (1)(i))

- (1) Determination on whether or not the disposition designated by Cabinet Order has been necessary to obtain for the working of the patented invention

In case an application for registration of extension for pharmaceutical inventions falls under any of (i) or (ii) in below, it is not deemed that the disposition designated by Cabinet Order has been necessary to obtain for the working of the patented invention, then a reason for refusal arises.

- (i) when an act of manufacturing and distribution of drug products or an act of manufacturing and import of agricultural chemicals subject to the present disposition does not fall under an act of working of the patented invention pertaining to an application for registration of extension for pharmaceutical inventions.

As a result of comparing the matters specifying the invention in the patented invention with the matters stated in the certificate of approval of drug products or a registration card of agricultural chemicals etc, the examiner notifies a reason for refusal when drug products or agricultural chemicals as a subject of the present disposition cannot be said as including all of the matters specifying the invention as to the patented invention related to any of the claims.

Example: Where the patented invention is "an insect killer including an active ingredient A and a surfactant B," the examiner notifies a reason for refusal unless the registered pesticides based on the matters stated in a registration card etc. of pesticides can be said as an insect killer including the active ingredient A or an active ingredient corresponding to a more specific concept thereof and the surfactant B or a surfactant corresponding to a more specific concept thereof.

- (ii) In case an act of manufacturing and distribution of drug products or an act of

manufacturing and import of agricultural chemicals subject to both the present disposition and the prior disposition falls under an act of working of the patented invention pertaining to an application for registration of extension **for pharmaceutical inventions**, when manufacturing and distribution of drug products or manufacturing and import of agricultural chemicals subject to the prior disposition include those subject to the present disposition.

When an act of manufacturing and distribution of drug products or an act of manufacturing and import of agricultural chemicals subject to both the present disposition and the prior disposition falls under an act of working of the patented invention pertaining to an application for registration of extension **for pharmaceutical inventions**, it is considered as follows:

(a) Basic idea

It is not deemed that the present disposition has been necessary to obtain for the working of the patented invention pertaining to the application for registration of extension **for pharmaceutical inventions**, when manufacturing and distribution of drug products or manufacturing and import of agricultural chemicals subject to the prior disposition are found to include those subject to the present disposition as a result of comparing the two dispositions with respect to the examination matters related directly to substantial identity as drug products or agricultural chemicals in the light of the type and subject of the patented invention pertaining to the application for registration of extension **for pharmaceutical inventions**. Then, the examiner issues a notification of a reason for refusal.

It is based on the following idea.

Considering the system and purpose of the registration of extension of the patent term **for pharmaceutical inventions**, it is not appropriate to compare the two dispositions concerning matters which are not related directly to substantial identity as drug products or agricultural chemicals in the light of the type and subject of the patent pertaining to the application for registration of extension **for pharmaceutical inventions**, because the two dispositions are compared concerning the matters which are not likely to inhibit the working of the patented invention of said drug products or agricultural chemicals and the registration of extension of the patent term **for pharmaceutical inventions** may be approved. Therefore, whether or not manufacturing and distribution of drug products or manufacturing and import of

agricultural chemicals subject to the prior disposition include those subject to the present disposition should be determined not by merely comparing all matters with respect to the prior disposition and the present disposition but by comparing the two dispositions with respect to the examination matters which are related directly to substantial identity as drug products or agricultural chemicals in the light of the type and subject of the patented invention pertaining to the application for registration of extension **for pharmaceutical inventions**.

(b) Inclusion

In cases where manufacturing and distribution of drug products or manufacturing and import of agricultural chemicals subject to the prior disposition are partially overlapped with those subject to the present disposition, it is also regarded as one of the aspects of inclusion (see 3.1.1(4)).

(c) Examination matters related directly to substantial identity

In a case where a prior disposition and a present disposition have been made, the two dispositions are compared with respect to the examination matters related directly to substantial identity as drug products or agricultural chemicals in the light of the type and subject of the patented invention pertaining to an application for registration of extension **for pharmaceutical inventions**. For example, the followings are shown as “examination matters related directly to substantial identity”.

- where the disposition designated by Cabinet Order is an approval of manufacturing and distribution of pharmaceutical products and the patented invention claimed in an application for registration of extension **for pharmaceutical inventions** is an invention of product, examination matters include “ingredient, dose, dosage, administration, efficacy and effect”.

- where the disposition designated by Cabinet Order is an approval of manufacturing and distribution of pharmaceutical products and the patented invention claimed in an application for registration of extension **for pharmaceutical inventions** is an invention of manufacturing process, examination matters include “ingredient, dose, dosage, administration, efficacy and effect” as well as matters related to the manufacturing process if necessary.

- where the disposition designated by Cabinet Order is an approval of manufacturing

and distribution of pharmaceutical products and the patented invention claimed in an application for registration of extension **for pharmaceutical inventions** is an invention of drug formulation, examination matters include “ingredient, dose, dosage, administration, efficacy and effect” as well as matters related to drug formulation if necessary.

- where the disposition designated by Cabinet Order is an approval of manufacturing and distribution of in vitro diagnostics and the patented invention claimed in an application for registration of extension **for pharmaceutical inventions** is an invention of product, examination matters include “ingredient, dose, structure, direction of use and capability”.

- where the disposition designated by Cabinet Order is an approval of manufacturing and distribution of products of regeneration medicine etc., and the patented invention claimed in an application for registration of extension **for pharmaceutical inventions** is an invention of product, examination matters include “constituent cells, transgene, structure, dosage, administration, direction of use, efficacy, effect and capability”.

- where the disposition designated by Cabinet Order is a registration of agricultural chemicals and the patented invention claimed in an application for registration of extension **for pharmaceutical inventions** is an invention of product, examination matters include “type of agricultural chemicals, physical and chemical property, types and contents of each component, a range of applicable diseases and insects pests (in the case of chemical agents used to promote or suppress the physiological functions of crops, etc., the range of applicable crops, etc. and the purpose of the application of the agricultural chemicals.) and methods of use.

(d) Where a patent right claimed in an application for registration of extension **for pharmaceutical inventions** including more than one claim

Where a patent right claimed in an application for registration of extension **for pharmaceutical inventions** includes more than one claim, it should be recognized that the disposition designated by Cabinet Order has been necessary to obtain for the working of the patented invention for at least any one of the claims.

Therefore, it is necessary to be recognized that any one of the claims pertaining to an application for registration of extension **for pharmaceutical inventions** does not

fall under both 3.1.1 (1)(i) and (ii). Namely, if any one of the claims is not deemed to be the following both (a) and (b), it is not recognized that the disposition designated by Cabinet Order has been necessary to obtain for the working of the patented invention, then a reason for refusal arises:

(a) an act of manufacturing and distribution of drug products or an act of manufacturing and import of agricultural chemicals subject to the present disposition falls under an act of working of the patented invention pertaining to an application for registration of extension **for pharmaceutical inventions**.

(b) when an act of manufacturing and distribution of drug products or an act of manufacturing and import of agricultural chemicals subject to both the present disposition and the prior disposition falls under an act of working of the patented invention claimed in an application for registration of extension **for pharmaceutical inventions**, manufacturing and distribution of drug products or manufacturing or import of agricultural chemicals subject to the prior disposition do not include those subject to the present disposition.

(e) The applicant is required to compare the present disposition with any prior dispositions that he/she has known and explain that manufacturing and distribution of drug products or manufacturing and import of agricultural chemicals subject to the prior disposition(s) do not include those subject to the present disposition (see 2.5(1)(iv)). When the applicant can explain that manufacturing and distribution of drug products or manufacturing and import of agricultural chemicals subject to the prior disposition do not include those subject to the present disposition by reason of the partial difference in examination matters related directly to substantial identity, he/she may explain only matters necessary for the examination.

## (2) Where multiple patent rights correspond to a single disposition

Where multiple patent rights correspond to a single disposition, a patent term extension will be registered for each of the patent rights respectively, provided that the disposition is deemed to be required for those respective patent rights in order to carry out the patented invention.

For example, where such multiple patent rights are comprising: a patent for substance as an active ingredient of an approved pharmaceutical product, a patent for pharmaceuticals wherein the active agent is used for the approved pharmaceutical use, and a patent for manufacturing process of the active ingredient, the patent term extension will be registered for any of those patent rights respectively, provided that such approval

is deemed to be required for those respective patent rights in order to carry out the patented invention.

(3) Where multiple dispositions correspond to a single patent right

Where multiple dispositions were issued for a single patent right, patent term extensions based on those different dispositions will be registered for the single patent right on a disposition-by-disposition basis, provided that those respective dispositions are deemed to be required for the working of the patented invention.

(4) Where manufacturing and distribution of drug products or manufacturing and import of agricultural chemicals subject to more than one disposition are partially overlapped each other

Where manufacturing and distribution of drug products or manufacturing and import of agricultural chemicals subject to the present disposition are partially overlapped with manufacturing and distribution of drug products or manufacturing and import of agricultural chemicals subject to the prior disposition (for example, where the efficacy and effect of a pharmaceutical product subject to the present disposition is a generic concept, while the efficacy and effect of a pharmaceutical product subject to the prior disposition is a more specific concept,) it is deemed that the present disposition has been necessary to obtain for the working of the patented invention except the part overlapped in the two dispositions.

For example, with respect to a patented invention for "Substance A," where the present disposition is obtained for a pharmaceutical product listed as having "active ingredient: Substance A, efficacy and effect: allergic rhinitis," even if the prior disposition has been obtained for a pharmaceutical product listed as having "active ingredient: Substance A, efficacy and effect: chronic allergic rhinitis," it is deemed that the present disposition has been necessary to obtain for the working of the patented invention except the part overlapped in the two dispositions.

(5) Pharmaceutical-related patent right which is ineligible for patent term extension

Any patent right for intermediates, catalysts, or manufacturing equipment that are used in the manufacturing process of any drug product or agricultural chemical is ineligible for patent term extension.

Drug products or agricultural chemicals as a final product contain no intermediates, catalysts, nor manufacturing equipment. Pharmaceutical and Medical Device Act and Agricultural Chemicals Control Act which provide for regulations on

manufacturing and distribution of drug products as final products, and manufacturing and import of agricultural chemicals as final products respectively, neither of which has intent to regulate mere use of intermediates, catalysts, nor manufacturing equipment. Thus, the above mentioned patent rights shall be ineligible for patent term extensions.

3.1.2 Where a patentee, an exclusive licensee or a non-exclusive licensee of the patent right has not obtained a disposition designated by Cabinet Order under **Article 67(4)** (**Article 67septies (1)(ii)**)

Even if more than one person jointly obtained a disposition and only some of them hold an exclusive license or a non-exclusive license of the patent right, 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 67septies (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 67septies (1)(iii)**)

(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 Cabinet Order (**Article 67(4)**).

This period begins on the date on which a testing necessary for obtaining the disposition designated by Cabinet Order commences or on which the relevant patent is registered, whichever comes later; and ends on the day before the date on which the approval or registration takes effect by reaching the applicant, i. e. the date on which the applicant actually learns of the approval or registration or could have learned of it (Note) (see Judgment of the Second Petty Bench of the Supreme Court of October 22, 1999, 1998(Gyo-Hi) No. 43, Law Reports of Civil Judgments of the Supreme Court Vol. 53 No. 7 pp.1270, and Judgment of the Second Petty Bench of the Supreme Court of October 22, 1999, 1998(Gyo-Hi) No. 44).

(Note) "The date on which the approval or registration takes effect by reaching the applicant, i.



e. 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 such certificate or card, the abovementioned date is considered to be the date on which the applicant actually learns of such approval or registration.

Pharmaceutical and Medical Device Law and Agricultural Chemicals Regulation Law each provides that any person who seeks approval for a drug product or registration of an agricultural chemical must include materials on test results when filing for the disposition. As such, testing is necessary to obtain test results. Furthermore, since a patented invention means an invention for which a patent has been granted (Article 2(2)), "the period during which the patented invention was unable to be worked" must be the period which comes after the registration of the patent right. Therefore, the "period during which the patented invention was unable to be worked" means the period after the date of patent registration, out of 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.

No extension will be allowed for the period which is considered as not necessary for obtaining the disposition even if such period falls under the above period.

While various types of testing are conducted according to the purpose, intent, 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 a disposition;
- (ii) Enterprises have little discretion in conducting the testing because the testing needs to be conducted in line with the standards for testing methods, description, etc. of testing set forth by administrative agencies; and
- (iii) The testing is closely related to obtaining a disposition.

(Note) The period during which a preclinical testing was conducted is much characterized as a research and development period to study the utility of the chemical substance which is the active ingredient of a pharmaceutical product, and is considered as being more like 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. Accordingly, the period during which the preclinical testing was conducted shall 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 the clinical testing (such as the date on which a notification of the clinical trial plan is submitted) or, in the case of an agricultural chemical, the commencement date of commissioned field trials conducted for the relevant chemical substance by specifying the name of the substance (such as the date on which a request for the commissioned field trial 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 day before the date on which the applicant is notified of the approval or registration, or in other words, on the day before the date on which the applicant actually learns of, or could have learned of, the approval or registration. 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) Comparison/determination of the period for which the extension is requested and the period during which the patented invention was unable to be worked

The examiner should calculate, by himself/herself, the period during which the patented invention was unable to be worked (in year-month-day format) in accordance with the calendar with reference to the information which should be included in materials stating a reason for extension. Then, he/she should compare the period for which the extension is requested (in year-month-day format) in the request to the calculated period during which the patented invention was unable to be worked, in order to determine the period for which the extension is requested exceeds the period during which the patented invention was unable to be worked.

(5) Points to note

In determining "the period during which the patented invention was unable to be worked" according to Article 67septies (1)(iii), not only the materials submitted by the

applicant but also the conventional process by which the disposition designated by 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 Cabinet Order is delivered, if it is found that the extension period sought by the applicant exceeds the period during which the patented invention was unable to be worked because of the need to obtain the disposition designated by Cabinet Order, the application will be refused under Article 67septies (1)(iii).

The extension period sought by the applicant will be acceptable unless the period is longer than the period during which the patented invention was unable to be worked because of the need to obtain the disposition designated by Cabinet Order. The two periods do not have 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 under Article 67septies (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 67septies (1)(iv))

If a person other than the patentee files an application for registration of extension for pharmaceutical inventions, it falls under Article 67septies (1)(iv), and the application will be refused.

#### 3.1.5 Where the application does not meet the requirements under Article 67bis(4) which is applied mutatis mutandis in Article 67-5(4) (Article 67-7(1)(v))

In the case of a jointly owned patent, if only some of the joint patentees file an application to register a patent term extension for pharmaceutical inventions, it falls under Article 67-7(1)(v), and the application will be refused.

### 3.2 Procedures of examination for the application for registration of extension for pharmaceutical inventions

#### 3.2.1 Notice of a reason for refusal

If an application for registration of extension for pharmaceutical inventions falls

under any of the items of Article 67septies (1), the examiner shall notify the applicant of the reasons therefore and give said applicant an opportunity to submit a written opinion, designating an adequate time limit for such purpose (Article 50 which is applied mutatis mutandis in Article 67quater which is applied mutatis mutandis in Article 67octies).

### 3.2.2 Response by the applicant

#### (1) Term allowable for amendment

A person undertaking a procedure before the Patent Office may make amendments only while the case is pending (Article 17(1)). As such, a person filing an application for registration of extension for pharmaceutical inventions may amend the same from time to time as long as the application is pending at the Patent Office.

#### (2) Scope allowable for amendment

The most significant part of the examination of an application for registration of extension for pharmaceutical inventions is in determining which patent right shall be the subject of extension and which disposition shall provide the basis for extension. Accordingly, if the matters for specifying the patent right and disposition (such as the patent number and the description of the disposition) are stated on the application form or in the materials stating the reasons for extension, at the time of filing the application, the amendment to correct the application form or the materials stating the reasons for extension will be allowed within the scope thereof.

### 3.2.3 Decision of refusal

If the application for registration of extension for pharmaceutical inventions still falls under any of the items of Article 67septies (1) even when the written opinion, etc. are taken into consideration, the examiner shall render his/her decision to the effect that the application is to be refused (Article 67septies (1)).

### 3.2.4 Decision of registration

If no reasons for refusal are found in the application for registration of extension for pharmaceutical inventions, the examiner shall render his/her decision to the effect that the extension is to be registered (Article 67septies (2)).

In case the extension of the duration of a patent right is registered, the following matters shall be published in a patent gazette (Article 67septies (4)):

- (i) Name and domicile or residence of the patentee;
- (ii) Patent number;
- (iii) Application number and filing date of the application for registration of extension under Article 67(4);
- (iv) Date of registration of extension for pharmaceutical inventions;
- (v) Extension period; and
- (vi) Details of the disposition designated by Cabinet Order under Article 67(4).