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Part IX Extension of Patent Term

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Chapter 1 Extension of a Patent Term as Compensation for the Curtailment of the Term (Patent Act Article 67(2))

1. Overview

The objective of the patent system is to protect and encourage invention by allowing an inventor to have exclusive rights to his/her invention for a certain period of time as compensation for disclosing the technology related to the invention and thereby contribute to industrial development.

A patent right is registered after examination, which is expected to take a certain period of time. In most cases, examination will be completed within such period of time. However, in some cases, longer time than such expected period of time is required to complete the process of filing an application, making an examiner's decision to grant a patent, and registering the patent right.

The term of a patent right expires after a period of 20 years from the filing date of the patent application (Article 67(1)).

On the other hand, it will become possible to seek an injunction based on a patent right and to exercise the right to demand payment of damages, etc. only after the applicant obtains a patent right upon registration of the right. Thus, if the registration of a patent right takes longer than such expected period of time, the period during which the patentee is entitled to exercise his/her rights would be shorter.

It will be beneficial for the patentee to have the term of his/her patent right extended in order to offset the time during which the patentee is unable to exercise his/her rights. On the other hand, from the viewpoint of third parties against which a patent right may be exercised, an extension of a patent term could threaten the stability, etc. of their business.

In order to solve this problem, the Patent Act gives a patentee sufficient time to exercise his/her rights and, in consideration of various factors such as the maintenance of fairness to all applicants and the possible consequences to third parties after an extension of the patent term, permits an extension of the patent term for an applicant who files an application to register a patent term extension if the patent right has been registered after either of the following dates, whichever is later: the date five years after the filing of the patent application or the date three years after the filing of a request for examination of the application (the "reference date") (Article 67(2)). The Patent Act specifies that, if such extension is permitted, the length of the extended period should not exceed the length of the period calculated by extracting the total length of the

periods specified in the items of Article 67(3) from the length of the period starting from the reference date and ending on the registration date of the patent right (the maximum permissible length of extension period) (Article 67(3)).

2. Application to register a patent term extension as compensation for the curtailment of the term (Article 67(2))
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2.1 Applicant

Only a patentee may file an application to register a patent term extension as compensation for the curtailment of the term (in this Part, it is sometimes referred to as an "application to register a patent term extension as compensation for the curtailment of the term") (Article 67ter (1)(iii)).

If a patent right is jointly owned, none of the joint owners may file an application to register a patent term extension as compensation for the curtailment of the term unless doing so jointly with all the other joint owners (Article 67bis (4)).

2.2 Period during which an application may be filed

An application to register a patent term extension as compensation for the curtailment of the term must be filed within the period of three months starting from the registration date of the patent right. However, if a person who is responsible for filing an application to register a patent term extension as compensation for the curtailment of the term fails to file an application within such period for any reason not attributable to him/her, he/she must file such application within the period of 14 days (or two months in the case of a person living outside Japan) from the date on which said reason ceased to exist (within the period of nine months if such period exceeds nine months) (Article 67bis (3)). After the expiration of the term of a patent right, an application to register a patent term extension as compensation for the curtailment of the term may not be filed.

2.3 Patent right for which an application may be filed

An application to register a patent term extension as compensation for the curtailment of the term may be filed for a patent right that was registered after the reference date (Article 67(2)).

(1) Reference date

The reference date is the date five years after the filing of the patent application or the date three years after the filing of a request for examination of the application, whichever is later (Article 67(2)).

(2) Filing date of a patent application used to calculate the reference date

Usually, the filing date of a patent application means the actual filing date of a patent application. In the case of certain types of patent application, namely, a divisional application, a converted application, or a patent application based on a utility model registration, or an application claiming to refer to an earlier patent application, a patent right will be registered if the formality requirements are satisfied. For this reason, the filing date of such application will be found based on whether the substantive requirements are satisfied or not as follows.

In the case of a divisional application, if the substantive requirements included in the requirements for division of a patent application are satisfied, the filing date of the original application will be found as the filing date of the patent application. On the other hand, if the substantive requirements are not satisfied, the actual filing date will be found as the filing date of the patent application.

In the case of a converted application, if the substantive requirements included in the requirements for conversion of a patent application are satisfied, the filing date of the original application will be found as the filing date of the patent application. On the other hand, if the substantive requirements are not satisfied, the actual filing date will be found as the filing date of the patent application.

In the case of a patent application based on a utility model registration, if the substantive requirements included in the requirements for the filing of a patent application based on a utility model registration are satisfied, the filing date of a utility model application related to the utility model registration will be found as the filing date of the patent application. On the other hand, if the substantive requirements are not satisfied, the actual filing date will be found as the filing date of the patent application.

In the case of an application claiming to refer to an earlier patent application, if the substantive requirements included in the requirements for the filing of an application claiming to refer to an earlier patent application are satisfied, the filing date of an application claiming to refer to an earlier patent application will be found as the filing date of the patent application. On the other hand, if the substantive requirements are not satisfied, the date of submission of the description or drawings will be found as the filing date of the patent application.

2.4 Information that must be presented in an application

Any person who files an application to register a patent term extension as compensation for the curtailment of the term must submit to the JPO Commissioner an application containing the following information (Article 67bis (1) and Article 38quaterdecies-ter (1) of the Regulation for Enforcement of the Patent Act):

- (i) Name and domicile or residence of the applicant;
- (ii) Patent number
- (iii) Length of the requested extension period;
- (iv) Application number and the filing date of the patent application;
- (v) Date on which a request for examination of the application was filed.

2.5 Information that must be presented in a document describing the grounds for calculation of the length of the requested extension period

The application must be accompanied by a document describing the grounds for calculation of the length of the requested extension period (Article 67bis (2)). If an applicant includes all the necessary information in an application, the applicant may omit the attachment of a document describing the grounds for calculation of the length of the requested extension period (Article 38quaterdecies-quarter (2) of the Regulation for Enforcement of the Patent Act). When an applicant attaches a document describing the grounds for calculation of the length of the requested extension period to the application, the applicant must state the following matters in the document (Article 38quaterdecies-quarter of the Regulation for Enforcement of the Patent Act):

- (i) Filing date of the patent application;
- (ii) Date on which a request for examination of the application was filed;
- (iii) Reference date;
- (iv) Registration date of the patent right;
- (v) Period from the reference date to the registration date of the patent right;
- (vi) Details concerning the periods that can be regarded as the periods specified in the items of Article 67(3) (Note) and the starting date and the ending date of each of those periods;
- (vii) Total length of the periods specified in the items of Article 67(3) (if those periods overlap with each other, the total length of the overlap periods should be deducted); and
- (viii) Maximum permissible length of extension period.

(Note) The "details concerning the periods that can be regarded as the periods specified in the items of Article 67(3)" means information showing which of the items of Article 67(3) each of those periods falls under and on what dates the period starts and ends.

2.6 Effects of the application

When an application to register a patent term extension as compensation for the curtailment of the term is filed, the term will be deemed to be extended until the time when an examiner's decision to reject such an application becomes final and binding or when a patent term extension is registered (Article 67bis (5)).

2.7 Publication of information in a patent gazette

When an application to register a patent term extension as compensation for the curtailment of the term is filed, the information specified in the items of Article 67bis (1) must be published in a patent gazette (Article 67bis (6)).

When a patent term extension is registered under Article 67ter (3), the information specified in the items of paragraph (4) of said Article must be published in a patent gazette (Article 67ter (4)).

<h2>3. Examination of an application to register a patent term extension as compensation for the curtailment of the term</h2>

3.1 Examiner's determination as to whether an application to register a patent term extension as compensation for the curtailment of the term satisfies the requirements or not

When an examiner examines an application to register a patent term extension as compensation for the curtailment of the term, the examiner must determine whether the application to register a patent term extension as compensation for the curtailment of the term falls under any of the items of Article 67ter (1), which are listed in the following items (1) to (4). If an application to register a patent term extension as compensation for the curtailment of the term falls under any of the following items (1) to (4), the grounds for rejection can be considered to exist:

(1) The registration date of the patent right is not on or after the reference date (Article 67ter (1)(i));

- (2) The length of the requested extension period is longer than the maximum permissible length of extension period (Article 67ter (1)(ii));
- (3) The person filing the application is not the patentee (Article 67ter (1)(iii)); or
- (4) The application does not satisfy the requirement specified in Article 67bis (4) (Article 67ter (1)(iv)).

3.1.1 In the case where the registration date of the patent right is not on or after the reference date (Article 67ter (1)(i))

If the registration date of the patent right is earlier than the reference date, the grounds for rejection specified in Article 67ter (1)(i) can be considered to exist.

3.1.2 In the case where the length of the requested extension period is longer than the maximum permissible length of extension period (Article 67ter (1)(ii))

(1) Maximum permissible length of extension period

The maximum permissible length of extension period means the length of period calculated by deducting the total length of the periods specified in the items of Article 67(3) from the length of period starting from the reference date and ending on the registration date of the patent right (Article 67(3)).

(2) Periods specified in the items of Article 67(3)

The periods specified in the items of Article 67(3) can be considered to be the periods specified in the following items (i) to (x) with regard to the patent application.

(i) Period that was consumed to carry out a necessary procedure upon receipt of a notice or an order from the JPO Commissioner or an examiner.

Article 67(3)(i) specifies that, in the case where a notice or an order (only those made by the JPO Commissioner or an examiner) is made based on the Patent Act (excluding Article 39(6) and Article 50), the Utility Model Act, the Act on Special Provisions of Procedures, etc. concerning Industrial Property Rights, or any regulations established based on these Acts, if the procedure that is necessary to be carried out upon receipt of such notice or order is carried out, the deductible period can be found to start from the date on which such notice or order is made and to end on the date on which such procedure is completed (including the case where the period during which such procedure should be carried out is extended).

As described above, the aforementioned notice or order does not include a notice of the grounds for rejection made under Article 50 and an instruction made under the name of the JPO Commissioner based on the results of consultations under Article 39(6). Thus, even if it takes time to take a necessary procedure upon receipt of such notice or instruction, such time may not be deducted.

(ii) Period that was consumed as a result of an extension of the period during which a procedure should be carried out

Article 67(3)(ii) specifies that, in the case where extension is made to the period during which a procedure should be carried out based on the Patent Act or any regulations established based on said Act (the "Patent Act and regulations"), the deductible period can be found to start from the date on which the period during which the procedure should be carried out expires and to end on the date on which the procedure is completed.

As mentioned in (i) above, even if it takes time to take a necessary procedure upon receipt of a notice of the grounds for rejection made under Article 50 and an instruction made under the name of the JPO Commissioner based on the results of consultations under Article 39(6), such time may not be deducted. However, the length of the period consumed as a result of an extension of the period during which such procedure should be carried out may be deducted.

(iii) Period that was consumed to take a procedure after the expiration of the period during which such procedure should be carried out

Article 67(3)(iii) specifies that, even in the case where a procedure specified in the Patent Act and regulations is required to be carried out within the prescribed period of time, if an applicant is permitted to carry out the procedure even after the expiration of the period during which the procedure should be carried out, the deductible period can be found to start from the date on which the period during which the procedure should be carried out expires and to end on the date on which the procedure is completed.

(iv) Period consumed as a result of the suspension of an administrative disposition or notification upon request or due to any other act of an applicant

Article 67(3)(iv) specifies that, in the case of the suspension of an administrative disposition or notification specified in the Patent Act, the Act on Special Provisions of Procedures, etc. concerning Industrial Property Rights, or any regulation established based on these Acts (the "laws and regulations related to the Patent Act")

upon request or due to any other act of an applicant (Note), the deductible period can be found to start from the date of such request or act and to end on the date on which the reasons for suspending such disposition or notification ceases to exist.

(Note) The "request or any other act of the applicant" includes not only an explicit request from the applicant but also any act of the applicant that would cause suspension of the disposition or notification.

Example: An applicant made an amendment to the description containing an error prior to the receipt of a notice of the grounds for rejection. Despite the JPO Commissioner's order to amend the proceedings with regard to the aforementioned amendment (Article 17(3)(ii)), the applicant failed to carry out the procedure that should be followed upon receipt of such order and saw the aforementioned amendment dismissed (Article 18(1)). In the course of these proceedings, a notice of the grounds for rejection was suspended. In this case, the deductible period can be found to start from the date on which the aforementioned amendment was made and to end on the date on which the amendment was dismissed.

(v) Period consumed as a result of the filing of a request for reduction or exemption of a patent fee or a handling fee or a request for deferment of payment thereof

Article 67(3)(v) specifies that, regarding the payment of a patent fee or handling fee specified in the Patent Act and regulations, if a decision is made with regard to the reduction or exemption of a patent fee or a handling fee or with regard to the deferment of payment thereof, the deductible period can be found to start from the date on which a request for reduction or exemption of a patent fee or a handling fee or a request for deferment of payment thereof is made and to end on the date on which such decision is made.

(vi) Period consumed as a result of the withdrawal of a written supplement for the description, etc.

Article 67(3)(vi) specifies that, if a written supplement for the description, etc. is withdrawn under Article 38quater (7), the deductible period can be found to start from the date on which a written supplement for the description, etc. is submitted under Article 38quater (3) and to end on the date on which the written supplement for the description, etc. is withdrawn under Article 38quater (7).

(vii) Period consumed as a result of an appeal against an examiner's decision of rejection

Article 67(3)(vii) specifies that, if an appeal against an examiner's decision of rejection is filed, the deductible period can be found to be the periods specified in (vii-1) to (vii-3) below for the classifications described in (vii-1) to (vii-3) respectively.

(vii-1) In an appeal against an examiner's decision of rejection (including a re-appeal against the final JPO decision concerning an appeal against an examiner's decision of rejection), if a JPO decision is made to grant a patent, the period starting from the date on which a certified copy of an examiner's decision of rejection is served and ending on the date on which a certified copy of the JPO decision is served (item (vii) a)

(vii-2) In the case where an examiner's decision is rescinded in an appeal against an examiner's decision of rejection (including a re-appeal against the final JPO decision concerning an appeal against an examiner's decision of rejection), if a JPO decision is made to conduct further examination, the period starting from the date on which a certified copy of the examiner's decision of rejection is served and ending on the date on which a certified copy of the JPO decision is served (item (vii) b)

(vii-3) In the case of reexamination before the appeal, if an examiner's decision to grant a patent is made, the period starting from the date on which a certified copy of the examiner's decision of refusal is served and ending on the date on which a certified copy of the examiner's decision to grant a patent is served (item (vii) c)

(viii) Period consumed as a result of carrying out a procedure specified in the Administrative Complaint Review Act

Article 67(3)(viii) specifies that, if an administrative determination is finalized in response to a request for review under the Administrative Complaint Review Act with regard to an administrative disposition made under the laws and regulations related to the Patent Act, the deductible period can be found to start from the date of the request for review and to end on the date on which a certified copy of the administrative determination is served.

(ix) Period consumed as a result of the procedure specified in the Administrative Case Litigation Act

Article 67(3)(ix) specifies that, if a judgment is finalized concerning an action filed under the Administrative Case Litigation Act with regard to an administrative disposition made under the laws and regulations related to the Patent Act, the deductible period can be found to start from the date of the filing of the action and to end on the date on which the judgment concerning the action is finalized.

(x) Period consumed as a result of suspension or discontinuation of a procedure specified in the Patent Act and regulations

Article 67(3)(x) specifies that, if a procedure specified in the Patent Act and regulations is suspended or discontinued, the deductible period can be found to be the same as the period of suspension or discontinuation.

(3) Case where overlapping periods are included in the periods specified in the items of Article 67(3)

If overlapping periods are included in the periods specified in the items of Article 67(3), the total of such periods should be deducted from the total length of the periods specified in the items of Article 67(3).

Example 1: In the case where orders for amendment of proceedings are made one after another under Article 17(3) with regard to the amendment of the description and the amendments to the scope of claims respectively, if the applicant makes an amendment in response to each of the orders, which would result in overlapping periods (Article 67(3)(i)).

Example 2: In the case where any of the periods specified in the items of Article 67(3) is included in the prescribed period related to an appeal against an examiner's decision of rejection (Article 67(3)(vii))

(4) Determination made based on a comparison between the length of the requested extension period and the maximum permissible length of extension period

An examiner must examine the information presented in a document describing the grounds for calculation of the length of the requested extension period and calculate the maximum permissible length of extension period (the period indicated by date, month, year) with reference to a calendar, and make a comparison between the length of the requested extension period stated in the application (the period indicated by date, month, year) and the calculated maximum permissible length of extension period, and make a determination as to whether the requested extension period exceeds the maximum permissible length of extension period.

(5) Note

If an examiner examines the information presented in a document describing the grounds for calculation of the length of the requested extension period and

determines that the extension period requested by the applicant exceeds the maximum permissible length of extension period, the examiner must reject the extension under Article 67ter (1)(ii).

The length of the requested extension period does not have to be the same as the maximum permissible length of extension period as long as the requested extension period does not exceed the maximum permissible length of extension period.

If the total of the periods specified in the items of Article 67(3) is longer than the period starting from the reference date and ending on the date on which the patent right is registered, no extension may be permitted. In such case, an extension would be rejected under Article 67ter (1) (ii).

3.1.3 In the case where the applicant is not the patentee (Article 67ter (1) (iii))

If any person other than the patentee files an application to register a patent term extension as compensation for the curtailment of the term, the grounds for rejection can be considered to exist under Article 67ter (1) (iii).

3.1.4 In the case where the patent application does not satisfy the requirement specified in Article 67bis (4) (Article 67ter (1) (iv))

In the case of a joint application, if only some of the applicants file an application to register a patent term extension as compensation for the curtailment of the term, the grounds for rejection can be considered to exist under Article 67ter (1) (iv).

3.2 How to examine an application to register a patent term extension as compensation for the curtailment of the term

3.2.1 Notice of the grounds for rejection

If an examiner finds an application to register a patent term extension as compensation for the curtailment of the term falls under any of the items of Article 67ter (1), the examiner must send the applicant a notice of the grounds for rejection and give an opportunity to submit a written opinion (Article 50 applied *mutatis mutandis* under Article 67quater).

3.2.2 Response from the applicant

(1) Period during which an amendment may be made

A person who has undertaken a procedure may make an amendment only while the relevant case is pending before the JPO (Article 17(1)). Thus, a person who filed an

application to register a patent term extension as compensation for the curtailment of the term may amend the application as long as it is pending before the JPO.

(2) Allowable scope of amendment

In the case where an examiner examines an application to register a patent term extension as compensation for the curtailment of the term, the most important checking point is which patent right will be subject to the patent term extension. Thus, if the matters specifying a patent right (such as the patent number) are stated in the application or a document describing the grounds for calculation of the length of the requested extension as of the time of the filing of the application, an amendment may be made to correct the application or the document describing the grounds for calculation of the length of the requested extension within the scope of information that can be obtained from those matters stated therein.

3.2.3 Examiner's decision of rejection

If an examiner finds that an application to register a patent term extension as compensation for the curtailment of the term falls under any of the items of Article 67ter (1) even after taking a written opinion, etc. into consideration, the examiner must make a decision to reject the application (Article 67ter (1)).

3.2.4 Examiner's decision of registration

If an examiner does not find any grounds to reject an application to register a patent term extension as compensation for the curtailment of the term, the examiner must make a decision to register the extension (Article 67ter (2)).

If such decision is made, the JPO will register the extension (Article 67ter (3)) and publish the following information in a patent gazette (Article 67ter (4)):

- (i) Name and domicile or residence of the patentee;
- (ii) Patent number;
- (iii) Application number and filing date of the application to register a patent term extension specified in Article 67(2);
- (iv) Registration date of the extension;
- (v) Length of the extension period;
- (vi) Application number and the filing date of the patent application; and
- (vii) Date on which a request for examination of the application was made.

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 and 65-3 Minshu 1654) and Determination of the Third Petty Bench of the Supreme Court, Nov. 17 2015 (2014 (Gyo Hi) No. 356 and 69-7 Minshu 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 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 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).

<Relevant provisions>

Patent Act

(Duration of patent rights)

Article 67

- (1) The duration of a patent right shall expire after a period of 20 years from the filing date of the patent application.
- (2) The duration of a patent right prescribed in the preceding paragraph may be extended upon the filing of a request for the registration of extension of the duration, where a patent registration is established to the application on or after the date when 5 years have passed since the date of patent application filing or the date when 3 years have passed since the date of examination request, whichever is later (hereinafter, referred to as the “reference date”).
- (3) The duration of a patent right that may be extended under the provision of the preceding paragraph shall be a period not longer than that from which the sum of a corresponding period between the reference date and the establishment date of the patent right registration and a corresponding period in accordance with each of the following items is deducted (hereinafter, referred to as “extendable period”). Where there is any overlap in the said periods, a total period of the overlap is deducted therefrom.
 - (i) Where any notification or order related to the patent application concerned is issued (made exclusively by the Commissioner or an examiner of Japan Patent Office) under the Patent Act (excluding Article 39(6) and Article 50), the Act on the Special Provisions for the Procedures related to Utility Model or Industrial Property (Act No. 30 of 1990), or the provisions in an ordinance in accordance with such acts, and where the procedure to be taken upon receiving the notification or order have actually been taken; a period between the date when the notification or order is issued and the date when the prescribed procedure is carried out.
 - (ii) Where the period when the procedures should be carried out is extended under the provisions in the Patent Act or the ordinances in accordance with the Patent Act (referred to as the “Patent Act or relevant ordinances” in the items (iii), (v) and (x) of Article 67(3)) related to the patent application concerned, a period between the date when the period is expired and the date when the procedure is actually carried out.
 - (iii) Where the period when the procedure under the Patent Act or relevant

ordinances related to the patent application concerned should be carried out is prescribed, and where the procedures can be carried out even after the expiration of the period when the procedures under the Patent Act or relevant ordinances related to the patent application concerned should be carried out by the applicant of the patent application concerned; a period between the date of expiration of the period when the procedures should have been carried out and the date when the procedures are actually carried out.

- (iv) Where the issuance of a disposition or notification under the provisions in the Patent Act, the acts related to the special provisions concerning the procedures associated with the industrial property, or the order in accordance with these acts (referred to as the “Patent Act, relevant acts, or ordinances” in the items (viii) and (ix) of Article 67) related to the patent application concerned is suspended due to the offering or action by an applicant of the patent application concerned; the period between the date when any offering or action is made by the applicant of the patent application concerned and the date when any reason for suspending the disposition or notification has ceased.
- (v) Where a decision of reduction of or exemption from the patent fee or any other fees is made, or a decision of deferment of payment due is made regarding the payment of the patent fee or any other fees for the patent application under the provisions in the Patent Act or relevant ordinances related to the patent application concerned; the period between the filing date of the request for the reduction, exemption, or deferment of payment and the date when the decision is made.
- (vi) Where withdrawal of the complement procedure for supplement of lacking parts of the specification or drawing(s) under Article 38quater (7) is made related to the patent application concerned, the period between the filing date of the complementary document(s) under Article 38quater (3) and the withdrawal date of the complementary document(s) under Article 38quater (7).
- (vii) Where a request for a trial against an examiner's decision of refusal related to the patent application concerned is made, the period prescribed in any one of the following category (a), (b), or (c):
 - (a) Where a decision is made to grant a patent under Article 51 applied mutatis mutandis to Article 159(3) (including a case where it is applied mutatis mutandis to Article 174(2)), the period between the transmittal date of a copy of a decision of refusal and the transmittal date of a copy of a trial decision.
 - (b) Where a trial decision is made for further examination on the patent application

under Article 160(1) (including a case where it is applied *mutatis mutandis* to Article 174(2)), the period between the transmittal date of a copy of a decision of refusal and the transmittal date of a copy of a trial decision.

- (c) Where a decision is made to grant a patent under Article 51 applied *mutatis mutandis* to Article 163 (3), the period between the transmittal date of a copy of decision of refusal and the transmittal date of a copy of decision to grant a patent.
- (viii) Where a final and binding court decision is made on an examination request under the Administrative Appeal Act (Act No. 68 of 2014) concerning the disposition under the Patent Act, relevant acts, or ordinances related to the patent application concerned, the period between the filing date of examination request and the transmittal date of a copy of the court decision.
- (ix) Where a decision is concluded to an action under the provision in the Administrative Case Litigation Act (Act No. 139 of 1962) concerning the disposition under the Patent Act, relevant acts, or ordinances related to the patent application concerned, the period between the date when the action is instituted and the date when the decision to the action is concluded.
- (x) Where the procedures under the provision in the Patent Act or relevant ordinances are suspended or terminated, the period of suspension or termination of the procedures related to a patent application under the Patent Act.

- (4) Where there is a period during which the patented invention is unable to be worked because approvals prescribed by relevant Acts that are intended to ensure the safety, etc. or any other disposition designated by Cabinet Order as requiring considerable time for the proper execution of the disposition in light of the purpose, procedures, etc., of such a disposition is necessary to obtain for the working of the patented invention, the duration of a patent right prescribed in Article 67(1) may be extended, upon the filing of a request for the registration of extension of the duration, by a period not exceeding 5 years. The duration prescribed in Article 67(1) is extended accordingly where the period is extended under Article 67(2). The same shall apply in the proviso to Article 67quinquies (3), Article 68bis, and Article 107(1).

(Registration of Extension of the Duration of a Patent Right)

Article 67bis

A person filing an application for the registration of extension of the duration under the paragraph (2) of the preceding Article shall submit, to the Commissioner of the

Patent Office, an application stating the following:

- (i) the name, and the domicile or residence of the applicant(s);
 - (ii) the number of the patent application;
 - (iii) the period for which the extension is requested;
 - (iv) the number and the filing date of the patent application; and
 - (v) the filing date of a request for examination of an application.
- (2) A document shall be attached to the application in the preceding paragraph, in which the basis of period calculation is stated as provided in the item (iii) of the said paragraph in accordance with the ordinance of the Ministry of Economy, Trade and Industry.
- (3) An application for the registration of extension of the duration of a patent right under the paragraph (2) of the preceding Article shall be filed before an expiration of 3 months after the date of the establishment of a patent right registration. Where the application cannot be filed within the said period due to a reason not attributable to the applicant, the application shall be filed within 14 days (where the applicant resides overseas, within two months) from the date on which the said reason has ceased. Where the total period exceeds 9 months, the application shall be filed within 9 months after the date when the establishment of a patent right registration. However, an application for the registration of extension of the duration of a patent right cannot be filed after the expiration of the duration prescribed in the paragraph (1) of the said Article.
- (4) Where a patent right is jointly owned, each patentee cannot file an application for the registration of extension of the duration under the paragraph (2) of the preceding Article unless it is a joint application.
- (5) Where an application for the registration of extension of the duration under the paragraph (2) of the preceding Article is filed, it shall be deemed that the duration under the paragraph (1) of the preceding Article is extended. However, this shall not apply to the case where the examiner's decision or trial decision to the effect that the patent application is to be refused has become final and binding, or the case where the registration of extension of the duration of a patent right is established under the paragraph (3) of the following Article.
- (6) Where an application for the registration of extension of the duration under the paragraph (2) of the preceding Article is filed, the Commissioner of the Patent Office shall publish the matters in each item of the Article 67 bis(1) in the patent gazette.

Article 67ter

Where an application for the registration of extension of the duration under Article 67(2) falls under any of the following items, the examiner shall issue a decision to the effect that a patent application is to be refused:

- (i) where the registration establishing the patent right has not been made even on the reference date or later;
 - (ii) where the period during which the extension is requested exceeds the extendable period associated with the duration of a patent right;
 - (iii) where the person who filed the application is not patentee of the application; and
 - (iv) where the application does not comply with the requirements as provided in the paragraph (4) in the preceding Article.
- (2) Where no reasons for refusal is found in an application for the registration of extension of the duration under Article 67(2), the examiner shall render an examiner's decision to the effect that the extension is to be registered.
- (3) Where the decision as provided in the preceding paragraph is made, the extension of the duration of a patent right shall be registered.
- (4) Where the registration under the preceding paragraph is made, the matters in following items shall be published in the patent gazette:
- (i) the name, and the domicile or residence of the applicant;
 - (ii) the patent number;
 - (iii) the number and filing date of an application for the registration of extension of the duration of a patent right under Article 67(2);
 - (iv) the date when the registration of extension of the duration of a patent right is established;
 - (v) the period of extension;
 - (vi) the number and filing date of the patent application; and
 - (vii) The date of the request for the examination of the patent application.

Article 67quater

The provisions in Article 47(1), Article 50, Article 52, and Article 139 (excluding the item (vii)) shall be applied mutatis mutandis to the examination of the registration of extension of the duration of a patent right under Article 67(2). In this case, “who is being appealed” in Article 139 (vi) shall be replaced with “concerning the patent application related to a patent right to which an application of the registration of extension of the duration of a patent right under Article 67(2) has been filed.”

Article 67quinquies

A person(s) filing an application for the registration of extension of the duration of a patent right under Article 67(4) shall submit a written application to the Commissioner of the Patent Office stating the following:

- (i) the name, and the domicile or residence of the applicant;
- (ii) the patent number;
- (iii) the period for which the extension is requested (not exceeding 5 years); and
- (iv) the description of the disposition designated by Cabinet Order as provided in Article 67(4).

(2) The written application under the preceding paragraph shall be accompanied by materials specifying the reason(s) for the extension, as provided by Ordinance of the Ministry of Economy, Trade and Industry.

(3) The application requesting the registration of extension of the duration of a patent right under Article 67(4) shall be filed within the time limit prescribed by Cabinet Order after the disposition prescribed by Cabinet Order under Article 67(4) is obtained; provided, however, that said written application may not be filed after the expiration of the duration as provided in Article 67(1).

(4) The provisions in Article 67bis (4), (5), and (6) shall apply mutatis mutandis to an application for the registration of extension of the duration of a patent right under Article 67(4). In this context, the “paragraph (3) of the following Article” in the proviso of Article 67bis (5) shall be deemed to be replaced with “Article 67septem (3),” and the “each item of the first paragraph” in the paragraph (6) of the said Article shall be deemed to be replaced with “each item of Article 67quinquies (1).”

Article 67sexies

Where the disposition designated by Cabinet Order under Article 67(4) is unlikely to be obtained prior to 6 months before the expiration of the duration of a patent right under Article 67(1), a person filing an application for the registration of extension of the duration of a patent right under Article 67(4) shall submit to the Commissioner of the Patent Office, on or before the time limit, a document stating the following:

- (i) the name, and domicile or residence of the person filing the application;
- (ii) the patent number; and
- (iii) the disposition designated by Cabinet Order under Article 67(4).

(2) Unless the document required to be submitted under the preceding paragraph is

submitted, an application for the registration of extension of the duration of a patent right under Article 67(4) may not be filed after 6 months before the expiration of the duration under Article 67(1).

(3) Where the document as provided in paragraph (1) is submitted, the matters prescribed in said paragraph shall be published in the patent gazette.

(4) Notwithstanding the provision in the paragraph (1), where, due to a reason beyond the control of the applicant, the applicant is unable to file the document prescribed in the paragraph (1) by the time limit as provided in the said paragraph, the applicant may file the document to the Commissioner of the Patent Office within 14 days (where the applicant resides overseas, within a month) from the date when the reason has ceased, but not later than two months after the expiration of the said time limit.

Article 67septies

(1) Where an application for the registration of extension of the duration of a patent right under Article 67(4) falls under any of the following items, the examiner shall render the examiner's decision to the effect that the application is to be refused:

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

(2) Where no reasons for refusal are found for the application for the registration of extension under Patent Act Article 67(4), the examiner shall render an examiner's decision to the effect that the extension is to be registered.

(3) Where the decision under the preceding paragraph, the extension of the duration of the patent right shall be registered.

(4) Where the registration of extension of the duration under the preceding paragraph

is made, the following matters shall be published in the patent gazette:

- (i) the name and domicile or residence of the patentee;
- (ii) the patent number;
- (iii) the number and filing date of the application for the registration of extension under Article 67(4);
- (iv) the date of the registration of extension;
- (v) the period of extension; and
- (vi) the description of the disposition designated by Cabinet Order under Article 67(4).

Article 67octies

The provision of the first sentence of Article 67quarter shall apply mutatis mutandis to examination on an application for the registration of extension of the duration of a patent right under Article 67(4). In this context, the item “(vii)” in the first sentence of Article 67quarter shall be deemed to be replaced with the items “(vi) and (vii)”.

(Effect of patent right in the case of duration extension under Article 67(4))

Article 68bis

Where the duration of a patent right under Article 67(1) is extended under the provision of Article 67(4) (including the case where the duration is deemed to have been extended under the main clause of Article 67bis (5) that is applied mutatis mutandis to Article 67quinquies (4)), such patent right shall not be effective against any act other than the working of the patented invention for the product which was the subject of the disposition designated by Cabinet Order under Article 67(4) which constituted the reason for the registration of extension (where the specific usage of the product is prescribed by the disposition, the product used for that usage).

Order for Enforcement of the Patent Act

(Dispositions which constitute reasons for registration of extension)

Article 2

The dispositions designated by Cabinet Order under Article 67(2) of the Patent Act shall be as follows.

1. Registration under Article 2(1) of the Agricultural Chemicals Regulation Law (Act No. 82 of 1948) (excluding the reregistration under paragraph (5) of the same Article), registration of change under Article 6bis(1) of the same Act (including the case of mutatis mutandis application in Article 15bis(6) of the same Act), and

registration under Article 15bis(1) of the same Act (excluding the reregistration under Article 2 (5) of the same Act as applied mutatis mutandis in paragraph (6) of the same Article).

2. Dispositions listed below:

- (i) The approval under Article 14(1) of the Law on Ensuring Quality, Efficacy and Safety of Pharmaceuticals and Medical Devices, etc." (Law No. 145 of 1960; hereinafter referred to as the "Pharmaceutical Products and Medical Devices Law") for the drug product set forth in the same paragraph, the approval under paragraph (9) of the same Article (including the case of mutatis mutandis application in Article 19bis(5) of the Pharmaceutical Products and Medical Devices Law), and the approval under Article 19bis(1) of the Pharmaceutical Products and Medical Devices Law;
- (ii) The approval under Article 23bis(5)(i) of the Pharmaceutical Products and Medical Devices Law for the in-vitro diagnostics set forth in the same paragraph, the approval under paragraph (11) of the same Article (including the case of mutatis mutandis application in Article 23bis-septies decies (v) of the Pharmaceutical Products and Medical Devices Law), and the approval under Article 23bis-septies decies (1) of the Pharmaceutical Products and Medical Devices Law;
- (iii) The authentication under Article 23bis-vicies ter(1) of the Pharmaceutical Products and Medical Devices Law for the in-vitro diagnostics set forth in the same paragraph and the authentication under paragraph (6) of the same Article;
- (iv) The approval under Article 23vicies quinquies (1) of the Pharmaceutical Products and Medical Devices Law (excluding the approval under Article 23vicies quinquies (1) of the Pharmaceutical Products and Medical Devices Law pursuant to the application under Article 23vicies sexies (5) of the Pharmaceutical Products and Medical Devices Law), the approval under Article 23vicies quinquies (9) of the Pharmaceutical Products and Medical Devices Law (including the case of mutatis mutandis application in Article 23tricies septies (5) of the Pharmaceutical Products and Medical Devices Law), and the approval under Article 23tricies septies (1) of the Pharmaceutical Products and Medical Devices Law (excluding the approval under Article 23tricies septies (1) of the Pharmaceutical Products and Medical Devices Law pursuant to the application under Article 23vicies sexies (5) of the Pharmaceutical Products and Medical Devices Law which is applied mutatis mutandis in paragraph (5) of the same

Article).

(Period for filing application for registration of extension)

Article 3

The period designated by Cabinet Order according to Article 67bis(3) of the Patent Act shall be three months; provided, however, that if the person filing an application for the registration of extension of the duration of a patent right is unable to file the application within the time limit due to reasons beyond its control, the applicant may file a patent application within 14 days (if the applicant is an overseas resident, within two months) from the date on which the reasons ceased to be applicable (if said period exceeds nine months, nine months).

Regulations under the Patent Act

(Form of the written application for application for registration of extension)

Article 38quindecies

The written application for application requesting the registration of extension of the duration of a patent right must be prepared with the Form No. 56.

(Document form)

Article 38quindecies-bis

The document according to Article 67bis(2)(i) of the Patent Act must be prepared with the Form No. 56-2.

(Document stating the reasons of extension)

Article 38sedecies

Pursuant to the provisions of Article 67bis(2) of the Patent Act, the materials which state the reasons for extension and which must be attached to the written application shall be as follows:

- (i) The materials required to demonstrate that it was necessary to obtain the disposition designated by Cabinet Order under Article 67(2) of the Patent Act in order to carry out the patented invention for the application of registration of extension;
 - (ii) The materials indicating the period during which the patented invention, which pertains to the application for registration of extension, was unable to be worked because it was necessary to obtain the disposition according to the preceding item;
- and

(iii) The materials necessary to demonstrate that the person who obtains the disposition of item (i) is an exclusive licensee or non-exclusive licensee of the patent right for the application for registration of extension, or the holder of said patent right.

(Description of the decision concerning application for registration of extension)

Article 38septies decies

With regard to the decision of an application requesting the registration of extension of the duration of a patent right, the following matters must be stated, with the examiner who rendered the decision placing his or her name and seal thereon; provided, however, that in the event of rendering the decision of refusal, the matters listed in items (iii) and (iv) do not have to be stated:

- (i) Number of the application for registration of extension;
- (ii) Patent number;
- (iii) Period of extension;
- (iv) Description of the disposition designated by Cabinet Order in Article 67(2) of the Patent Act;
- (v) Name of the applicant for registration of extension or of the agent for the applicant;
- (vi) Conclusion and reasons for the decision; and
- (vii) Date of the decision.