

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

(Applied to applications for registration of patent term extension filed on January 1, 2000 or later.)

However, 2.2 and 3.1.3 of this chapter shall be applied to applications for registration of patent term extension filed on December 31, 1999 or before, while the case is pending before the Patent Office (See the Decision of the Supreme Court in 1998 (Gyo Hi) No. 43, 44).

1. Purport of the System

1.1 Necessity

One of the purposes of the patent system lies in protecting and encouraging inventions by granting exclusive rights to inventors for a certain period in return for the disclosure of the arts pertaining to their inventions, and thus contributing to industrial development. However, problems exist in certain fields, such as pharmaceuticals, where long periods are necessarily consumed in the testing and examinations required for obtaining approvals provided under legal regulations designed for ensuring product safety, during which periods the benefit of exclusive rights cannot be enjoyed despite the validity of patent rights.

Although the legal regulations themselves are indispensable in view of their purposes, they nonetheless preclude working of the patent which otherwise could have been exploited during the period affected by said regulations. In the interest of product safety, the possibility of shortening the periods devoted to drug examinations is limited.

Such situations pose problems affecting the basis of the patent system, and a measure of extending the patent terms is therefore necessary in order to resolve the situation.

1.2 Purport

As such, an extension to the patent term by up to five years is made available through application for registration of patent term extension, if the invention could not be worked for the necessity of obtaining an approval or other disposition prescribed by Cabinet Order, such as an approval provided under legal regulations designed for ensuring product safety.

The dispositions prescribed by Cabinet Order shall be limited to those which necessarily require considerable time to be rendered properly, in view of their objectives and procedures involved.

2. Application

2.1 Applicant Eligibility

The applicant applying for registration of patent term extension is limited to the patentee concerned (Patent Act 67ter(1)(iv)). However, where a patent is owned jointly, each of the joint owners may not, except jointly with the other owners, apply for registration of patent term extension (Patent Act 67bis(4)). In addition, it is required that the patentee, exclusive licensee or registered non-exclusive licensee under the patent obtain the disposition as prescribed by Cabinet Order, referred to in Article 67(2) (Patent Act 67ter(1)(ii)).

2.2 Filing Date Requirements

The application for registration of patent term extension must be filed within a 3 month period following and including the rendered date of the disposition prescribed by Cabinet Order referred to in Patent Act Article 67(2). However, if the application could not be filed within 3 months following the rendered date of the disposition due to reason beyond control of

the applicant, the application must be filed within 14 days after the extinguishment of said reason (or within 9 months following the rendered date of the disposition, whichever period expires earlier). "The date of obtaining the disposition prescribed by Cabinet Order," means the date when an approval or a registration reaches a requester, i.e., the date when it is accepted by the requester, or it is placed in an acceptable state. (Note)

However, the application shall not be accepted after the expiration of the original patent term (Patent Act 67bis(3), Patent Act Enforcement Order Article 4).

Where it is expected that the applicant cannot obtain the disposition, as prescribed by Cabinet Order, by the day before six months prior to the expiration of the original patent term, he/she shall submit by that day a document stating the following matters (Patent Act Article 67bis-bis(1)):

- (i) the name and the domicile or residence of the person desiring the application;
- (ii) the Patent Number; and
- (iii) the disposition as prescribed by Cabinet Order referred to in Patent Act Article 67(2).

If the aforementioned document is not submitted, an application for patent term extension may not be accepted for after six months prior to the expiration of patent term.

(Note) "The date of obtaining the disposition prescribed by Cabinet Order, i.e., the date when it is accepted by the requester, or it is placed in an acceptable state." does not necessarily mean the arrival of the "written approval" or the "written registration." In cases where the applicant knows of the approval or registration before any "written approval" or "written registration" actually arrives, the date when the applicant actually knew of the approval or registration becomes the date of obtaining the disposition.

2.3 Patents Eligible for Application

A patent, whose patented invention could not be worked for the necessity of obtaining an approval or other disposition, prescribed by Cabinet Order in Patent Act Article 67(2), are eligible as a subject of application to the registration of patent term extension.

2.4 Description of Application

Those who wish to apply for registration of patent term extension shall submit to the Commissioner of the Patent Office an application stating the following matters (Patent Act Article 67bis(1), Regulations under the Patent Act Article 38quindecies):

- (i) the name and the domicile or residence of the applicant;
- (ii) the Patent Number;
- (iii) the term of the extension applied for (limited to a period not exceeding five years);
- (iv) contents of the disposition as prescribed by Cabinet Order referred to in Patent Act Article 67(2); and
- (v) the date of obtaining the disposition prescribed by Cabinet Order referred to in Patent Act Article 67(2).

For "contents of the disposition prescribed by Cabinet Order referred to in Patent Act Article 67(2)," the contents of the disposition constituting the grounds for extension, obtained by the patentee (or exclusive licensee or registered non-exclusive licensee), are stated.

More specifically, it is required to state the disposition constituting the grounds for extension (e.g., approval under the Pharmaceutical Affairs Act Article 14(1) for pharmaceuticals referred under the same), the number specifying the disposition (e.g., the approval number), the product which obtained the disposition (e.g., active ingredients and the manufacturing process of active ingredients where necessary) and use for the product if

specified in the disposition (e.g. efficacy/effect).

2.5 Description of Material Describing the Grounds for Extension

A request shall be accompanied by material describing the grounds for extension. (Patent Act Article 67bis(2)).

The material describing the grounds for extension which are to be attached to the request, are as follows (Regulations under Patent Act Article 38sedecies):

- (i) Material necessary for certifying the necessity of obtaining the disposition, prescribed by Cabinet Order referred to in Patent Act Article 67 (2) for working of the patented invention for which registration of extension is applied (Item 1);
- (ii) Material describing the period during which the patented invention for which registration of extension is applied for, could not be worked due to the necessity of obtaining the disposition referred in the previous Item (Item 2); and
- (iii) Material necessary for certifying that the person obtaining the disposition of No.1 is exclusive licensee, registered non-exclusive licensee, or patentee of the patented invention for which registration of extension is applied (Item 3).

Since all the above material are either material necessary for proving or material indicating the certification, they must include material which support their description.

For example, in a case of pharmaceuticals, the material describing the grounds for extension shall contain the following matters, and shall be accompanied by supporting material (e.g., a copy of a written approval or a notification of a trial case plan, etc., issued by the Ministry of Health, Labor and Welfare).

- (1) Material necessary to show that it was necessary to obtain a disposition prescribed by Cabinet Order for working of the patented invention, indicating:
 - (i) that the invention has been patented (date of registration, date of expiration, payment state of annual registration fee, etc.)
 - (ii) that approval under the Pharmaceutical Affairs Act has been granted (matters necessary in identifying the approval, active ingredients, efficacy/effect, manufacturing process for the active ingredients where necessary etc.)
 - (iii) that the approved active ingredients (or active ingredients and efficacy/effect) have been described in the original claim
 - (iv) that the approval is the earliest for the active ingredients or efficacy/effect
- (2) Materials expressing the period during which the patented invention could not be worked, due to the necessity of obtaining a disposition prescribed by Cabinet Order, indicating:
 - (i) circumstances leading to the approval (major facts and their dates)
 - (ii) the period during which the patented invention could not be worked
- (3) Materials necessary for proving that the person obtaining the disposition prescribed by Cabinet Order is the exclusive licensee, registered non-exclusive licensee, or patentee of the patented invention, indicating:
 - (i) that the patentee has obtained the approval, or
 - (ii) that the exclusive licensee or registered non-exclusive licensee of the patent right has obtained the approval.

2.6 Effect of Application

When an application for registration of patent term extension is filed, the patent term shall be deemed extended until the decision of refusal becomes final and conclusive, or registration of extension is made (Patent Act Article 67bis(5)).

2.7 Publication in the Patent Gazette

When an application for registration of patent term extension is filed, matters stated in Patent Act Article 67bis(1), the application number, and the application date shall be published in the Patent Gazette (Patent Act Article 67bis(6)).

Where the document provided for in Patent Act Article 67bis-bis(1) is submitted, the matters set forth under each of the paragraphs in Paragraph (1) shall be published in the Patent Gazette (Patent Act Article 67bis-bis(3)).

3.Examination

3.1 Decision of Refusal

The examiner shall make a decision of refusal, when an application for registration of patent term extension comes under any of the Conditions prescribed in the Items of Article 67ter(1) (Patent Act Article 67ter(1)).

Furthermore, before making a decision of refusal, the examiner shall issue a notification of reasons for refusal to the applicant, and designate a due period for the applicant to submit a written argument (Article 50 applied mutatis mutandis under Article 67 quater).

The reasons for refusal are explained below.

3.1.1 When it is Found that Obtaining the Disposition as Prescribed by Cabinet Order Referred to in Article 67(2) was Unnecessary for the Working of the Patented Invention (Patent Act Article 67ter(1)(i))

(1) Cases in which obtaining the disposition as prescribed by Cabinet Order are decided necessary for working of the patented invention

In view of its purpose, the essence of legal regulations such as the Pharmaceutical Affairs Act lies in regulating the manufacture and sales of particular products (or products for particular use). Therefore, the most important factor among the matters specified in the disposition is the product (or the product and its use).

As a result, if the product (or the product and its use) specified in the disposition is described in the Claims, the necessity to obtain a disposition in working the patented invention would be assumed.

Actual examination in fields such as pharmaceuticals shall be carried out by comparing the product (or the product and its use) specified in the disposition and the product defined in the Scope of Claims in the following manner:

- (i) If the claimed invention is a product (use not specified), comparison shall be made between the product and the product specified in the disposition. The use of the product will not be considered, even if it is specified in the disposition.
- (ii) If the claimed invention is a use for a product, comparison shall be made between the product and use described in the Scope of Claims, and those specified in the disposition.
- (iii) If the claimed invention is a manufacturing process of a product, comparison shall be made between the product obtained by such process and the product specified in the disposition. Comparison of manufacturing processes is not made. The use for the product will not be considered in examination as well, even if it is specified in the disposition.

When several dispositions relate to the same product (or for the same product and use if the dispositions specify the use), dispositions other than the earliest disposition are not considered necessary for working the patented invention, since the earliest disposition would be sufficient for working the product (or product for the specified use) of the patented invention.

For example, when approvals are granted to pharmaceuticals with the same active ingredient (product) and efficacy/effect (use) and differing only in manufacturing processes, dosage forms, etc., patent term extension shall be granted on basis of the earliest approval only.

(2) Where there are multiple patents corresponding to one disposition

Where there are multiple patents corresponding to one disposal, the application for the registration of an extension of the term of each of these patent rights is individually allowable, as long as there is a necessity to obtain a disposition for the working of the all of the patented inventions concerned.

For example, where there are a patent for a chemical compound which is the active ingredient of an approved pharmaceutical, a use patent for applying the said active ingredient to an approved medical use and a process patent for the manufacturing process of the said active ingredient, then patent term extension shall be registered for each patent, provided that approval is found to be necessary for the working of each patent.

(3) Where there are multiple dispositions corresponding to one patent

In a case where there are multiple dispositions corresponding to one patent right, patent term extension shall be granted on basis of each disposition, provided that the products (or the products or their uses, if the uses are specified) specified in the dispositions differ from one another.

For example, if several approvals for different active ingredients or efficacy/effect are granted against a single patent for pharmaceutical, then plural registrations of patent term extension shall be made on basis of each approval.

(Note) As for applications concerning products substantially identical with the product obtaining the disposition prescribed by Cabinet Order, refer to (4) below.

In contrast, an application for patent term extension based on a later approval of a pharmaceutical with active ingredient and efficacy/effect both identical to those specified in another earlier approval (differing only in dosage form, manufacturing process etc.) shall be refused, since obtaining of the later approval is not considered necessary in the working of the patented invention.

(4) Where a product is substantially identical with the product obtaining the approval of pharmaceuticals, etc.

If a product is substantially identical with the product obtaining the disposition prescribed by Cabinet Order, and the use of the former is similar to the use for product already specified in the earlier disposition, the obtaining of disposition for the latter product shall not be considered necessary in working the patented invention.

For example, in a case where there is a patent right in which a compound as well as its salt are claimed, and an approval has already been given to a pharmaceutical containing the sodium salt of that compound as active ingredient, an application for registration of patent term extension based on the approval of a pharmaceutical containing the potassium salt of that compound as active ingredient and with similar efficacy/effect would be refused.

(5) Use for approved products such as pharmaceuticals

When the use for a product which has obtained an disposition earlier partly overlaps the use for the same product which has received an disposition later, working of the patented invention for use not common among those specified in the two dispositions becomes possible only upon rendering of the second disposition, Therefore, obtaining of the second disposition shall be considered as having been necessary for the working of the patented invention.

For example, if an active ingredient with specified use belonging to generic concept (e.g. pharmaceutical for use against allergic rhinitis) is approved after approval of the same active ingredient with specified use belonging to specific concept (e.g. pharmaceutical for use against chronic allergic rhinitis), the second approval would be considered as having been necessary for working of the patented invention.

(6) Pharmaceutical related patents excluded from patent term extension

Patents relating to intermediates, or catalysts and manufacturing equipment used in the manufacture of final product, are excluded from patent term extension.

Acts designed for ensuring product safety such as the Pharmaceutical Affairs Act regulate the manufacture and sales of end products, but not the manufacture and sales of intermediates synthesized in the process of manufacture. Hence, obtaining of disposition is not considered necessary in working the patented invention relating to intermediates.

Patents relating to intermediates are therefore excluded from registration of extension, even if the final products are subject to disposition.

The same applies to patents relating to catalysts and manufacturing equipment, which are also excluded from patent term extension.

3.1.2 When neither Patent Owner, nor Exclusive or Registered Non-Exclusive Licensee has Obtained the Disposition Prescribed by Cabinet Order under Article 67(2) (Patent Act Article 67ter(1)(ii))

To avoid such situation, the registration of non-exclusive license need only be made by the time the decision is made to register the extension of patent term.

Also, the condition for refusal provided under Article 67ter(1)(ii) shall not apply when any person among those who have jointly obtained the disposition holds an exclusive license or registered non-exclusive license to the patent, because the fact remains unchanged that the disposition has been rendered against the patent owner or the holder of exclusive or registered non-exclusive license.

3.1.3 When the Term of Extension being Sought Exceeds the Period During which the Patented Invention could not be Worked (Patent Act Article 67ter(1)(iii))

The “period during which the patented invention could not be worked” refers to the period during which working of the invention has been precluded for reason of requirement to obtain an disposition prescribed by Cabinet Order (Patent Act Article 67(2)).

This period is calculated either from the starting date of tests meeting the conditions mentioned below and required for obtaining an disposition prescribed by Cabinet Order, or on the registration date of the patent, whichever is later, to the day before an approval or a registration has reached a requester, namely, when the requester actually accepts it or it is placed into an acceptable state (Note).

(Note) “The date of obtaining the disposition prescribed by Cabinet Order, i.e., the date when it is accepted by the requester, or it is placed in an acceptable state.” does not necessarily mean the arrival of the “written approval” or the “written registration.” In cases where the applicant knows of the approval or registration before any “written approval” or “written registration” actually arrives, the date of obtaining the disposition becomes the date when the applicant actually knew of the approval or registration.

Acts designed for ensuring product safety such as the Pharmaceutical Affairs Act provide that dispositions be rendered upon examination of data on the results of tests, and testing is

necessary to obtain the data. Hence, the “period during which the patented invention could not be worked” is defined as the period after registration of the patent, of the combined period required in performing the tests and in obtaining the disposition.

Although the periods required in performing the tests would vary according to the objectives, purposes and contents of various legal regulations, the “period during which the patented invention could not be worked” shall not include the period consumed in tests which do not satisfy the requirements 1 to 3 set out below, since the time consumed in such tests are not considered necessary in obtaining the disposition:

- 1 The examination must be indispensable for obtaining the disposition.
- 2 The degree of freedom in tests made by enterprises must be restricted for reason of requirements to conform with standards established by the authority regarding the method and contents of tests.
- 3 The examination must be closely related to the obtaining of the disposition

As a patented invention is defined as the invention pertaining to a registered patent, the “period during which the patented invention could not be worked” occurs only on registration of the patent.

Furthermore, the reason the period shall be completed on a previous day of a date when the approval or the registration reached a requester, i.e., the date when the requester actually accepts it or it is put in an acceptable state, is that the "prohibited" condition due to the legal regulation is lifted when the approval or the registration reached the requester.

In the field of pharmaceuticals, the " period during which the patented invention could not be worked" commences on the day clinical tests are started, or on the date of patent registration, whichever is later, and expires on the day before the day when the approval reached the requester, i.e., the day when it is accepted by the requester, or is placed in an acceptable state (Supreme Court Judgment in 1998 (Gyo Hi) No. 43, 44).

(Note) The period devoted to pre-clinical tests is not included in the period during which the patented invention could not be worked, because such tests take on the character of research and development on the effectiveness of the chemical substances contained in a pharmaceutical as active ingredient, and is considered to be equivalent to the product development stage in other industrial fields, and therefore could not necessarily be considered as being closely related to the obtaining a disposition.

For agricultural chemicals, the “period during which the patented invention could not be worked” means a period from the starting date of supervised field trial on efficacy wherein the name of the compound is explicitly stated, or on the date of patent registration, whichever is later, to the day previous to the date when the registration reaches a requester, namely, when it is accepted by the requester or is placed in an acceptable state.

When a requester files an application for the registration of patent term extension, he/she shall submit “a document expressing a period of the time during which the patented invention related to application of register of its extension could not be worked because of the necessity to obtain a disposition prescribed by Cabinet Order” prescribed under Regulations under Patent Act Article 38 sedecies(1)(ii).

As a document expressing the aforementioned period, for example, the following documents can be submitted with respect to the invention of the pharmaceuticals.

- 1 A copy of the written approval
- 2 In cases where the requester did not know the approval at the date of approval, a document objectively expressing the first date when a requester accepted the approval or it was placed into an acceptable state, along with the copy of the written approval.

As a document expressing the aforementioned period, for example, the following documents can be submitted with respect to the invention of the agricultural chemicals

1 A copy of the written registration

2 In cases where the requester did not know the approval at the date of approval, a document objectively expressing the first date when a requester accepted the approval or it was placed into an acceptable state, along with the copy of the written approval.

In cases where the necessity of obtaining the disposition was not admitted, the period shall not be extended, since the intention of the extension system is to solely extend the period during which the patented invention could not be worked, due the necessity to obtain a disposition prescribed by Patent Act Article 67(2).

As to the judgment of the “period of time during which the patented invention could not be worked” under the Article 67ter(1)(iii), a general arrival process of the disposition prescribed by Cabinet Order shall be taken into consideration as well as the document submitted by an applicant. As a result of considering the submitted documents and the general arrival process of the disposition prescribed by Cabinet Order, if the term for extension of an applicant is judged to exceed the period during which the patented invention could not be worked, due to the necessity of obtaining a disposition provided for in the Patent Act Article, it shall be rejected under the provisions referred to in Patent Act Article 67ter(1)(iii).

The term seeking extension is admissible so far as it does not exceed the period during which the patented invention could not be worked. The two periods need not be equal.

If the disposition prescribed by Cabinet Order is obtained before registration of the patent, the application for registration of patent term extension shall be refused on grounds of provision under Article 67ter(1)(iii), since there would exist no period during which the patented invention could not be worked.

3.1.4 When the Applicant is not the Patentee Concerned (Patent Act Article 67ter(1)(iv))

3.1.5 When the Application does not Comply with the Requirements of Article 67bis(4) (Patent Act Article 67ter(1)(v))

An application for registration of patent term extension for a jointly owned patent shall be refused unless all joint owners apply in conjunction.

3.2 Decision of Registration

The examiner shall make a decision to register the extension of patent term, if no reason of refusal is found in an application for registration of patent term extension (Patent Act Article 67ter(2)).

3.3 Publication in the Patent Gazette

The following information shall be published in the Patent Gazette when registration of patent term extension has been made (Patent Act Article 67ter(4)):

- (1) the name and the domicile or residence of the patentee;
- (2) the Patent Number;
- (3) the date of the registration of the extension;
- (4) the term of the extension; and
- (5) particulars of the disposition as prescribed by Cabinet Order referred to in Article 67(2).

3.4 Amendments

3.4.1 Period During which Amendments could be Made

Applicants for registration of patent term extension may submit amendments at any time so far as the application is pending before the Patent Office, as Patent Act provides that amendments are allowable while the case is pending before the Patent Office (Patent Act Article 17(1)).

While Article 17(1) proviso prescribes periods during which amendments can be made, this provision applies only to amendments to the specification and drawings, and not to amendments to application for registration of patent term extension.

3.4.2 Scope of Amendment Allowed

In the examination of applications for registration of patent term extension, amendments to the request or to the documents describing the grounds for extension shall be allowed, so long as the information necessary in identifying the patent and the disposition (e.g. patent number and contents of disposition) are supplied at the time of filing on the request, or in the documents describing the grounds for extension, since most importance is placed on the determination of which patent to allow an extension, and on which disposition to form the basis of the extension.