

<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 as 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(4) of the Patent Act shall be as follows.

1. Registration under Article 3(1) of the Agricultural Chemicals Regulation Law (Act No. 82 of 1948), registration of change under Article 7(1) of the same Act (including the case of mutatis mutandis application in Article 34(6) of the same Act), and registration under Article 34(1) of the same Act.



## 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 (excluding the approval based on the application under Article 14bis-bis(5) of the Pharmaceutical Products and Medical Devices Law), the approval under Article 14(15) of the Pharmaceutical Products and Medical Devices Law (including the case of mutatis mutandis application in Article 19bis(5) of the Pharmaceutical Products and Medical Devices Law) (excluding the approval based on the application under Article 14bis-bis(5) of the Pharmaceutical Products and Medical Devices Law (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 (excluding the approval based on the application under Article 14bis-bis(5) of the Pharmaceutical Products and Medical Devices Law applied mutatis mutandis to paragraph (5) of the same Article);

(ii) The approval under Article 23bis-quinquies(1) of the Pharmaceutical Products and Medical Devices Law for the in-vitro diagnostics set forth in the same paragraph (excluding the approval based on the application under Article 23bis-sexies-bis(5) of the Pharmaceutical Products and Medical Devices Law), the approval under Article 23bis-quinquies(15) (including the case of mutatis mutandis application in Article 23bis-septies decies (5) of the Pharmaceutical Products and Medical Devices Law) (excluding the approval based on the application under Article 23bis-sexies-bis(5) of the Pharmaceutical Products and Medical Devices Law (including the case of mutatis mutandis application in Article 23bis-septies decies (5) 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 (excluding the approval based on the application under Article 23bis-sexies-bis(5) of the Pharmaceutical Products and Medical Devices Law applied mutatis mutandis to paragraph (5) of the same Article);

(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 (7) of the same Article;

(iv) The approval under Article 23vicies quinquies (1) of the Pharmaceutical Products and Medical Devices Law (excluding the approval based on the application under Article 23vicies sexes (5) of the Pharmaceutical Products and Medical Devices Law (including the case of mutatis mutandis application in Article 23vicies sexes-bis (3) of the Pharmaceutical Products and Medical Devices Law)), the approval under Article 23vicies quinquies (11) 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) (excluding the approval based on the application under Article 23vicies sexes(5) 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) applied mutatis mutandis to Article 23vicies sexes-bis (3) (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 based on the application under Article 23vicies sexes (5) of the Pharmaceutical Products and Medical Devices Law (including the case of the mutatis mutandis application in Article 23vicies sexes-bis (3) of the Pharmaceutical Products and Medical Devices Law applied mutatis mutandis to Article 23tricies septies (5) of the Pharmaceutical Products and Medical Devices Law) applied mutatis mutandis to paragraph (5) of the Article 23tricies septies of the Pharmaceutical Products and Medical Devices Law).

(Period for filing application for registration of extension)

#### Article 3

The period designated by Cabinet Order according to Article 67quinquies(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.

Act on the Promotion of Ensuring National Security through Integrated Implementation of Economic Measures (Economic Security Promotion Act)

(Special Provisions on the Patent Act, etc.)

Article 82 (Omitted)

(2), (3) (Omitted)

(4) Regarding the application of the provisions of Article 67, paragraph (3) of the Patent Act when a security designation has been made, the term "the period listed in the following items" in Article 67, paragraph (3) of the Patent Act is deemed to be replaced with "the period listed in the following items and the period from the date of receipt of a notification under the provisions of Article 70, paragraph (1) of the Act on the Promotion of Ensuring National Security through Integrated Implementation of Economic Measures (Act No. 43 of 2022) through the date of receipt of a notification under Article 77, paragraph (2) of the said Act."

(5) (Omitted)