

<Relevant provisions>

Patent Act

(Registration of extension of duration)

Article 67bis

(1) A person(s) filing an application for the registration of extension of the duration of a patent right 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(2).

(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 shall be filed within the time limit prescribed by Cabinet Order after the disposition prescribed by Cabinet Order under Article 67(2) is obtained; provided, however, that said written application may not be filed after the expiration of the duration of a patent right as provided in Article 67(1).

(4) Where a patent right is jointly owned, none of the joint owners may file an application for the registration of extension of the duration of a patent right unless jointly with all the other joint owners.

(5) Where an application for the registration of extension of the duration of a patent right is filed, the duration shall be deemed to have been extended; provided, however, that this shall not apply where the examiner's decision to the effect that the application is to be refused has become final and binding or where the extension of the duration of a patent right has been registered.

(6) Where an application for the registration of extension of the duration of a patent right is filed, matters stated in paragraph (1) and the number and the filing date of the application shall be published in the patent gazette.

Article 67bis-bis

(1) Where the disposition designated by Cabinet Order under Article 67(2) 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 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(2).

(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 may not be filed after 6 months before the expiration of the duration of the patent right 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.

#### Article 67ter

(1) Where an application for the registration of extension of the duration of a patent right 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(2) 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(2);
- (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).

(2) Where no reasons for refusal are found for the application for the registration of extension of the duration of a patent right, the examiner shall render an examiner's decision to the effect that the extension is to be registered.

(3) Where the examiner's decision or trial decision to the effect that the extension of the duration of the patent right is to be registered is rendered, the extension of the duration of the patent right shall be registered.

(4) Where the registration 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 of the duration of the patent right;
- (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(2).

(Effect of patent right in the case of duration extension)

#### Article 68bis

Where the duration of a patent right is extended (including the case where the duration is deemed to have been extended under Article 67bis(5)), 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(2) 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.