

Decree No. 26/2004. (II. 26.) Korm.

on the rules necessary for the implementation of the European Community Regulations concerning the supplementary protection for certain products

By virtue of the authorization under Article 118(2) of Act XXXIII of 1995 on the Protection of Inventions by Patents (hereinafter referred to as “the Patent Act”) the Government orders as follows:

General provisions

Article 1

For the purposes of this Decree

(a) “Community Regulation” means Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products;

(b) “application” means the application for the grant of a supplementary protection certificate by virtue of the Community Regulation;

(c) “certificate” means the certificate on supplementary protection obtained on the basis of the application;

(d) “request for the extension of the duration” means the request for the extension of the duration of the certificate by virtue of the Community Regulation.

Competence of the Hungarian Intellectual Property Office

Article 2

The Hungarian Intellectual Property Office (hereinafter referred to as “the Office”) shall have authority in the following matters concerning certificates:

- (a) grant of certificates;
- (b) decision on lapse of certificates and restoration of certificates;
- (c) decision on invalidity of certificates;
- (d) decision on lack of infringement;
- (e) extension of the duration of certificates and revocation of an extension;
- (f) interpretation of certificates;
- (g) keeping the registers of applications and certificates, including matters concerning their maintenance;
- (h) official information on applications and certificates.

Procedure for the grant of certificates

Article 3

(1) The application referred to in Article 8 of the Community Regulation shall be filed with the Office.

(2) The filing date shall be the date on which the application filed with the Office contains at least:

(a) an indication that a certificate is sought with the name of the product;

(b) information identifying the applicant;

(c) the registration number of the basic patent and the title of the invention; and

(d) the number and date of the first authorization to place the product on the market, as referred to in Article 3(b) of the Community Regulation and, if this authorization is not the first authorization for placing the product on the market in the Community, the number and date of that authorization.

(3) Following the filing of an application, the Office shall examine whether the application meets the conditions laid down for according a filing date. Where the filing date cannot be accorded, the applicant shall be invited to rectify the irregularities within 30 days. If the irregularities are rectified within the specified time limit, the date of receipt of the rectification of irregularities shall be accorded as the filing date. Otherwise, the application shall be considered withdrawn.

(4) A fee, determined by special legislation, shall be paid for filing the application within two months of the filing date.

(5) Where the filing fee is not settled, the Office shall invite the applicant to rectify the irregularity within the specified time limit. In the event of failure to rectify the irregularity, the application shall be considered withdrawn.

(6) Where the application meets the conditions examined under paragraph (3), the Office shall in its official journal publish, in accordance with Article 9 of the Community Regulation, a notification of the application for a certificate and it shall record it referring to the basic patent in the patent register.

(7) Where the application meets the conditions examined under paragraph (3), the Office shall examine whether the application meets the conditions laid down in the Community Regulation, in the Patent Act and in this Decree.

(8) The examination of the Office shall also cover, in accordance with Article 3(c) and (d) of the Community Regulation, whether the product designated by the applicant has already been the subject of a certificate, and whether the authorization to place the product on the market as a basis for the certificate is considered the first authorization to place the product on the market.

(9) The application may not be modified to the effect that the certificate extends to a product, to an authorization to place a product on the market, or to a basic patent different from the ones designated at the filing of the application.

(10) If the application does not meet the conditions laid down in the Community Regulation, in the Patent Act and in this Decree, the applicant shall be invited to rectify the irregularities or to submit his comments. The application shall be rejected if it does not meet the conditions examined after rectification of irregularities or submitting comments. Failing to comply with the said invitation within the specified time limit, the application shall be considered withdrawn.

Article 4

(1) Where the application meets the conditions laid down in the Community Regulation, in the Patent Act and in this Decree, the Office shall grant a certificate for the subject of the application.

(2) The Office shall, in accordance with Article 11 of the Community Regulation, publish a notification in its official journal of the certificate has been granted and of the application rejected or considered withdrawn.

(3) The grant of a certificate shall be recorded referring to the basic patent in the patent register and entered in the register of certificates (Article 6).

Extension of the duration of the certificate

Article 4/A

(1) The request for the extension of the duration shall be filed with the Office.

(2) A fee, determined by special legislation, shall be paid for the request for the extension of the duration within two months of the filing date; the provisions of Article 3(5) shall apply *mutatis mutandis* to the payment of the fee.

(3) The Office shall give information in its official journal on the filing of the request for the extension of the duration in accordance with Article 9 of the Community Regulation.

(4) The Office shall examine the request for the extension of the duration whether it satisfies the requirements laid down in the Community Regulation, in the Patent Act and in this Decree.

(5) Where the request for the extension of the duration does not comply with the requirements examined under paragraph (4), the applicant shall be invited to rectify the irregularities or submit comments. The request shall be rejected if it does not meet the conditions examined after rectification of irregularities or submitting comments. Where the applicant does not reply to the said invitation within the specified time limit, the request shall be considered withdrawn.

Article 4/B

(1) If the request for the extension of the duration satisfies the conditions laid down in the Community Regulation, in the Patent Act and in this Decree, the Office shall extend the duration of the certificate as prescribed in Article 13(3) of the Community Regulation.

(2) If the request for the extension of the duration is filed simultaneously with the application or is submitted in the course of the procedure for the grant of the certificate, the Office shall decide on the request in its final decision on the grant of the certificate.

(3) The procedure for the extension of the duration of a certificate already granted shall be suspended until the decision on the lapse or invalidity of the certificate becomes final. If the Office establishes the lapse or invalidity of the certificate, the request for the extension of the duration shall be considered withdrawn; otherwise the procedure for the extension of the duration of the certificate shall be continued.

(4) The Office shall, in accordance with Article 11 of the Community Regulation, give information to the public in its official journal on the fact that the duration of the certificate has been extended or the request has been refused or considered withdrawn.

(5) The extension of the duration shall be recorded in the register of certificates.

Article 5

(1) In the absence of a provision of the Patent Act to the contrary, the Office may modify or withdraw its decisions – terminating the procedure – taken in the following matters only if a request for review is made and only until such request is transmitted to the court:

- (a) grant of certificates and extension of the duration of certificates;
- (b) decision on lapse of certificates and restoration of certificates;
- (c) decision on invalidity of certificates;
- (d) decision on lack of infringement;
- (e) revocation of the extension of the duration of certificates.

(2) The Office may modify or withdraw its decision – terminating the procedure – taken in the matters referred to in paragraph (1)(c) – provided the proceedings have been instituted on the grounds of Article 9 (4) – or in paragraph (d) and (e) even on the basis of a request for review only if it establishes that its decision infringes legislation or if the parties request unanimously the modification or withdrawal of the decision.

(3) In any other matters, concerning the procedure for the grant or for the extension of the duration of certificates, the general provisions governing patent procedures before the Office (Chapter VII of the Patent Act) shall apply *mutatis mutandis* with the following exceptions:

- (a) *restitutio in integrum* shall be excluded in the event of failure to comply with the time limit referred to in Article 7 of the Community Regulation;
- (b) rules of the Patent Act concerning access to files (Article 53) shall apply *mutatis mutandis* from the date of filing;
- (c) matters concerning certificates shall not be managed electronically.

Register of certificates

Article 6

(1) The Office shall keep a register of applications and certificates, which shall contain all facts and circumstances concerning certificates. The register of certificates shall contain, in particular, the following entries:

- (a) the registration number of the certificate;
- (b) the reference number of the certificate;
- (c) the title of the certificate;
- (d) the name and address of the holder of the certificate;
- (e) the name and place of business of the representative;
- (f) the registration number, title and filing date of the basic patent;
- (g) the number and date of the authorizations to place the product on the market referred to in Article 8(1)(b) and (c) of the Community Regulation and the product included therein;
- (h) the duration of the certificate, the extension of the duration and the revocation of the extension;
- (i) the date of the decision on the grant of the certificate;
- (j) the amount of the annual fees paid for and the date of payment;
- (k) the lapse of the certificate or the decision on its invalidity, the grounds and the date thereof;
- (l) the exploitation licenses.

(2) In any other matters the provisions of the Patent Act concerning the patent register (Articles 54 and 55) shall apply *mutatis mutandis* to the register of certificates.

Provisions concerning certificates

Article 7

(1) Subject to paragraph (2), the provisions of Chapters II to V of the Patent Act shall also apply *mutatis mutandis* to the rights and obligations resulting from a certificate, to exploitation licenses concerning certificates, to compulsory licenses and to the infringement of certificates.

(2) In accordance with Article 22/A(4) of the Patent Act, for the duration of the certificate an annual fee shall be paid as determined by special legislation. The annual fees which become due before the grant of the certificate shall be payable within a period of six months from the date on which the ruling on the grant comes into effect. If the last year of the duration of the certificate is an incomplete year, the annual fee shall be paid proportionately together with the total amount of the annual fee for the last complete year.

Lapse and invalidity of certificates

Article 8

(1) Article 40, Article 41(1), (2) and (4) and Article 43 of the Patent Act shall also apply to the lapse of certificates. To the date of lapse of protection Article 39(a) to (c) shall apply *mutatis mutandis*.

(2) Once the certificate declared invalid, the certificate shall lapse with retroactive effect to the filing date of the application. Should the request for declaration of the invalidity of a certificate be rejected by a final decision, a new procedure for the invalidity of the same certification on the same grounds may not be instituted by any person.

Revocation of the extension of the duration

Article 8/A

(1) Once the extension of the duration revoked, the certificate shall have effect until the period prescribed by Article 13 (1) and (2) of the Community Regulation.

(2) Should the request for revocation of the extension of the duration be rejected by a final decision, a new procedure for revocation of the extension of the duration of the same certificate on the same grounds may not be instituted by any person.

(3) The Office shall – in accordance with Article 16 (2) of the Community Regulation – publish official information in its official journal on the revocation of the extension of the duration.

Other procedures concerning certificates

Article 9

(1) The Office shall decide on the lapse of a certificate in accordance with Article 14(b) to (d) of the Community Regulation, and shall restore the certificate by virtue of Article

40 of the Patent Act. Article 79(2) of the Patent Act shall apply *mutatis mutandis* to the decision on lapse and restoration.

(2) Where the Office decides on the lapse of a certificate in accordance with Article 14(d) of the Community Regulation upon request, the holder of the certificate shall be invited to submit comments concerning the request. In such proceedings the Office shall, after written preparatory work, decide on the lapse of the certificate in accordance with Article 14(d) of the Community Regulation or on the rejection of the request.

(3) The Office may also institute proceedings *ex officio* for the establishment of invalidity of a certificate under Article 15(1)(b) of the Community Regulation and, if the basic patent is revoked, under (c) thereof.

(4) In proceedings for establishing invalidity of a certificate and in proceedings for revocation of the extension of the duration, except if the proceedings were initiated on one of the grounds specified under paragraph (3), the Office shall proceed and shall take a ruling at the hearing in the form of a board consisting of three members.

(5) Where the Office has extended the duration of an already granted certificate on the basis of the Community Regulation and Articles 4/A–4/B, it shall, simultaneously with the ruling on invalidity or lapse of the certificate, repeal the decision on the extension of the duration of the certificate.

(6) In any other matters concerning the proceedings for establishment of invalidity of the certificate and for revocation of the extension of the duration, Articles 80 to 81/A of the Patent Act shall apply *mutatis mutandis*.

(7) In proceedings instituted for the establishment of lack of infringement on a certificate Articles 82 and 83 of the Patent Act shall apply *mutatis mutandis*.

(8) In the case of a dispute concerning the interpretation of a certificate, the Office shall, at the request of the court or other authority, give an expert opinion taking the certificate, the basic patent and the authorization to place the product on the market together.

Court proceedings concerning certificates

Article 10

The provisions for court proceedings concerning patents shall apply *mutatis mutandis* to court proceedings concerning certificates.

Provisions concerning supplementary protection certificates for plant protection products

Article 11

(1) This Decree shall also apply, with the exception referred to in paragraph (2), to the application for the grant of a supplementary protection certificate in accordance with Regulation (EC) No 1610/96 of the European Parliament and of the Council concerning the creation of a supplementary protection certificate for plant protection products, and to the supplementary protection certificate obtained on the basis of such an application.

(2) The examination by the Office in accordance with Article 3(8) extends to establishing, by virtue of Article 3(1)(c) and (d) of the Community Regulation referred to in paragraph (1), whether a certificate has already been granted for the product designated by the

applicant, and if the authorization to place the product on the market, as a basis for the certificate, is considered the first authorization to place the product on the market.

Entry into force

Article 12

This Decree shall enter into force on the day of entry into force of the Act promulgating the Treaty concerning the Accession of the Republic of Hungary to the European Union.