

Patent Regulations (Extension of Protection – Procedures for Order Application, for Opposition to an order and for Application for Revocation), 5758-1998

(As Consolidated 2014)

[Prepared by WIPO]

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Pursuant to my authority under section 64E, 64M, 64P and 194(2), (11), and (13) to the Patent Law, 5727–1967 (hereafter – the Law), with the approval of the Minister of Finance under section 39B of the Basics of the Budget, 5745–1985, and with the approval of the Knesset’s Constitution, Law and Justice Committee, I hereby enact the following regulations:

Definitions

1. In these regulations –

“ Extension fee” – the fee paid in the period the extension order is in effect under section 64J of the Law.

“Application for an extension” - an application for an extension order as defined under section 64B of the Law;

“material”, “Basic Patent”, “Pharmaceutical product” – as defined under section 64A of the Law;

“Applicant” – a person who applies for an extension

“claim” - as defined under section 13(a) of the Law;

“Patent Regulations on Office Procedures” – Patent Regulations (Application of the Patent Cooperation treaty), 5756–1996.

Application to grant an extension order

2. (a) An extension application shall be submitted to the Registrar, in writing, on the date prescribed under section 64P of the Law, and it shall specify the follow:

(1) The name of the applicant

- (2) The names registered in the patent register as the owners of the basic patent, if applicable;
 - (3) The details of registration for the pharmaceutical product in the products register, as said in section 64D(2) and (3) of the Law (Hereafter – the registration in the products register), including the registration number, the name of the pharmaceutical product, the material's generic name, the material's formula, and the dates of registration and submission of the registration application (day, month, year);
 - (4) The basic patent number, the claim number in the basic patent in which the pharmaceutical product is claimed, the material, its' manufacturing process or usage;
 - (5) The member states which allow actions for the purpose of obtaining a license in the patent period, and at which applications for a patent corresponding to the basic patent were filed, and if the aforesaid extension was granted –The period of extension (beginning and end dates);
 - (6) The date at which the first license in one of the member states was granted, as defined in section 64J, for the material, its' manufacturing process, its' usage or for the product which contains it, the name of the member state and the name of the pharmaceutical product or the material as registered in that state.
- (b) The following shall be attached to the extension application:
- (1) a copy of the certificate of registration in the product register.
 - (2) an approval of extension or a copy of an extension application (without stubs), pursuant to subregulation (a)(5);
 - (3) A certified copy of the first licensing document, as said under subregulation (a)(6), per the required details;
 - (4) An affidavit specifying the following:
 - (a) that the basic patent is registered in the register;
 - (b) the rights of others registered in the register for the basic patent;
 - (c) As per the date of the first registration of the product in the products register – the date of submission of application for registration, the registration number, the date of registration, the composition of the product, and if registration was requested for Israel only – any additional information attesting to the fact that the submission of the application and the treatment thereof were performed in good faith and with the appropriate expediency;
 - (d) If another product containing the same material is registered – the date of the first registration and the registration number;
 - (e) If an extension order has already been given for the basic patent or for the material;

- (f) Any submitted extension applications, the status of application and if an extension was granted – the period of extension (beginning and end dates) and the date at which any extension granted expires;
 - (5) certification of payment of fees;
 - (6) If the application is submitted via a proxy – power of attorney.
- (c) Where an extension application has been submitted, the Registrar shall certify for the applicant, as soon as possible, the fact thereof and the date of submission, which will be the day it was first submitted.
- (d) Where a defect or deficiency was found in the extension application, the Registrar shall notify the application to that effect, and the applicant shall complete the missing particular or correct the defect within two months from the date of notification.

Opposition to an extension order

3. (a) Opposition to an extension order shall be submitted vis-à-vis written notice to the registrar, in the date prescribed under section 64E of the Law; the notification shall include a statement of claims, specifying cause of opposition, as said under section 64G of the Law and the claims of the opponent, accompanied by evidence thereto and a receipt for the payment of opposition fee, as prescribed in the Schedule.
- (b) The statement of claims for the party petitioning to grant and extension order, accompanied by evidence thereto, shall be submitted within 3 months from the submission of the opposition notice. Where it had not be been submitted, the applicant shall be deemed as if he had admitted to the facts claimed to by the opponent and had agreed to grant the relief sought.
- (c) Evidence in response to facts explicitly denied by applicant or which had were brought up for the first time in the applicant's evidence, shall be submitted within 60 days from the date the applicant's evidence was submitted, if the opponent found use in submitting evidence in response.
- (d) the provisions of the fourth part of the Patent Regulation on Office Procedures shall apply on opposition to grant an extension order, excluding regulations 57 to 62 and 66.

Application to revoke an extension order

4. Regulation 3 shall apply, mutatis mutandis, regarding an application to revoke an extension order.

Notice to the fact of a change of registration in the products register

5. Where the registration in the products register was changed, revoked or renewed, a notice to the effect shall be provided to the Registrar by was granted with the extension order, within 30 days after becoming aware of the change, revocation or renewal as aforesaid. The notice shall be accompanied by an updated copy of the registration certificate of the products register.

Additional documents and details

6. The Registrar may, at any stage of processing the extension application, of an opposition to an extension order, or of an application to revoke an extension order, demand from the applicant and any party to the proceeding of opposition or revocation thereof, any document which he deems necessary for reaching a decision regarding the application for extension, opposition or revocation of the extension application.

Fees

7. (a) Extension fees shall be paid during the three months prior to the following dates:
 - (1) Six months before the end of the basic patent term;
 - (2) Six months before the end of any yearly extension.
- (b) The amounts of the fees are as detailed in the Schedule
- (c) The amounts in the Schedule shall follow the index and change the 1st of January of each year (Hereafter – the day of change), according to the rate of change of the new index over the base index. For this purpose –
 - “Index” – the Consumer Price Index published by the Central Bureau of Statistics;
 - “New Index” – the Index published in the month of November preceding the date of change;
 - “Base Index” – the Index published in the month of November preceding the date of the previous change; With regards to the first day of change after the date of effect for the Patent Regulations (Extension of Protection – Procedures for Order Application, for Opposition to an order and for Application for Revocation) (amendment), 5774–2013, the index published in the November of 2012.
- (d) an amount changed as said in subregulation (c) shall be rounded –
 - (1) if higher than 10NIS – to the closest whole shekel, and amount of a half a shekel shall be rounded up;
 - (2) if lower than 10NIS – to the closest 10 agorot.

(e) The Director General of the Ministry of Justice shall publish in the Reshumot the version of the second schedule as changed in following the aforesaid in this regulation.

Schedules
(Regulation 3 and 7(b))
Application fee and Extension Fees

(1)	Application fee (Regulation 2(b)(5))	1,099
(2)	Extension fee (Regulation 7(a)(1))	2,954
(3)	Extension fee (Regulation 7(a)(2))	
	(a) Before the end of the first year's extension	3,545
	(b) Before the end of the second year's extension	4,254
	(c) Before the end of the third year's extension	5,104
	(d) Before the end of the fourth year's extension	6,125
(4)	Opposition fee (Regulation 3(a))	The prescribed fee for the purpose of section 30 of the Law in item 11 of the second Schedule in the Patent Regulations on Office Procedures
(5)	Application for revocation (Regulation 4)	Twice the fee aforementioned in item (3)

12th of Sivan, 5758 (June 24th, 1998)

Tzachi Hanegbi
Minister of Justice