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סימנכם	סימננו	תאריך
Your Ref.	Our Ref.	Date
		March 2009

To Whom It May Concern:

Patent Term Extensions in Israel

We refer to our previous advice regarding Patent Term Extensions in Israel.

As some Amendments to the law and to the regulations have occurred, we are advising herewith the updated status.

1. The term for Patent Protection in Israel is twenty years.

   Under Israeli Law, certain pharmaceutical-related Patents and medical device Patents which require regulatory approval as a condition for marketing the device, are eligible for Patent Extension. The term of extension is available for a period of up to five years at most.

2. The extension of Patent Term is designed to compensate Patent Owners for-

   a. The delay in the exploitation of Inventions due to the time lapse until their Owners obtain regulatory approval for their patented products and processes;
   b. The fact that an experimental-use exemption is available under Law to competitors experimenting with the pharmaceutical/medical device Inventions during the term of the Patent.

Here is an overview of the key provisions in the Israeli Patent Law regarding Patent Extensions:

A. What Patented Inventions are Eligible for Patent Extension under Israeli Law

3. Patent Extensions may be sought for patents protecting one or more of the following-

   a. A Product - i.e. the active ingredient in a pharmaceutical preparation, as well as salts, esters, hydrates or crystalline forms of said ingredient;
   b. A Process - for the manufacture of said Product;
   c. The Use of said Product;
   d. Pharmaceutical Preparations containing the Product – i.e. any form of processed medicinal drugs, including preparations for veterinary use and preparations of nutritional value for intravenous injection;
   e. Processes for Manufacturing said Pharmaceutical Preparations;
   f. Medical Devices – provided that these devices are subject under Israeli Law to regulatory approval for marketing.

   For the sake of convenience, we shall refer to these six Product/Process categories as "**the Product/Process**".

B. What are the Substantive Conditions for a Grant of Patent Extensions

4. The conditions for granting a Patent Extension by the Israeli Patent Office are:

   a. The Registrar is satisfied that the Application for Extension was filed in good faith;
   b. The Product/Process in question is claimed in the Patent for which extension is sought (This Patent shall be referred to as "the Basic Patent") and that the Basic Patent is in force;
   c. If the Patent is sought for a Pharmaceutical Preparation – that the preparation is registered at the Ministry of Health (hereinafter: "Regulatory Approval");
   d. That said Regulatory Approval is the first approval allowing the use of the Product for pharmaceutical use;
   e. No previous Patent Extensions were granted for the Basic Patent or in respect of the Product;
   f. Special Provision for Reference US Patents - that regulatory approval was granted in the US in respect of the Pharmaceutical Preparation or the Medical Device covered in the US Reference Patent[1] – if a Patent Extension was granted in the US for said Reference Patent in respect of the Pharmaceutical Preparation/Medical Device;
   g. Special Provision for Reference Patents in certain other countries – that regulatory approval was granted one of the following 15 countries in respect of the Pharmaceutical Preparation or the Medical Device covered in a Reference Patent for that country – if a Patent Extension was granted in that country for said Reference Patent in respect of the Pharmaceutical Preparation/Medical Device
      These 15 countries are: *Austria, Italy, Ireland, Belgium, England, Germany, Denmark, the Netherlands, Greece, Luxemburg, Spain, Portugal, Finland, France, Sweden;*
   h. That the Application is filed in good faith.

. . . / 3

[1] A "Reference Patent" means a Patent claiming the Products/Process mentioned in Section 3a-3f above which are claimed in the Basic Patent, irrespective of whether said Reference Patent is identical to the Basic Patent.

C. What is the Maximum Term of Patent Extension and When do Patent Extensions Expire

5. The maximum Term of Extension is five years following the term of protection of the Basic Patent (i.e. up to a total of 25 years), subject however to the following limitations –

   a. The overall Term of Protection (under the Basic Term and the extension combined) shall not exceed 14 (fourteen) years from the Date of Grant of first regulatory approval for the Product/Process in one of the following 21 countries:
      Australia, USA, Iceland, Japan, Norway, Switzerland, Austria, Italy, Ireland, Belgium, England, Germany, Denmark, the Netherlands, Greece, Luxemburg, Spain, Portugal, Finland, France, Sweden;
   b. The Patent Extension in Israel shall not exceed the expiration date of the earliest expired Reference Patent for which Patent Extension was granted in one of the 21 countries mentioned in subsection (a) above;
   c. If regulatory approval for the patented Invention was sought in Israel only (i.e. no Patent Extensions were filed elsewhere), the Patent Extension shall be equal to the time lapsed while Regulatory Approval was pending in Israel (i.e. from the Filing Date of the Petition for Regulatory Approval until Regulatory Approval was granted), all provided that the Applicant acted with the appropriate urgency in filing and handling the Regulatory Approval process *bona fide*.

6. The Patent Extension shall expire in Israel, at the earliest occurrence of the following –

   a. Immediate expiration upon the earliest expiry of a Reference Patent which was extended in one of the 21 countries mentioned in subsection 5(a) above;
   b. Immediate expiration upon the expiration of the Regulatory Approval for the Pharmaceutical Preparation containing the Product at the Ministry of Health[2];
   c. If the Basic Patent is invalidated or otherwise amended to exclude protection for the Product/Process;
   d. Failure to pay Official Fees.

D. When Should the Application for Patent Extension be Filed to the Patent Office

7. The Application must be filed to the Israeli Patent Office within ninety days after Regulatory Approval in Israel (the Date of Grant of the Approval for the Pharmaceutical Preparation at the Ministry of Health).

8. This term is non-extendible, except in exceptional circumstances where the Registrar of Patents is persuaded that the Application was filed late due to circumstances that were beyond the control of the Applicant and its Patent Attorney and could not be avoided.

E. Challenges to Patent Extensions

9. After the Registrar examines and issues a Notice of Allowance for an Application for Patent Extension, the Allowance and the Term of Extension are published for Oppositions in the Official Gazette.

. . . / 4

[2] The Applicant is under duty to inform the Patent Office within 30 days of the expiration of Regulatory Approval - in due course.

The decision to extend can be challenged by third parties in one of two ways:

a. Challenging prior to the Grant of the Patent Extension (by way of pre-grant Opposition Proceedings) – within three months of Publication;
b. Challenging after the Grant of the Extension at any time (by way of Revocation Proceedings) – at any time thereafter.

In such a case, the Opposition/Revocation Proceedings are litigated before the Registrar of Patents.

F. Who May File the Application for a Patent Extension

10. The Application can be filed by the Patent Owner or by its Exclusive Licensee.

G. Information and Documents Required for Filing an Application for Patent Extension

11. Information needed: The Application for Patent Extension should specify the following –

a. Applicant's name;
b. Names of other Rights Holders in the Basic Patent that are recorded in the Patent Registry (e.g. an Exclusive Licensee and other Licenses, Holders of Liens etc);
c. Details of the Pharmaceutical Preparation (for which Regulatory Approval was granted) as recorded at the Ministry of Health, including –

    i. Serial Number of the Registration;
    ii. Name of the pharmaceutical preparation;
    iii. Generic name of the Product;
    iv. Formula of the Product;
    v. Filing Date of the Petition for Regulatory Approval and the date of the Grant of said Approval.

d. The number of the Basic Patent in the Patent Registry;
e. The Claim numbers in the Basic Patent claiming the Product/Process;
f. A list of those of the 21 countries where Applications for Patent Extensions were filed in respect of the Reference Patents;
g. A list of those countries mentioned in sub-section (f) where Patent Extensions were granted and details of the Extension (starting date, ending date);
h. In respect of the first Regulatory Approval granted for marketing the Product/Process the following details are needed –

    i. Date of Approval;
    ii. Name of country (should be from one of the 21 countries mentioned above);
    iii. Name of Product or Pharmaceutical Preparation as approved in that Country.

12. Documents Needed:
    a. Copy of the Certificate of the Regulatory Approval issued by the Israeli Ministry of Health;
    b. Copies of Applications for Patent Extension in all countries referred to in Section 11(f) above [Annexes not required];
    c. Copies of Certificates of Patent Extensions from all countries referred to in Section 11(g) above;
    d. A certified copy of the first Regulatory Approval Certificate in the country mentioned in Section 11(h) above;
    e. Certificate of Payment of the Official Fee;
    f. Copy of Power of Attorney.

13. Affidavit Required in support of the Application: the Application should be supported by a sworn Affidavit specifying the following:

    a. That the Basic Patent appears in the Israeli Patent Registry;
    b. What other Rights Holders (if any) are recorded in the Registry in respect of the Basic Patent;
    c. Regarding the Regulatory Approval in Israel–

        i. The Filing Date of the Petition for Regulatory Approval (Registration Certificate) at the Israeli Ministry of Health;
        ii. The serial number of the Registration Certificate;
        iii. The Date of Grant of the Approval;
        iv. The composition of the Preparation;
        v. Special Provision where Regulatory Approval was sought in Israel only - all additional information certifying that the Application and its handling were made *bona fide* and with the appropriate urgency;
        vi. If another preparation comprising the same Product was granted Regulatory Approval, specify the date of the first Approval and the serial number of the first Registration;
        vii. If other Patent Extensions were granted in Israel in respect of the Basic Patent or in respect of the Product, specify the term of the Patent Extension (date of the beginning and ending date) and the date on which the Patent Extension will expire;
        viii. If other Applications for Patent Extension are pending, specify their status.

14. Omissions and faults in the Application for Extension - may be corrected within two months after the Patent Office gives Notice of such a fault

H. Miscellaneous Provisions

15. Publication of Filing – The Registrar publishes a Notice in the Official Gazette regarding the filing of Patent Extensions.

16. Payment of Patent Extension Fees – are paid 6 months prior to the expiration of the Basic Patent and then annually during each extended year within the time prescribed.

Please do not hesitate to contact us should you require further assistance and/or clarification.

Yours very truly,

DR. YITZHAK HESS & PARTNERS