DANISH PATENT AND TRADEMARK OFFICE

Application for grant of a Supplementary Protection Certificate for a Medicinal Product

Danish Patent
and Trademark Office

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Ministry of Industry, Business
and Financial Affairs

Please consult the Guide for filling in the Application for grant of a Supplementary Protection Certificate for a Medical Product.

1. Your reference:

2. Applicant details (full name and address): ☐ Additional applicants on reverse page
(Applicant(s)=proprietor(s) of the basic patent)

CVR number: P number: E-mail:
Tel. (residence): Tel. (work): Mobile:

3. Representative (name, address and CVR number, if any):

Tel.: Fax:

4. a) The product you want to protect:

b) Trade name:

5. Basic patent:
a) Number:
b) Title of the invention:

6. First marketing authorization for the product as a medicinal product in Denmark:

a) Number: b) Date:

c) This marketing authorization is the first within the Community: ☐ Yes (do not fill in box 7) ☐ No (fill in box 7)

d) Identification of the product according to this marketing authorization: ☐ Stated on reverse page

7. First marketing authorization for the product as a medicinal product in the Community:

a) Number: b) Date:

c) Identification of the product according to this marketing authorization: ☐ Stated on reverse page

d) Legal provision under which the authorization took place: ☐ Stated on reverse page

10. ☐ The application has previously been filed by fax on:

11. Date and signature:

8. Fees:

☐ Application fee

9. Enclosed documents:

☐ Copy of the first marketing authorization in Denmark (including summary of pro duct characteristics)

☐ Copy of the notice publishing the authorization in another Community member state in the appropriate official publication

☐ Translation of this

☐ Power of Attorney

☐ Information regarding how the product is protected by the basic patent

☐ Information on the identity of the product

12.

☐ Processing in English of the application etc. is requested

Application continued:

Applicant details (full name and address):

CVR number:	P number:	E-mail:
Tel. (residence):	Tel. (work):	Mobile:

Applicant details (full name and address):

CVR number:	P number:	E-mail:
Tel. (residence):	Tel. (work):	Mobile:

6. a) First marketing authorization for the product as a medicinal product in Denmark (continued):

6. d) Identification of the product according to this marketing authorization:

7. a) First marketing authorization for the product as a medicinal product in the Community (continued):

7. c) Identification of the product according to this marketing authorization:

7. d) Legal provision under which the authorization took place:

Guide for filling in "Application for grant of a Supplementary Protection Certificate"

The numbering below corresponds to the numbers on the application form.

1. This box is for your own reference.

2. Only the proprietor (or proprietors if more than one) of the basic patent can apply for a certificate. If the basic patent has more than one proprietor, please state all of them in this box. In the event that one of the proprietors of the basic patent is entitled to receive correspondence on behalf of all proprietors, please indicate this by underlining the name in question. You may also appoint a representative (please see 3). For practical reasons, please check whether the register information of the basic patent is (still) correct.

3. If someone else is representing you during the processing of the application, you must provide the name and address of this representative. Power of Attorney must be enclosed; a form can be obtained from the DKPTO.

4. a) In this box you shall state the product you want to protect i.e. the active ingredient or a combination of active ingredients of the medicinal product.
b) In this box you must state the name, under which the medicinal product is sold, i.e. the trade name.

5. In this box you shall state the Danish patent (or the European patent valid in Denmark) on which the application is based. As mentioned in 2, the applicant must be the proprietor of the basic patent. The active ingredient or a combination of active ingredients for which the certificate is applied must be protected by the patent. The selection of a basic patent is final; it cannot be replaced after filing of the application.

In b) you shall state the title of the invention of the basic patent. You will find the title in the basic patent or in the patent register.

6. State the first marketing authorization to place the product on the market as a medicinal product in Denmark. It is of no importance to whom the authorization has been granted, e.g. a licensee. The date of the first marketing authorization in Denmark is decisive for the time limit for filing an application for a Supplementary Protection Certificate. You shall enclose a copy of this marketing authorization when filing the application for a certificate. (Please see 9).

In b) you must specify the date of the marketing authorization. If the marketing authorization is issued by EMA (European Medicine Agency), the Notification-date is specified.

In c) you shall tick the relevant box indicating whether the first marketing authorization in Denmark was the first in the Community.

In d) you shall state which product the market authorization covers. The identification shall be in such a way that it can be proved that the marketing authorization in Denmark covers the same product (active ingredient or a combination of active ingredients) as the product covered by the basic patent.

7. You shall only fill in this box if the marketing authorization in Denmark (please see 6) is not the first marketing authorization in the Community. If that is the case, you shall state the number and date of the first marketing authorization in the Community. Following the EEA agreement, authorizations in an EFTA country (Norway, Iceland, Liechtenstein), are equal to an authorization in a country within the EU. Together these countries constitute the EEA area. A first authorization in Switzerland, which is effective in Liechtenstein, may count as the first authorization to place the product on the market as a medicinal product in the Community. Again it is of no importance to whom the authorization is granted.
The date for the first authorization in the Community is decisive for the duration of the certificate. Marketing authorization from another Community member states does not have to be granted pursuant to directive 65/65 (EEC) or directive 81/851 (EEC). The authorization might be granted before the country in question became a member of the Community.

You shall enclose a copy of the notice publishing the marketing authorization in another Community member state in the appropriate official publication. Please state the number and date as it appears in the official publication, in box a) and b).

In c) you shall state the product covered by the marketing authorization from another Community member state. The identification shall be in such a way that it can be proved that the authorization covers the same product (active ingredient or a combination of active ingredients) as the product covered by the basic patent
(5) and by the first marketing authorization in Denmark (6).

In d) you shall state the legal provision in the country in question under which the marketing authorization was granted.

8. The application fee shall be paid when filing the application. Refund of fees is not possible. This also applies if you withdraw the application or, for other reasons, the application is not granted. The fee appears from our price list.

9. Please refer to the notes concerning 3, 6 and 7.

The first marketing authorization in Denmark:
You shall forward a copy of the signed document (including summary of product characteristics).

Information showing that the product is protected by the basic patent:
We recommend that you by stating the claim, page, paragraph, substituent significance, sequences etc, identify the relevant passages showing that the product is protected by the basic patent (optional).

Information on the identity of the product:
You shall include information identifying the product, when filing the application (e.g. structural formula).

Marketing authorization from another Community member state:
You shall enclose a copy of the notice publishing the marketing authorization in another community member state in the appropriate official publication. If this is not in Danish, Swedish, Norwegian or English, the DKPTO might request a Danish translation of the notice publishing the authorization.

Power of Attorney:
Under certain circumstances the DKPTO may request Power of Attorney enclosed to the application.

10. If you previously sent the application by fax, please tick the box.

11. The application must be signed by the applicant (or applicants if more than one). In the event that the applicant is an enterprise, the signature must be accompanied by the enterprise’s stamp.
If a representative has been appointed, the representative is entitled to sign on behalf of the applicant.

12. Please tick this box if you wish the processing of the application and the correspondence to be in English.
If English is not selected, the processing will be in Danish.

Please contact us if you have any further questions on telephone 43 50 83 01.