The Danish Patent Office Order No. 77 of 30 January 1997

Order Concerning Patents and Supplementary Protection Certificates

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Pursuant to sections 5 (2), 6 (1), 2nd clause, 6 (2), 8 *a*, 9, 34, 45 (2), 48 (3), 69, 90, 91 and 97 of the Danish Patents Act, cf. Consolidated Act No. 824 of 13 September 1996, and by order under section 1 of the Ministry of Industry Order No. 416 of 27 May 1992, it is laid down that:

CHAPTER I
PATENT APPLICATIONS

Part 1
Scope

1. Unless otherwise provided, the provisions relating to patent applications shall only apply to:

(i) Danish patent applications,

(ii) international applications proceeded with under section 31 of the Patents Act, or taken up for examination and other processing under section 38 of the Patents Act, and

(iii) European patent applications converted into Danish patent applications under section 88 of the Patents Act.

Part 2
Filing and Recording of Applications

2.—(1) Danish patent applications shall be filed with the Patent Office.

(2) International applications designating Denmark shall be filed with an authority or an international organisation being the prescribed receiving Office under the Patent Cooperation Treaty. Provisions relating to the Patent Office as receiving Office are found in sections 99 to 103 of this Order.

(3) European patent applications designating Denmark shall be filed with an authority or a European organisation being the prescribed receiving Office under the European Patent Convention. Provisions relating to receipt by the Patent Office of European patent applications are found in sections 108 to 109 of this Order.

3.—(1) A Danish patent application shall be made in writing. The application shall be filed with the Patent Office in the number of copies prescribed by the Office. The application form shall be provided free of charge by the Patent Office.

(2) The application shall be signed by the applicant or his agent and shall indicate:

(i) the applicant's name or firm name, mailing address and, if the applicant is not represented by an agent, his telephone and fax number, if any, and, if the applicant is represented by an agent, the latter's name or firm name, mailing address and telephone and fax number, if any,

(ii) the inventor's name and mailing address,

(iii) a brief and factual title of the claimed invention,

(iv) if a patent is applied for by several applicants jointly, and these are not represented by an agent, whether one of the applicants shall be authorised to receive communications from the Patent Authority on behalf of all the applicants,

(v) whether the application comprises the deposit of a culture of a micro-organism as referred to in section 8*a* (1) of the Patents Act, information hereof, and

(vi) the documents accompanying the application.

(3) The documents accompanying the application shall include:

(i) a description of the invention, including drawings or photos if required for the understanding of the invention, and a sequence list, if required, cf. section 18 of this Order, patent claims and an abstract,

(ii) if the applicant is represented by an agent, a power of attorney for the agent unless a power of attorney is given separately in the application, and

(iii) if the patent is applied for by someone other than the inventor, documentary evidence of the applicant's title.

(4) The Patent Authority may grant exemption from the requirement to provide a written power of attorney.

(5) The prescribed application fee shall accompany the application.

4.—(1) If the applicant wishes the search referred to in section 9 of the Patents Act, a written request to that effect shall be made not later than 3 months from the date of filing of the application or from the date on which the application shall be deemed to have been filed, cf. section 37 of this Order.

5. The Patent Authority shall mark the application with the date on which it was filed.

6.—(1) The Patent Office shall keep a record of patent applications filed.

(2) In the record, the following data shall be entered:

(i) the number of the application,

(ii) the classes of the application according to the international patent classification system,

(iii) the applicant's name or firm name and mailing address,

(iv) if the applicant is represented by an agent, the name or firm name and mailing address of the agent,

(v) the inventor's name and mailing address,

(vi) the title of the invention,

(vii)*a)* if the application is a Danish patent application, the date of filing of the application and the effective date of the application if different from the date of filing,

(vii)*b)* If the application is an international application, the international date of filing and the date on which the application was proceeded with under section 31 of the Patents Act or is deemed to have been filed under section 38 (3) of the Patents Act, and the number of the international application,

(vii)*c)* if the application is a converted European patent application, the number of the European patent application, its date of filing under the European Patent Convention and the date on which the European patent application was converted into a Danish patent application,

(viii) if priority is claimed under section 6 of the Patents Act where the application serving as a basis for claiming a right of priority has been filed and the date of filing and number of such application,

(ix) if the application is made on the basis of division or excision, the number of the patent application,

(x) If the application comprises the deposit of a culture of a micro-organism, information to that effect and concerning the institution at which the culture has been deposited and the number which the deposited culture has been accorded by the institution,

(xi) where new applications result from diversion or excision from the application, information to that effect and indication of the numbers of those applications,

(xii) if the application has been made available to the public under section 22 (3) of the Patents Act, the date thereof,

(xiii) where a utility model application results from the patent application under section 6 of the Utility Models Act, information to that effect and the number of the utility model application,

(xiv) Communications received and fees paid in respect of the application, and

(xv) notifications and communications sent in respect of the application.

(3) The record shall be available to the public when the application has been made available to the public. However, the Patent Office may decide that some of the data referred to in subsection 2 hereof shall be available to the public before the said date.

7. The Patent Office may advertise information on the applications referred to in section 6 of this Order. If so, such advertisement shall contain the information stated in section 6 (2), (i) and (iii) to (ix) of this Order.

Part 3
Drawing Up of Applications

8.—(1) Description, drawings, photos, patent claims and abstract shall be in the Danish language. Other documents may be in Danish, Norwegian or Swedish.

(2) If a document is drawn up in any other language than those prescribed in subsection 1 hereof, a translation shall be filed. If the description, drawings, photos and patent claims at the filing of the application are in a language other than Danish, Norwegian or Swedish, the Patent Office may, however, abstain from requiring a translation of the parts thereof which are not part of the basis documents, cf. 24 (2) of this Order. The Patent Office may also abstain from requiring a translation of documents other than the description, drawings, photos, patent claims and abstract, or accept a translation of such other documents into a language other than those mentioned in subsection 1 of this section. The Patent Office may require that the translation be certified by a translator or in another manner approved by the Patent Office.

(3) A search and examination of patentability may be undertaken for an application on the basis of description, patent claims and abstract in Norwegian or Swedish. In special cases, a search and examination of patentability may be undertaken in respect of an application based on a description, claims and abstract in English, if the applicant so requests in writing and pays the prescribed fee. In either case the Patent Office shall not demand the translation referred to in subsection 2 hereof until the applicant has received a reply to the search.

9.—(1) The description, patent claims, drawings, photos and abstract shall be presented in a form suitable for reproduction.

(2) These documents and amendments to them shall be filed in the number of copies and in the physical form prescribed by the Patent Office.

Part 4
Priority

10.—(1) In order to obtain priority under section 6 of the Patents Act, the applicant shall submit a claim to that effect in writing within 3 months of the filing of the application in this country or from the date on which the application shall be deemed to have been filed, cf. however subsection 2 hereof. The claim shall also state where the application whose priority is claimed was filed, its date of filing and, if it is an international application, at least one of the designated States. For a Danish patent application, the applicant shall also state the number of the application whose priority is claimed as soon as possible.

(2) For international patent applications, priority shall be claimed at the same time as the filing of the application. The claim shall state where the application whose priority is claimed was filed, its date of filing and, if it is an international application, at least one of the designated States. The applicant shall state the number of the application whose priority is claimed to the receiving Office in question or to the International Bureau of the World Intellectual Property Organisation within 16 months from the priority date.

(3) If an application is divided under section 27 of this Order, the priority claim for the parent application shall apply, without any separate claim for priority, to new applications resulting from the division.

(4) If priority is claimed after the filing of the application, this shall take place by separate letter. Withdrawal of a priority shall be effected by separate letter.

§ 10 a. The provision in section 6 (1), 1st clause, of the Patents Act shall similarly be applicable for applications filed in a state which has ratified or has acceded to the Agreement on the Establishment of the World Trade Organisation (WTO).

11.—(1) An applicant who has claimed priority shall, within 16 months from the priority date, file with the Patent Authority a certificate from the authority which received the original application, stating its date of filing and the applicant's name, as well as a copy of the application certified by the same authority. For international applications, a copy of the application whose priority is claimed shall instead be filed in accordance with Rule 17 (1) of the Regulations under the Patent Cooperation Treaty, to the International Bureau referred to in section 10 of this Order, to the receiving Office, or a request shall be made to transfer it to the International Bureau according to the same rule.

(2) The Patent Authority may provide for exemption from the obligation to file the documentation referred to in subsection 1, 1st clause, hereof.

(3) If the applicant fails to file the said documentation in due time, the applicant's right of priority shall lapse.

(4) If a copy of the application whose priority is claimed has been filed in connection with an international application with the International Bureau referred to in section 10 of this Order, the Patent Authority may only require a copy and a translation of such copy in accordance with Rule 17 (2) of the Regulations under the Patent Cooperation Treaty.

12.—(1) For an application to be capable of serving as a basis for priority under section 10 of this Order, it shall be the first application in which the invention is disclosed.

(2) If the person who filed the first application or his successor in title has filed a subsequent application relating to the same invention with the same authority, the subsequent application may be claimed as a basis for priority provided that, at the time of the filing of the subsequent application, the first application has been withdrawn, shelved or refused without having been made available to the public and without leaving any rights outstanding or having served as a basis for claiming a right of priority. If priority has been obtained on the basis of such subsequent application, the previous application may no longer serve as a basis for claiming a right of priority.

13. Priority may be claimed for part of an application. For one and the same application, priority may be claimed from several applications, even if they relate to different countries. Several applications may be claimed as a basis for priority for a single patent claim. If priority is claimed on the basis of several applications, the time limits commencing on the date of priority shall have effect from the earliest priority date.

Part 5
Patent Claims, Description and Abstract

14.—(1) The patent claims shall indicate the invention to be protected, reflected in the technical characteristics necessary to achieve the desired effect. Patent claims shall partly contain an introduction including the title of the invention and, if possible, a statement of the art in relation to which the invention constitutes something new (the state of the art), partly a characteristic part beginning with the words: 'characterised by' or the like stating the novel and characteristic features of the invention. A different wording of the patent claims may be permitted, if there are special reasons for this, e.g. in the case of claims concerning use.

(2) Each patent claim shall relate to one invention only.

(3) If possible, the invention shall be referred to one of the following categories: product, apparatus, process or use.

(4) A patent claim shall not contain anything that is irrelevant to the invention specified in the claim or immaterial to the exclusive right applied for.

(5) To facilitate the understanding of patent claims, references primarily in brackets to the drawings or photos shall be included both in the introduction and in the characteristic part. General remarks such as 'as described' or 'as shown in the drawing' shall not be included in the claims. References may, as an exception, be made directly to line charts or the like which are shown in the drawings.

15.—(1) A patent application may contain several patent claims. If so, they shall be arranged collectedly and numbered consecutively.

(2) A patent claim may be independent or dependent. An independent claim is a claim which relates to an embodiment of an invention disclosed in another patent claim of the application, and which therefore comprises all of the features of the said claim. All other claims are dependent.

(3) An independent claim may rank pari passu with another independent claim. An independent claim ranking pari passu with another independent claim shall fully state the invention in question. An independent claim ranking pari passu with another independent claim may be formally attached to another claim.

(4) One or more dependent claims may be attached to a patent claim. A dependent claim may be attached to several preceding patent claims. It shall begin with a reference to such preceding patent claims and then list the additional features of the invention. Dependent claims shall be grouped directly after the independent claim to which reference is made directly or through another dependent claim.

16.—(1) If an application contains several inventions, it shall only be considered to be in accordance with section 10 of the Patents Act, if there is a technical connection between the inventions. The technical connection shall manifest itself in the inventions having, in whole or in part, the same or similar special technical characteristics. The term special technical

characteristics shall mean the technical characteristics contributed by each single invention going beyond the state of the art.

(2) The question whether there is a connection between a number of inventions shall be determined irrespective of whether they are stated in separate patent claims or as alternatives in a single claim.

(3) Several independent claims within the same category shall only be accepted, if there is a pronounced technical connection, and there are obvious difficulties e.g. in the form of alternatives, in specifying the inventions sufficiently, if they were to be included under common provisions in one and the same patent claim. Also inventions of the sender-receiver type may be stated in separate, independent patent claims.

17.—(1) The description shall

(i) start by stating a brief and factual title of the invention,

(ii) state the technical field to which the invention relates as well as the technology on which the invention is based, possibly supplemented by reference to known literature illustrating the technology concerned, if such information is required,

(iii) explain the invention which is to be protected in such a way that the technical problem and its solution can be understood and state what is achieved by the invention based on the state of the art and the means required to achieve this,

(iv) illuminate the invention by means of explanatory examples or embodiments, referring to drawings or photos, if any, so that the claims may be deemed sufficiently documented, and

(v) expressly state how the invention may be exploited commercially if this does not appear clearly from the description or from the nature of the invention.

(2) If the patent claims include several independent claims, the inventions shall, according to these claims, be referred to in the description in the way indicated in subsection 1 hereof.

(3) The description of the invention shall only contain subject-matter which contributes to the understanding of the invention. Where newly coined terms or terms which are not generally accepted are used, their meanings shall be explained. Physical sizes and quantities shall be stated in units which are generally accepted in international practice, preferably according to the metric system using SI units. Data which do not comply with this condition shall be supplemented with a statement in units which are generally accepted in international practice. In mathematical formulas generally accepted symbol shall be used. In chemical formulas generally accepted symbols, atomic weights and molecular or structural formulas shall be used. As a rule, such technical expressions, signs and symbols as are generally accepted in the relevant area shall be used.

(4) If the patent application includes the deposit of a culture of a micro-organism, cf. section 8*a* of the Patents Act, the application shall, at the date of filing, contain all such relevant information on the characteristics of the microorganism as is known to the applicant.

18.—(1) If an application relates to or includes sequences of nucleotides or amino acids, the description shall contain a sequence list. The sequence list shall be drawn up in accordance with the standard laid down by the Patent Office.

(2) The Patent Office may decide that a sequence list as referred to in subsection 1 hereof shall also be filed in machine readable form. When a sequence list in machine readable form is filed, the applicant shall file a declaration to the effect that the information in machine readable form is identical with the written sequence list.

19. Drawings and photos shall be made as follows:

(i) Drawings shall show the details necessary to understand the description, and these details shall be marked with corresponding letters and figures in the description and drawings.

(ii) Cross sections shall be hatched.

(iii) Figures of the drawings must have consecutive numbers disregarding any numbering of the individual sheets. Photos must be numbered consecutively.

(iv) Drawings and photos shall not include any text except for a single or a few words when absolutely necessary to understand them.

20.—(1) The abstract of a Danish patent application shall relate to the description and claims as presented in the basic documents, cf. section 24 (1) and section 30 (1) of this Order. The abstract shall contain the title of the invention. It shall be drafted so that it is evident to which technical problem the invention pertains, what are the principles for the solution of the problem through the invention, and what is the principal use of the invention. The final wording of the abstract shall, where possible, be determined before the application is made available to the public under section 22 (2) of the Patents Act.

(2) If an International Searching Authority or the European Patent Office has determined the abstract for an international patent application or a converted European patent application, the said abstract shall be used. Where that is not the case, the Patent Office shall determine the abstract also of such applications, and subsection 1 hereof shall apply *mutatis mutandis*.

Part 6
Deposits

21.—(1) Deposits under section 8*a* (1) of the Patents Act shall be made with an institution which is an international depositary authority under the Treaty done at Budapest on 28 April 1977 on the International Recognition of the Deposit of Micro-Organisms for the Purposes of Patent Procedure (the Budapest Treaty) or with one of the other depositary institutions recognised by the European Patent Office.

(2) The deposit shall be made in accordance with the Budapest Treaty.

(3) The Patent Office shall make a list of the institutions with which deposits can be made.

22.—(1) If a deposit of a culture of a micro-organism has been made, the applicant shall within 16 months from the date of filing of the application or, if priority is claimed, from the date of priority, inform the Patent Office in writing of the institution with which the deposit has been made and the number which the institution has accorded to the deposit. For international patent applications, the said information shall be submitted within the same time limit to the International Bureau referred to in section 10 of this Order.

(2) If, prior to the expiry of the time limit referred to in subsection 1 hereof, the applicant requests that the documents relating to the application be made available earlier than prescribed in section 22 (1) and (2) of the Patents Act, the information referred to in subsection 1 hereof shall be submitted together with the request at the latest. If, for an international patent application, prior to the expiry of the time limit referred to in subsection 1 hereof, the applicant requests early publication of the application under Article 21 (2*b)* of the Patent Cooperation Treaty, the information shall be submitted to the International Bureau referred to in section 10 of this Order together with the request for publication at the latest.

(3) If a deposited micro-organism has been transferred from one depositary institution to another under Rule 5 (1) of the Regulations under the Budapest Treaty, the applicant shall as soon as possible after having received a receipt in respect of the transferred deposit inform the Patent Office thereof and of the new number accorded to the deposited culture.

(4) As proof that the information referred to in subsections 1 and 3 hereof is correct, the Patent Office may require a copy of the receipt issued by the depositary institution for the deposit.

23.—(1) A new deposit as referred to in section 8*a* (2) of the Patents Act shall be made pursuant to the provisions of the Budapest Treaty for a new deposit.

(2) A new deposit shall be made within 3 months from the date when the depositor received notification from the depositary institution that samples from the previously deposited culture cannot be furnished. If the institution has ceased to be an international depositary authority for the kind of micro-organisms to which the deposit belonged, or if it has ceased to comply with its obligation under the Budapest Treaty, and the depositor has not received notification to that effect within 6 months from the announcement of the event by the International Bureau referred to in section 10 of this Order, the new deposit may, however, be made within 9 months from the said announcement. For the other depositary institutions the time limits referred to in the second clause shall apply from the time of the corresponding announcement by the European Patent Office.

(3) Within 4 months from the date when the new deposit is made, the applicant shall submit to the Patent Office a copy of the receipt issued by the depositary institution on the basis of the new deposit. If the time limit referred to in section 22 (1) or (2) of this Order expires later, the copy of the receipt may, however, be submitted within that time limit. When

the copy of the receipt is submitted, the number of the application or the patent to which the deposit relates shall be stated.

CHAPTER II
EXAMINATION AND OTHER PROCESSING OF APPLICATIONS

Part 7
Amendment of Patent Applications

24.—(1) For Danish patent applications, patent applications for which examination and other processing are commenced under section 38 of the Patents Act and European patent applications for which conversion is requested pursuant to section 88 of the Patents Act, the basic documents shall consist of the description with accompanying drawings, photos and patent claims drawn up in Danish, Norwegian or Swedish present at the filing of the application or on the date on which the application is deemed to have been filed, respectively.

(2) If no such documents are present on the date of the filing of the application, or on the date on which the application is deemed to have been filed, respectively, the basic documents shall consist of the translation of the description with accompanying drawings, photos and patent claims filed in Danish to the extent their contents appear clearly from the documents present on the date referred to.

(3) For international applications which are proceeded with under section 31 of the Patents Act, the basic documents shall consist of the translation of the description, drawings, photos and patent claims filed under the said provision with the amendments of the translation which may have been made prior to the expiry of the time limit applying under section 105 of this Order. If the international application is filed with the receiving Office in Danish, the basic documents shall consist of the copy of the description, drawings, photos and patent claims filed under section 31 of the Patents Act.

(4) If with the consent of the applicant a patent has been granted, or if the application has been refused prior to expiry of the time limit applying under section 105 of this Order, cf. section 34 of the Patents Act, the basic documents shall consist of the description, drawings, photos and patent claims present at the time of deciding on the application.

(5) If, at the filing of a patent application, it is stated that an application relating to the same invention has been filed previously abroad, and the number and date of filing of the said application are stated, a certified copy, subsequently filed, of the foreign application shall be considered to have been filed on the date of filing of the Danish application.

25.—(1) Patent claims shall not be amended so as to contain subject-matter not disclosed in the basic documents, cf. section 24 (1) to (4) and section 30 (1) of this Order. If a patent claim is amended by the addition of new definitions, the applicant shall state at the same time where the new definitions have their counterparts in the basic documents.

(2) After the Patent Office has commented on the performed search, claims disclosing an invention which is independent of the inventions disclosed in the previously filed claims shall not be included in the same patent application.

(3) Comments on the search of an international patent application shall not be made prior to the expiry of the time limit applying under section 105 of this Order, unless the applicant gives his consent thereto.

(4) The applicant may only make amendments or additions to the description, drawings and photos if necessary in view of section 8 of the Patents Act, including further explanatory examples, if they are necessary for illustrative or corrective purposes. Such amendments or additions shall not make the patent claims contain subject-matter which extends beyond the contents of the basic documents.

(5) At the filing of new copies of the description, the applicant shall file a declaration stating where the description does not correspond word for word to a previously filed description.

26. Unless the Patent Authority allows otherwise, amendments or additions to claims shall be made by filing new copy of the claims. This copy shall comprise all the maintained claims in consecutive order.

Part 8
Division and Excision

27.—(1) If several inventions are described in the basic documents, the applicant may divide the application into several applications. At the applicant's request, a new application relating to an invention extracted from the original application (the parent application) shall be considered to have been filed at the same time as the parent application. The new application may only relate to such subject-matter as, under section 19 (2) of the Patents Act, could have been included in the claims of the parent application at the time when the new application was filed.

(2) If the applicant requires protection for an independent invention in an international application, the application shall be divided and a new application fee paid even if an additional fee as referred to in section 36 (1) of the Patents Act has been paid.

28. If, as a result of an addition to the description or claims, or in another way, an invention has been stated which does not appear from the basic documents, a new application relating to that invention may be excised from the parent application and, at the applicant's request, be considered to have been filed on the date when the document disclosing the invention was received by the Patent Office. Excision shall take place in compliance with section 19 (2) of the Patents Act, and in the new application protection shall only be requested as regards the subject-matter of the parent application on the date of filing of the document concerned.

29.—(1) If an application results from division or excision, the parts of the parent application on which the claims of the new application are based shall be stated. Moreover, the applicant shall state in the application that division or excision has taken place.

(2) Division or excision may take place as long as a final decision regarding the parent application has not been taken. Division or excision in the parent applications shall thus take place before a patent has been granted according to section 20 (1) of the Patents Act. If the parent application has been rejected or shelved, division and excision may take place until expiry of the time limit applying to appeal or resumption, irrespective of whether an appeal is filed after consideration of the application recommences.

(3) If division or excision of the application takes place after a grant for approval for patent notification has be forwarded, however, the limitations as regards the contents shall apply according to the provision in section 19 (2) of the Patents, cf. sections 27 (1) and 28 of this Order.

30.—(1) In the event of division or excision, the basic documents shall be held to be the description with accompanying drawings and patent claims filed in connection with the new application.

(2) A new application shall only be considered as resulting from division or excision, if this is evident from the application when filed. The date of filing and number of the original application shall be indicated in applications resulting from division or excision.

Part 9
Applications Available to the Public

31.—(1) When the documents of a patent application, prior to the granting of a patent, are made available to the public under section 22 of the Patents Act, the abstract shall be published as soon as its final wording has been determined. The Patent Office may also publish other parts of the application together with the abstract. Copies of the published abstract shall be obtainable from the Patent Office against payment.

(2) The advertisement to be made when an application is made available to the public shall state the number and classes of the application, its date of filing, the effective date, if different from the date of filing, the title of the invention, the applicant's name or firm name and mailing address and, if he is represented by an agent, the agent's name or firm name and the inventor's name and mailing address. If priority has been claimed, the advertisement shall also state where the application whose priority is claimed was filed, the date of filing of the said application and its number. If the application includes a deposit of a culture of a micro-organism, this shall be stated in the advertisement. If the applicant has requested under section 22 (7) of the Patents Act that a sample shall be furnished only to an expert in the art, this shall also be advertised.

(3) If the translation of the description and the patent claims of an international application have been amended prior to the expiry of the time limit applying under section

105 of this Order, but after the files of the application have been made available to the public, this fact shall be advertised.

32.—(1) A request under section 22 (8), 1st clause, of the Patents Act for the furnishing of a sample of a deposited culture of a micro-organism shall be drawn up in accordance with Rule 11 of the Regulations under the Budapest Treaty.

(2) If the request referred to in subsection 1 hereof is made before the patent application to which the deposit relates has been finally decided upon, the person requesting the sample shall undertake vis-a-vis the applicant to use the sample for experimental purposes only, until such time as the patent application is finally decided upon, and not to make the sample available to any third party within the same period or, if a patent is granted, until such time as the patent ceases to have effect.

(3) If the request referred to in subsection 1hereof is made for a sample of a deposit relating to a patent, the person requesting the sample shall undertake vis-a-vis the proprietor of the patent not to make the sample available to any third party until such time as the patent ceases to have effect.

(4) As far as cultures are concerned which are derived from the sample and still exhibit the characteristics of the deposited culture which are essential to carrying out the invention, the person requesting the sample shall accept the same obligations as those applying to the sample.

(5) Where the person requesting the sample is required to accept the said obligations, it shall be done in a written declaration accompanying the request.

33.—(1) A request under section 22 (7) of the Patents Act to the effect that the furnishing of a sample shall only be effected to an expert in the art shall be submitted to the Patent Office not later than on the date on which the application is made available to the public under section 22 of the Patents Act.

(2) The Patent Office shall draw up a list of suitable persons who have declared their willingness to undertake the commission as an expert in the art and who are qualified therefor. Entries of persons on the list of experts shall be advertised. It shall also be advertised when persons are deleted from the list.

(3) If the furnishing of a sample may only be effected to an expert in the art, cf. subsection 1 hereof, the request for a sample shall indicate the expert to be used. The request shall be accompanied by a written declaration from the expert in which he accepts the obligations visa-vis the applicant to the extent referred to in section 32 (2) and (4) of this Order. In those cases the person making the request shall not be required to make any declaration himself.

(4) Any person entered on the list or any person approved by the applicant in the individual case may be used as an expert.

34. Notwithstanding any declaration made under sections 32 and 33 of this Order, a culture derived from a furnished sample may be deposited for the purpose of a patent or utility model application, if the deposit of the derived culture is required for that application.

35.—(1) If a request has been made for the furnishing of a sample, and if under the Patents Act or this Order there is nothing to prevent such furnishing, the Patent Office shall issue a certificate to that effect. The Patent Office shall transmit the request for the furnishing of a sample and the certificate to the depositary institution with which the culture is deposited. At the same time, the Patent Office shall transmit a copy of the request and the certificate to the applicant or the proprietor of the patent.

(2) If the Patent Office finds that the certificate referred to in subsection 1 hereof cannot be issued, the Patent Office shall notify the person who has requested the sample accordingly.

Part 10
Examination of Patentability

36.—(1) In examining whether the conditions laid down in section 2 of the Patents Act for the grant of a patent are complied with, the Patent Authority shall consider everything that comes to its attention.

(2) The search shall be made to the necessary extent on the basis of patent specifications, specification of accepted patent applications or published patent applications, or abstracts thereof, from Denmark, Sweden, Finland, Norway, the Federal Republic of Germany, the former German Reich, Great Britain, France, the United States of America and the European Patent Office, published international patent applications or abstracts thereof, utility model specifications from Denmark and Danish patent or utility model applications available to the public. If deemed necessary, the search shall also be based on other available literature.

37.—(1) If the applicant wishes the search referred to in section 9 of the Patents Act to be performed, he shall, within 3 months from the date of filing of the application, or from the date on which the application shall be deemed to have been filed, make a written request to that effect to the Patent Office and pay the fee prescribed by the Searching Authority and a handling fee to the Patent Office.

(2) If the applicant wishes the search to be performed by one particular of several possible international authorities, he shall specify that Authority in his request.

(3) If the patent application is not written in a language accepted by the Searching Authority, the request shall be accompanied by a translation of the application into a language approved by the Searching Authority. If the Swedish Patent Authority is stated in the request, a translation shall be made into Danish or English, and if the European Patent Office is stated in the request, into English, French or German.

(4) If on expiry of the time limit stated in subsection 1 hereof the patent application and the prescribed translation do not comply with the requirements as to form which apply to international patent applications, the request shall be deemed to be withdrawn.

38.—(1) If the Patent Office has informed the applicant that an application relates to two or more mutually independent inventions, the application shall not be restricted to relate to one invention first and then, if this proves not to be patentable, be amended to relate to another one of the inventions. The application shall not be related parallel to several inventions.

(2) When the patent claims have been restricted due to lack of unity, the applicant shall be deemed in the application in question finally to have waived the invention or inventions cancelled from the claims in connection with restriction.

39. If required for the examination and further processing of the application, the Patent Authority may consult other experts.

40. The Patent Authority may call upon the applicant to submit a model, sample or the like, or to carry out investigations or experiments.

41.—(1) If the applicant has also applied for a patent for the same invention abroad, the Patent Authority may, with the limitation specified in section 69 (3), 2nd clause, demand that the applicant furnish information about any communication from the patent institution in question concerning the novelty of the invention or its patentability in other respects.

(2) The applicant shall, to the extent the Patent Authority so requests, indicate the patent institutions with which he has applied for a patent for the invention and file a copy or a transcript of the correspondence with the said patent institutions concerning the novelty of the invention or its patentability in other respects. If the applicant has not received any such communication, the applicant shall submit a declaration to that effect.

42. If, during the examination of a patent application, letters of importance for the examination of the application (objection), the applicant shall be notified thereof. The party filing such a letter shall, where relevant, be notified of the possibility of entering an opposition when patent is granted.

CHAPTER III
GRANT OF PATENTS, ETC.

Part 11
Grant of Patents

43.—(1) If the Patent Authority finds that patent may be granted, and if it has not already been established that the applicant approves the text on the basis of which patent may be granted, subsections 2 and 3 hereof shall apply.

(2) The Patent Authority shall invite the applicant within 2 months to file his observations on the text on the basis of which patent may be granted. If the applicant approves the text, section 19 of the Patents Act shall apply.

(3) If the applicant does not approve the text, the examination of the application may be proceeded with. If the Patent Authority finds no reason to proceed with the examination, the application shall be refused. The invitation according to subsection 2 hereof shall state that the application may be refused, if the applicant does not approve the text.

44.—(1) If, on the grant of a patent to the applicant under section 19 (1) of the Patents Act, no documents are available which are suitable for reproduction, the applicant shall file such documents within 2 months after the grant has been made.

(2) The documents for reproduction shall comply with the documents accepted for the grant of the patent. The applicant shall submit a declaration to that effect.

45. Postponement of the grant of patent shall only be granted, however, if the decision to grant a patent has been made prior to the application being made available to the public under section 22 (2) and (3) of the Patents Act. If so, the grant of patent may be postponed at the applicant's request until the application is made available to the public pursuant to the said provisions.

46. Publication of the description, drawings, photos, patent claims and abstract pursuant to section 20 of the Patents Act (patent specifications) shall be effected at the instance of the Patent Authority and shall be initiated as soon as possible after the patent has been granted. The patent specifications shall indicate the date of the grant of the patent, and

(i) the number of the application and the registration number of the patent,

(ii) the classes of the patent,

(iii) the name or firm name and mailing address of the proprietor of the patent,

(iv) if the proprietor of the patent is represented by an agent, the name or firm name of the agent,

(v) the inventor's name and mailing address,

(vi) the title of the patent,

(vii)*a)* if the application was filed as a Danish patent application, the date of filing of the application and the effective date of the application if different from the date of filing,

(vii)*b)* if the application was filed as an international patent application, the international date of filing and the date on which the application was proceeded with under section 31 of the Patents Act or is deemed to have been filed under section 38 (3) of the Patents Act, and the number of the international application,

(vii)*c)* if the application was filed as a converted European patent application, the number of the European patent application, its date of filing under the European Patent

Convention and the date on which the European patent application was converted into a Danish patent application,

(viii) if priority is claimed under section 6 of the Patents Act where the application serving as a basis for claiming a right of priority has been filed and the date of filing and number of such application,

(ix) if the application is made on the basis of division or excision, the number of the parent application,

(x) if the patent comprises the deposit of a culture of a micro-organism, information thereof,

(xi) the date when the documents of the application were made available to the public, and

(xii) cited documents.

47. The advertisement of the grant of patent under section 20 of the Patents Act shall contain the items of information to be given in the patent specifications under section 46 of this Order with the exception of cited documents.

Part 12
The Register of Patents

48. The Patent Office shall keep a register of the patents granted in this country and of European patents having effect in this country.

49. For patents granted in this country, the following items shall be entered in the Register of Patents

(i) the number of the application and the registration number of the patent,

(ii) the classes of the patent,

(iii) the name or firm name and mailing address of the proprietor of the patent,

(iv) if the proprietor of the patent is represented by an agent, the name or firm name and mailing address of the agent,

(v) the inventor's name and mailing address,

(vi) the title of the invention,

(vii)*a)* if the patent is granted on the basis of a Danish patent application, the date of filing of the application and the effective date of the application if different from the date of filing,

(vii)*b)* if the patent is granted on the basis of an international application, the international date of filing, and the date on which the application was proceeded with under

section 31 of the Patents Act, or the date on which the application is deemed to have been filed under section 38 (3) of the Patents Act, and the number of the international application,

(vii)*c)* if the patent is granted on the basis of a converted European patent application, the number of the European patent application and its date of filing under the European Patent Convention, and the date on which the European patent application was converted into a Danish patent application,

(viii) if priority is claimed under section 6 of the Patents Act where the application serving as a basis for claiming a right of priority has been filed and the date of filing and number of such application,

(ix) if the patent has been granted on the basis of an application made on the basis of division or excision, the number of the patent application,

(x) if the patent comprises the deposit of a culture of a micro-organism, information concerning the institution at which the culture has been deposited and the number which the deposited culture has been accorded by the institution,

(xi) the date when the files of the application were made available to the public, and

(xii) the date on which the grant of the patent was advertised under section 20 of the Patents Act.

50.—(1) European patents designating Denmark shall be entered in the Register of Patents when the European Patent Office has published its decision to let the patent application proceed to grant, and the applicant, in due time, has filed a translation into Danish and paid the prescribed fee under section 77 (1), 1st clause, of the Patents Act.

(2) If the requirements referred to in subsection 1 hereof have been complied with, the following shall be entered in the Register

(i) the date on which the European patent Office has published its decision to grant the patent,

(ii) the date on which the translation was filed and the fee was paid under section 77 (1), 1st clause, of the Patents Act and the date on which advertisement to that effect was made,

(iii) the date accorded as the date of filing of the application and, if the application is a European divisional application, the date on which the divisional application was filed, and

(iv) information corresponding to the items specified in section 49, (i) to (vi), (vii)*b)*, (viii), (x) and (xi).

(3) If the European Patent Office has published its decision to maintain a European patent designating Denmark in an amended form, the date on which the decision was published shall be entered in the Register. If the proprietor of the patent, within the time limit prescribed in section 112 (1) of this Order, files a new translation and pays the fee under

section 77 (1), 2nd clause, of the Patents Act, the date on which that took place and the date on which the amendment was advertised by the Patent Office shall be entered in the Register.

(4) If the translation and the fee referred to in subsection 3 hereof are not received within the time limit prescribed in section 112 (1) of this Order, information to that effect shall be entered in the Register.

(5) If the European Patent Office has revoked a European patent designating Denmark, information to that effect shall be entered in the Register.

(6) If the proprietor of the patent files a corrected translation and pays the fee under section 86 (1) of the Patents Act, the date on which that took place and the date on which the correction was advertised shall be entered in the Register.

51.—(1) When a renewal fee has been paid, an entry to that effect shall be made in the Register of Patents or in a special register of fees annexed thereto.

(2) If a patent has lapsed under section 51 of the Patents Act, the date from which the patent ceased to have effect shall be entered in the Register.

(3) If a request has been made under section 72 of the Patents Act to the effect that a renewal fee shall be deemed to have been paid in due time, an entry to that effect shall be made in the Register, and the decision on the request shall also be entered.

52.—(1) If the Patent Office is notified to the effect that proceedings have been instituted for the revocation of a patent, the transfer of a patent, or a compulsory licence, cf. section 63 (1) of the Patents Act, an entry to that effect shall be made in the Register.

(2) When an office copy of a court decision has been sent to the Patent Office under section 65 of the Patents Act, an entry to that effect shall be made in the Register of Patents. When the court decision is final, the entry shall be made in such a way that the principal outcome of the case appears from the Register.

(3) If the Patent Office has declared the patent to have ceased to have effect under section 54 of the Patents Act, an entry to that effect shall be made in the Register.

53.—(1) The entry made on the filing of an opposition, a request for administrative reexamination and a request for termination, cf. chapter IV, shall contain

(i) name or firm name and mailing address of the opponent or the party having submitted the request, respectively,

(ii) if the opponent or the party who has submitted the request is represented by an agent, the name or firm name and mailing address of the agent,

(iii) the date of the opposition or the request for administrative re-examination or termination, and

(iv) in case of a request for termination, the number of the Community patent or European patent which is considered to cover the same invention.

(2) The decision made in respect of an opposition, a request for administrative reexamination or a request for termination shall be entered in the Register of Patents, cf. sections 61, 71 (2) and 80 (2) of this Order. The entry shall state the decision made and the date on which the decision was advertised.

54.—(1) An entry under section 44 of the Patents Act concerning the transfer of a patent, the grant of a licence, pledging or execution proceedings shall comprise the name or firm name and mailing address of the holder of the right in question as well as the date of the creation of the right. As far as licences are concerned, an entry shall be made, if so requested, as to whether the right of the proprietor of the patent to grant additional licences is restricted. If the question of entry cannot be decided upon immediately, it shall be stated in the Register that an entry has been requested.

(2) Notifications in respect of patents as regards changes of agent or the name, firm name or mailing address of the proprietor of the patent shall be entered in the Register.

(3) A request for an entry as referred to in subsections 1 and 2 hereof shall be made in writing accompanied by proper documentation for such change.

(4) If with respect to a patent the Patent Office has received notification of the transfer of a deposited micro-organism as referred to in section 22 (3) of this Order, or has received a copy of the receipt for a new deposit, cf. section 23 (3) of this Order, an entry concerning the transfer or the new deposit shall be made in the Register.

CHAPTER IV
OPPOSITION, ADMINISTRATIVE RE-EXAMINATION, TERMINATION

Part 13
Examination of Oppositions

55.—(1) The opposition shall be made in writing stating

(i) the opponent's name or firm name and mailing address,

(ii) the registration number of the patent against which the opposition is filed, the name or firm name of the proprietor and the title of the invention,

(iii) a statement as to the extent of the opposition filed as well as all the grounds on which the opposition is filed, and a complete account of all the facts, documentation and representations stated to support these grounds, and

(iv) if the opponent is represented by an agent, the name or firm name and mailing address of the agent.

(2) The opposition shall be accompanied by the prescribed fee.

(3) The opposition and subsequent contributions with accompanying documents from the proprietor of the patent and the opponent shall be filed in the number of copies prescribed by the Patent Office.

56.—(1) If the opposition does not comply with the provisions in section 55 (1), (iii), and (2) of this Order, before expiry of the period prescribed for filing of oppositions, the opposition shall be refused. The same shall apply, if the patent against which an opposition is filed is not identified in the opposition, or if it cannot be established who has filed the opposition.

(2) If, after expiry of the period prescribed for filing of oppositions, the opposition does not comply with the provisions in section 55 (1), (i) to (ii) and (iv) of this Order, the Patent Office shall call upon the opponent to rectify the defect within 1 month. If the opposition is not corrected in time, it shall be refused.

(3) An entry of the filing of an opposition shall be made in the Register of Patents. Advertisement of the filing of an opposition shall be made according to section 62 of this Order when the prescribed period for filing of oppositions has expired, if the opposition is not refused.

57.—(1) A copy of the opposition with accompanying documents shall be forwarded to the proprietor of the patent who—after expiry of the period prescribed for filing of oppositions, and unless the opposition is rejected—shall be invited to comment on the opposition within 6 months and possibly file amended description, patent claims, drawings and photos. If more than one opposition has been forwarded, the opponents shall be informed hereof after expiry of the period prescribed for filing oppositions by the forwarding of a copy of the other oppositions and a copy of the abovementioned invitation to the proprietor of the patent.

(2) If the proprietor of the patent files a response to the opposition, the Patent Authority shall decide whether further correspondence between the parties is required. The parties shall be informed of this decision. For the opponents a copy of the patent proprietor's reply shall be enclosed.

58. If the Patent Authority decides to revoke the patent, the parties shall be notified hereof. The same shall apply, if the Patent Authority decides that the patent may be maintained unamended.

59.—(1) If the Patent Authority finds that the patent may be maintained as amended, the parties shall be notified hereof. Besides, the proprietor of the patent shall be invited to file his observations within 2 months, if he does not approve the text on the basis of which the patent is to be maintained.

(2) If the proprietor of the patent approves the text, the Patent Authority shall decide to maintain the patent as amended. The opponent shall be notified to that effect.

(3) If the proprietor of the patent does not approve the text, the examination of the opposition may be proceeded with, if the Patent Authority finds that there is reason to do so. If there is no reason to proceed with the examination, the patent shall be revoked.

(4) When a final decision has been made to grant a patent as amended, the proprietor of the patent shall be called upon within 2 months to pay the fee for publication of new patent

specifications and, if necessary, to file documents suitable for reproduction. The documents shall comply with the documents accepted by the Patent Authority, and the proprietor of the patent shall submit a declaration to that effect. If the publication fee is paid, the proprietor of the patent shall under any circumstances be considered to agree to the maintenance of the patent as amended. If, on the other hand, the publication fee is not paid, the patent shall be revoked.

(5) The decision to maintain a patent as amended shall state the text on the basis of which the patent is maintained.

60. The publication of new patent specifications with description, drawings, photos and patent claims as amended under section 23 of the Patents Act shall be effected at the instance of the Patent Office and shall be initiated as soon as possible after the publication fee has been paid. The patent specifications shall also include the information stated in section 46 of this Order. Section 9 (2) of this Order shall similarly apply.

61. The advertisement of the decision concerning an opposition under section 23 (5) of the Patents Act shall be effected when the opposition has been finally decided. At the same time, such decision shall be entered in the Register of Patents.

62. The advertisement of the filing of an opposition and of the decision hereon shall state the name or firm name of the proprietor of the patent, the date of filing and the number of the application, the registration number and classes of the patent, the title of the invention and the date when the patent was granted. The advertisement of the filing of an opposition shall also state the opponent's name or firm name.

Part 14
Administrative Re-Examination

63.—(1) A request for administrative re-examination shall be made in writing and shall contain

(i) name or firm name and mailing address of the person making the request for reexamination,

(ii) the registration number of the patent for which re-examination is requested, as well as the name or firm name of the proprietor of the patent and the title of the invention,

(iii) a statement as to the extent of the re-examination requested as well as all the grounds on which the request is filed and a complete account of all the facts, documentation and representations stated to support these grounds, or,

if the request is made by the proprietor of the patent, the desired amendments,

(iv) if the person requesting a re-examination, is represented by an agent, the name or firm name and mailing address of the agent, and

(v) if licensees are entered in the Register of Patents, documentation to prove that such licensees have been informed that re-examination has been requested.

(2) A request for re-examination shall be accompanied by the prescribed fee.

(3) A request for re-examination and subsequent contributions with accompanying documents from the person requesting re-examination or from the proprietor of the patent shall be filed in the number of copies prescribed by the Patent Office.

64.—(1) If the request for re-examination does not comply with the provisions in section 53 *b* (1), 3rd clause, of the Patents Act and section 63 (2) of this Order, or if it is not possible to establish who made the request, the request shall be refused.

(2) If the request for re-examination does not otherwise comply with the provisions in section 63 (1) of this Order, the Patent Authority shall call upon the person making the request to rectify the defects within 1 month. If the request is not corrected in time, it shall be refused.

(3) An entry of the filing of a request for reexamination shall be made in the Register of Patents. Advertisement of the filing of a request for re-examination shall take place pursuant to section 71 of this Order, if the request is not refused.

Request for Re-Examination by Persons Other than the Proprietor of the Patent

65.—(1) A copy of the request for re-examination with accompanying documents shall be forwarded to the proprietor of the patent who shall be invited to comment on the request and file any description, claims, drawings and photos as amended within 6 months.

(2) If the proprietor of the patent files a response to the request for re-examination, the Patent Authority shall decide whether further correspondence between the parties is required.

66.—(1) If the Patent Authority does not find that the grounds invoked in respect of revocation exist, the request for re-examination shall be refused, and the patent shall be maintained unamended.

(2) If the grounds for revocation invoked exist, the Patent Authority shall then examine whether the patent may be maintained as amended or shall be revoked in consideration of the grounds for revocation referred to in section 52 (1) of the Patents Act.

(3) The examination shall be effected on the basis of the material produced in connection with the request for re-examination and which was available when the patent was granted pursuant to sections 36 to 42 of this Order, and other material produced in connection with a previous amendment of the patent.

67. If the Patent Authority decides to revoke the patent, the parties shall be notified to that effect. The same shall apply, if the Patent Authority decides to maintain the patent unamended.

68.—(1) If the Patent Authority finds that the patent may best maintained as amended, the parties shall be notified hereof. At the same time, the proprietor of the patent shall be

invited to file his observations within 2 months, if he does not approve the text on the basis of which the patent is to be maintained.

(2) If the proprietor of the patent agrees to the text, or if the proprietor of the patent forwards no comments, the Patent Authority shall decide to maintain the patent as amended. The proprietor of the patent shall be notified hereof, and at the same time the proprietor of the patent shall be called upon to pay the fee for publication of new patent specifications within 2 months and, if necessary, to file documents suitable for reproduction. The documents shall be identical to the documents accepted by the Patent Authority, and the proprietor of the patent shall submit a declaration to that effect. If the publication fee is not paid, the patent shall be revoked.

(3) When the publication fee is paid, a new patent specification is drawn up. The decision is then published and at the same time the person requesting a re-examination shall be notified of the decision.

(4) If the proprietor of the patent does not agree to the text, the requested examination may be continued, if the Patent Authority finds that there is reason to do so. If there is no reason to continue with the requested examination, the patent shall be revoked.

(5) The decision to maintain a patent as amended shall state the text on the basis of which the patent is maintained.

Request for Re-Examination by the Proprietor of the Patent

69.—(1) If the proprietor of the patent himself requests that his patent be restricted, the Patent Authority only examines whether the grounds for revocation referred to in section 52 (1) of the Patents Act prejudice the desired amendment of the patent.

(2) If the patent may be amended as desired, the proprietor of the patent shall be notified to that effect. The proprietor shall then within a period of 2 months file amended description, claims, drawings and photos suitable for reproduction. The documents shall comply with the documents accepted by the Patent Authority, and the proprietor of the patent shall submit a declaration to that effect. The proprietor shall moreover pay the publication fee within the same time limit. If the fee is not paid within the time limit, the patent shall be repealed.

(3) If the patent cannot be amended as desired after possible correspondence in this respect, the request shall be refused, and the patent shall be maintained unamended.

Publication and Advertisement, etc.

70. The publication of new patent specifications with description, drawings, photos and patent claims as amended under section 53 of the Patents Act shall be effected at the instance of the Patent Office and shall be initiated as soon as possible after the publication fee has been paid. The patent specifications shall also include the information stated in section 46 of this Order. Section 9 (2) of this Order shall similarly apply.

71.—(1) The advertisement of the filing and decision of a request for re-examination shall state the name or firm name of the proprietor of the patent, the date of filing and the number of the application, the registration number and classes of the patent, the title of the invention and the date when the patent was granted. The advertisement of the filing of a request for a reexamination shall also state the name or firm name of the person requesting the re-examination.

(2) An entry of the decision shall be made in the Register of Patents.

Part 15
Request for Termination of Patents

72.—(1) A request for the Patent Authority's decision on the termination of a patent, in whole or in part, under section 96 of the Patents Act shall be made in writing and shall include

(i) name or firm name and mailing address of the person making the request for termination of the patent,

(ii) the registration number of the patent which is to terminate as well as the name of the proprietor of the patent and the title of the invention,

(iii) the number of the Community patent or European patent for Denmark which is considered to cover the same invention as the patent,

(iv) if the person requesting the termination of a patent is represented by an agent, the name or firm name and mailing address of the agent, and

(v) if licensees are entered in the Register of Patents, documentation to prove that such licensees have been informed that the termination of the patent has been requested.

(2) A request for termination shall be accompanied by the prescribed fee.

(3) A request for termination and subsequent contributions with accompanying documents from the person requesting termination, and contributions from the proprietor of the patent shall be filed in the number of copies prescribed by the Patent Office.

73.—(1) If the request for termination does not comply with the provisions in section 72 (2) of this Order, or if it is not possible to establish who made the request, the request shall be refused.

(2) If the request for termination does not otherwise comply with the provisions in section 72 (1) of this Order, the Patent Office shall call upon the person making the request to rectify the defects within 1 month. If the request is not corrected in time, it shall be refused.

(3) An entry of the filing of a request for termination shall be made in the Register of Patents. Advertisement of the filing of a request for termination shall take place pursuant to section 80 of this Order, if the request is not refused.

Request for Termination by Persons other than the Proprietor of the Patent

74.—(1) A copy of the request for termination with accompanying documents shall be forwarded to the proprietor of the patent who shall be invited to comment on the request and file any description, claims, drawings and photos as amended within 6 months.

(2) If the proprietor of thee patent files a response to the request, the Patent Authority shall decide whether further correspondence between the parties is required.

75.—(1) The Patent Authority shall examine whether and to which extent the conditions for termination under section 96 (1) of the Patents Act exist.

(2) If the conditions for termination in part under section 96 (1) of the Patents Act exist, the Patent Authority shall examine whether the national patent may then be maintained as amended or shall be revoked in consideration of the grounds for revocation referred to in section 52 (1) of the Patents Act. The examination shall be effected on the basis of the material available when the patent was granted pursuant to sections 36 to 42 of this Order, and other material produced in connection with a previous amendment of the national patent.

76.—(1) If the conditions for termination in whole under section 96 (1) of the Patents Act exist, the national patent shall be declared to be terminated in whole.

(2) If the conditions under section 96 (1) of the Patents Act do not exist, the request shall be refused, and the national patent shall be maintained unamended.

(3) The parties shall be notified of the decision of the Patent Authority under subsections 1 and 2 hereof.

77.—(1) If the Patent Authority, where the conditions for termination exist, finds that the national patent may be maintained as amended, the parties shall be notified hereof. At the same time, the proprietor of the patent shall be invited to file his observations within 2 months, if the proprietor does not approve the text on the basis of which the Patent Authority intends to maintain the national patent.

(2) If the proprietor of the patent approves the text, the Patent Authority shall decide to maintain the patent as amended. The person requesting termination shall be notified to that effect.

(3) If the proprietor of the patent does not approve the text, the examination of the request may be proceeded with, if the Patent Authority finds that there is reason to do so. If there is no reason to proceed with the examination, it shall be decided to maintain the patent as amended. The parties shall be notified to that effect.

(4) When a final decision has been made to maintain a patent as amended, the proprietor of the patent shall be called upon within 2 months to pay the fee for publication of new patent specifications and, if necessary, to file documents suitable for reproduction. The documents shall comply with the documents accepted by the Patent Authority, and the proprietor of the patent shall submit a declaration to that effect. If the publication fee is paid,

the proprietor of the patent shall be considered to agree to the maintenance of the patent as amended. If, on the other hand, the publication fee is not paid, the patent shall be terminated.

(5) The decision to maintain a patent as amended shall state the text on the basis of which the patent is maintained.

Request for Termination by the Proprietor of a Patent

78. If the request for termination is made by the proprietor of the patent himself, sections 72 to 77 of this Order with the amendments resulting from the proprietor being the only party to the case shall apply.

Publication and Advertisement, etc.

79. The publication of new patent specifications with description, drawings, photos and patent claims under section 96 (2) of the Patents Act and patent claims as amended shall be effected at the instance of the Patent Office and shall be initiated as soon as possible after the publication fee has been paid. The patent specifications shall also include the information stated in section 46 of this Order.

80.—(1) The advertisement of the filing and decision of a request for termination shall state, both in respect of the national patent and the corresponding Community patent or European patent, the name or firm name of the proprietor of the patent, the date of filing and number of the application, the registration number and classes of the patent, the title of the invention and the date when the patent was granted and, where relevant, the date of termination or maintenance of the national patent as amended.

(2) An entry of the decision shall be made in the Register of Patents.

CHAPTER V
SUPPLEMENTARY PROTECTION CERTIFICATES FOR MEDICINAL PRODUCTS AND PLANT PROTECTION PRODUCTS

Part 16
Application for a Certificate and the Register of Certificates, etc.

Definitions

81.—(1) 'Certificate' means a supplementary protection certificate under Council Regulation (EEC) No. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, or a supplementary protection certificate under European Parliament and Council Regulation (EC) No. 1610/96 of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products.

(2) 'Regulation' means the Council Regulation (EEC) No. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, and the European Parliament and Council Regulation (EC) No. 1610/96 of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products.

Applications for Certificates, their Examination and Other Processing, etc.

82.—(1) An application for a certificate shall be made in writing. The application shall be filed with the Patent Office in the number of copies prescribed by the Office. The application form shall be provided free of charge by the Patent Office.

(2) The application shall be signed by the applicant or his agent.

(3) Apart from the items stated in article 8 of the Regulations, the application shall indicate if a certificate is applied for by several persons jointly and these are not represented by an agent, whether any of them shall be authorised to receive communications from the Patent Authority on behalf of all of them, and

(4) If the Patent Authority so requests, the applicant shall provide such additional information as to the nature of the product as is necessary for the examination of the application.

(5) The application fee shall accompany the application.

(6) The number and date of filing of the application shall be advertised together with the information referred to in article 9 (2) of the Regulations.

(7) The date of signature by the Public Health Authorities of the authorization to place the product on the market shall be regarded as the date or grant of authorization mentioned in article 8 (1), *(a)*, (iv), and article 9 (2), *(d)*.

83. The application shall be in the Danish language. If a document accompanying the application is drawn up in any other language, a translation shall be filed unless the Patent Office decides otherwise in each individual case. The Patent Office may require that the translation be certified by a translator or in another manner approved by the Patent Office.

84. An application for a certificate shall not be amended in such manner that a certificate is applied for in respect of another product or with another basic patent.

85.—(1)The Patent Office shall keep a record of applications filed. In the record, the following data shall be entered

(i) the information referred to in article 9 (2), *(a)* to *(e)*, of the Regulations,

(ii) the number and date of filing of the application,

(iii) if the applicant is represented by an agent, the name or firm name and mailing address of the agent,

(iv) the letters filed and fees paid in the case, and

(v) notifications and communications sent in respect of the application.

(2) The record and the files of the case shall be available to the public.

86.—(1) The Patent Authority shall consider everything that comes to its knowledge in the examination of the application.

(2) The Patent Authority shall not examine whether the conditions in Article 3 *(d)* of the Regulations are met.

87.—(1) The rules in section 15 (2) and (3) and section 16 of the Patents Act shall apply to time limits under article 10 (3) of the Regulations. The prescribed fee shall be paid for resumption.

88.—(1) The advertisement of a certificate issued pursuant to article 11 (1) of the Regulations shall, in addition to the information stated therein, also include information on the number and date of filing of the certificate application as well as the registration number of the certificate.

(2) A certificate shall include the information referred to in subsection 1 hereof.

The Register of Certificates, etc.

89.—(1) The Patent Office shall keep a register of the certificates issued. The information and amendments hereto referred to in section 88 (1) of this Order shall be entered in the Register. Information on items referred to in sections 52 to 54 of this Order shall also be entered in the Register of Certificates.

(2) Information concerning transfer, pledging, execution, licences, etc. which has been or is entered in respect of the basic patent in the Register of Patents pursuant to sections 52 to 54 of this Order shall be entered in the Register of Certificates at the same time.

90. If an application for a certificate is finally refused or shelved, this shall be advertised together with the information referred to in section 82 (6) of this Order.

Payment of Renewal Fees

91.—(1) A renewal fee shall be paid for each year commenced after expiry of the term of the basic patent.

(2) The renewal fee shall fall due on the last day of the month in which the fee year begins. The renewal fee may not be paid earlier than 3 months before the due date.

(3) The renewal fee may, together with the prescribed additional fee, be paid within 6 months after its due date.

Part 17
Administrative Re-Examination of Certificates, etc.

Administrative Re-Examination Article 15 of the Regulations

92.—(1) The request for administrative re-examination shall be made in writing stating

(i) name or firm name and mailing address of the person requesting a re-examination,

(ii) the registration number of the certificate for which re-examination is requested, and the certificate holder's name or firm name,

(iii) all the grounds in article 15 (1) of the Regulations on which the request is filed, and a complete account of all the facts, documentation and representations stated to support these grounds,

(iv) if the person requesting the re-examination is represented by an agent, the name or firm name and mailing address of the agent, and

(v) if licensees are entered in the Register of Certificates, documentation to prove that these persons have been notified of the request for re-examination.

(2) If, the request is filed on the grounds stated in Article 15 *(c)* of the Regulations, reexamination of the basic patent shall be requested at the same time, cf. section 94 of this Order.

(3) A request for re-examination shall be accompanied by the prescribed fee.

(4) A request for re-examination with accompanying documents and subsequent contributions from the person having requested a re-examination, and from the certificate holder shall be filed in the number of copies prescribed by the Patent Office.

(5) If the request for re-examination does not comply with the provision in subsection 3 hereof, or if it cannot be established who has filed the request, the request shall be refused.

(6) If the request for re-examination does not otherwise comply with the provisions in subsection 1 or 2 hereof, the Patent Authority shall call upon the person making the request to rectify the defects within 1 month. If the request is not corrected in time, it shall be refused.

(7) An entry of the filing of a request for re-examination shall be made in the Register of Certificates. Advertisement of the filing of a request for re-examination shall take place pursuant to section 97 of this Order, if the request is not refused.

93.—(1) If a request for re-examination of the certificate is filed based on the grounds stated in article 15 (1), *(a)* or *(b)*, of the Regulations, subsections (2) and (3) hereof shall apply.

(2) A copy of the request for re-examination with accompanying documents shall be sent to the certificate holder who shall be invited to comment on the request within 6 months.

If the certificate holder files a response to the request for re-examination, the Patent Authority shall decide whether further correspondence is required.

(3) If the Patent Authority does not find that further correspondence between the parties is required, the Patent Authority shall decide whether the request for re-examination shall be met. If the request cannot be met, it shall be refused. If the request is met, the certificate shall be revoked.

94.—(1) If a request for re-examination of a certificate is filed on the grounds stated in article 15 (1), *(c)*, of the Regulations, a request for re-examination of the basic patent shall also be filed, cf. however subsections 3 to 5 hereof. The request for re-examination of the basic patent shall state that a re-examination of the certificate has also been requested.

(2) A request for re-examination of the basic patent shall be examined according to the rules in sections 63 to 69 of this Order. When notified under section 65 of this Order, the proprietor of the patent shall be informed that a request for re-examination also of the certificate has been made. The examination of the request for reexamination of the certificate shall be suspended, until the re-examination of the basic patent has been finally settled. Then section 95 of this Order shall apply.

(3) If the request is filed on the sole ground that the product is no longer covered by the claims of the basic patent, the Patent Authority shall make its decision in accordance with section 95 (2) of this Order without any further examination of the basic patent.

(4) If the prescribed period for filing of oppositions against the basic patent has not expired, or if an opposition is filed against the basic patent, the Patent Authority shall suspend the examination of the request for re-examination of the certificate until the prescribed period for filing of oppositions has expired, or until the matter has been finally settled. Then section 95 of this Order shall apply.

(5) If re-examination or termination of the basic patent has been requested prior to a request for re-examination of the certificate, the request for re-examination of the certificate shall be suspended, until a final decision concerning the basic patent has been made. The examination of the request for re-examination of the basic patent shall be suspended until the re-examination of the basic patent has been finally settled. Then section 95 of this Order shall apply.

95.—(1) If a final decision has been made to revoke the basic patent, or to repeal it, the Patent Authority shall revoke the certificate under article 15 of the Regulations.

(2) If a final decision has been made to maintain the basic patent as amended, the Patent Authority shall decide, after having given the parties an opportunity to file their observations, whether the product for which a certificate has been issued is still protected by the basic patent. If this is not the case, the certificate shall be revoked.

(3) If a request for re-examination of the certificate cannot be met, it shall be refused, and the certificate shall be maintained.

Administrative Re-Examination of the Terms of the Certificate

96.—(1) Any person shall be entitled, against payment of the prescribed fee, to file a request for re-examination of the term calculated for the certificate with the Patent Authority.

(2) Section 92 of this Order shall apply, however, in the case of a request for re-examination of the term of the certificate, reference shall be made to the grounds referred to in article 13 of the Regulations.

(3) If a request for re-examination is filed by another person than the certificate holder, a copy of the request with accompanying documents shall be forwarded to the certificate holder who shall be invited to file his observations within 2 months. If the certificate holder files a response, the Patent Authority shall decide whether further correspondence between the parties is required.

(4) If the Patent Authority finds that no further correspondence between the parties is required, the Patent Authority shall decide whether the request for re-examination may be met. If the request cannot be met, it shall be refused. If the request can be met, the Patent Authority shall change the term.

Advertisement and Entry in the Register of Certificates Concerning Re-Examination

97.—(1) The advertisement concerning the filing of and the decision on a request for reexamination shall state the certificate holder's name or firm name, the number and date of filing of the application, the registration number of the certificate, the number and classes of the basic patent, the title of the invention and the term of the certificate. The advertisement of the filing of a request for re-examination shall also state the name or firm name of the person who has requested the re-examination.

(2) An entry shall be made of the decision in the Register of Certificates.

Re-Establishment after Lapse

98.—(1) The provisions in section 72 of the Patents Act shall apply to loss of rights as a consequence of failure to comply with a specifically fixed time limit in the Regulations. Re-establishment may also be made when a certificate has lapsed under article 14, *(c)* or *(d)*, of the Regulations.

(2) For the request of re-establishment under subsection 1 hereof the prescribed fee shall be paid.

(3) When a request under subsection 1 hereof has been met, this shall be advertised.

CHAPTER VI
INTERNATIONAL APPLICATIONS AND EUROPEAN APPLICATIONS AND PATENTS

Part 18
Receipt of International Applications, etc.

99.—(1) The Patent Office is the receiving Office for international applications from applicants who are Danish nationals and applicants who are residents of Denmark or have a commercial establishment in Denmark or who are legal entities recognised according to Danish law.

(2) If an international application is filed by several applicants, and if at least one of the applicants complies with the conditions referred to in subsection 1 hereof, that subsection shall apply with respect to the filing of the application.

(3) An applicant who is not a resident of this country shall have an agent residing in this country to represent him before the Patent Office in all matters concerning the application.

100.—(1) In its capacity as receiving Office, the Patent Office shall receive, check and transmit international applications in accordance with the Patent Cooperation Treaty and its Regulations.

(2) The applicant shall pay the following fees to the Patent Office in its capacity as receiving Office:

(i) the basic fee referred to in Rule 15 (1) of the Regulations under the Patent Cooperation Treaty within 1 month from receipt of the application,

(ii) the designation fee referred to in Rule 15 (1) of the said Regulations within 1 year of the international date of filing of the application, or, if priority is claimed, from the date of priority, however, in the latter case the fee may always be paid within 1 month from receipt of the application,

(iii) the search fee referred to in Rule 16 (1) of the said Regulations within 1 month from receipt of the application,

(iv) the fee for the Patent Office's handling of the application as receiving Office (the transmittal fee) referred to in Rule 14 of the said Regulations within 1 month from receipt of the application, and

(v) the confirmation fee referred to in Rule 15 (5) of the said Regulations within 15 months of the international date of filing of the application, or, if priority is claimed, from the date of priority.

(3) If one of the fees referred to in subsection 2 hereof have not been paid in due time, or has been paid in an insufficient amount at the expiry of the time limit, Rule 16 ^{bis} of the said Regulations shall apply.

101.—(1) The applicant may choose whether the Swedish Patent Authority or the European Patent Office shall be the International Searching Authority considering the applications referred to in section 99 (1) of this Order. If the Swedish Patent Authority is elected as Searching Authority, the application shall be written in Danish or English. If the European Patent Office is elected, the application shall be written in English, French or German.

(2) International applications filed with the Patent Office shall be filed in a single copy. They shall be written in a language accepted by the International Searching Authority, cf. subsection 1 hereof. A request form in English may be used even if the other documents of the application are written in Danish.

102. A separate record shall be kept of international patent applications filed with the Patent Office. The record shall not be open to the public.

103. Provided that the international application is not comprised by the Danish Secret Patents Act, the Patent Office shall, in accordance with the Patent Cooperation Treaty and its Regulations, transmit the application to the International Bureau referred to in section 10 of this Order.

Part 19
Proceeding with International Applications

104.—(1) The provisions of section 8 (2) of this Order shall apply *mutatis mutandis* in respect of the filing of a translation when proceeding with an international application under section 31 of the Patents Act, and when the review referred to in section 38 (1) of the Patents Act is requested.

(2) The Patent Office may reduce the obligation to file a translation in cases where only part of an international application is proceeded with in this country. If translation of only part of an international application is filed, the applicant shall make a declaration from which it appears which parts of the international application are not included in the translation. The declaration shall also state the reason for leaving out the parts concerned.

105.—(1) The time limit referred to in section 34 of the Patents Act shall expire 4 months after the expiry of the time limit prescribed in section 31 (1) of the said Act.

(2) If, however, the applicant within 19 months from the international date of filing or, if priority is claimed, from the priority date, has filed a declaration as referred to in section 31 (2) of the said Act, the time limit referred to in section 34 of the Patents Act shall, however, expire at the same time as the time limit for proceeding with the application laid down in the said subsection.

106. If, with respect to an international application, the applicant has complied with the provisions of section 31 of the Patents Act, but the Patent Office has not yet received notification from the International Bureau referred to in section 10 of this Order to the effect that the Bureau has received the application, the Patent Office shall notify the Bureau thereof.

107.—(1) The time limit for presenting a request for a review under section 38 (2) of the Patents Act shall expire 2 months after the date on which the receiving Office or the International Bureau referred to in section 10 of this Order has notified the applicant of such decision as referred to in section 38 (1) of the Patents Act.

(2) If the applicant proves that he has received the notification referred to in subsection 1 hereof later than 7 days after the date of the notification, the time limit shall be extended by as many days in excess of 7 as have passed from the date of the notification until the date on which the applicant received the notification.

Part 20
European Patent Applications and Patents, etc.

108.—(1) If a European patent application is filed with the Patent Office, the Patent Office shall indicate the date of filing on the documents of the application, issue a receipt for the documents and notify the European Patent Office thereof, cf. Rule 24 (2) and (3) of the Regulations under the European Patent Convention.

(2) Provided that the European application is not comprised by the Danish Secret Patents Act, the Patent Office shall, in accordance with Article 77 of the European Patent Convention and its Regulations, transmit the application to the European Patent Office.

109. If the Patent Office, under Article 136 (2) of the European Patent Convention, receives a request for conversion from the applicant, the Patent Office shall immediately transmit the request together with a copy of the application to the Patent Authorities of the countries specified in the request.

110.—(1) If a European patent application is transmitted to the Patent Office under Article 136 of the European Patent Convention, the Patent Office shall inform the applicant thereof without delay.

(2) The application fee and the translation or, if the European application is written in Danish, a copy of the application as required under section 88 (1) (iii) of the Patents Act, shall be received by the Patent Office within 3 months from the date on which the Patent Office sent the notification referred to in subsection 1 hereof to the applicant.

(3) If the applicant has filed a request for search and examination of the patentability of an application based on documents in English, cf. section 8 (3) of this Order, the translation referred to in subsection 2 hereof shall be filed within 3 months from the date on which the Patent Office notified the applicant of the result of the examination.

111.—(1) The Patent Office shall keep a separate record of European patent applications for which translations have been filed pursuant to sections 83 and 95 of the Patents Act. The record shall be open to the public.

(2) In the record shall be entered the application's number with the European Patent Office, the applicant's name or firm name and mailing address and the date on which the translation or a corrected translation was received by the Patent Office as well as the date on

which the filing of the translation or a corrected translation was advertised. Finally, the date which has been accorded as the filing date of the application, the information referred to in section 6 (2), (iv) to (vi), (xi) and (xiv) to (xv) and, if the application is a European divisional application, the date of filing of the divisional application shall be recorded.

(3) If a translation is filed and the fee is paid under section 77 of the Patents Act, a note to that effect as well as the date of the advertisement thereof under section 112 of this Order shall be entered in the record. The same shall apply to any correction of such a translation received before the patent is entered in the Register under section 50 of this Order.

112.—(1) Within 3 months from the date on which the European Patent Office has published its decision to let the patent application proceed to grant or to maintain the patent in an amended form, the filing of the translation and the payment of the fee under section 77 of the Patents Act shall take place.

(2) The translation under subsection 1 hereof shall comprise the title of the invention, the description, including any drawings and photos and sequence list necessary for the understanding of the invention, and the patent claims.

(3) The translation under section 77 (1), 1st clause, of the Patents Act shall be accompanied by a separate letter stating the number of the patent application and the applicant's name or firm name and mailing address. The translation under section 77 (1), 2nd clause, of the Act shall be accompanied by a separate letter stating the number of the patent and the name or firm name and mailing address of the proprietor of the patent.

(4) If the requirements of subsections 2 and 3 hereof are not complied with, the translation shall be deemed not to have been filed.

113. The translation under sections 83 and 95 of the Patents Act shall be accompanied by a separate letter stating the number of the application and the applicant's name or firm name and mailing address. If that requirement is not complied with, the translation shall be deemed not to have been filed.

114.—(1) Advertisements concerning translations under section 77 of the Patents Act shall contain the information referred to in section 112 (3) of this Order, the classes of the patent application or the patent, the title of the invention, the date accorded as the filing date of the application, and the date on which the European Patent Office has published its decision to let the patent application proceed to grant or to maintain the patent in an amended form and, if priority is claimed, where the previous application whose priority is claimed was filed and the date of filing and number of that application.

(2) Advertisements concerning translations under sections 83 and 95 of the Patents Act shall contain the information referred to in section 113 of this Order, as well as information on the classes of the application, the title of the invention, the date accorded as the filing date of the application and, if priority is claimed, where the previous application whose priority is claimed was filed and the date of filing and number of that application.

115.—(1) Correction of the translation under section 86 of the Patents Act shall be made by filing a new copy of the document clearly indicating the correction accompanied by a separate letter stating the number of the patent or the patent application and the name and address of the proprietor of the patent or the applicant, respectively.

(2) If the requirements in subsection l hereof are not complied with, the corrected translation shall be deemed not to have been filed.

(3) Advertisements under section 86 (1) of the Patents Act shall contain the information referred to in section 112 (3) of this Order, the classes of the patent application or the patent, the title of the invention, and the date on which the Patent Office received the corrected translation and the prescribed fee.

(4) Advertisements under section 86 (2) of the Patents Act shall contain the information referred to in section 113 of this Order, the classes of the application, the title of the invention, and the date on which the Patent Office received the corrected translation.

116. In the examination and other processing of translations of European patent applications pursuant to sections 83 and 95 of the Patents Act, the Patent Office may grant exemption from the obligation to have an agent of section 12 of the Patents Act.

CHAPTER VII
MISCELLANEOUS PROVISIONS

Part 21
[Without Title]

117. Notwithstanding a granted patent, spare parts and accessories for aircraft may be imported into and used in this country for the repair of aircraft belonging to another State being a party to the Convention of 7 December 1944 on International Civil Aviation and either being a party to the Paris Convention for the Protection of Industrial property of 20 March 1883 or having a patent legislation which recognises inventions made by nationals of another State which is a party to the first-mentioned Convention and protects such inventions by a legislation which is in principle in conformity with the Paris Convention.

118. Advertisements shall be inserted in »Dansk Patenttidende« (the Danish Patent Gazette) issued by the Patent Office.

119.—(1) If the parties to an opposition, a request for administrative re-examination or a request for termination are represented by an agent, power of attorney shall be filed. However, the Patent Authority may grant exemption from the requirement concerning a written power of attorney.

(2) The documents for the examination of the cases referred to in subsection 1 hereof shall be in Danish, Norwegian or Swedish. If the documents are drawn up in any other language, section 8 (2) of this Order shall apply *mutatis mutandis*.

120.—(1) In the evaluation of the possibility of obtaining a compulsory licence under section 45 (1) of the Patents Act, working within the European Communities or working in a state which has ratified or has acceded to the Agreement on the European Economic Area (EEA) or the Agreement on the Establishment of the World Trade Organisation (WTO) shall be equivalent to working in this country.

(2) In the evaluation of the possibility of obtaining a compulsory licence under section 48 of the Patents Act, exploitation within the European Communities or exploitation in a state which has ratified or has acceded to the Agreement on the European Economic Area (EEA) or the Agreement on the Establishment of the World Trade Organisation (WTO) shall be equivalent to exploitation in this country.

CHAPTER VIII
ENTRY INTO FORCE, TRANSITIONAL PROVISIONS

Part 22
Entry into Force

121.—(1) This Order shall enter into force on 8 February 1997.

(2) The provisions in sections 72 to 98 and sections 108 to 116 of this Order shall not apply to the Faroe Islands and Greenland.

(3) At the same time Order No. 1193 of 23 December 1992 shall be repealed.

(4) The provisions of this Order relating to international preliminary examination under the Patent Cooperation Treaty have been put into force by Order No. 602 of 26 August 1988.

Transitional Provisions

122. This Order shall also apply to patent applications which on its entry into force are pending before the Patent Authority with the following exceptions:

(i) Section 10 *a* shall apply to applications filed after 31 December 1995.

(ii) Section 12 (3) of Order No. 1193 of 23 December 1992 shall apply to applications filed prior to 1 January, 1996.

(iii) The provision of section 18 shall apply to applications filed after 31 December 1992.

(iv) If the applicant has been informed prior to 1 January 1993 that the application has been accepted for laying open to public inspection, the examination of the application shall be finished under the existing rules.

(v) If the applicant has been informed prior to 1 December 1978 that the application has been accepted for laying open to public inspection, the provisions of Order No. 481 of 20 December 1967 shall apply.

(vi) The provisions of sections 2, 9, 10 and 56 of Order No. 481 of 20 December 1967 shall apply to applications filed prior to 1 December 1978.

(vii) The provisions of Order No. 481 of 20 December 1967 shall apply to applications for additional patents.

(viii) The provisions of this Order concerning the deposit of cultures of micro-organisms shall only apply to applications filed after 1 July 1985.

The Danish Patent Office, 30 January 1997

Mogens Kring
/ Pia H. Rønager

Annex

Council Regulation (EEC) No. 1768/92 of 18 June 1992 Concerning the Creation of a Supplementary Protection Certificate for Medicinal Products

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100*a* thereof,

Having regard to the proposal from the Commission[(1)],

In cooperation with the European Parliament[(2)],

Having regard to the opinion of the Economic and Social Committee[(3)],

Whereas pharmaceutical research plays a decisive role in the continuing improvement in public health;

Whereas medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research;

Whereas at the moment the period that elapses between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research;

Whereas this situation leads to a lack of protection which penalizes pharmaceutical research;

Whereas the current situation is creating the risk of research centres situated in the Member States relocating to countries that already offer greater protection;

Whereas a uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly affect the establishment and the functioning of the internal market;

Whereas, therefore, the creation of a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which marketing authorization has been granted is necessary; whereas a Regulation is therefore the most appropriate legal instrument;

Whereas the duration of the protection granted by the certificate should be such as to provide adequate effective protection; whereas, for this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of fifteen years of exclusively

from the time the medicinal product in question first obtains authorization to be placed on the market in the Community;

Whereas all the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector must nevertheless be taken into account; whereas, for this purpose, the certificate cannot be granted for a period exceeding five years; whereas the protection granted should furthermore be strictly confined to the product which obtained authorization to be placed on the market as a medicinal product;

Whereas a fair balance should also be struck with regard to the determination of the transitional arrangements; whereas such arrangements should enable the Community pharmaceutical industry to catch up to some extent with its main competitors who, for a number of years, have been covered by laws guaranteeing them more adequate protection, while making sure that the arrangements do not compromise the achievement of other legitimate objectives concerning the health policies pursued both at national and Community level;

Whereas the transitional arrangements applicable to applications for certificates filed and to certificates granted under national legislation prior to the entry into force of this Regulation should be defined;

Whereas special arrangements should be allowed in Member States whose laws introduced the patentability of pharmaceutical products only very recently;

Whereas provision should be made for appropriate limitation of the duration of the certificate in the special case where a patent term has already been extended under a specific national law,

HAS ADOPTED THIS REGULATION:

Definitions

1. For the purposes of this Regulation:

(a) 'medicinal product' means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;

(b) 'product' means the active ingredient or combination of active ingredients of a medicinal product;

(c) 'basic patent' means a patent which protects a product as defined in *(b)* as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;

(d) 'certificate' means the supplementary protection certificate.

Scope

2. Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorization procedure as laid down in Council Directive 65/65/EEC[(4)] or Directive 81/851/EEC[(5)] may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.

Conditions for Obtaining a Certificate

3. A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:

(a) the product is protected by a basic patent in force:

(b) a valid authorization to place the product on the market as a medicinal product has been granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC, as appropriate;

(c) the product has not already been the subject of a certificate;

(d) the authorization referred to in *(b)* is the first authorization to place the product on the market as a medicinal product.

Subject-Matter of Protection

4. Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorization to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorized before the expiry of the certificate.

Effects of the Certificate

5. Subject to the provisions of Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.

Entitlement to the Certificate

6. The certificate shall be granted to the holder of the basic patent or his successor in title.

Application for a Certificate

7.—(1) The application for a certificate shall be lodged within six months of the date on which the authorization referred to in Article 3 *(b)* to place the product on the market as a medicinal product was granted.

(2) Notwithstanding paragraph 1, where the authorization to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within six months of the date on which the patent is granted.

Content of the Application for a Certificate

8.—(1) The application for a certificate shall contain:

(a) a request for the grant of a certificate, stating in particular:

(i) the name and address of the applicant;

(ii) if he has appointed a representative, the name and address of the representative;

(iii) the number of the basic patent and the title of the invention;

(iv) the number and date of the first authorization to place the product on the market, as referred to in Article 3 *(b)* 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;

(b) a copy of the authorization to place the product on the market, as referred to in Article 3 *(b)*, in which the product is identified, containing in particular the number and date of the authorization and the summary of the product characteristics listed in Article 4*a* of Directive 65/65/EEC or Article 5*a* of Directive 81/851/EEC;

(c) if the authorization referred to in *(b)* is not the first authorization for placing the product on the market as a medicinal product in the Community, information regarding the identity of the product thus authorized and the legal provision under which the authorization procedure took place, together with a copy of the notice publishing the authorization in the appropriate official publication.

2. Member States may provide that a fee is to be payable upon application for a certificate.

Lodging of an Application for a Certificate

9.—(1) The application for a certificate shall be lodged with the competent industrial property office of the Member State which granted the basic patent or on whose behalf it was granted and in which the authorization referred to in Article 3 *(b)* to place the product on the market was obtained, unless the Member State designates another authority for the purpose.

(2) Notification of the application for a certificate shall be published by the authority referred to in paragraph 1. The notification shall contain at least the following information:

(a) the name and address of the applicant;

(b) the number of the basic patent;

(c) the title of the invention;

(d) the number and date of the authorization to place the product on the market, referred to in Article 3 *(b)*, and the product identified in that authorization;

(e) where relevant, the number and date of the first authorization to place the product on the market in the Community.

Grant of the Certificate or Rejection of the Application

10.—(1) Where the application for a certificate and the product to which it relates meet the conditions laid down in this Regulation, the authority referred to in Article 9 (1) shall grant the certificate.

(2) The authority referred to in Article 9 (1) shall, subject to paragraph 3, reject the application for a certificate if the application or the product to which it relates does not meet the conditions laid down in this Regulation.

(3) Where the application for a certificate does not meet the conditions laid down in Article 8, the authority referred to in Article 9 (1) shall ask the applicant to rectify the irregularity, or to settle the fee, within a stated time.

(4) If the irregularity is not rectified or the fee is not settled under paragraph 3 within the stated time, the authority shall reject the application.

(5) Member states may provide that the authority referred to in Article 9 (1) is to grant certificates without verifying that the conditions laid down in Article 3 *(c)* and *(d)* are met.

Publication

11.—(1) Notification of the fact that a certificate has been granted shall be published by the authority referred to in Article 9 (1). The notification shall contain at least the following information:

(a) the name and address of the holder of the certificate;

(b) the number of the basic patent;

(c) the title of the invention;

(d) the number and date of the authorization to place the product on the market referred to in Article 3 *(b)* and the product identified in that authorization;

(e) where relevant, the number and date of the first authorization to place the product on the market in the Community;

(f) the duration of the certificate.

2. Notification of the fact that the application for a certificate has been rejected shall be published by the authority referred to in Article 9 (1). The notification shall contain at least the information listed in Article 9 (2).

Annual Fees

12. Member States may require that the certificate be subject to the payment of annual fees.

Duration of the Certificate

13.—(1) The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community reduced by a period of five years.

(2) Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect.

Expiry of the Certificate

14. The certificate shall lapse:

(a) at the end of the period provided for in Article 13;

(b) if the certificate-holder surrenders it;

(c) if the annual fee laid down in accordance with Article 12 is not paid in time;

(d) if and as long as the product covered by the certificate may no longer be placed on the market following the withdrawal of the appropriate authorization or authorizations to place on the market in accordance with Directive 65/65/EEC or Directive 81/851/EEC. The authority referred to in Article 9 (1) may decide on the lapse of the certificate either of its own motion or at the request of a third party.

Invalidity of the Certificate

15.—(1) The certificate shall be invalid if:

(a) it was granted contrary to the provisions of Article 3;

(b) the basic patent has lapsed before its lawful term expires;

(c) the basic patent is revoked or limited to the extent that the product for which the certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.

(2) Any person may submit an application or bring an action for a declaration of invalidity of the certificate before the body responsible under national law for the renovation of the corresponding basic patent.

Notification of Lapse or Invalidity

16. If the certificate lapses in accordance with Article 14 *(b)*, *(c)* or *(d)* or is invalid in accordance with Article 15, notification thereof shall be published by the authority referred to in Article 9 (1).

Appeals

17. The decisions of the authority referred to in Article 9 (1) or of the body referred to in Article 15 (2) taken under this Regulation shall be open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents.

Procedure

18.—(1) In the absence of procedural provisions in this Regulation, the procedural provisions applicable under national law to the corresponding basic patent shall apply to the certificate, unless that law lays down special procedural provisions for certificates.

(2) Notwithstanding paragraph 1, the procedure for opposition to the granting of a certificate shall be excluded.

Transitional Provisions

19.—(1) Any product which, on the date on which this Regulation enters into force, is protected by a valid basis patent and for which the first authorization to place it on the market as a medicinal product in the Community was obtained after 1 January 1985 may be granted a certificate.

In the case of certificates to be granted in Denmark and in Germany, the date of 1 January 1985 shall be replaced by that of 1 January 1988.

In the case of certificates to be granted in Belgium and in Italy, the date of 1 January 1985 shall be replaced by that of 1 January 1982.

(2) An application for a certificate as referred to in paragraph 1 shall be submitted within six months of the date on which this Regulation enters into force.

[Without Title]

20. This Regulation shall not apply to certificates granted in accordance with the national legislation of a Member State before the date on which this Regulation enters into force or to applications for a certificate filed in accordance with that legislation before the date of publication of this Regulation in the *Official Journal of the European Communities.*

[Without Title]

21. In those Member States whose national law did not on 1 January 1990 provide for the patentability of pharmaceutical products, this Regulation shall apply five years after the entry into force of this Regulation.

Article 19 shall not apply in those Member States.

[Without Title]

22. Where a certificate is granted for a product protected by a patent which, before the date on which this Regulation enters into force, has had its term extended or for which such extension was applied for, under national patent law, the term of protection to be afforded under this certificate shall be reduced by the number of years by which the term of the patent exceeds 20 years.

FINAL PROVISION

Entry into Force

23. This Regulation shall enter into force six months after its publication in the *Official Journal of the European Communities.*

This Regulation is binding in its entirety and directly applicable in all Member States.

Done at Luxembourg, 18 June 1992.

For the Council

The President

Vitor MARTINS

(1) OJ No C 114, 8.5.1990, p. 10.

(2) OJ No C 19, 28.1.1991, p. 94, and OJ No C 150, 15.6.1992.

(3) OJ No C 69, 18.3.1991, p. 22.

(4) OJ No L 22, 9.12.1965, p. 369. Last amended by Directive 89/341 /EEC (OJ No L 142, 25.5.1989, p. 1).

(5) OJ No L317, 6.11.1981, p. 1. Amended by Directive 90/676/EEC. (OJ No L 373, 31.12.1990, p. 15).

Regulation (EC) No. 1610/96 of the European Parliament and of the Council

of 23 July 1996
Concerning the Creation of a Supplementary Protection Certificate for Plant Protection products

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION.

Having regard to the Treaty. establishing the European Community, and in particular Article 100*a* thereof, Having regard to the proposal from the Commission(1),

Having regard to the opinion of the Economic and Social Committee(2)

Acting in accordance with the procedure referred to in Article 189*b* of the Treaty(3),

(1) Whereas research into plant protection products contributes to the continuing improvement in the production and procurement of plentiful food of good quality at affordable prices;

(2) Whereas plant protection research contributes to the continuing improvement in crop production;

(3) Whereas plant protection products, especially those that are the result of long, costly research, will continue to be developed in the Community and in Europe if they are covered by favourable rules that provide for sufficient protection to encourage such research;

(4) Whereas the competitiveness of the plant protection sector, by the very nature of the industry, requires a level of protection for innovation which is equivalent to that granted to medicinal products by Council Regulation (EEC) No. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products(4);

(5) Whereas, at the moment, the period that elapses between the filing of an application for a patent for a new plant protection product and authorization to place the said plant protection product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research and to generate the resources needed to maintain a high level of research;

(6) Whereas this situation leads to a lack of protection which penalizes plant protection research and the competitiveness of the sector;

(7) Whereas one of the main objectives of the supplementary protection certificate is to place European industry on the same competitive footing as its North American and Japanese counterparts;

(8) Whereas, in its Resolution of 1 February 1993(5) on a Community programme of policy and action in relation to the environment and sustainable development, the Council adopted the general approach and strategy of the programme presented by the Commission,

which stressed the interdependence of economic growth and environmental quality; whereas improving protection of the environment means maintaining the economic competitiveness of industry; whereas, accordingly, the issue of a supplementary protection certificate can be regarded as a positive measure in favour of environmental protection;

(9) Whereas a uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to hinder the free movement of plant protection products within the Community and thus directly affect the functioning of the internal market; whereas this is in accordance with the principle of subsidiarity as defined by Article 3*b* of the Treaty;

(10) Whereas, therefore, there is a need to create a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a plant protection product for which marketing authorization has been granted is necessary; whereas a Regulation is therefore the most appropriate legal instrument;

(11) Whereas the duration of the protection granted by the certificate should be such as to provide adequate, effective protection; whereas, for this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of fifteen years of exclusivity from the time the plant protection product in question first obtains authorization to be placed on the market in the Community;

(12) Whereas all the interests at stake in a sector as complex and sensitive as plant protection must nevertheless be taken into account; whereas, for this purpose, the certificate cannot be granted for a period exceeding five years;

(13) Whereas the certificate confers the same rights as those conferred by the basic patent; whereas, consequently, where the basic patent covers an active substance and its various derivatives (salts and esters), the certificate confers the same protection;

(14) Whereas the issue of a certificate for a product consisting of an active substance does not prejudice the issue of other certificates for derivatives (salts and esters) of the substance, provided that the derivatives are the subject of patents specifically covering them;

(15) Whereas a fair balance should also be stuck with regard to the determination of the transitional arrangements; whereas such arrangements should enable the Community plant protection industry to catch up to some extent with its main competitors, while making sure that the arrangements do not compromise the achievement of other legitimate objectives concerning the agricultural policy and environment protection policy pursued at both national and Community level;

(16) Whereas only action at Community level will enable the objective, which consists in ensuring adequate protection for innovation in the field of plant protection, while guaranteeing the proper functioning of the internal market for plant protection products, to be attained effectively;

(17) Whereas the detailed rules in recitals 12, 13 and 14 and in Articles 3 (2), 4, 8 (1) *(c)* and 17 (2) of this Regulation are also valid, *mutatis mutandis*, for the interpretation in particular of recital 9 and Articles 3, 4, 8 (1) *(c)* and 17 of Council Regulation (EEC) No. 1768/92,

(1) OJ C 390, 31.12.1994, p. 21 and OJ C 335, 13.12.1995, p. 15.

(2) OJ No C 155, 21.6.1995, p. 14.

(3) Opinion of the European Parliament of 15 June 1995 (OJ C 166, 3.7.1995, p. 89), common position of the Council of 27 November 1995 (OJ C 353, 30.12.1995, p. 36) and decision of the European Parliament of 12 March 1996 (OJ C 96, 1.4.1996, .p. 30).

(4) OJ No L 182 2.7.1992, p. 1.

(5) OJ No C 138, 17.5.1993, p. 1.

HAVE ADOPTED THIS REGULATION:

Definitions

1. For the purposes of this Regulation, the following definitions shall apply:

(1) 'plant protection products': active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to:

(a) protect plants or plant products against all harmful organisms or prevent the action of such organisms, in so far as such substances or preparations are not otherwise defined below;

(b) influence the life processes of plants, other than as a nutrient (e.g. plant growth regulators);

(c) preserve plant products, in so far as such substances or products are not subject to special Council or Commission provisions on preservatives;

(d) destroy undesirable plants; or

(e) destroy parts of plants, check or prevent undesirable growth of plants;

(2) 'substances': chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process;

(3) 'active substances': substances or micro-organisms including viruses, having general or specific action:

(a) against harmful organisms; or

(b) on plants, parts of plants or plant products;

(4) 'preparations': mixtures or solutions composed of two or more substances, of which at least one is an active substance, intended for use as plant protection products;

(5) 'plants': live plants and live parts of plants, including fresh fruit and seeds;

(6) 'plant products': products in the unprocessed state or having undergone only simple preparation such as milling, drying or pressing, derived from plants but excluding plants themselves as defined in point 5;

(7) 'harmful organisms': pests of plants or plant products belonging to the animal or plant kingdom, and also viruses, bacteria and mycoplasmas and other pathogens;

(8) 'product': the active substance as defined in point 3 or combination of active substances of a plant protection product;

(9) 'basic patent': a patent which protects a product as defined in point 8 as such, a preparation as defined in point 4, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;

(10) 'certificate': the supplementary protection certificate.

Scope

2. Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a plant protection product, to an administrative authorization procedure as laid down in Article 4 of Directive 91/414/EEC[(1)], or pursuant to an equivalent provision of national law if it is a plant protection product in respect of which the application for authorization was lodged before Directive 91/414/EEC was implemented by the Member State concerned, may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.

Conditions for Obtaining a Certificate

3.—(1) A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted, at the date of that application:

(a) the product is protected by a basic patent in force;

(b) a valid authorization to place the product on the market as a plant protection product has been granted in accordance with Article 4 of Directive 91/414/EEC or an equivalent provision of national law;

(c) the product has not already been the subject of a certificate;

(d) the authorization referred to in *(b)* is the first authorization to place the product on the market as a plant protection product.

(2) The holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for this product may be issued to each of these holders.

Subject-Matter of Protection

4. Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorizations to place the corresponding plant protection product on the market and for any use of the product as a plant protection product that has been authorized before the expiry of the certificate.

Effects of the Certificate

5. Subject to Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.

Entitlement to the Certificate

6. The certificate shall be granted to the holder of the basic patent or his successor in title.

Application for a Certificate

7.—(1) The application for a certificate shall be lodged within six months of the date on which the authorization referred to in Article 3 (1) *(b)* to place the product on the market as a plant protection product was granted.

(2) Notwithstanding paragraph 1, where the authorization to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within six months of the date on which the patent is granted.

Content of the Application for a Certificate

8.—(1) The application for a certificate shall contain:

(a) a request for the grant of a certificate, stating in particular:

(i) the name and address of the applicant;

(ii) the name and address of the representative, if any;

(iii) the number of the basic patent and the title of the invention;

(iv) the number and date of the first authorization to place the product on the market, as referred to in Article 3 (1) *(b)* and, if this authorization is not the first authorization to place the product on the market in the Community, the number and date of that authorization;

(b) a copy of the authorization to place the product on the market, as referred to in Article 3 (1) *(b)*, in which the product is identified, containing in particular the number and date of the authorization and the summary of the product characteristics listed in Part A.I (points 1-7) or B.I (points 1-7) of Annex 11 to Directive 91/414/EEC or in equivalent national laws of the Member State in which the application was lodged;

(c) if the authorization referred to in *(b)* is not the first authorization to place the product on the market as a plant protection product in the Community, information regarding the identity of the product thus authorized and the legal provision under which the authorization procedure took place, together with a copy of the notice publishing the authorization in the appropriate official publication or, failing such a notice, any other document proving that the authorization has been issued, the date on which it was issued and the identity of the product authorized.

(2) Member States may require a fee to be payable upon application for a certificate.

Lodging of an Application for a Certificate

9.—(l) The application for a certificate shall be lodged with the competent industrial property office of the Member State which granted the basic patent or on whose behalf it was granted and in which the authorization referred to in Article 3 (1) *(b)* to place the product on the market was obtained, unless the member State designates another authority for the purpose.

(2) Notification of the application for a certificate shall be published by the authority referred to in paragraph 1.

The notification shall contain at least the following information:

(a) the name and address of the applicant;

(b) the number of the basic patent;

(c) the title of the invention;

(d) the number and date of the authorization to place the product on the market, referred to in Article 3 (1) *(b)*, and the product identified in that authorization;

(e) where relevant, the number and date of the first authorization to place the product on the market in the Community.

Grant of the Certificate or Rejection of the Application

10.—(1) Where the application for a certificate and the product to which it relates meet the conditions laid down in this Regulation, the authority referred to in Article 9 (1) shall grant the certificate.

(2) The authority referred to in Article 9 (1) shall, subject to paragraph 3, reject the application for a certificate if the application or the product to which it relates does not meet the conditions laid down in this Regulation.

(3) Where the application for a certificate does not meet the conditions laid down in Article 8, the authority referred to in Article 9 (1) shall ask the applicant to rectify the irregularity, or to settle the fee, within a stated time.

(4) If the irregularity is not rectified or the fee is not settled under paragraph 3 within the stated time, the application shall be rejected.

(5) Member States may provide that the authority referred to in Article 9 (1) is to grant certificates without verifying that the conditions laid down in Article 3 (1) *(c)* and *(d)* are met.

Publication

11.—(1) Notification of the fact that a certificate has been granted shall be published by the authority referred to in Article 9 (1). The notification shall contain at least the following information:

(a) the name and address of the holder of the certificate;

(b) the number of the basic patent;

(c) the title of the invention;

(d) the number and date of the authorization to place the product on the market referred to in Article 3 (1) *(b)* and the product identified in that authorization;

(e) where relevant, the number and date of the first authorization to place the product on the market in the Community;

(f) the duration of the certificate.

(2) Notification of the fact that the application for a certificate has been rejected shall be published by the authority referred to in Article 9 (1). The notification shall contain at least the information listed in Article 9 (2).

Annual Fees

12. Member States may require the certificate to be subject to the payment of annual fees.

Duration of the Certificate

13.—(1) The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community, reduced by a period of five years.

(2) Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect.

(3) For the purposes of calculating the duration of the certificate, account shall be taken of a provisional first marketing authorization only if it is directly followed by a definitive authorization concerning the same product.

Expiry of the Certificate

14. The certificate shall lapse:

(a) at the end of the period provided for in Article 13;

(b) if the certificate-holder surrenders it;

(c) if the annual fee laid down in accordance 12 is not paid in time;

(d) if and as long as the product covered by the certificate may no longer be placed on the market following the withdrawal of the appropriate authorization or authorizations to place it on the market in accordance with Article 4 of Directive 91/414/EEC or equivalent provisions of national law. The authority referred to in Article 9 (1) may decide on the lapse of the certificate either on its own initiative or at the request of a third party.

Invalidity of the Certificate

15.—(1) The certificate shall be invalid if

(a) it was granted contrary to the provisions of Article 3;

(b) the basic patent has lapsed before its lawful term expires;

(c) the basic patent is revoked or limited to the extent that the product for which the certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation.

(2) Any person may submit an application or bring an action for a declaration of invalidity of the certificate before the body responsible under national law for the revocation of the corresponding basic patent.

Notification of Lapse or Invalidity

16. If the certificate lapses in accordance with Article 14 *(b)*, *(c)* or *(d)* or is invalid in accordance with Article 15, notification thereof shall be published by the authority referred to in Article 9 (1).

Appeals

17.—(1) The decisions of the authority referred to in Article 9 (1) or of the body referred to in Article 15 (2) taken under this Regulation shall be open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents.

(2) The decision to grant the certificate shall be open to an appeal aimed at rectifying the duration of the certificate where the date of the first authorization to place the product on

the market in the Community, contained in the application for a certificate as provided for in Article 8, is incorrect.

Procedure

18.—(1) In the absence of procedural provisions in this Regulation, the procedural provisions applicable under national law to the corresponding basic patent and, where appropriate, the procedural provisions applicable to the certificates referred to in Regulation (EEC) No. 1768/92 shall apply to the certificate, unless national law lays down special procedural provisions for certificates as referred to in this Regulation.

(2) Notwithstanding paragraph 1, the procedure for opposition to the granting of a certificate shall be excluded.

Transitional Provisions

19.—(1) Any product which, on the date on which this Regulation enters into force, is protected by a valid basic patent and for which the first authorization to place it on the market as a plant protection product in the Community was obtained after 1 January 1985 under Article 4 of Directive 91/414/EEC or an equivalent national provision may be granted a certificate.

(2) An application made under paragraph 1 for a certificate shall be submitted within six months of the date on which this Regulation enters into force.

[Without Title]

20. In those Member States whose national law did not, on 1 January 1990, provide for the patentability of plant protection products, this Regulation shall apply from 2 January 1998.

Article 19 shall not apply in those Member States.

FINAL PROVISION

Entry into Force

21. This Regulation shall enter into force six months after its publication in the *Official Journal of the European Communities*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 23 July 1996.

For the European Parliament

The President

K. HÄNSCH

For the Council

The President
M. Lowry

(1) of L 230, 19.8.1991, p. 1. Directive as last amended by Directive 95/36/EC (OJ L 172, 22.7.1995, p. 8).