

European Court of Justice, 16 September 1999, Farmitalia



PATENT LAW

Scope of certificate

- where a product in the form referred to in the marketing authorisation is protected by a basic patent in force, the certificate is capable of covering that product, as a medicinal product, in any of the forms enjoying the protection of the basic patent.

By its first question, the national court asks, in substance, whether, on a proper construction of Article 3(b) of Regulation No 1768/92, the certificate can protect the product only in the specific form stated in the marketing authorisation.

In that regard, all the interested parties who have submitted observations have maintained, in particular, that while the certificate could protect only the particular salt form of the active ingredient mentioned as the active constituent in the marketing authorisation, whereas the basic patent protects the active ingredient as such as well as salts thereof, including the one which is the subject-matter of the marketing authorisation, any competitor would be able, after the basic patent had expired, to apply for and, in some circumstances, obtain marketing authorisation for a different salt of the same active ingredient, formerly protected by that patent. It would therefore be possible for medicinal products which were, in principle, therapeutically equivalent to that protected by the certificate to compete with the latter. The result would be to frustrate the purpose of Regulation No 1768/92, which is to ensure the holder of the basic patent of exclusivity on the market during a given period extending beyond the period of validity of the basic patent.

That line of argument must be accepted. If the certificate did not cover the actual medicinal product, as protected by the basic patent and one of the possible forms of which is the subject-matter of a marketing authorisation, the fundamental objective of Regulation No 1768/92, as set out in the first and second recitals in the preamble thereto, which is to provide for sufficient protection to encourage research in the pharmaceutical field, which plays a decisive role in the continuing improvement in public health, could not, for the reasons set out in paragraph 18 of this judgment, be attained.

Moreover, it should be borne in mind that the 13th recital in the preamble to Regulation (EC) 1610/96 of the

European Parliament and of the Council of 23 July 1996 which, by virtue of the 17th recital, is also valid, *mutatis mutandis*, for the interpretation *inter alia* of Article 3 of Regulation No 1768/92, states that the certificate confers the same rights as those conferred by the basic patent, with the result that, where the basic patent covers an active substance and its various derivatives (salts and esters), the certificate confers the same protection.

Accordingly, where an active ingredient in the form of a salt is referred to in the marketing authorisation concerned and is protected by a basic patent in force, the certificate is capable of covering the active ingredient as such and also its various derived forms such as salts and esters, as medicinal products, in so far as they are covered by the protection of the basic patent.

Consequently, the answer to the first question must be that, on a proper construction of Regulation No 1768/92 and, in particular, Article 3(b) thereof, where a product in the form referred to in the marketing authorisation is protected by a basic patent in force, the certificate is capable of covering that product, as a medicinal product, in any of the forms enjoying the protection of the basic patent.

Extent of patent protection

- whether a product is protected by a basic patent, reference must be made to the rules which govern that patent.

As Community law now stands, the provisions concerning patents have not yet been made the subject of harmonisation at Community level or of an approximation of laws.

Accordingly, in the absence of Community harmonisation of patent law, the extent of patent protection can be determined only in the light of the non-Community rules which govern patents.

As is clear in particular from paragraph 21 of this judgment, the protection conferred by the certificate cannot exceed the scope of the protection conferred by the basic patent.

The answer to be given to the second question must therefore be that, in order to determine, in connection with the application of Regulation No 1768/92 and, in particular, Article 3(a) thereof, whether a product is protected by a basic patent, reference must be made to the rules which govern that patent.

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European Court of Justice, 16 September 1999

(J.-P. Puissechot, P. Jann, C. Gulmann, D.A.O. Edward and L. Sevón)

JUDGMENT OF THE COURT (Fifth Chamber)

16 September 1999 (1)

(Proprietary medicinal products — Supplementary protection certificate)

In Case C-392/97,

REFERENCE to the Court under Article 177 of the EC Treaty (now Article 234 EC) by the Bundesgerichtshof,

Germany, for a preliminary ruling in the proceedings brought before that court by Farmitalia Carlo Erba Srl,

on the interpretation of Article 3(a) and (b) of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ 1992 L 182, p. 1),

THE COURT (Fifth Chamber),

composed of: J.-P. Puissochet, President of the Chamber, P. Jann, C. Gulmann (Rapporteur), D.A.O. Edward and L. Sevón, Judges,

Advocate General: N. Fennelly,

Registrar: L. Hewlett, Administrator,

after considering the written observations submitted on behalf of:

— Farmitalia Carlo Erba Srl, by M. Kindler, Rechtsanwalt, Munich,

— the German Government, by A. Dittrich, Ministerialrat in the Federal Ministry of Justice, and E. Röder, Regierungsdirektor in the Federal Ministry of Economic Affairs, acting as Agents,

— the French Government, by K. Rispal-Bellanger, Head of the Subdirectorate for International Economic Law and Community Law in the Legal Affairs Directorate of the Ministry of Foreign Affairs, and R. Loosli-Surrans, Chargé de Mission in the same Directorate, acting as Agents,

— the Netherlands Government, by J.G. Lammers, Acting Legal Adviser in the Ministry of Foreign Affairs, acting as Agent,

— the United Kingdom Government, by D. Cooper, Treasury Solicitor, acting as Agent,

— the Commission of the European Communities, by K. Banks, of its Legal Service, acting as Agent, assisted by I. Brinker, of the Brussels Bar,

having regard to the Report for the Hearing,

after hearing the oral observations of Farmitalia Carlo Erba Srl, represented by M. Kindler; of the French Government, represented by R. Loosli-Surrans; of the Netherlands Government, represented by J.S. van den Oosterkamp, Deputy Legal Adviser in the Ministry of Foreign Affairs, acting as Agent, and the Commission, represented by K. Banks, assisted by I. Brinker at the hearing on 4 March 1999,

after hearing the [Opinion of the Advocate General](#) at the sitting on 3 June 1999,

gives the following

Judgment

1. By order of 17 June 1997, received at the Court on 18 November 1997, the Bundesgerichtshof (Federal Supreme Court) referred to the Court for a preliminary ruling under Article 177 of the EC Treaty (now Article 234 EC), two questions on the interpretation of Article 3(a) and (b) of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ 1992 L 182, p. 1).

2. Those questions were raised in an appeal brought by Farmitalia Carlo Erba Srl ('Farmitalia') against the rejection by the Bundespatentgericht (Federal Patent

Court) of Farmitalia's application for the grant of a supplementary protection certificate ('the certificate') in the terms used by that company.

3. It is clear from the third and fourth recitals in the preamble to Regulation EEC No 1768/92 that, before the regulation was adopted, the period of effective protection under the patent was insufficient to cover the investment put into pharmaceutical research. The regulation is specifically intended to remedy that insufficiency by creating a certificate for medicinal products.

4. Article 1 of Regulation No 1768/92 provides:

'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 ...;

(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.'

5. Article 3 of Regulation No 1768/92, which defines the conditions for obtaining the certificate, provides:

'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 authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 65/65/EEC ...;

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

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

6. Farmitalia was the holder of German patent No 25 25 633, notified on 9 June 1975, the legal period of protection of which has now expired. The patent concerned alpha-anomers of 4-Demethoxy-daunomycin, processes for manufacturing them and medicaments containing those compositions. Claims 1 and 4 of that patent referred respectively to alpha-anomers of 4-Demethoxy-daunomycin with an indication of the corresponding formula, and the medicaments containing one of the compositions referred to in Claims 1 and 2 and usual additives and/or vehicles.

7. The short designation recommended by the World Health Organisation for chemical compositions structured according to the formula in Claim 1 is 'idarubicin'.

8. In Germany, Farmitalia obtained market authorisation, under the names 'Zavedos 5mg' and 'Zavedos 10mg', for medicinal products for treatment of acute myelitic leukaemias in humans, in which the active ingredient is idarubicin hydrochloride and the ancillary ingredient is dehydrated lactose.

9. By decision of 9 June 1993 the Deutsche Patentamt (German Patent Office) issued to Farmitalia, on the basis of Germany patent 25 25 633, a certificate 'for the medicament Zavedos containing as its active ingredient idarubicin hydrochloride'. It declined, however, to issue the certificate, which was primarily sought, for 'idarubicin and salt thereof including idarubicin hydrochloride'.

10. Farmitalia brought proceedings before the Bundespatentgericht seeking, primarily, to obtain a certificate for 'idarubicin and salts thereof including idarubicin hydrochloride' and, in the alternative, a certificate for 'idarubicin and idarubicin hydrochloride'. That application was rejected.

11. According to the Bundespatentgericht, both the main and the ancillary application fail to satisfy Article 3(b) of Regulation No 1768/92. By virtue of that provision, a certificate can be granted only for a product which is stated to be an 'active ingredient' in the decision to grant marketing authorisation under pharmaceutical legislation. In the present case, that condition is fulfilled only in respect of the active ingredient 'idarubicin hydrochloride' which, at the time of notification of the application, was the only ingredient to have received marketing authorisation under the pharmaceutical legislation applicable in Germany.

12. According to the Bundespatentgericht, the main application also appears to be unfounded because the conditions specified in Article 3(a) of Regulation No 1768/92 are not satisfied for all idarubicin salts. In order to determine whether the product is 'protected by a basic patent', reference must be made to the subject-matter of the protection conferred by the patent, that is to say, the technical teaching which the basic patent is intended to protect as patentable. The Bundespatentgericht points out that, in addition to the matters set out verbatim in the specification, the only further matters required are those which, in the view of an average expert, are self-explanatory or all but indispensable in regard to the patented teaching without the need for special mention, or which the expert, on an attentive reading of the patent specification, can recognise without difficulty and follow at once in his own mind.

13. That is not the case regarding the idarubicin salts for which the claim is made in the proceedings before the national court. To an average expert, it is neither self-explanatory nor immediately evident that, in addition to idarubicin hydrochloride which is mentioned in an embodiment, any other idarubicin salts, not mentioned in the patent itself, could yield the active ingredient of a medicinal substance distinguished by the same properties as those stated in the patent. On the contrary, since their chemical composition is different from that of idarubicin and idarubicin hydrochloride, the expert will be prompted at least to consider it possible that differences exist in the therapeutic effectiveness of those salts.

14. In its appeal brought before the Bundesgerichtshof, Farmitalia maintains its request for the grant of a certificate for 'idarubicin and salts thereof including

idarubicin hydrochloride' and, in the alternative, 'for idarubicin and idarubicin hydrochloride'.

15. Noting that Farmitalia has already obtained a certificate for idarubicin hydrochloride, the Bundesgerichtshof considers that, for the purposes of its decision, an interpretation of Article 3(a) and (b) of Regulation No 1768/92, starting with (b), is needed. According to that court, only if the grant of a certificate is not restricted to the active ingredient indicated in the marketing authorisation granted under the pharmaceutical legislation will the application for a certificate not automatically fail under Article 3(b) of the regulation and will it be necessary to deal with the other question, concerning Article 3(a), to ascertain what criteria determine whether the product 'is protected by a basic patent'. If the wording of the claim for the patent is decisive, then the ancillary application must succeed. If, on the other hand, attention has to be focused on the whole area of protection of the basic patent, the primary application made by the appellant in the main proceedings could be well founded.

16. In those circumstances, the Bundesgerichtshof decided to stay proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) Is it a condition of the application of Article 3(b) that the product in respect of which the grant of a protection certificate is sought is described as an "active ingredient" in the medicinal authorisation?

Are, then, the terms of Article 3(b) not satisfied where only one individual salt of a substance is stated in the notice of authorisation to be an "active ingredient", but the grant of a protection certificate is sought for the free base and/or for other salts of the active ingredient?

2. If the questions at (1) are answered in the negative:

According to which criteria is it to be determined whether the product is protected by a basic patent within the meaning of Article 3(a), where the grant of a protection certificate is sought for the free base of an active ingredient including any of its salts, but the basic patent in its patent claims mentions only the free base of this substance and, moreover, mentions only a single salt of this free base? Is the wording of the claim for the basic patent or the latter's scope of protection the determining criterion?'

The first question

17. By its first question, the national court asks, in substance, whether, on a proper construction of Article 3(b) of Regulation No 1768/92, the certificate can protect the product only in the specific form stated in the marketing authorisation.

18. In that regard, all the interested parties who have submitted observations have maintained, in particular, that while the certificate could protect only the particular salt form of the active ingredient mentioned as the active constituent in the marketing authorisation, whereas the basic patent protects the active ingredient as such as well as salts thereof, including the one which is the subject-matter of the marketing authorisation, any competitor would be able, after the basic patent had expired, to apply for and, in some circumstances, obtain

marketing authorisation for a different salt of the same active ingredient, formerly protected by that patent. It would therefore be possible for medicinal products which were, in principle, therapeutically equivalent to that protected by the certificate to compete with the latter. The result would be to frustrate the purpose of Regulation No 1768/92, which is to ensure the holder of the basic patent of exclusivity on the market during a given period extending beyond the period of validity of the basic patent.

19. That line of argument must be accepted. If the certificate did not cover the actual medicinal product, as protected by the basic patent and one of the possible forms of which is the subject-matter of a marketing authorisation, the fundamental objective of Regulation No 1768/92, as set out in the first and second recitals in the preamble thereto, which is to provide for sufficient protection to encourage research in the pharmaceutical field, which plays a decisive role in the continuing improvement in public health, could not, for the reasons set out in paragraph 18 of this judgment, be attained.

20. Moreover, it should be borne in mind that the 13th recital in the preamble to Regulation (EC) 1610/96 of the European Parliament and of the Council of 23 July 1996 which, by virtue of the 17th recital, is also valid, *mutatis mutandis*, for the interpretation *inter alia* of Article 3 of Regulation No 1768/92, states that the certificate confers the same rights as those conferred by the basic patent, with the result that, where the basic patent covers an active substance and its various derivatives (salts and esters), the certificate confers the same protection.

21. Accordingly, where an active ingredient in the form of a salt is referred to in the marketing authorisation concerned and is protected by a basic patent in force, the certificate is capable of covering the active ingredient as such and also its various derived forms such as salts and esters, as medicinal products, in so far as they are covered by the protection of the basic patent.

22. Consequently, the answer to the first question must be that, on a proper construction of Regulation No 1768/92 and, in particular, Article 3(b) thereof, where a product in the form referred to in the marketing authorisation is protected by a basic patent in force, the certificate is capable of covering that product, as a medicinal product, in any of the forms enjoying the protection of the basic patent.

The second question

23. By its second question, the Bundesgerichtshof is, in substance, asking what are the criteria, according to Regulation No 1768/92 and in particular Article 3(a) thereof for determining whether or not a product is protected by a basic patent.

24. In that connection, it should be noted that one of the conditions for obtaining a certificate is that the product should be protected by a basic patent in force.

25. As indicated in the seventh recital in the preamble to Regulation No 1768/92, the patent concerned may be either national or European.

26. As Community law now stands, the provisions concerning patents have not yet been made the subject of harmonisation at Community level or of an approximation of laws.

27. Accordingly, in the absence of Community harmonisation of patent law, the extent of patent protection can be determined only in the light of the non-Community rules which govern patents.

28. As is clear in particular from paragraph 21 of this judgment, the protection conferred by the certificate cannot exceed the scope of the protection conferred by the basic patent.

29. The answer to be given to the second question must therefore be that, in order to determine, in connection with the application of Regulation No 1768/92 and, in particular, Article 3(a) thereof, whether a product is protected by a basic patent, reference must be made to the rules which govern that patent.

Costs

30. The costs incurred by the French, German, Netherlands and United Kingdom Governments and by the Commission, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT (Fifth Chamber),

in answer to the questions referred to it by the Bundesgerichtshof by order of 17 June 1997, hereby rules:

1. On a proper construction of Council Regulation EEC No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products and, in particular, Article 3(b) thereof, where a product in the form referred to in the marketing authorisation is protected by a basic patent in force, the supplementary protection certificate is capable of covering the product, as a medicinal product, in any of the forms enjoying the protection of the basic patent.

2. In order to determine, in connection with the application of Regulation No 1768/92 and, in particular, Article 3(a) thereof, whether a product is protected by a basic patent, reference must be made to the rules which govern that patent.

OPINION OF ADVOCATE GENERAL FENNELLY

delivered on 3 June 1999 (1)

Case C-392/97

Farmitalia Carlo Erba S.r.l.

v

Patentamt

I — Introduction

1. This case raises the question of the terms in which a supplementary protection certificate should be granted under Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (2) (here-

inafter 'the SPC Regulation' or 'the Regulation') where the necessary authorisation to place a medicinal product on the market relates only to a single salt of a free base protected by the basic patent, where a medicinal product with equivalent properties could probably be manufactured from different salts of this free base and where it is argued that the scope of protection of the basic patent extends by implication to all such salts.

II — Legal and factual context

(i) Community legislation and other instruments

2. The extended period of protection provided by a certificate granted pursuant to the SPC Regulation is designed to compensate the holder of a basic patent for the delay necessarily attendant on the grant of an authorisation to market a medicinal product (hereinafter a 'marketing authorisation') whose active ingredient is covered by that patent. It is inherent in this scheme that, as the ninth recital states, 'the protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product'.

3. The principal relevant provisions of the SPC Regulation are as follows:

Article 1

'For the purpose 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;

... '

Article 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 authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 65/65/EEC [(3)] or Directive 81/851/EEC, [(4)] as appropriate;

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

... '

Article 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 authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.'

Article 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.'

4. The 17th recital in the preamble to 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 (5) (hereinafter 'the 1996 Regulation') states that 'the detailed rules in recitals 12, 13 and 14 ... are also valid, mutatis mutandis, for the interpretation in particular of recital 9 ... of [the SPC Regulation]'. The 13th and 14th recitals state, respectively:

'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;

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.'

5. Article 69(1) of the European Patent Convention, done at Munich on 5 October 1973, provides:

'The extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims. Nevertheless, the description and drawings shall be used to interpret the claims.'

The Protocol on the interpretation of Article 69 of the Convention, which is an integral part thereof, states:

'Article 69 should not be interpreted in the sense that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Neither should it be interpreted in the sense that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patentee has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patentee with a reasonable degree of certainty for third parties.'

(ii) Factual background and national proceedings

6. The appellant in the main proceedings, Farmitalia Carlo Erba S.r.l. (hereinafter 'Farmitalia'), holds a German patent notified on 9 June 1975 for alpha-anomer of 4-Demethoxydaunomycin, its manufacturing process and the medicament containing that substance. The short designation recommended by the World Health Organisation for chemical compositions so structured is idarubicin. The patent claims mention the salt idarubicin hydrochloride as an embodiment of the invention.

7. Farmitalia subsequently obtained an authorisation to market the products 'Zavedos 5 mg' and 'Zavedos 10

mg' in Germany as medicinal products for treatment of acute myelitic leukaemias. These products contain the salt idarubicin hydrochloride and, as an ancillary ingredient, dehydrated lactose.

8. The original patent has since expired. Farmitalia applied for a supplementary protection certificate (hereinafter 'SPC' or 'certificate') for the free base 'idarubicin and salts thereof including idarubicin hydrochloride'. (6) However, on 9 June 1993, the defendant in the main proceedings, the Patentamt (German Patent Office, hereinafter 'the defendant'), granted a German certificate only in respect of 'the medicament Zavedos containing as its active ingredient idarubicin hydrochloride'.

9. Farmitalia commenced complaint proceedings before the Bundespatentgericht (Federal Patents Court) seeking a certificate in the terms initially requested or, in the alternative, for 'idarubicin and idarubicin hydrochloride'. That court rejected both the main and the subsidiary applications.

10. The Bundespatentgericht took the view that neither the main nor the subsidiary application satisfied Article 3(b) of the SPC Regulation, as an SPC could only be granted to a product stated to be an active ingredient of a medicinal product in the relevant marketing authorisation. In the present case, idarubicin hydrochloride was the named active ingredient of the two authorised Zavedos products, so that an SPC could not be granted in wider terms.

11. Furthermore, in the view of the Bundespatentgericht, the main application did not satisfy Article 3(a) of the SPC Regulation, because not all the salts of idarubicin were protected by the basic patent. In addition to the free base idarubicin itself, only one salt, idarubicin hydrochloride, was mentioned in the patent. The Bundespatentgericht considered that the protection by a basic patent required by Article 3(a) did not refer to the effective scope of patent protection in any notional infringement proceedings, but, rather, to the technical doctrine protected by the basic patent, that is, in addition to the matters mentioned expressly in the patent, such other matters which, in the view of a person skilled in the art, are self-explanatory or all but indispensable in regard to the patented discovery without the need for special mention to be made of them, or which the person skilled in the art on an attentive reading of the patent papers can recognise and follow in his own thought processes. This was not the case regarding idarubicin salts as, owing to their different chemical composition in comparison with idarubicin and idarubicin hydrochloride, the expert could at least consider it possible that there might be differences in their therapeutic effectiveness.

12. On appeal to the Bundesgerichtshof (Federal Court of Justice, hereinafter 'the national court'), Farmitalia argued, in respect of Article 3(b) of the SPC Regulation, that the term 'active ingredient' should be understood as designating e pharmacologically active base including its derivatives (salts and esters). Article 3(b) did not, therefore, require a marketing authorisation in respect of every

possible variant of the active ingredient, provided it had been authorised in one of its possible forms. Regarding Article 3(a) of the Regulation, Farmitalia submitted that the Bundespatentgericht had erred, as a matter of German law, concerning the scope of the protection conferred by the basic German patent, as a person skilled in the art would have known that other pharmaceutically consistent salts of idarubicin would have been equally as suitable as idarubicin hydrochloride as a means of dispensing the active ingredient idarubicin.

13. The national court observed that, on the one hand, it would be difficult for the national authorities responsible for issuing SPCs to determine the pharmaceutical equivalence of salts in the abstract. On the other hand, it felt that it would be unsatisfactory if an SPC could not be obtained for a variant of a patented pharmaceutical invention for which a marketing authorisation was obtained and which, although falling within the effective scope of protection of the basic patent, was not expressly mentioned therein. The national court proposed an intermediate approach, whereby an SPC could only be granted in respect of the substance identified in the marketing authorisation but the scope of the protection conferred by that certificate would extend, in accordance with the criteria applicable to the basic patent, to pharmaceutically acceptable equivalent substances. In the light of the dispute regarding the proper interpretation of the SPC Regulation, the national court has referred the following questions to the Court for a preliminary ruling pursuant to Article 177 of the EC Treaty:

'1 Does Article 3(b) presuppose that the product in respect of which the grant of a protection certificate is sought is described as an "active constituent" in the authorisation for marketing as a medicinal product?

Is, then, Article 3(b) not complied with where a single individual salt of an active ingredient is stated in the notice of authorisation to be an "active constituent", but the issue of a protection certificate is sought for the free base and/or for other salts of the active ingredient?

2. If the questions at 1. are answered in the negative:

According to which criteria is it to be determined whether the product, as referred to in Article 3(a), is protected by a basic patent where the issue of a protection certificate is sought for the free base of an active ingredient including any of its salts, but the basic patent in its patent claims mentions only the free base of that ingredient and, moreover, mentions in an embodiment a single salt of this free base? Is the wording of the claim for the basic patent or the latter's scope of protection the determining criterion?'

III — Observations

14. Written and oral observations have been submitted by Farmitalia, the French Republic, the Kingdom of the Netherlands and the Commission. Written observations were also submitted by the Federal Republic of Germany and the United Kingdom of Great Britain and Northern Ireland.

15. Regarding the first question, all those submitting observations have argued that a certificate may be granted in respect of a product which is not expressly

mentioned as an active constituent in the marketing authorisation referred to in Article 3(b) of the SPC Regulation, provided that that authorisation relates to a salt of that product. A number of arguments have been put forward in support of this conclusion:

— Article 3(b) of the Regulation does not require that the product be mentioned in the marketing authorisation, but, rather, that the marketing of the product as a medicinal product has been authorised;

— the pharmaceutical effects of a free base, its salts and its esters are normally equivalent. Exceptional cases would not have to be specifically identified when an SPC is granted, as this could be done when the scope of protection of the certificate is determined, for example in infringement proceedings regarding such a salt or ester;

— the certificate is granted in respect of an active ingredient as such, and not in respect of any particular mode of administration; in this regard, the definition of a product in Article 1(b) of the Regulation, based on the concept of the active ingredient, may be linked to that of a medicinal product in Article 1(a), which emphasises its therapeutic or diagnostic properties rather than its form;

— the Commission's Explanatory Memorandum (7) for the proposed SPC Regulation indicates that a new certificate cannot be issued in respect of an active ingredient which already benefits from one simply because of minor changes in the related medicinal product, such as the use of different salts; this implies that the active ingredient is understood as being the relevant free base or parent compound;

— the minutes to the Council meeting at which it reached a common position on the proposed SPC Regulation state that the Commission and the Council considered that the definition of a 'product' in Article 1(b) of the Regulation did not exclude salts and esters from the protection of a certificate and did not prevent the issue of a new certificate for those which could be qualified as new active ingredients. This point of view was accepted by all but two delegations at a subsequent meeting of national experts on industrial property hosted by the Commission on 3 February 1995;

— the same view is expressed in the 13th, 14th and 17th recitals in the preamble to Regulation No 1610/96. Although these cannot modify the SPC Regulation, they serve to clarify its interpretation. Thus, the ninth recital in the preamble to the SPC Regulation serves only to exclude the grant of an SPC in respect of non-medicinal uses of a product covered by the basic patent. Although the national court does not consider this to affect the interpretation of Article 3(b) of the Regulation, it is argued that the fact that a single certificate can confer protection on a base, its salts and its esters, pursuant to Article 4, implies that Article 3(b) can be satisfied, in respect of such a range of variants, by a single marketing authorisation in respect of just one form of administration of a product;

— the objective of the SPC Regulation would not be achieved if a certificate could only be granted in re-

spect of the particular salt of an active ingredient mentioned in a marketing authorisation, because, once the basic patent expired, generic manufacturers would then be free to obtain marketing authorisations for medicinal products using other salts of the same free base, with equivalent therapeutic or diagnostic effects, simply by conducting a small number of bio-equivalence tests, which could be carried out in advance outside the Community, in the light of the known literature. The intermediate approach suggested by the national court would oblige SPC holders to establish the equivalence of the generic medicinal product with the protected product in lengthy, costly and unsatisfactory infringement proceedings. Furthermore, the scope of protection of national patents differs, so that this approach would not achieve the uniform solution, by way of a certificate granted under the same conditions, referred to in the sixth and seventh recitals in the preamble to the Regulation; (8)

— reference has been made to guidelines issued by the competent authorities in Denmark (9) and the United Kingdom (10) and to appellate decisions in France (11) and the Netherlands. (12) These all interpret the reference in

Article 3(b) of the Regulation to 'the product' in a broad fashion, distinguishing it from the pharmaceutical speciality in respect of which the marketing authorisation is expressly granted and construing the term 'active ingredient' to include derivatives such as salts and esters in addition to the free base. This reflects international practice, which normally treats bases and their salts as being interchangeable.

16. Regarding the second question, Farmitalia, Germany and the Commission argue that, for the purposes of Article 3(a) of the SPC Regulation, the relevant criterion for determining whether a product is protected by a patent is the effective scope of the protection conferred by that patent in national law, as determined by the national courts, and not the literal text of the claims in the patent itself. Exclusive reliance on the patent claims would be too formalistic and there is no reference to them in the text of Article 3(a). The importance of the scope of protection of the patent is confirmed by the recitals in the preamble to Regulation No 1610/96 and by the conclusions of the 1995 meeting of national experts referred to above. Administrative difficulties cannot be permitted to dictate a reduction in protection. In practical terms, the pharmaceutical equivalence of the free base and its salts can be presumed when a certificate is awarded. It would be necessary for the competent national authority simply to check that the variant in respect of which a marketing authorisation has been granted is covered by the patent. Disputes regarding whether other variants are in fact covered by the patent and, thus, by the SPC could be determined in the course of any subsequent infringement proceedings. However, the Commission stated in response to a question at the oral hearing that it would be sufficient to mention only the free base or parent compound when granting the SPC; Farmitalia, on the other hand, persisted in its argument that the certificate should

expressly refer to idarubicin and its salts in order to avoid having to establish equivalence in infringement proceedings.

17. The Netherlands submits, on the contrary, that, as Article 18(2) of the Regulation rules out an opposition procedure, compliance with Article 3(a) should be determined on the basis of the basic patent claims, as clarified by the description. This objective, easily verified criterion would result in a simple, transparent award system. It adds that, by virtue of Article 4 of the Regulation, the national courts could determine that the protection afforded by a certificate granted in such terms could extend to the ensemble of pharmaceutically equivalent variants of the protected compound in the same way as would that afforded by the basic patent.

18. France also proposes that compliance with Article 3(a) of the Regulation be judged by reference to the basic patent claims, interpreted in the light of the accompanying description. It derives this interpretative approach from Article 69 of the European Patent Convention, which prescribes the extent of the protection conferred by a European patent. However, France alone also proposes that the extent of the protection conferred by the SPC be determined in the same fashion. As an exceptional extension of patent holders' monopoly rights, the SPC should be strictly construed. The reference in the ninth recital in the preamble to the SPC Regulation to the interest in public health requires that account be taken of the national health policy of favouring the commercialisation of generic drugs. Furthermore, a uniform approach, on the basis of the European Patent Convention, to the grant of SPCs and to the extent of the protection conferred by them would be consistent with the Regulation's sixth and seventh recitals and with the judgment in *Spain v Council*. (13)

IV — Analysis

19. I wish to make a number of general observations at the outset of my analysis of the present case. First, both of the questions referred by the national court relate to the conditions for the grant of an SPC set out in Article 3 of the SPC Regulation. What is at issue is not whether or not a certificate should be granted, but its terms. The criteria for the grant of a certificate are procedurally and substantively distinct from those which determine the effective scope of the protection it confers. The latter are applied when it is sought to enforce the SPC in infringement proceedings, whereas the former are considered by the competent national industrial property office at the time of application for the award of a certificate.

20. Secondly, and in spite of this distinction, the conditions for the grant of an SPC cannot be construed in isolation from the general scheme established by the Regulation and, in particular, from the provisions governing the scope and effect of the protection it encompasses. These two elements of the scheme combine to determine in practice the extent to which patentees can recover investment in research, which is the essential purpose of the Regulation.

21. Thirdly, although the SPC regime creates a distinct, new form of intellectual property right, rather

than simply extending the period of protection guaranteed by existing patents, it is, none the less, closely connected with the national systems under which pharmaceutical patent rights are initially granted and protected. Thus, in substantive terms, a certificate can only be granted if a product is protected by a basic patent and the protection conferred by a certificate must be within the limits of that conferred by the basic patent. The certificate holder enjoys the same rights and is subject to the same limitations and obligations as affected the basic patent. The Regulation replicates the basic procedural model of distinct phases for the administrative grant and judicial enforcement of patents which is common to all the Member States.

22. Fourthly, the first question referred by the national court turns entirely, and the second substantially, on the interpretation to be given to the term 'product' in Article 3(a) and (b) of the Regulation, which is defined in Article 1(b) by reference to the concept of an 'active ingredient'. Thus, in the first question, the national court essentially asks whether the product can be understood in wider terms than those used to describe the medicinal product in the relevant marketing authorisation. In the second question, the issue whether the protection of a product by a basic patent is determined in accordance with the patent claims or on the basis of the effective scope of protection of the patent only arises if it is at least possible to conceive of the product in terms wider than those used in the claims. Article 3(c) and (d) also employs the term 'product'; Article 3(c) in particular may be of relevance to the interpretation of the term.

23. Furthermore, by virtue of Article 4 of the Regulation, the concept of a 'product' is also central to the determination of the protection conferred by a certificate. As it is defined only once, in Article 1(b), in the absence of a contrary indication, the term should, normally, be given a uniform interpretation in the different contexts in which it is used in the Regulation. In particular, the Regulation's provisions on the grant and enforcement, respectively, of SPCs cannot be construed in isolation one from the other.

24. Therefore, I will first examine the underlying question of the proper construction of the definition of a product in Article 1(b) of the Regulation and will then indicate how this affects the application of Article 3(a) and (b).

25. The term 'product' is open to a number of possible interpretations, none of which can be excluded on purely textual grounds. (14) The term 'active ingredient ... of a medicinal product' is not defined in the SPC Regulation. On the one hand, it would be possible to construe the term 'product' as being the particular form of a patented pharmaceutical, for example the particular salt of a free base which is the 'active constituent' referred to in a marketing authorisation. (15) An alternative approach is to interpret the term 'product' as referring, broadly speaking, either exclusively to the parent compound or variants expressly referred to in the patent claims, or to the ensemble of the parent compound and its pharmaceutically acceptable deriva-

tives for which patent protection can be secured in infringement proceedings. The number of possible options increases when one takes into account the fact that the effective scope of protection of the basic patent can vary according to whether it is granted pursuant to the European Patent Convention and is subject, thus, to Article 69 of that Convention, or is granted under the national patent regime, as the national rules on the extent of the protection conferred by the patent are not identical in all Member States to those established by Article 69 of the Convention.

26. Each of these alternative approaches can be reconciled in a practical way with the terms of the Regulation. The first approach (which is that favoured by the defendant) offers a relatively straightforward means of establishing whether a product is protected by a basic patent in force, especially if it is actually mentioned in the description accompanying the patent claims for the free base. The 'one certificate per product' rule set out in Article 3(c) of the Regulation could be easily applied; it does not exclude the admittedly improbable grant of further certificates for other variants of the patented free base which have benefited from separate marketing authorisations. It is open to question whether an SPC issued in these restricted terms could, none the less, secure for its holder the wide scope of protection suggested by the national court in its proposed intermediate approach, as the concept of the 'product' is also central to that question, (16) but it would, at the very least, secure a level of protection regarded as adequate by the defendant, the Bundespatentgericht and two delegations to the meeting of national experts on industrial property of 3 February 1995.

27. Moving to the other extreme, if the product were taken to be a patented free base together with all its pharmaceutically acceptable salts and esters, one variant of which was the subject of a marketing authorisation, then it would only be logical to construe the requirement in Article 3(a) that it be protected by a basic patent as referring to the extent of the protection conferred by the patent rather than to the usually more restricted terms of the claims. In such a case, the 'one certificate per product' rule in Article 3(c) would, in effect, become one of 'one certificate per patent'. Furthermore, as the certificate would itself expressly contemplate any pharmaceutically acceptable variant of the authorised medicinal product and could not have a scope of protection wider than that conferred by the basic patent, Article 4 would give rise to, at most, factual disputes regarding the pharmaceutical properties of certain variants. (17)

28. How is one to choose between these different possible constructions? As I have already observed, the possible textual arguments do not appear to me to be decisive. The most that can be said is that they are not inconsistent with certain outcomes. The fact that a 'medicinal product' is defined in Article 1(a) of the Regulation by reference to its properties does not seem to me to be sufficient on its own to establish that, when one looks at Article 1(b), its active ingredient includes

any variant of a patented substance which displays those properties, rather than the single variant which has in fact been authorised to be marketed as a medicinal product. To observe that Article 3(b) does not state that the product should itself be mentioned in the marketing authorisation, or that Article 3(a) does not refer to the patent claims, is, I think, simply to beg the question. The argument that the use of the terms 'protected' or 'protection' implicitly refers to the scope of protection of the basic patent, although plausible, hardly determines the terms of the certificate. It refers, in any event, to a question which is posterior to that of the interpretation of the term 'product' — if 'active ingredient' and, thus, 'product' are narrowly construed, the debate over the meaning of Article 3(a) would be largely pointless, because the product, so construed, would, in the circumstances of the present case at least, fall clearly within even the terms of the patent claims, read in the light of the description. It has been suggested that the implicit distinction between an active ingredient and an active moiety in Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products (18) points towards a narrow interpretation of the former term, confined to variants which are actually the subject of a marketing authorisation, but this is in the context of a different regulatory regime. (19)

29. It is necessary, therefore, to look to the scheme and objectives of the SPC Regulation for further assistance. In this regard, the following considerations appear to me to be crucial. First, the SPC Regulation is intended, as I observed in paragraph 2 above, to confer an additional compensatory period of protection for pharmaceutical inventions. The Regulation would not achieve this aim if it were interpreted as providing for SPC protection limited to the narrow category of authorised medicinal products, or to the invention set out in the patent claims; that interpretation would permit other manufacturers to produce pharmaceutically equivalent medicinal products, on the basis of other derivatives of the patented invention, which could have been prohibited pursuant to national infringement proceedings during the life of the patent itself. (20) The argument of France regarding the public-health interest in the availability of generic drugs does not convince me in this regard, because it is inconsistent with the principal objective of the Regulation; that interest can, perhaps, be understood as having been addressed by the temporal limits imposed on SPCs. (21)

30. Secondly, as is clear from Article 5, the SPC can never afford greater protection than is afforded by the patent itself. To my mind, this limitation has a procedural as well as a substantive component. Thus, the Regulation should not be interpreted in such a fashion that the certificate holder has greater procedural advantages than he enjoyed qua patent holder. This could arise, for example, if an SPC were granted in terms much wider than those used in the original patent, thus potentially affecting the relative burdens of evidence

and proof borne by the certificate holder and another manufacturer in subsequent infringement proceedings. More generally, the supplementary protection regime should, in the absence of contrary indications, mirror the procedural steps typical to the national and European patent systems on which it is dependent and, to a large extent, modelled. Thus, to the greatest extent possible, the respective roles of the administrative authorities responsible for granting patents and the judicial bodies responsible for enforcing them should be replicated under the SPC Regulation. (22)

31. Thirdly, as stated in the seventh recital in the preamble, the SPC must be 'granted under the same conditions by each of the Member States'. However, the conditions for the grant of a certificate must be distinguished from those governing the protection it confers. The extent of this protection, and the rights, limitations and obligations ensuing therefrom, are chiefly determined by reference to the basic patent (subject, of course, to it being confined to the product which is the subject of the relevant marketing authorisation) and, thus, by national patent law. (23) Although the sixth recital in the preamble to Regulation indicates that it was designed to provide for 'a uniform Community solution' and to prevent 'the heterogenous development of national laws leading to further disparities' (24) which would directly affect the internal market, it is clear to me that this refers primarily to the development, before the Regulation's adoption, of diverse national supplementary protection regimes. (25) The Regulation does not seek to harmonise the underlying national patent rules, upon which the supplementary protection regime is grafted. As a result, in spite of the significance of Article 69 of the European Patent Convention both for the application of that Convention and in the purely national patent systems of a number of Member States, there are no grounds for concluding that the Regulation requires a uniform approach to the question of the extent of the protection conferred by an SPC.

32. Fourthly, regard may be had to a variety of sources of evidence of the objectives of the Commission in proposing and of the Council in adopting the SPC Regulation. It is clear from the Explanatory Memorandum that the Commission understood an active ingredient as being a pharmaceutically active basic compound, of which several variants could exist, so that the use, for example, of a different salt would be regarded as a minor change which could not give rise to a new certificate. (26) Consistently with this view, it refers to the possibility of a product being the subject of several marketing authorisations in different pharmaceutical forms, (27) implying, therefore, that the product is not simply the substance which is the subject of any given marketing authorisation, but may be more widely defined. (28)

33. The statement in the Council minutes that 'the Council and Commission consider that the definition of "product" does not mean that salts and esters are excluded from the protection' is of more doubtful interpretative value in the light of the consistent view

of the Court that such material should not be used unless its content is reflected in the wording of the provision being interpreted. (29) However, reference is occasionally made to such material where it is consistent with an interpretation of the legislative text in question already favoured by the Court on other grounds. (30) In the present case, the statement is a little ambiguous. Although it clearly indicates that salts and esters should normally fall within the effective scope of protection of an SPC, it does not state that they should be considered to be within the definition of the 'product', which determines the terms in which the SPC is granted. The statement that that definition would not prevent the issue of a new certificate for salts and esters which could be qualified as new active ingredients implies, however, that this is the case. Without prejudice to the question whether the Community legislature is entitled to seek to influence the judicial interpretation of a legislative measure through the inclusion of interpretative 'rules' in later legislation which does not purport to amend the earlier measure, it is also clear that the 13th and 14th recitals in the preamble to the 1996 Regulation are consistent with the statement in the Council minutes. (31)

34. The Commission's statement to the meeting of national experts in 1995, assented to by several delegations and opposed by two, that the certificate 'covered both the compound (the base) and its pharmaceutically acceptable salts and esters' and its further statement that a salt or ester with a distinct activity profile could be considered to be a new product and could, thus, benefit from a further certificate are consistent with the foregoing interpretative material. However, while the minutes of such meetings illustrate the (not entirely uniform) views of the Commission and the Member States acting in their administrative capacities, they cannot, in my view, be treated as shedding light, *ex post facto*, on the objectives of the Community legislator when it adopted the SPC Regulation.

35. All of these statements are, in themselves, inconclusive. However, they recognise that, as pointed out by the United Kingdom in its observations, the marketing authorisation, being principally concerned with clinical use, will almost inevitably name the active constituent by reference not to the parent compound but to its salt or ester. In the light of all of the foregoing factors, I would construe an active ingredient as being the pharmacologically active free base or parent compound underlying a medicinal product which is subject to a marketing authorisation. Different salts and esters can normally be understood as being simply variants of the active ingredient and, thus, of the product, rather than as being either products in their own right or distinct elements of the product. As a result, and in view of the fact that the patent claims will normally be phrased, as in the present case, in terms of the free base, these can be taken as defining the product and, therefore, as dictating the terms in which a subsequent SPC is granted. In my view, therefore, the certificate should be granted in the same terms as the patent claims. This would have the advantage of establishing a uniform criterion for the

grant of a certificate, which could not easily be arrived at on the basis of the scope of protection of the basic patent, and of permitting national competent authorities to grant certificates without having to engage in an inquiry into the likely additional scope of protection of the patent and of the certificate, which is alien to their normal function. Furthermore, it would preserve the normal division of functions between those authorities and the national courts, permitting the latter to decide the ultimate scope of protection of a certificate worded in terms of the patent claims on the basis of the same principles of national law as are applied to the patent itself (subject always to the caveat required by Article 4 that the certificate's scope be limited to authorised medicinal uses of the product). Thus, manufacturers of generic pharmaceutical products would enjoy no greater freedom than under the basic patent, and infringement proceedings could be conducted on broadly the same procedural lines as those in respect of a patent, with the same balance of advantage between the parties.

36. To return to the questions referred by the national court, my recommended approach to the definition of the product would result in a negative answer to both parts of the first question regarding the definition of the active ingredient and, as should already be clear, in the second question being answered in favour of the use of the wording of the patent claims rather than the use of the scope of protection of the basic patent to define the product in question and, thus, to determine whether it is protected by a basic patent.

V — Conclusion

37. In conclusion, I recommend that the Court answer the questions referred by the Bundesgerichtshof as follows:

- (1) It is not necessary for the purposes of the application of Article 3(b) of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products that the product in respect of which the grant of a supplementary protection certificate is sought is described as an active constituent in the relevant authorisation to place a medicinal product on the market, provided that that authorisation relates to a pharmaceutically equivalent variant of the product in question;
- (2) For the purposes of the application of Article 3(a) of Regulation No 1768/92, the product, defined by reference to the pharmacologically active free base or parent compound underlying the medicinal product which is subject to a marketing authorisation, should be deemed to be protected by a basic patent in force where it comes within the terms of the claims of the relevant patent.

proprietary medicinal products, OJ, English Special Edition 1965-66 (I), p. 20.

4: — Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products, OJ 1981 L 317, p. 1.

5: — OJ 1996 L 198, p. 30.

6: — It appears that an SPC was granted in these terms in the United Kingdom.

7: — COM(90) 101 final — SYN 255, 11 April 1990, paragraph 36.

8: — See Case C-350/92 Spain v Council [1995] ECR I-1985, paragraphs 35 and 36.

9: — Guidelines P 3.4-2, September 1994.

10: — The Patent Office, Supplementary Protection Certificates for Medicinal Products: A Guide for Applicants (Newport, 1992), paragraph 1.6.

11: — *Fisons plc v Le Directeur de l'Institut National de la Propriété Industrielle*, Cour d'Appel de Paris, judgment of 7 July 1994. However, this case appears to deal with the French SPC legislation which preceded the adoption of the SPC Regulation.

12: — SPC Application No. 930006, Merck & Co., Inc., Patent Office Board of Appeal, decision of 12 July 1995.

13: — Case C-350/92, loc. cit.

14: — Some textual arguments are discussed below, but, in my view, none is in itself conclusive.

15: — Nor is any consistent guidance furnished by Council Directive 65/65/EEC, loc. cit. The English version uses the term 'active constituent'. The German text of Directive 65/65/EEC also uses a distinct term, 'wirksamer Bestandteil', rather than the term 'Wirkstoff' employed in the SPC Regulation. On the other hand, however, the French versions of both measures employ the term 'principe actif'.

16: — This depends, of course, on the construction of Article 4 of the Regulation, which is not at issue in the present case, but which it is necessary to consider in order to assess the overall impact of any given approach to the interpretation of the definition of a 'product' in Article 1(b).

17: — Disputes could arise either where it is alleged that a particular variant does not have any therapeutic or diagnostic effect, or where the marketing of a variant as a medicinal product has been separately authorised because of its substantially different therapeutic or diagnostic effect.

18: — OJ 1975 L 147, p. 1.

19: — See J.N. Adams, 'Supplementary Protection Certificates: The "Salt" Problem' (1995) 6, *European Intellectual Property Review* 277, at p. 279.

20: — See the second to fourth recitals in the preamble to the SPC Regulation. The ninth recital does not afford any great assistance in this regard, as it uses the term 'product' in a manner similar to its use in Article 4.

21: — See the ninth recital in the preamble to the SPC Regulation.

22: — This is, I think, implicit in Articles 5, 9(1), 17 and 18(1) of the SPC Regulation.

1: Original language: English.

2: — OJ 1992 L 182, p. 1.

3: — Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to

23: — Article 4 of the SPC Regulation would seem to dictate that Article 69 of the European Patent Convention be applied by analogy when determining the scope of a certificate founded upon a patent granted under the Convention.

24: — Emphasis added.

25: — See *Spain v Council*, loc. cit., paragraphs 34 and 35.

26: — Explanatory Memorandum, loc. cit., paragraph 36. See Case 131/86 *United Kingdom v Council* [1988] ECR 905, paragraphs 26 and 27, regarding the use of preparatory documents to assist in construing legislative measures.

27: — *Ibid.*, paragraph 35.

28: — It follows from the judgment in Case C-181/95 *Biogen v Smithkline Beecham Biologicals* [1997] ECR I-357 that the product may also be more narrowly defined than the medicinal product referred to in a marketing authorisation, where the latter is the subject of a number of patents.

29: — Case C-292/89 *Antonissen* [1991] ECR I-745, paragraph 18; Case C-368/96 *The Queen v Licensing Authority established by the Medicines Act 1968, ex parte Generics (UK) Ltd* [1998] ECR I-0000.

30: — Case C-106/96 *United Kingdom v Commission* [1998] ECR I-2729, paragraph 29.

31: — The use of the term 'active substance' in the recitals in the English version of the preamble to the 1996 Regulation, as opposed to the term 'active ingredient', does not appear to me to indicate a material distinction. The term 'substance' is also used in the definition of a medicinal product in Article 1(a) of the SPC Regulation. Although the term 'substance' might be thought in the latter context to indicate a finished medicinal product, including, for example, an excipient, such a construction is clearly not intended in the case of the 1996 Regulation. Furthermore, the use of distinct terms is not consistent in the different language versions of the two Regulations. For example, the French versions of the two Regulations use the terms 'substance active', 'principe actif' and 'substance' in the same fashion as in the English, whereas the German versions of both Article 1(b) of the SPC Regulation and of the 13th and 14th recitals in the preamble to the 1996 Regulation employ the term 'Wirkstoff', while the term 'Stoff' is confined to Article 1(a) of the SPC Regulation.