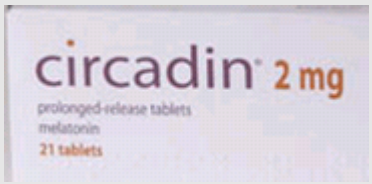
Court of Justice EU, 19 July 2012, Neurim Pharmaceuticals v Comptroller-General of Patents



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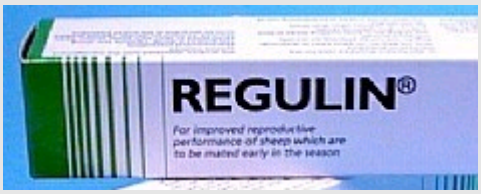

PATENT LAW – SPC

Mere existence of earlier authorisation veterinary medicinal product does not preclude SPC for different application within basic patent

- **that Articles 3 and 4 of the SPC Regulation are to be interpreted as meaning that, in a case such as that in the main proceedings, the mere existence of an earlier MA obtained for a veterinary medicinal product does not preclude the grant of an SPC for a different application of the same product for which an MA has been granted, provided that the application is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the SPC.**

Article 13 SPC Regulation: marketing authorisation (MA) of product which is within basic patent

- **that Article 13(1) of the SPC Regulation is to be interpreted as meaning that it refers to the MA of a product which is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the SPC.**

Irrelevant whether same active ingredient is present in two medicinal products, second MA required full application, or product was within different patent which belonged to other proprietor

- **that the answers to the preceding questions would not be different if, in a situation such as that in the main proceedings where the same active ingredient is present in two medicinal products having obtained successive MAs, the second MA required a full application in accordance with Article 8(3) of Directive 2001/83, or if the product covered by the first MA of the corresponding medicinal product is within the scope of protection of a different patent which belongs to a different registered proprietor from the SPC applicant.**

Source: **curia.europa.eu**

Court of Justice EU, 19 July 2012

(J.-C. Bonichot, (Rapporteur), A. Prechal, K. Schiemann, C. Toader and E. Jarašiūnas)
JUDGMENT OF THE COURT (Fourth Chamber)
19 July 2012 (*)
(Medicinal products for human use – Supplementary protection certificate – Regulation (EC) No 469/2009 – Article 3 – Conditions for obtaining a supplementary protection certificate – Medicinal product having obtained a valid marketing authorisation – First authorisation – Product successively authorised as a veterinary medicinal product and a human medicinal product)
In Case C-130/11,
REFERENCE for a preliminary ruling under Article 267 TFEU from the Court of Appeal (England and Wales) (Civil Division) (United Kingdom), made by decision of 11 March 2011, received at the Court on 16 March 2011, in the proceedings
Neurim Pharmaceuticals (1991) Ltd
v
Comptroller-General of Patents,
THE COURT (Fourth Chamber),
composed of J.-C. Bonichot (Rapporteur), President of the Chamber, A. Prechal, K. Schiemann, C. Toader and E. Jarašiūnas, Judges, Advocate General: V. Trstenjak,
Registrar: L. Hewlett, Principal Administrator,
having regard to the written procedure and further to the hearing on 15 March 2012, after considering the observations submitted on behalf of:
– Neurim Pharmaceuticals (1991) Ltd, by J. Turner QC, A. Waugh, barrister, and E. Oates and H. Goodfellow, attorneys,
– the United Kingdom Government, by S. Ossowski and A. Robinson, acting as Agents, assisted by C. May, barrister,
– the Portuguese Government, by L. Inez Fernandes and P.A. Antunes, acting as Agents,
– the European Commission, by F. Bulst and J. Samnadda, acting as Agents
after hearing **the Opinion of the Advocate General at the sitting on 3 May 2012, gives the following**
Judgment
1 This reference for a preliminary ruling relates to the interpretation of, first, Articles 3 and 13(1) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (codified version) (OJ 2009 L 152, p. 1; 'the SPC Regulation'), and secondly, Article 8(3) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67).
2 The reference has been made in the context of a dispute between Neurim Pharmaceuticals (1991) Ltd ('Neurim') and the Comptroller-General of Patents, representing the United Kingdom Intellectual Property Office ('IPO'), relating to a refusal to grant a supplementary protection certificate ('SPC') for a medicinal product protected by a European patent.
Legal context

The SPC Regulation

3 Recitals 1 and 4 to 10 of the SPC Regulation read as follows:

'(1) Council Regulation (EEC) No 1768/92 ... has been substantially amended several times. In the interests of clarity and rationality the said Regulation should be codified.

...

(4) At the moment, the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market [the "MA"] makes the period of effective protection under the patent insufficient to cover the investment put into the research.

(5) This situation leads to a lack of protection which penalises pharmaceutical research.

(6) There exists a risk of research centres situated in the Member States relocating to countries that offer greater protection.

(7) 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 functioning of the internal market.

(8) Therefore, the provision of an [SPC] 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 [MA] has been granted is necessary. A regulation is therefore the most appropriate legal instrument.

(9) The duration of the protection granted by the certificate should be such as to provide adequate effective protection. For this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of 15 years of exclusivity from the time the medicinal product in question first obtains [an MA] in the Community.

(10) All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account. For this purpose, the certificate cannot be granted for a period exceeding five years. The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product.'

4 Article 1 of the regulation provides:

'Definitions

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

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 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 2 of the SPC Regulation, entitled 'Scope', provides:

'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 authorisation procedure as laid down in Directive 2001/83/EC ... or Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products [OJ 2001 L 311, p. 1] may, under the terms and conditions provided for in this Regulation, be the subject of a certificate.'

6 Article 3 of the SPC Regulation, entitled 'Conditions for obtaining a 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 ...;

(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.'

7 Article 4 of the SPC Regulation, entitled 'Subject matter of protection', provides:

'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.'

8 Article 7(1) of the SPC Regulation, entitled 'Application for a certificate' provides:

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

9 Article 13(1) of the SPC Regulation, entitled 'Duration of the certificate', provides:

'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 [MA] in the Community, reduced by a period of five years.'

10 In accordance with Article 23, the SPC Regulation entered into force on 6 July 2009.

Directive 2001/83

11 Article 8(3) of Directive 2001/83 lists the information and documents which must be submitted with the application for an MA of a medicinal product for human use.

The dispute in the main proceedings and the questions referred for a preliminary ruling

12 Following research carried out on melatonin, a natural hormone which has not, as such, been patented, Neurim discovered that appropriate formulations of melatonin could be used as a medicine for insomnia. Neurim subsequently obtained a European patent, which it applied for on 23 April 1992, concerning its formulation of melatonin, in order to sell it in the form of a medicinal product for human use called 'Circadin'.

13 When the European Commission issued Neurim with an MA enabling it to market that medicinal product ('the Circadin MA') on 28 June 2007, the patent protecting that new medicinal product had less than five years to run.

14 Neurim therefore applied for an SPC, basing its application on the Circadin MA which it had just obtained.

15 By a decision of 15 December 2009, after the SPC Regulation had come into force, the IPO refused to grant that request. It had identified an earlier MA, dating from 2001, for melatonin for use in sheep and sold under the mark Regulin. Regulin, which was used as a method of regulating the seasonal breeding activity of sheep, had been protected by a patent held by the company Hoechst since 1987 but which had expired in May 2007. The IPO's refusal was thus based on the fact that, contrary to the requirement of Article 3(d) of the SPC Regulation, the Circadin MA was not the first MA relating to melatonin.

16 That refusal was challenged before the High Court of Justice (Chancery Division – Patents Court) by Neurim, which argued, in essence, that the relevant MA for the application of Article 3(d) of the SPC Regulation is that which concerns the product for which the application for the SPC is made. Since its action was dismissed, Neurim appealed to the Court of Appeal (England & Wales) (Civil Division). Although that court considered that Neurim's arguments were well founded, none the less it decided to stay the proceedings in order to refer the following questions to the Court for a preliminary ruling:

'1. In interpreting Article 3 of [the SPC Regulation], when [an MA] (A) has been granted for a medicinal product comprising an active ingredient, is Article 3(d) to be construed as precluding the grant of an SPC based on a later [MA] (B) which is for a different medicinal product comprising the same active ingredient where the limits of the protection conferred by the basic patent do not extend to placing the product the subject of the earlier MA on the market within the meaning of Article 4?

2. If the grant of the SPC is not precluded, does it follow that in interpreting Article 13(1) of the SPC Regulation, "the first [MA] in the Community" needs to be an authorisation to place a medicinal product on the market within the limits of the protection conferred by the basic patent within the meaning of Article 4?

3. Are the answers to the above questions different if the earlier [MA] has been granted for a veterinary medicinal product for a particular indication and the later [MA] has been granted for a medicinal product for human use for a different indication?

4. Are the answers to the above questions different if the later [MA] required a full application for marketing approval in accordance with Article 8(3) of Directive 2001/83/EC (formerly a full application under Article 4 of Directive 65/65/EEC)?

5. Are the answers to the above questions different if the product covered by the authorisation (A) to place the corresponding medicinal product on the market is within the scope of protection of a different patent which belongs to a different registered proprietor from the SPC applicant?'

The questions referred

The first and third questions

17 As a preliminary point, it should be noted that in the main proceedings it is undisputed that, first, the active ingredient in the two medicinal products at issue is not, as such, protected by a patent. Secondly, the basic patent for which the application for the SPC was made protects an application of that active ingredient which, as a medicinal product for human use, has obtained a valid MA. Finally, another MA, also valid, was granted previously to a veterinary medicinal product comprising the same active ingredient.

18 Accordingly, by its first and third questions, which must be examined together, the referring court asks, in essence, whether the provisions of Article 3 and 4 of the SPC Regulation are to be interpreted as meaning that, in a case such as that in the main proceedings, the existence of an earlier MA for a veterinary medicinal product is sufficient to preclude the grant of an SPC for the product application which obtained the other MA.

19 As the Commission pointed out in its observations submitted to the Court, those questions are essentially aimed at establishing whether there is a link between, on the one hand, the MA referred to in Article 3(b) and (d) of the SPC Regulation, and on the other, the basic patent referred to in Article 3(a) of that regulation.

20 As is apparent from the respective headings of Articles 2 and 3 of the SPC Regulation, namely, 'Scope' and 'Conditions for obtaining [an SPC]', first, Article 2 of that regulation seeks to determine in a general manner which products may be the subject of an SPC and, then, Article 3 sets out the conditions under which those products may be granted an SPC **(see Case C-195/09 Synthon [2011] ECR I-0000, paragraph 41).**

21 The first three conditions set out in Article 3 of the SPC Regulation for the grant of an SPC concern the relevant 'product' and require it to be protected by a basic patent in force, to have obtained a valid MA as a medicinal product, and to have not already been the subject of a certificate.

22 That being so, it must also be noted that the fundamental objective of the SPC Regulation is to

ensure sufficient protection to encourage pharmaceutical research, which plays a decisive role in the continuing improvement in public health (see Case C-322/10 Medeva [2011] ECR I-0000, paragraph 30 and the case-law cited, and Case C-422/10 Georgetown University and Others [2011] ECR I-0000, paragraph 24).

23 The reason given for the adoption of the SPC Regulation is the fact that the period of effective protection under the patent is insufficient to cover the investment put into pharmaceutical research and the regulation thus sought to make up for that insufficiency by creating an SPC for medicinal products (see Medeva, paragraph 31, and Georgetown University and Others, paragraph 25).

24 It is apparent from paragraph 29 of the explanatory memorandum to the proposal for a Council Regulation (EEC) of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final), that, like a patent protecting a 'product' or a patent protecting a process by which a 'product' is obtained, a patent protecting a new application of a new or known product, such as that at issue in the main proceedings, may, in accordance with Article 2 of the SPC Regulation, enable an SPC to be granted and, in that case, in accordance with Article 5 of the regulation, the SPC confers the same rights as conferred by the basic patent as regards the new use of that product, within the limits laid down by Article 4 of that regulation (see, by analogy, Medeva, paragraph 32, and order of 25 November 2011 in Case C-630/10 University of Queensland and CSL, ECR I-0000, paragraph 38).

25 Therefore, if a patent protects a therapeutic application of a known active ingredient which has already been marketed as a medicinal product, for veterinary or human use, for other therapeutic indications, whether or not protected by an earlier patent, the placement on the market of a new medicinal product commercially exploiting the new therapeutic application of the same active ingredient, as protected by the new patent, may enable its proprietor to obtain an SPC, the scope of which, in any event, could cover, not the active ingredient, but only the new use of that product.

26 In such a situation, only the MA of the first medicinal product, comprising the product and authorised for a therapeutic use corresponding to that protected by the patent relied upon for the purposes of the application for the SPC, may be considered to be the first MA of 'that product' as a medicinal product exploiting that new use within the meaning of Article 3(d) of the SPC Regulation.

27 In the light of all the above considerations, the answer to the first and third questions is that Articles 3 and 4 of the SPC Regulation are to be interpreted as meaning that, in a case such as that in the main proceedings, the mere existence of an earlier MA obtained for a veterinary medicinal product does not preclude the grant of an SPC for a different application of the same product for which an MA has been granted, provided that the application is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the SPC.

The second question

28 By its second question, the referring court asks, in essence, whether, inasmuch as it determines the duration of the protection conferred by the SPC by referring to, inter alia, the date of the first MA in the European Union, Article 13(1) of the SPC Regulation is to be interpreted as meaning that it also refers to the authorisation of a product which is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the SPC.

29 It must be pointed out that the MA in the European Union referred to in Article 13(1) of the SPC Regulation is not intended to take the place of the MA provided for in Article 3(b) of that regulation, that is to say, the authorisation granted by the Member State in which the application is submitted; instead, it constitutes a further condition applying in the event that the latter authorisation is not the first authorisation to place the product on the market as a medicinal product in the European Union (see, to that effect, Case C-127/00 Hässle [2003] ECR I-14781, paragraph 73).

30 However, although those two provisions of the SPC Regulation thus refer to the two different territorial areas of the authorisations in question in defining the duration of the protection conferred by the SPC in a particular situation, there is no reason why, as regards the assessment of the very nature of those authorisations, it is necessary to use different criteria according to which the article is applicable. Therefore, the MA referred to in Article 13(1) of the SPC Regulation is the authorisation of a product which is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the SPC.

31 It follows from the above that the answer to the second question is that Article 13(1) of the SPC Regulation is to be interpreted as meaning that it refers to the MA of a product which is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the SPC.

The fourth and fifth questions

32 By its fourth and fifth questions, which must be examined together, the referring court asks, in essence, whether, in a situation such as that in the main proceedings where the same active ingredient is present in two medicinal products having obtained successive MAs, the answer to the previous questions would be different if (i) the second MA required a full application for an MA in accordance with Article 8(3) of Directive 2001/83 or (ii) the product covered by the first MA of the corresponding medicinal product is within the scope of protection of a different patent which belongs to a different registered proprietor from the SPC applicant.

33 Suffice it to note, first, that the provisions of Article 8(3) of Directive 2001/83 have a purely procedural object. Therefore, they cannot by themselves, in any event, have an effect on the assessment of the

substantive conditions laid down in the SPC Regulation for determining, as regards that regulation, which of the successive MAs it refers to. Since the preceding questions concern the examination of those substantive conditions, the answers given to them do not depend on the provisions of Article 8(3) of Directive 2001/83.

34 Secondly, the preceding questions called for answers justified by considerations concerning, in essence, the link between the successive MAs and the limits of the protection conferred by the basic patent for which the application for the SPC is made. Hence, those considerations are wholly distinct from those concerning the determination of the proprietors of the authorisations, patents, or the application for the SPC. Those answers do not, therefore, depend on those latter considerations.

35 Consequently, the answer to the fourth and fifth questions is that the answers to the preceding questions would not be different if, in a situation such as that in the main proceedings where the same active ingredient is present in two medicinal products having obtained successive MAs, the second MA required a full application in accordance with Article 8(3) of Directive 2001/83, or if the product covered by the first MA of the corresponding medicinal product is within the scope of protection of a different patent which belongs to a different registered proprietor from the SPC applicant.

Costs

36 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. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable. On those grounds, the Court (Fourth Chamber) hereby rules:

1. Articles 3 and 4 of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as meaning that, in a case such as that in the main proceedings, the mere existence of an earlier marketing authorisation obtained for a veterinary medicinal product does not preclude the grant of a supplementary protection certificate for a different application of the same product for which a marketing authorisation has been granted, provided that the application is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the supplementary protection certificate.

2. Article 13(1) of Regulation (EC) No 469/2009 must be interpreted as meaning that it refers to the marketing authorisation of a product which comes within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the supplementary protection certificate.

3. The answers to the above questions would not be different if, in a situation such as that in the main proceedings where the same active ingredient is present in two medicinal products having obtained successive marketing authorisations, the second marketing authorisation required a full application in accordance with Article 8(3) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, or if the product covered by the first marketing authorisation of the corresponding medicinal product is within the scope of protection of a different patent which belongs to a different registered proprietor from the SPC applicant.

OPINION OF ADVOCATE GENERAL TRSTENJAK

delivered on 3 May 2012 (1)

Case C-130/11

Neurim Pharmaceuticals (1991) Ltd

v

Comptroller-General of Patents

(Reference for a preliminary ruling from the Court of Appeal (United Kingdom))

(Medicinal products for human use – Supplementary protection certificate – Regulation (EEC) No 1768/92 – Article 3 – Conditions for obtaining supplementary protection certificates – First authorisation to place a product on the market in the Member State for which the application is made – Successive authorisations to place a product on the market as a veterinary medicinal product and as a medicinal product for human use)

I – Introduction

1. The present reference for a preliminary ruling under Article 267 TFEU once again concerns the interpretation of Article 3 of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, (2) letters (a) to (d) of which lay down the four main conditions for obtaining supplementary protection certificates. After the Court, most recently in Medeva (3) and Georgetown University and Others, (4) has clarified the substance and the scope of the conditions defined in Article 3(a) (on the protection of the product by a basic patent in force) and (b) (on the existence of a valid authorisation to place the product on the market as a medicinal product), (5) in the present preliminary ruling proceedings the request is for additional clarification regarding the requirement contained in Article 3(d) under which the authorisation to place the product on the market as a medicinal product within the meaning of letter (b) must be the first authorisation to place that product on the market as a medicinal product.

II – Legislative framework

2. Article 1 of Regulation No 1768/92, which is entitled ‘Definitions’, 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 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;
…'

3. Articles 3 to 5 of Regulation No 1768/92 read as follows:

'Article 3 – Conditions for obtaining a certificate
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 or Directive 81/851/EEC, as appropriate;
(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.

Article 4 – Subject-matter of protection
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 – Effects of the certificate
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. Article 7 of Regulation No 1768/92, which is entitled 'Application for a certificate', provides:

'1. The application for a certificate shall be lodged within six months of the date on which the authorisation 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 authorisation 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.
…'

5. Article 13 of Regulation No 1768/92, which is entitled 'Duration of the certificate', provides:

'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 authorisation 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.
…'

III – Facts and reference for a preliminary ruling

6. Melatonin is a natural hormone, which is not patented as such and for which a patent has not been filed thus far.

7. The pharmaceuticals undertaking Neurim Pharmaceuticals (1991) Limited ('Neurim Pharmaceuticals') discovered in its research that certain formulations of melatonin can be used as a medicine for insomnia. Accordingly, on 23 April 1992 Neurim Pharmaceuticals submitted an application for a European patent concerning certain formulations of melatonin. Claim 1 reads as follows:

'A pharmaceutical formulation, for use in correcting a melatonin deficiency or distortion in the plasma melatonin level and profile in a human subject, which comprises melatonin in combination with at least one pharmaceutical carrier, diluent or coating, wherein the melatonin is present in the formulation in controlled-release form adapted to release melatonin following administration to a human patient, over substantially the whole of a single nocturnal period of at least about 9 hours, such that melatonin release occurs according to a profile which, taking into account the existing nocturnal profile, simulates a normal human endogenous melatonin nocturnal profile in plasma, in that administration of the formulation at the beginning of said at least about 9 hour single nocturnal period causes melatonin to be detectable in the plasma in an amount which increases to a peak in the course of said period and subsequently decreases to a post-peak minimum essentially at the end of said period.'

8. According to the referring court, it is certain that the patent claims, even though only for melatonin formulations, are novel and inventive. It is also not disputed that the research conducted by Neurim Pharmaceuticals has led to a highly beneficial and new medicine.

9. Neurim Pharmaceuticals applied for an authorisation to place the melatonin formulation in question on the market as a medicinal product for human use (also 'Neurim's marketing authorisation'), which was not, however, granted until June 2007. This medicinal product for human use is currently sold under the name Circadin.

10. By the time of the grant of Neurim's marketing authorisation, the patent had less than five years to run. Neurim Pharmaceuticals accordingly applied for a supplementary protection certificate, basing its application on its June 2007 marketing authorisation and designated that marketing authorisation as the first authorisation to place the product on the market within the meaning of Article 3(d) of Regulation No 1768/92.

11. The UK Intellectual Property Office (IPO) objected to the application. It said that Neurim's marketing authorisation was not the relevant first authorisation to place the product on the market within the meaning of Article 3(d) of Regulation No 1768/92. There was an earlier marketing authorisation, which was for melatonin for use in sheep. It had been granted between January and March 2001 by the UK Veterinary Medicines Directorate under Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products. (6) The veterinary medicinal product was sold under the trade mark 'Regulin'.

12. According to Neurim Pharmaceuticals, there is a further marketing authorisation for a formulation of melatonin. That authorisation was granted in the Netherlands on 19 February 1992. It is for a formulation of melatonin for enhancing fur growth in mink; the trade mark of the medicinal product is 'Prime-X'. However, it states, the scope of Neurim Pharmaceuticals' patent does not extend to the product covered by the marketing authorisation for Prime-X. It is not known whether there was ever a patent for Prime-X.

13. Neurim Pharmaceuticals first brought an action against the refusal of its application for a supplementary protection certificate before the national court having jurisdiction, which confirmed the IPO's decision. Neurim Pharmaceuticals then appealed against that judgment to the referring court.

14. Since the referring court has doubts as to the interpretation of Regulation No 1768/92, in particular Article 3(d), in a case like the main proceedings, it has referred the following questions to the Court for a preliminary ruling:

'(1) In interpreting Article 3 of Regulation (EEC) No 1768/92 [now Regulation (EC) No 469/2009] ("the SPC Regulation"), when a marketing authorisation (A) has been granted for a medicinal product comprising an active ingredient, is Article 3(d) to be construed as precluding the grant of an SPC based on a later marketing authorisation (B) which is for a different medicinal product comprising the same active ingredient where the limits of the protection conferred by the basic patent do not extend to placing the product the subject of the earlier [marketing authorisation] on the market within the meaning of Article 4?

(2) If the grant of the SPC is not precluded, does it follow that in interpreting Article 13(1) of the SPC Regulation, "the first authorisation to place the product on the market in the Community" needs to be an authorisation to place a medicinal product on the market within the limits of the protection conferred by the basic patent within the meaning of Article 4?

(3) Are the answers to the above questions different if the earlier marketing authorisation has been granted for a veterinary medicinal product for a particular indication and the later marketing authorisation has been granted for a medicinal product for human use for a different indication?

(4) Are the answers to the above questions different if the later marketing authorisation required a full application for marketing approval in accordance with Article 8(3) of Directive 2001/83/EC (formerly a full application under Article 4 of Directive 65/65/EEC)?

(5) Are the answers to the above questions different if the product covered by authorisation (A) to place the corresponding medicinal product on the market is within the scope of protection of a different patent which belongs to a different registered proprietor from the SPC applicant?'

IV – Procedure before the Court

15. The order for reference dated 8 March 2011 was lodged at the Registry of the Court of Justice on 17 March 2011. Written observations were submitted by Neurim Pharmaceuticals, the United Kingdom Government, the Portuguese Government and the European Commission. At the hearing on 15 March 2012, oral argument was presented by the representatives of Neurim Pharmaceuticals, the United Kingdom, the Portuguese Republic and the Commission.

V – Arguments of the parties

16. The Commission and Neurim Pharmaceuticals propose that the first question be answered in the negative, to the effect that Article 3(d) of Regulation No 1768/92 and of Regulation No 469/2009 does not preclude the grant of a supplementary protection certificate based on a marketing authorisation (B) for a medicinal product comprising an active ingredient where an earlier marketing authorisation (A) has been granted which is for a different medicinal product comprising that active ingredient, where the limits of the protection conferred by the basic patent within the meaning of Article 4 do not extend to the medicinal product the subject of the earlier marketing authorisation and provided that the other requirements under Article 3 are satisfied. In the light of this proposed answer, Neurim Pharmaceuticals and the Commission then propose that the second question be answered in the affirmative and that the third to fifth questions be answered in the negative.

17. The Portuguese Republic and the United Kingdom propose that the first question be answered in the affirmative and that the third, fourth and fifth questions be answered in the negative. Because of the affirmative answer to the first question, in the view of the Portuguese Republic, there is no need to answer the second question. The United Kingdom answers the second question also in the negative.

VI – Legal assessment

A – The first question

18. By its first question, the referring court is essentially seeking clarification as to the substance and the scope of the requirement laid down in Article 3(d) of Regulation No 1768/92 under which a supplementary protection certificate for a patented active ingredient or a patented combination of active ingredients may be granted only on the basis of the first authorisation to place that product on the market as a medicinal product in the Member State for which the

application is made. The referring court is seeking to ascertain in particular whether Article 3(d) precludes the grant of a supplementary protection certificate based on a second authorisation to place a product on the market as a medicinal product even where the second medicinal product, which comprises the same active ingredient as the medicinal product covered by the first marketing authorisation, is protected by a basic patent for the common active ingredient, the protective scope of which does not extend to the earlier medicinal product.

19. This question has not yet been answered definitively by the Court in its previous case-law and there are valid arguments both for and against the possibility of obtaining a supplementary protection certificate in a case like the main proceedings. (7)

20. Against that background, I will begin by analysing Article 3(d) of Regulation No 1768/92 on the basis of its wording and explain the conclusions which can be drawn from a purely literal interpretation in a case like the main proceedings. I will then assess the result of that literal interpretation with reference to the scheme and the objectives of Regulation No 1768/92. On the basis of these schematic and teleological observations, I will then answer the first question. Lastly, I will briefly explain how my proposed answer can be classified in the Court's case-law on the grant of supplementary protection certificates.

1. Interpretation of Article 3(d) of Regulation No 1768/92 on the basis of its wording

21. The requirements for obtaining supplementary protection certificates are laid down in Article 3 of Regulation No 1768/92. Under that provision, in the Member State for which the application is made the product must be protected by a basic patent in force (a), there must be an authorisation to place that product on the market as a medicinal product for human use or as a veterinary medicinal product (b), the product may not already have been the subject of a certificate (c), and the authorisation referred to in (b) must be the first marketing authorisation for the product as a medicinal product.

22. Article 1 of Regulation No 1768/92 contains definitions for the terms 'medicinal product', 'product' and 'basic patent'. Under Article 1(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. Under Article 1(b), a 'product' means the active ingredient or combination of active ingredients of a medicinal product. (8) The 'basic patent' under Article 1(c) means a patent which protects a product as such, a process to obtain a product or an application of a product.

23. As worded, Article 3(d) of Regulation No 1768/92 provides that a supplementary protection certificate for a product and thus for an active ingredient or for a combination of active ingredients may be applied for only on the basis of the first authorisation to place that active ingredient or that combination of active ingredients on the market as a medicinal product for human use or as a veterinary medicinal product. It follows directly that any further authorisation to place that active ingredient or that combination of active ingredients on the market as a medicinal product is to be regarded as a later authorisation, on the basis of which – according to the wording of Article 3(d) – an application for a new supplementary protection certificate cannot be made.

24. Accordingly, a purely literal interpretation of Article 3(d) of Regulation No 1768/92 would mean that, in a case like the main proceedings, no supplementary protection certificate can be granted for the medicinal product for human use Circadin. This follows directly from the combined operation of Article 1 and Article 3 of Regulation No 1768/92.

25. According to the facts as stated by the referring court, both the medicinal product for human use developed by Neurim Pharmaceuticals, Circadin, and the earlier veterinary medicinal product sold under the trade mark, 'Regulin', contain the active ingredient melatonin. Consequently, that active ingredient constitutes the 'product' within the meaning of Article 1(b) of Regulation No 1768/9 in relation to both medicinal products.

26. The order for reference also states that in 2001 an authorisation to place the active ingredient melatonin on the market as a medicinal product under Directive 81/851 was granted, under which that (veterinary) medicinal product was sold under the name 'Regulin'. In 2007 a further authorisation to place the product on the market was granted under Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, (9) under which that medicinal product (for human use) was sold under the name 'Circadin'.

27. Both the marketing authorisation for the active ingredient melatonin in a veterinary medicinal product and the marketing authorisation for the active ingredient melatonin in a medicinal product for human use constitute an authorisation within the meaning of Article 3(b) of Regulation No 1768/92 in relation to that active ingredient. Because, according to its wording, Article 3(d) of Regulation No 1768/92 has regard to the first authorisation within the meaning of Article 3(b), a purely literal interpretation of Article 3 of Regulation No 1768/92 therefore means that in a case like the main proceedings the marketing authorisation for the active ingredient melatonin in the veterinary medicinal product 'Regalin' constitutes the first authorisation to place the product on the market within the meaning of Article 3(d) of Regulation No 1768/92, with the result that it is not possible to apply for a supplementary protection certificate on the basis of the later marketing authorisation for the active ingredient melatonin in the medicinal product for human use 'Circadin'.

2. Interpretation of Article 3(d) of Regulation No 1768/92 on the basis of its scheme and objective

28. In interpreting EU legislation, in addition to a literal interpretation, great importance is also attached to a schematic and teleological interpretation. (10) Against this background, I will examine below whether the result of the literal interpretation of Article 3(d) of Regulation No 1768/92 is compatible with the scheme and with the objectives of that regulation.

a) Observations relating to the scheme of the requirements for obtaining a supplementary protection certificate under Article 3 of Regulation No 1768/92

29. A supplementary protection certificate may be granted, in principle, only if all the requirements under Article 3 of Regulation No 1768/92 are satisfied. Against that background, I will examine below whether the scheme of the individual requirements under Article 3 supports a literal interpretation of Article 3(d).

30. Under Article 3(a) of Regulation No 1768/92, the grant of a supplementary protection certificate for a product requires the product to be protected by a basic patent in force in the Member State for which the application is made. The notion of basic patent is defined in Article 1 (c) of Regulation No 1768/92 as a patent which protects a product 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.

31. This definition of the basic patent refers to the three major categories of patent into which the basic patent can fall, namely: (1) product patents relating to a physical entity; (2) process patents relating to a process; and (3) use patents relating to the application of an object or a process. (11)

32. The question whether, in an individual case, a product as such, a process to obtain a product or an application of a product is the subject of a patent for the purposes of Article 1(c) of Regulation No 1768/92 and whether the product is therefore protected by a basic patent in force in accordance with Article 3(a) (12) must, as EU law stands at present, be answered on the basis of the national rules applicable to that patent, there being no European Union harmonisation of patent law. (13)

33. As is apparent from the situation in the main proceedings, it is perfectly possible, under the national patent rules, for an active ingredient to be the subject-matter of different patents. According to the description given by the referring court, not only was the medicinal product for human use sold under the trade mark 'Circadin' protected by a European patent, but also the veterinary medicinal product with the active ingredient melatonin sold under the trade mark 'Regulin'. The latter was applied for by Hoechst on 21 May 1987 and expired in May 2007. (14)

34. Under national patent law, an active ingredient can thus form the subject-matter of more than one different patent. Since the definition of the basic patent in Article 1(c) of Regulation No 1768/92 refers to the three major categories of patent into which the basic patent can fall, a product may be protected at the same time by more than one basic patent in force within the meaning of Article 3(a) of Regulation No 1768/92. It must therefore be assumed that, in principle, Article 3(a) permits the grant of more than one supplementary protection certificate for a product.

35. The same finding applies to Article 3(b) of Regulation No 1768/92. Because both an authorisation to place a product on the market as a medicinal product for human use under Directive 65/65 (now Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (15)) and an authorisation to place a product on the market as a veterinary medicinal product under Directive 81/851 (now Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (16)) form a possible basis for obtaining a supplementary protection certificate, Article 3(b) also permits, in principle, multiple supplementary protection certificates for products which are used as active ingredients in different medicinal products.

36. Although, according to its wording, Article 3(c) of Regulation No 1768/92 provides that a supplementary protection certificate may be granted only if the product has not already been the subject of a certificate, that requirement may not be construed as meaning that only one supplementary protection certificate could be granted for a patented active ingredient or for a patented combination of active ingredients. Rather, according to the Court's case-law, Article 3(c) must be interpreted to the effect that only one certificate may be granted for each basic patent which protects an active ingredient or a combination of active ingredients. (17) Furthermore, the Court has ruled that Article 3(c) of Regulation No 1768/92 does not preclude the grant of a supplementary protection certificate to the holder of a basic patent for a product for which, at the time the supplementary protection certificate application is submitted, one or more supplementary protection certificates have already been granted to one or more holders of one or more other basic patents. (18)

37. A common feature of the conditions under Article 3(a), (b) and (c) of Regulation No 1768/92 is therefore that, in principle, they permit the grant of more than one supplementary protection certificate for a product. Against that background, the schematic context of Article 3(d) of Regulation No 1768/92 suggests an interpretation of that provision which essentially also permits the grant of more than one supplementary protection certificate for a product.

b) Teleological interpretation of Article 3(d) of Regulation No 1768/92

i) General observations

38. My above observations on the scheme of the requirements for obtaining a supplementary protection certificate under Article 3 of Regulation No 1768/92 suggest an interpretation of Article 3(d) according to which the grant of more than one supplementary

protection certificate for a product should be possible under certain conditions. In my view, such a broad interpretation would also be most consistent with the objectives of Regulation No 1768/92.

39. As I stated in my Joined Opinion in Medeva and Georgetown University and Others, (19) the aim of granting supplementary protection certificates for medicinal products is essentially to extend the term of patent protection for active ingredients used in medicinal products.

40. The standard term of patent protection is 20 years, calculated from the date of application for registration of the invention. If an authorisation to place medicinal products on the market is granted after the filing of an application to have the patent registered, manufacturers of medicinal products (20) will be unable commercially to exploit their position of exclusivity in relation to the patented active ingredients of that medicinal product during the period which elapses between the application to have the patent registered and the authorisation to place the medicinal product concerned on the market. Since, in the view of the European Union legislature, that would make the period of effective protection under the patent insufficient to cover the investment in research and to generate the resources needed to maintain a high level of research, (21) Regulation No 1768/92 grants those manufacturers the possibility to extend their rights to exclusivity in the patented active ingredients of a medicinal product by applying for a supplementary protection certificate to cover a period not exceeding 15 years from the time at which the product first obtains authorisation to be placed on the market within the European Union. (22)

41. Those rules are intended to achieve a balance between the various interests at stake in the pharmaceutical sector. Those interests include, on the one hand, the interests of the undertakings and institutions, some of which pursue very cost-intensive research in the pharmaceutical sector and therefore favour an extension of the term of protection for their inventions in order to be able to balance out the investment costs. On the other hand, there are the interests of the producers of generic medicines who, as a consequence of the extension of the term of protection of the active ingredients under patent protection, are precluded from producing and marketing generic medicines. It is also relevant in this connection that, in general, the marketing of generic medicinal products has the effect of lowering the prices of the relevant medicinal products. Against that background, the interests of patients lie between the interests of the undertakings and institutions conducting research and those of the producers of generic medicines. That is because patients have an interest, on the one hand, in the development of new active ingredients for medicinal products, but, on the other, they also have an interest in those products then being offered for sale as cheaply as possible. The same applies to State health systems in general which, in addition, have a particular interest in preventing old active ingredients from being brought onto the market in slightly modified form under the protection of certificates but without genuine innovation and thereby artificially driving up expenditure in the health sector.

42. Against the background of that complex situation as regards interests, Regulation No 1768/92 sought to achieve a balanced solution taking due account of the interests of all parties. In view of the complexity of that balance of interests, it is necessary to proceed with great caution when making a teleological interpretation of the individual provisions of the regulation.

ii) Teleological interpretation of Article 3(d) of Regulation No 1768/92

43. In the overall scheme of Regulation No 1768/92, Article 3(d) has a dual function. (23) First, it follows from Article 3(b) and (d) in conjunction with Article 7(1) that the application for the certificate must be lodged within six months of the date on which the first authorisation is granted to place the product on the market as a medicinal product in the Member State for which the application is made, provided the basic patent has already been granted. Those time-limits were designed to respect, first, the interests of the patent holder and, second, those of third parties wishing to know as early as possible whether or not the product in question will be protected by a supplementary protection certificate. (24)

44. Where that first authorisation to place the product on the market in a Member State within the meaning of Article 3(d) of Regulation No 1768/92 is also the first authorisation to place the product on the market in the European Union under Article 13(1) of that regulation, that authorisation also determines the duration of the certificate. Under Article 13(1) of Regulation No 1768/92, the supplementary protection certificate is to 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 authorisation to place the product on the market in the European Union reduced by a period of five years. Under Article 13(2), the duration of the certificate may not exceed five years from the date on which it takes effect.

45. In this overall context, Article 3(d) of Regulation No 1768/92 does not, in my view, seek to preclude without exception the grant of a supplementary protection certificate based on an authorisation to place a product on the market as a medicinal product in the Member State for which the application is made where there is an earlier authorisation to place that product on the market as a medicinal product in that Member State. Furthermore, such an absolute preclusive effect of Article 3(d) would be not compatible with the objectives of Regulation No 1768/92.

46. This is clearly shown by the situation in the main proceedings.

47. As the referring court stated, through its research into a natural hormone already used in veterinary medicinal products, Neurim Pharmaceuticals developed a new medicinal product for human use, for which a patent was granted.

48. According to the referring court, this kind of pharmaceutical research, where new formulations and uses of known active ingredients are investigated, is an important part of research in the pharmaceutical sector. (25) Neurim Pharmaceuticals also states in this context that increasingly pharmaceutical research involves new formulations of old active substances. (26)

49. This statement, to the effect that inventions deserving of protection can also be produced in pharmaceutical research into known active ingredients, is supported by Article 54(5) of the European Patent Convention (EPC), which was inserted into the EPC by the revision in 2000. Article 54(5) EPC expressly recognises the patentability of 'second and further medical uses' of substances whose use in other medical processes already forms part of the state of the art. (27) Such second medical uses are essentially the new and inventive specific use of known medical active ingredients. Legal literature emphasises that such patent protection for second and further uses takes account of legitimate interests because research into therapeutic effects of known substances has considerable health and economic importance. (28)

50. It should also be stated in this connection that, in its explanatory memorandum for the original Proposal for a Regulation concerning the creation of a supplementary protection certificate for medicinal products, the Commission had also stressed that all research, whatever the strategy or final result, must be given sufficient protection. Against that background, the proposal for a regulation was not confined to new products only. A new process for obtaining the product or a new application of the product could also be protected by a certificate. (29)

51. These observations show that manufacturers of medicinal products which, as a result of their research, discover new therapeutic applications of active ingredients which are already used in authorised medicinal products and are also granted patent protection may have a legitimate interest in the extension of that exclusive protection by obtaining a supplementary protection certificate in order to cover the investment in research in accordance with the objective of Regulation No 1768/92. In my view, it would therefore be contrary to the aims of Regulation No 1768/92 if, in a case like the main proceedings, an application for a supplementary protection certificate would inevitably be unsuccessful because the patented active ingredient has already been placed on the market in another medicinal product.

52. In the light of the foregoing, I conclude that the literal interpretation of Article 3(d) of Regulation No 1768/92 must be supplemented by a schematic-teleological interpretation, according to which a supplementary protection certificate may also be granted under certain conditions on the basis of a second or further authorisation to place a patented active ingredient on the market as a medicinal product in the Member State for which the application is made.

3. Result of the interpretation of Article 3(d) on the basis of its scheme and objective

53. In the light of my above observations, Article 3(d) of Regulation No 1768/92 is to be interpreted, on the basis of its scheme and its objective, to the effect that a supplementary protection certificate may also be granted under certain conditions on the basis of a second or further authorisation to place a patented active ingredient on the market as a medicinal product in the Member State for which the application is made. At the same time, however, it should be ensured that this schematic-teleological interpretation does not go beyond the aim of achieving the balance of interests sought by the EU legislature through Regulation No 1768/92.

54. In my view, this balance of interests can be achieved if Article 3(d) of Regulation No 1768/92 is interpreted with reference to the basic patent and the resulting patent protection. Having regard to the case-law on Article 3(c) of Regulation No 1768/92, according to which that provision prohibits the grant of more than one certificate for each basic patent, (30) Article 3(d) must therefore also be interpreted to the effect that a supplementary protection certificate may be granted for a product protected by a basic patent in force only on the basis of the first valid marketing authorisation, in the Member State for which the application is made, for a veterinary medicinal product or a medicinal product for human use which contains that product and is within the scope of protection of that basic patent.

55. This interpretation of Article 3(d) of Regulation No 1768/92, to the effect that a first authorisation to place a product on the market as a medicinal product for human use or a veterinary medicinal product in the Member State for which the application is made does not preclude the grant of a supplementary protection certificate based on a further authorisation to place that product on the market as a medicinal product in the Member State for which the application is made, provided that the previously authorised use of that product as a medicinal product for human use or a veterinary medicinal product is not within the scope of protection of the basic patent designated by the applicant, ensures, first of all, that in principle a supplementary protection certificate may be applied for, in respect of each basic patent, on the basis of the first authorisation to place the product on the market as a medicinal product which is within the scope of protection conferred by that basic patent. If all the requirements are satisfied and a supplementary protection certificate is granted, under Article 4 of Regulation No 1768/92 that protection certificate covers any use of the product and all formulations comprising that product which have been authorised before the expiry of the certificate and are within the scope of protection conferred by the basic patent.

56. Second, since the first authorisation to place a product on the market in the European Union as a medicinal product which is within the scope of protection of the basic patent designated by the applicant determines the duration of the certificate under Article 13 of Regulation No 1768/92, (31)

manufacturers of medicinal products are prevented from being able to optimise the protection granted by a basic patent through the phased authorisation of several uses of a product protected by a basic patent as a medicinal product in order to undermine the system of limitation of the duration of supplementary protection certificates envisaged by the legislature through several 'first' marketing authorisations as a medicinal product for different uses of a product which are all within the scope of protection of the same basic patent.

57. In the light of the foregoing, I conclude that the answer to the first question must be that a supplementary protection certificate for a product which is protected by a basic patent in force may be granted under Article 3(d) of Regulation No 1768/92 only on the basis of the first authorisation which permits that product to be placed on the market as a medicinal product within the scope of protection conferred by the basic patent in the Member State for which the application is made. The fact that the same product has previously been authorised as a medicinal product for human use or a veterinary medicinal product in the Member State for which the application is made does not preclude the grant of a supplementary protection certificate based on a later authorisation to place that product on the market as a new medicinal product, provided the first-authorised medicinal product is not within the scope of protection conferred by the patent designated by the applicant as the basic patent.

4. Classification of the result of the schematic-teleological interpretation of Article 3(d) in the different lines of the Court's case-law on Regulation No 1768/92

58. The guiding principle behind my schematic-teleological interpretation of Article 3(d) of Regulation No 1768/92 is the idea that any basic patent should, in principle, be open to an extension of its term of protection under the conditions laid down in Article 3 of Regulation No 1768/92 where the subject-matter of that patent is the result of work which is worthy of protection in the light of the objectives of that regulation. It should be pointed out, however, that the Court appears to assess the relationship between patent protection and the supplementary protection certificates differently in some judgments, with the result that, from this perspective, a distinction must be drawn between several lines of case-law which are, in some cases, difficult to reconcile.

59. In a first set of judgments, in interpreting Regulation No 1768/92 the Court has been guided by my adopted principle that a supplementary protection certificate should, in principle, be able to be granted for each basic patent, provided that this is compatible with the balancing of interests laid down in Regulation No 1768/92. That case-law may also be attributable to the idea that the grant of a patent normally confirms the eligibility for protection of the patented invention or teaching, with the result that, in the light of the objectives of Regulation No 1768/92, it should also be possible to grant an extension of the term of protection for that invention or teaching under the conditions laid down in Article 3 of Regulation No 1768/92 which are to be interpreted along these lines.

60. This line of case-law includes, for example, Medeva (32) and Georgetown University and Others, (33) in which the Court, highlighting the objectives of Regulation No 469/2009, interpreted Article 3(b) to the effect that a valid authorisation to place the product on the market within the meaning of that provision can exist even where the authorisation under Directive 2001/83 or Directive 2001/82 relates to a medicinal product which also comprises, in addition to the patented active ingredient or in addition to the patented combination of active ingredients, in respect of which a supplementary protection certificate is applied for, one or more other active ingredients. By this interpretation of Article 3(b), manufacturers of medicinal products were permitted, in principle, to apply for a supplementary protection certificate for individual patented active ingredients even where those active ingredients have been placed on the market together with other unpatented active ingredients in a combination medicinal product.

61. A further example of this line of case-law is AHP Manufacturing, (34) in which Article 3 (c) of Regulation No 1768/92, despite the wording of the second sentence of Article 3(2) of Regulation No 1610/96 – which must be taken into consideration in interpreting that regulation – was interpreted as not precluding the grant of a supplementary protection certificate to the holder of a basic patent for a product for which, at the time the certificate application is submitted, one or more certificates have already been granted to one or more holders of one or more other basic patents.

62. There is also, however, a second series of judgments in which, in interpreting Regulation No 1768/92, the Court tends towards a stricter interpretation of the conditions for obtaining a supplementary protection certificate.

63. The most recent examples of this second line of case-law can be seen in the Court's judgments in Synthon (35) and Generics (UK), (36) in which the Court concluded that active ingredients which were placed on the market in the European Union as a medicinal product for human use before obtaining a marketing authorisation in accordance with Directive 65/65 and without undergoing safety and efficacy testing are not, in principle, within the scope of Regulation No 1768/92.

64. My proposed schematic-teleological interpretation of Article 3(b) of the regulation can be classified in the first line of the Court's case-law in which the Court tends towards an interpretation of the requirements for obtaining supplementary protection certificates under which, in principle, one – and only one – supplementary protection certificate may be granted for each basic patent under the conditions referred to in the regulation. Because, in my view, this line of case-law is most consistent with the aims of Regulation No 1768/92, I propose that it is also confirmed in the

answers to the present reference for a preliminary ruling.

B – The second to fifth questions

65. By its second question, the referring court asks how the duration of the certificate under Article 13 of Regulation No 1768/92 is to be calculated where, in a case like the main proceedings, the product can be the subject-matter of more than one supplementary protection certificate.

66. The starting point for the answer to this question is my proposed answer to the first question, according to which Article 3(d) of Regulation No 1768/92 is to be interpreted to the effect that a supplementary protection certificate for a product may be granted only on the basis of the first authorisation which permits that product to be placed on the market as a medicinal product which is within the scope of protection conferred by the basic patent in the Member State for which the application is made. Having regard to the Court's case-law, according to which the words used in Regulation No 1768/92 must in principle be given a uniform interpretation, (37) this interpretation of the notion of 'first authorisation' within the meaning of Article 3(d) of Regulation No 1768/92 means that the 'first authorisation' to place the product on the market in the European Union to which Article 13(1) refers is also to be understood as the first authorisation to place a product on the market in the European Union as a medicinal product which is within the scope of protection conferred by the basic patent designated by the applicant.

67. By its third question, the referring court would like to know whether the answers to the first and second questions are different if the earlier marketing authorisation has been granted for a veterinary medicinal product for a particular indication and the later marketing authorisation has been granted for a medicinal product for human use for a different indication.

68. This question must be answered in the negative. The crucial factor for the answer to the first – and therefore also the second – question is that the first authorised use of a product as a medicinal product is not within the scope of protection conferred by the patent which has been designated by the applicant as the basic patent for a further use of that product in another medicinal product. From this perspective, it is essentially irrelevant whether the different authorised uses of the product are uses in veterinary medicinal products or uses in medicinal products for human use. (38)

69. By its fourth question, the referring court asks whether the answers to the above questions are different if the later marketing authorisation required a full application for marketing approval in accordance with Article 8(3) of Directive 2001/83. This question must also be answered in the negative in the light of my above statements.

70. By its fifth question, the referring court asks whether the answers to the above questions are different if the product covered by the earlier authorisation to place the corresponding medicinal product on the market is within the scope of protection of a different patent which belongs to a different registered proprietor from the SPC applicant.

71. By this question, the referring court is clearly addressing the situation in the main proceedings where an active ingredient is used in two different medicinal products and the firstauthorised medicinal product is protected by its own patent which belongs to a different registered proprietor from the SPC applicant for the subsequently authorised medicinal product.

72. In the light of my above observations, the answer to the fifth question must also be that the fact that the first-authorised medicinal product is protected by its own patent and that the person who is applying for a supplementary protection certificate for a subsequently authorised medicinal product with the same active ingredient is not the holder of the first patent is irrelevant to the answer to the first – and therefore also the second – question. The crucial factor for the answer to the first question is that the first use of an active ingredient which is authorised as a medicinal product is not within the scope of protection conferred by the patent which has been designated by the applicant as the basic patent for a further use of that active ingredient in another medicinal product.

VII – Conclusion

73. In the light of the foregoing, I propose that the Court answer the questions referred as follows:

(1) Under Article 3(d) of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, a supplementary protection certificate for a product which is protected by a basic patent in force may be granted only on the basis of the first authorisation which permits that product to be placed on the market as a medicinal product which is within the scope of protection conferred by the basic patent in the Member State for which the application is made. The fact that the same product has previously been authorised as a medicinal product for human use or a veterinary medicinal product in the Member State for which the application is made does not preclude the grant of a supplementary protection certificate based on a later authorisation to place that product on the market as a new medicinal product, provided the first-authorised medicinal product is not within the scope of protection conferred by the patent designated by the applicant as the basic patent.

(2) The first authorisation to place the product on the market in the European Union to which Article 13(1) of Regulation No 1768/92 refers must also be understood as the first authorisation to place a product on the market in the European Union as a medicinal product which is within the scope of protection conferred by the basic patent designated by the applicant.

(3) The answers to the above questions are no different if

– in the Member State for which the application is made, a first authorisation has been granted to place a product on the market as veterinary medicinal product

for a particular indication and a second authorisation has been granted to place that product on the market as a medicinal product for human use for a different indication;
– there are two authorisations to place a product on the market as a medicinal product and the later authorisation required a full application under Article 4 of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products;
– the product covered by an earlier authorisation to place the medicinal product on the market is within the scope of protection of a patent which belongs to a different registered proprietor from the person who applied for a supplementary protection certificate on the basis of a later authorisation to place that product on the market as a new medicinal product and on the basis of a different patent.

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1 – Original language of the Opinion: German.
Language of the case: English.
2 – OJ 1992 L 182, p. 1, as amended by Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ 2006 L 378, p. 1).
3 – Case C-322/10 [2011] ECR I-0000.
4 – Case C-422/10 [2011] ECR I-0000.
5 – The judgments in Medeva and Georgetown University and Others concerned Article 3(a) and (b) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ 2009 L 152, p. 1). Since, in the interests of clarity and rationality, Regulation No 1768/92 has been codified by Regulation No 469/2009 without any significant substantive amendments, the Court's findings in the judgments relating to Regulation No 469/2009 are fully transferable, in principle, to the corresponding provisions of Regulation No 1768/92, and vice versa.
6 – OJ 1981 L 317, p. 1.
7 – It should be mentioned in this connection that, in his Opinion in Case C-195/09 Synthon [2011] ECR I-0000, point 88 et seq., Advocate General Mengozzi concluded that Regulation No 1768/92 justifies an interpretation according to which, for the purposes of the application of Articles 13 and 19, the first marketing authorisation for the product as a medicinal product must be regarded as the first marketing authorisation in the Community, regardless of the kind of medical use which constitutes the subject-matter of that authorisation and regardless of whether that use is the same as the use protected by the basic patent.
8 – As I stated in my Joined Opinion in Medeva and in Georgetown University and Others (Cases C-322/10 and C-422/10, judgments cited above in footnotes 3 and 4, point 89 et seq.), it is necessary to interpret the definition of 'product' in Article 1(b) of Regulation No 469/2009 teleologically to the effect that the product within the meaning of the regulation includes not only 'the' active ingredient or 'the' combination of active ingredients, but also 'an' active ingredient or 'a' combination of active ingredients of a medicinal product.
9 – OJ, English Special Edition 1965-1966, p. 24. Now Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ 2001 L 311, p. 67.
10 – With regard to the importance of a schematic and teleological interpretation in the context of Regulation No 1768/92, see Case C-125/10 Merck Sharp & Dohme Corporation [2011] ECR I-0000, paragraph 29 and the cited case-law.
11 – See, with regard to these categories of patent, Melullis, K.-J., in Europäisches Patentübereinkommen, Benkard, G. (ed.), Munich 2002, Article 52, paragraph 105 et seq.
12 – As I stated in my Joined Opinion in Medeva and in Georgetown University and Others (cited above in footnote 8, point 98 et seq.), Article 3(a) of Regulation No 469/2009 – and thus also of Regulation No 1768/92 – must be interpreted as meaning that the product within the meaning of that provision is the same as the product which forms the subject-matter of the basic patent within the meaning of Article 1(c). In the context of a judicial application of Article 3(a), it must therefore be determined, according to the rules governing the basic patent, whether a product which forms the subject-matter of the basic patent is before the court. If the answer to that question is in the affirmative, the further condition laid down by Article 3(a), namely that that product must be protected by a basic patent in force, is, as a rule, satisfied by that fact alone.
13 – Medeva, cited above in footnote 3, paragraph 21 et seq., and Case C-392/97 Farmitalia [1999] ECR I-5553, paragraph 26 et seq. See also the orders in Case C-518/10 Yeda Research and Development Company and Aventis Holdings [2011] ECR I-0000, paragraph 35; Case C-630/10 University of Queensland and CSL [2011] ECR I-0000, paragraph 27 et seq.; and Case C-6/11 Daiichi Sankyo [2011] ECR I-0000, paragraph 26.
14 – Order for reference, p. 8.
15 – OJ 2001 L 311, p. 67.
16 – OJ 2001 L 311, p. 1.
17 – Case C-181/95 Biogen [1997] ECR I-357, paragraph 28. See also Medeva, cited above in footnote 3, paragraph 41, and Georgetown University and Others, cited above in footnote 4, paragraph 34. See also the order in University of Queensland and CSL, cited above in footnote 13, paragraph 35.
18 – Case C-482/07 AHP Manufacturing [2009] ECR I-7295, paragraph 43.
19 – Cited above in footnote 8, point 75 et seq.
20 – Although the proprietor of the basic patent for an active ingredient or the holder of the supplementary

protection certificate does not necessarily have to be the holder of the marketing authorisation for the medicinal product, I am proceeding, for the sake of clarity, in my legal assessment of the questions referred, on the assumption that the manufacturer of the medicinal product is the proprietor of the basic patent and holds the marketing authorisation and has also applied for the supplementary protection certificate.
21 – See the third and fourth recitals in the preamble to Regulation No 1768/92.
22 – See Article 13 of Regulation No 1768/92 and the eighth recital in the preamble.
23 – See Hacker, F., 'PatG – Anhang zu § 16a', in Patentgesetz (founder: Busse, R.), Berlin 2003, 6th edition, paragraph 50.
24 – See AHP Manufacturing, cited above in footnote 18, paragraph 28.
25 – Order for reference, p. 13.
26 – Written observations submitted by Neurim Pharmaceuticals, paragraph 74.
27 – See Reich, H., Materielles Europäisches Patentrecht, Cologne 2009, p. 251 et seq.
28 – See Kraßer, R., Patentrecht, Munich 2009, § 14, III, letter f(dd), paragraph 1 et seq.
29 – Explanatory memorandum for the Commission's Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products, COM (90) 101 final – SYN 255, [German version] printed in Schennen, D., Die Verlängerung der Patentlaufzeit für Arzneimittel im Gemeinsamen Markt, Cologne: Bundesanzeiger, 1993, p. 92 et seq., paragraph 12.
30 – See the case-law cited in footnote 17.
31 – See point 65 et seq. of the present Opinion.
32 – Cited above in footnote 3, paragraph 29 et seq.
33 – Cited above in footnote 4, paragraph 23 et seq.
34 – Cited above in footnote 18.
35 – Case C-195/09 Synthon [2011] ECR I-0000.
36 – Case C-427/092 Generics (UK) [2011] ECR I-0000.
37 – Case C-127/00 Hässle [2003] ECR I-14781, paragraphs 57 and 72.
38 – See also Case C-31/03 Pharmacia Italia [2004] ECR I-10001, paragraph 18, in which the Court confirmed that Regulation No 1768/92 does not draw a distinction in principle between the marketing authorisations granted for medicinal products for human use and those granted for veterinary medicinal products.