Reports of Cases

JUDGMENT OF THE COURT (Grand Chamber)

9 July 2020 *

(Reference for a preliminary ruling — Medicinal product for human use — Supplementary protection certificate for medicinal products — Regulation (EC) No 469/2009 — Article 3(d) — Conditions for the grant of a certificate — Obtaining the first authorisation to place the product on the market as a medicinal product — Authorisation to place on the market a new therapeutic application of a known active ingredient)

In Case C-673/18,

REQUEST for a preliminary ruling under Article 267 TFEU from the Cour d'appel de Paris (Court of Appeal, Paris, France), made by decision of 9 October 2018, received at the Court on 30 October 2018, in the proceedings

Santen SAS

v

Directeur général de l'Institut national de la propriété industrielle,

THE COURT (Grand Chamber),

composed of K. Lenaerts, President, R. Silva de Lapuerta, Vice-President, J.-C. Bonichot, M. Vilaras, E. Regan, M. Safjan, S. Rodin and P.G. Xuereb, Presidents of Chambers, T. von Danwitz, D. Šváby, F. Biltgen, K. Jürimäe (Rapporteur) and C. Lycourgos, Judges,

Advocate General: G. Pitruzzella,

Registrar: V. Giacobbo, Administrator,

having regard to the written procedure and further to the hearing on 5 November 2019,

after considering the observations submitted on behalf of:

– Santen SAS, by T. Bouvet and L. Romestant, avocats, and by C. Fulda, Rechtsanwalt,

– the French Government, by A.-L. Desjonquères and A. Daniel, acting as Agents,

– the Hungarian Government, by M.Z. Fehér, acting as Agent,

– the Netherlands Government, by M.K. Bulterman and C. Schillemans, acting as Agents,

– the European Commission, by É. Gippini Fournier, S.L. Kalėda and J. Samnadda, acting as Agents,

* Language of the case: French.

after hearing the Opinion of the Advocate General at the sitting on 23 January 2020,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Article 3(d) 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).

2 The request has been made in proceedings between Santen SAS and the Director-General of the Institut National de la Propriété Industrielle (the National Institute for Industrial Property, France) ('the Director-General of the INPI') concerning the latter's decision to reject the application for a supplementary protection certificate ('SPC') lodged by Santen for a medicinal product marketed under the name 'Ikervis', with ciclosporin as its active ingredient.

Legal context

Regulation (EEC) No 1768/92

3 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), repealed and replaced by Regulation No 469/2009, provided in Article 2 thereof as follows:

'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 [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 (OJ, English special edition: Series I, Volume 1965-1966 p. 20)] or [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)] may, under the terms and conditions provided for in this Regulation, be the subject of [an SPC].'

4 Article 19(1) of Regulation No 1768/92, as amended by the Act concerning the conditions of accession of the Kingdom of Norway, the Republic of Austria, the Republic of Finland and the Kingdom of Sweden and the adjustments to the Treaties on which the European Union is founded (OJ 1994 C 241, p. 21), provided:

'Any product which on the date of accession is protected by a valid patent and for which the first authorisation to place it on the market as a medicinal product in the Community or within the territories of Austria, Finland or Sweden was obtained after 1 January 1985 may be granted [an SPC].

…'

Regulation No 469/2009

5 Recitals 3, 4 and 7 to 10 of Regulation No 469/2009 state:

'(3) Medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research.

(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 makes the period of effective protection under the patent insufficient to cover the investment put into the research.

…

(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 marketing authorisation has been granted is necessary. A regulation is therefore the most appropriate legal instrument.

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

6 Article 1 of that regulation provides as follows:

'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 [an SPC];

…'

7 Article 2 of that regulation provides as follows:

'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 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)] 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 [an SPC].'

8 Article 3 of that regulation, entitled 'Conditions for obtaining [an SPC]', is worded as follows:

'[An SPC] 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 [2001/83] or Directive [2001/82], as appropriate;

(c) the product has not already been the subject of [an SPC];

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

9 Under Article 4 of Regulation No 469/2009, entitled 'Subject matter of protection':

'Within the limits of the protection conferred by the basic patent, the protection conferred by [an SPC] 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 [SPC].'

10 Article 5 of that regulation, entitled 'Effects of the [SPC]', provides as follows:

'Subject to the provisions of Article 4, the [SPC] shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.'

11 Article 7(1) of that regulation provides as follows:

'The application for [an SPC] 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.'

12 Under Article 13 of that regulation, entitled 'Duration of the [SPC]':

'1. The [SPC] 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 [SPC] may not exceed five years from the date on which it takes effect.

3. The periods laid down in paragraphs 1 and 2 shall be extended by six months in the case where Article 36 of 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)] applies. In that case, the duration of the period laid down in paragraph 1 of this Article may be extended only once.

4. Where [an SPC] is granted for a product protected by a patent which, before 2 January 1993, had its term extended or for which such extension was applied for, under national law, the term of protection to be afforded under this [SPC] shall be reduced by the number of years by which the term of the patent exceeds 20 years.'

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

13 Santen is a pharmaceutical laboratory specialising in ophthalmology. It holds European patent (FR) No 057959306, filed on 10 October 2005, ('the basic patent at issue'), which protects, inter alia, an ophthalmic emulsion in which the active ingredient is ciclosporin, an immunosuppressive agent.

14 Santen obtained a marketing authorisation ('MA'), granted on 19 March 2015 by the European Medicines Agency (EMA) for a medicinal product marketed under the name 'Ikervis', the active ingredient of which is ciclosporin ('the MA at issue'). That medicinal product is used to treat severe keratitis in adult patients with dry eye disease that has not improved despite treatment with tear substitutes, causing inflammation of the cornea.

15 On the basis of the basic patent at issue and the MA at issue, on 3 June 2015 Santen filed an application for an SPC for a product called 'Ciclosporin for use in the treatment of keratitis'. By decision of 6 October 2017, the Director-General of the INPI rejected that application for an SPC, taking the view that the MA at issue was not the first MA, for the purpose of Article 3(d) of Regulation No 469/2009, for ciclosporin.

16 The Director-General of the INPI based its decision on the ground that, on 23 December 1983, an MA had been granted for a medicinal product, marketed under the name 'Sandimmun', that also had ciclosporin as its active ingredient. That medicinal product was presented in the form of an oral solution and was indicated for preventing the rejection of solid organ and bone marrow grafts and for other therapeutic indications, including the treatment of endogenous uveitis, an inflammation of all or part of the uvea, the middle part of the eyeball.

17 Santen brought an action against the decision of the Director-General of the INPI before the referring court, the Cour d'appel de Paris (Court of Appeal, Paris, France). Before that court, Santen sought, as its primary claim, the annulment of that decision and, in the alternative, to refer a question to the Court of Justice for a preliminary ruling concerning the interpretation of Article 3 of Regulation No 469/2009.

18 The referring court points out that, in its judgment of 19 July 2012, *Neurim Pharmaceuticals (1991)* (C-130/11, EU:C:2012:489) ('the judgment in *Neurim*'), the Court ruled that Articles 3 and 4 of Regulation No 469/2009 must be interpreted as meaning that, in a situation such as that at issue in the case which gave rise to that judgment, 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 that application is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the SPC.

19 That court notes that the Director-General of the INPI is in dispute with Santen over the interpretation of the concepts of 'different application of the same product' and 'application … within the limits of the protection conferred by the basic patent', upheld by the Court in the judgment in *Neurim* for the purposes of interpreting, in particular, Article 3 of Regulation No 469/2009.

20 As regards the concept of 'different application' of the same product, the Director-General of the INPI takes the view that that concept must be interpreted strictly. He submits that the MA relied upon must relate to an indication within a new therapeutic field, in the sense of a new medical specialism,

compared with the earlier MA, or to a medicinal product in which the active ingredient acts differently from the way in which it acts in the medicinal product to which the first MA relates. According to the Director-General, it is also necessary to ask the Court whether, in the light of the objectives of Regulation No 469/2009 of establishing a balanced system that takes into account all the interests at stake, including those of public health, the concept of a 'new therapeutic use' must be assessed according to stricter criteria than those used for assessing the patentability of a new therapeutic application.

21 Santen, on the other hand, claims that the concept of 'different [therapeutic] application' within the meaning of the judgment in *Neurim*, must be interpreted broadly, including not only therapeutic indications and uses for different diseases, but also different formulations, posologies and/or means of administration.

22 As regards the condition fixed by the Court in the judgment in *Neurim*, according to which the therapeutic application covered by the MA which serves as a basis for the SPC application must fall within the limits of the protection conferred by the basic patent, the Director-General of the INPI raises the issues, first, of the way in which the link should be established between the different therapeutic application and that patent and, second, of whether the scope of that patent must correspond to that of the MA relied upon and, therefore, be limited to the new therapeutic application corresponding to the indication of that MA.

23 In those circumstances, the Cour d'appel de Paris (Court of Appeal, Paris) decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) Must the concept of a "different application" within the meaning of [the judgment in *Neurim*] be interpreted strictly, that is to say:

– as being limited only to the situation where an application for human use follows a veterinary application;

– or as relating to an indication within a new therapeutic field, in the sense of a new medical specialism, as compared with the earlier MA, or to a medicinal product in which the active ingredient acts differently from the way in which it acts in the medicinal product to which the first MA related;

– or more generally, in the light of the objectives of [Regulation No 469/2009] of establishing a balanced system taking into account all the interests at stake, including those of public health, must the concept of a "new therapeutic use" be assessed according to stricter criteria than those for assessing the patentability of the invention;

or must it on the other hand be interpreted broadly, that is to say, as including not only different therapeutic indications and diseases, but also different formulations, posologies and/or means of administration?

(2) Does the expression "[application] within the limits of the protection conferred by the basic patent" within the meaning of the judgment [in *Neurim*], mean that the scope of the basic patent must be the same as that of the MA relied upon and, therefore, be limited to the new medical use corresponding to the therapeutic indication of that MA?'

Consideration of the questions referred

Admissibility of the request for a preliminary ruling

24 In its written observations, the Netherlands Government claims that the request for a preliminary ruling is inadmissible inasmuch as the situation at issue in the main proceedings does not fall within the scope of Regulation No 469/2009.

25 The Netherlands Government argues that the Court decided, in paragraph 48 of the judgment of 28 July 2011, *Synthon* (C-195/09, EU:C:2011:518), that it follows from Article 19(1) of Regulation No 1768/92 that that regulation is not applicable to products placed on the market in France before 1 January 1985. That interpretation of Regulation No 1768/92 is fully transposable to Regulation No 469/2009, since that latter regulation is merely a codification of Regulation No 1768/92. The Netherlands Government infers from this that, since an MA was granted in France for a medicinal product whose active ingredient is 'ciclosporin' on 23 December 1983, Santen's application does not fall within the scope of Regulation No 469/2009. The questions referred for a preliminary ruling are thus hypothetical.

26 In that regard, it should be recalled that it is solely for the national court before which the dispute has been brought, and which must assume responsibility for the subsequent judicial decision, to determine in the light of the particular circumstances of the case both the need for a preliminary ruling in order to enable it to deliver judgment and the relevance of the questions which it submits to the Court. Consequently, where the questions submitted concern the interpretation of a rule of EU law, the Court is in principle bound to give a ruling (judgment of 10 December 2018, *Wightman and Others*, C-621/18, EU:C:2018:999, paragraph 26 and the case-law cited).

27 It follows that questions relating to EU law enjoy a presumption of relevance. The Court may refuse to rule on a question referred for a preliminary ruling by a national court only where it is quite obvious that the interpretation of EU law that is sought bears no relation to the actual facts of the main action or its purpose, where the problem is hypothetical, or where the Court does not have before it the factual or legal material necessary to give a useful answer to the questions submitted to it (judgment of 10 December 2018, *Wightman and Others*, C-621/18, EU:C:2018:999, paragraph 27 and the case-law cited).

28 In the present case, the questions referred for a preliminary ruling concern, in essence, the interpretation of Article 3(d) of Regulation No 469/2009 and, more specifically, the interpretation of the concept of 'first [MA for the product] as a medicinal product' for the purpose of that provision, read in the light of the judgment in *Neurim*.

29 By its arguments concerning the inadmissibility of the request for a preliminary ruling, the Netherlands Government starts from the premiss that the MA granted on 23 December 1983 in France for Sandimmun, containing the active ingredient 'ciclosporin', is the first MA for that product as a medicinal product and that, therefore, Regulation No 469/2009 is not applicable to that product, that is at issue in the main proceedings.

30 However, in order to ascertain whether that premiss is well founded it is first necessary to answer the questions referred for a preliminary ruling, which concern the interpretation of Article 3(d) of Regulation No 469/2009. It follows that the arguments of the Netherlands Government referred to in paragraph 25 above do not permit the conclusion that those questions are hypothetical on the ground that they bear no relation to the actual facts of the main action or its purpose.

31 It follows that the request for a preliminary ruling is admissible.

Substance

32 By its questions, which must be examined together, the referring court requests the Court of Justice, in essence, to interpret the concept of 'first [MA for the product] as a medicinal product' for the purpose of Article 3(d) of Regulation No 469/2009, which requires, in the view of that court, that the Court of Justice specify the scope of the concepts of 'different [therapeutic] application' and '[therapeutic] application … within the limits of the protection conferred by the basic patent' in point 1 of the operative part of the judgment in *Neurim*.

33 In point 1 of the operative part of that judgment, the Court held that Articles 3 and 4 of Regulation No 469/2009 must be interpreted as meaning that, in a situation such as that in the case which gave rise to that judgment, the mere existence of an earlier MA obtained for a veterinary medicinal product such as the one at issue in that case does not preclude the grant of an SPC for a different therapeutic 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.

34 The questions referred are thus based on the premiss, arising from the judgment in *Neurim*, that it is possible, in certain circumstances that, according to the referring court, are still to be defined, to obtain an SPC for a new therapeutic application of an active ingredient which has already been the subject of an MA prior to the MA on which the application for that SPC is based.

35 In this connection, according to settled case-law, even if, formally, the referring court has limited its questions to the interpretation of certain aspects of EU law, that does not prevent this Court from providing the referring court with all the elements of interpretation of EU law which may be of assistance in adjudicating in the case pending before it, whether or not that court has referred to them in the wording of its questions (see, to that effect, judgment of 5 June 2018, *Coman and Others*, C-673/16, EU:C:2018:385, paragraph 22 and the case-law cited).

36 It is important to bear in mind the fact that, in the case in the main proceedings, the referring court must decide whether an application for an SPC covering ciclosporin, for its use in the treatment of keratitis, can be accepted on the basis of the MA at issue, which was granted for Ikervis on 19 March 2015, even though on 23 December 1983 an MA had already been granted for a different therapeutic application of ciclosporin.

37 Thus, in order to provide a useful answer to the referring court, it is necessary to examine whether Article 3(d) of Regulation No 469/2009 must be interpreted as meaning that an MA may be considered to be the first MA, for the purpose of that provision, where it covers a new therapeutic application of an active ingredient or of a combination of active ingredients and that active ingredient or combination has already been the subject of an MA for a different therapeutic application.

38 In this respect, the MA to which Article 3(d) of Regulation No 469/2009 refers must be granted for a specified product, as defined in Article 1(b) of that regulation.

39 It is therefore necessary, in the first place, to determine whether the concept of a 'product', as defined in Article 1(b) of Regulation No 469/2009, is dependent on the therapeutic application of the active ingredient and, in particular, whether a new therapeutic application of an active ingredient may be considered to be a product distinct from a different, already known, therapeutic application of the same active ingredient.

40 Under that provision, 'product' means the active ingredient or combination of active ingredients of a medicinal product.

41 In the absence of any definition of the concept of 'active ingredient' in Regulation No 469/2009, the meaning and scope of those terms must be determined by considering the general context in which they are used and their usual meaning in everyday language (judgments of 4 May 2006, *Massachusetts Institute of Technology*,C-431/04, EU:C:2006:291, paragraph 17, and of 21 March 2019, *Abraxis Bioscience*, C-443/17, EU:C:2019:238, paragraph 25).

42 The Court has already held in this respect that the term 'active ingredient' is generally accepted in pharmacology not to include substances forming part of a medicinal product which do not have an effect of their own on the human or animal body (judgments of 4 May 2006, *Massachusetts Institute of Technology*, C-431/04, EU:C:2006:291, paragraph 18, and of 15 January 2015, *Forsgren*, C-631/13, EU:C:2015:13, paragraph 23) and that, for the purposes of applying Regulation No 469/2009, that term concerns substances producing a pharmacological, immunological or metabolic action of their own (judgment of 15 January 2015, *Forsgren*, C-631/13, EU:C:2015:13, paragraph 25). It follows that the term concerned refers to substances which have, at least, a therapeutic effect of their own.

43 Moreover, it follows from a reading of Article 1(b) of Regulation No 469/2009 in conjunction with Article 4 thereof that the term 'product' is understood, for the purposes of applying that regulation, to mean the active ingredient or combination of active ingredients of a medicinal product, without its being necessary to limit its scope only to one of the therapeutic applications to which such an active ingredient or combination of active ingredients may give rise.

44 Under Article 4 of that regulation, the protection conferred on the product by the SPC, although it extends only to the product covered by the MA, covers, on the other hand, any use of that product as a medicinal product which was authorised before the expiry of the SPC. It follows that the term 'product' within the meaning of Regulation No 469/2009 is not dependent on the manner in which that product is used and that the intended use of the medicinal product does not constitute a decisive factor for the grant of an SPC (see, to that effect, judgment of 19 October 2004, *Pharmacia Italia*, C-31/03, EU:C:2004:641, paragraphs 19 and 20).

45 Such an interpretation is supported by an analysis of the origins of Regulation No 469/2009. Thus, paragraph 11 of the Explanatory Memorandum of 11 April 1990 to the Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final), which led to Regulation No 1768/92, itself repealed and replaced by Regulation No 469/2009, indicates that the term 'product' is understood to mean an active ingredient in the strict sense and that minor changes to the medicinal product such as a new dose, the use of a different salt or ester or even of a different pharmaceutical form will not lead to the issue of a new SPC (see, to that effect, judgments of 4 May 2006, *Massachusetts Institute of Technology*, C-431/04, EU:C:2006:291, paragraph 19, and of 21 March 2019, *Abraxis Bioscience*, C-443/17, EU:C:2019:238, paragraph 26).

46 That strict view of the term 'product' was given concrete form in Article 1(b) of Regulation No 469/2009, which defines that term by reference to an active ingredient or combination of active ingredients and not by reference to the therapeutic application of an active ingredient protected by the basic patent or a combination of active ingredients protected by that patent.

47 It follows from the foregoing considerations that Article 1(b) of Regulation No 469/2009 must be interpreted as meaning that the fact that an active ingredient, or a combination of active ingredients, is used for the purposes of a new therapeutic application does not confer on it the status of a distinct product where the same active ingredient, or the same combination of active ingredients, has been used for the purposes of a different, already known, therapeutic application.

48 In the second place, it is appropriate to determine whether an MA granted for a new therapeutic application of an active ingredient or of a combination of active ingredients may be regarded as being the first MA granted for that product as a medicinal product, for the purpose of Article 3(d) of Regulation No 469/2009, in the case where that MA is the first MA to fall within the limits of the protection of the basic patent relied on in support of the application for an SPC.

49 According to the condition for the grant of an SPC laid down in that provision, the MA obtained for the product which is the subject of the SPC application must, at the date of that application, be the first MA for that product as a medicinal product in the Member State in which that application is submitted.

50 In this respect, the wording of that provision does not refer to the limits of the protection of the basic patent.

51 In addition, in the light of the strict definition of the term 'product' within the meaning of Article 1(b) of Regulation No 469/2009, as is apparent from paragraphs 40 to 45 above, the analysis of the wording of Article 3(d) of that regulation presupposes that the first MA for the product as a medicinal product for the purpose of that provision means the first MA for a medicinal product incorporating the active ingredient or the combination of active ingredients at issue (see, to that effect, judgment of 21 March 2019, *Abraxis Bioscience*, C-443/17, EU:C:2019:238, paragraph 34), irrespective of the therapeutic application of that active ingredient, or of that combination of active ingredients, in respect of which that MA was obtained.

52 To take the view that the concept of 'first MA for the product as a medicinal product' for the purpose of Article 3(d) of Regulation No 469/2009 refers exclusively to the first MA to fall within the limits of the protection of the basic patent relied upon in support of the SPC application would necessarily call into question that strict definition of the term 'product' within the meaning of Article 1(b) of that regulation, since it is possible, as Article 1(c) of that regulation makes clear, that the basic patent in question covers only one therapeutic application of the product at issue. If that were the case, that therapeutic application might justify the grant of an SPC notwithstanding the fact that the same active ingredient, or the same combination of active ingredients, is covered by a different, already known, therapeutic application which gave rise to an earlier MA.

53 It follows that, contrary to what the Court held in paragraph 27 of the judgment in *Neurim*, to define the concept of 'first [MA for the product] as a medicinal product' for the purpose of Article 3(d) of Regulation No 469/2009, there is no need to take into account the limits of the protection of the basic patent.

54 Likewise, an analysis of the objectives of Regulation No 469/2009 confirms that interpretation.

55 Thus, as is apparent from paragraph 11 of the Explanatory Memorandum referred to in paragraph 45 above, the EU legislature intended, in establishing the SPC regime, to protect not all pharmaceutical research giving rise to the grant of a patent and the marketing of a new medicinal product, but to protect research leading to the first placing on the market of an active ingredient or a combination of active ingredients as a medicinal product (see, to that effect, judgment of 21 March 2019, *Abraxis Bioscience*, C-443/17, EU:C:2019:238, paragraph 37).

56 That objective would be undermined if it were possible, in order to fulfil the condition set out in Article 3(d) of Regulation No 469/2009, to take into account solely the first MA to fall within the limits of the protection of the basic patent covering a new therapeutic application of a given active ingredient, or a given combination of active ingredients, and to disregard an MA which had been granted previously for a different therapeutic application of the same active ingredient or of the same combination (see, to that effect, judgment of 21 March 2019, *Abraxis Bioscience*, C-443/17, EU:C:2019:238, paragraph 38).

57 That interpretation also enables a fair balance to be struck between, on the one hand, the objective of the SPC regime, as it is made apparent from recitals 3 to 5 and 9 of Regulation No 469/2009, of compensating for the inadequacy of protection conferred by a patent for the purpose of covering the investment put into research concerning new active ingredients or combinations of active ingredients and, therefore, of encouraging such research and, on the other hand, the EU legislature's intention, as set out in recital 10 of that Regulation, to achieve that objective in a manner that takes into account all the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector (see, to that effect, judgment of 21 March 2019, *Abraxis Bioscience*, C-443/17, EU:C:2019:238, paragraph 36).

58 That interpretation is not moreover not called into question by paragraph 12 of the Explanatory Memorandum, from which it is apparent that Regulation No 469/2009 is not confined to new products only, since a new process for obtaining a product or a new application of a product may also be protected by an SPC. The condition set out in Article 3(d) of Regulation No 469/2009 may, inter alia, be satisfied where the MA serving as a basis for the SPC application covers a product which was already known before the basic patent was granted but which had never given rise to an MA as a medicinal product.

59 Furthermore, as the Advocate General observed in points 55 and 56 of his Opinion, an interpretation of Article 3(d) of Regulation No 469/2009 such as that set out in paragraph 56 above might compromise the simplicity and the predictability which the EU legislature intended the system to have in order to guarantee the implementation of a uniform solution at EU level by the national patent offices. The introduction of a distinction between different therapeutic applications, without that concept even being defined in that regulation, could lead those national offices to adopt complex and divergent interpretations of the condition laid down in that provision.

60 It follows from the foregoing that the premiss on which the referring court relies, mentioned in paragraph 34 above, must be disregarded and that an MA for a therapeutic application of a product cannot be regarded as the first MA for that product as a medicinal product, for the purpose of Article 3(d) of Regulation No 469/2009, where another MA was granted previously for a different therapeutic application of the same product. The fact that the most recent MA is the first MA to fall within the limits of the protection of the basic patent relied on in support of the SPC application cannot call that interpretation into question.

61 In the light of all the foregoing, the answer to the questions referred is that Article 3(d) of Regulation No 469/2009 must be interpreted as meaning that an MA cannot be considered to be the first MA, for the purpose of that provision, where it covers a new therapeutic application of an active ingredient, or of a combination of active ingredients, and that active ingredient or combination has already been the subject of an MA for a different therapeutic application.

Costs

62 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 (Grand Chamber) hereby rules:

Article 3(d) 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 a marketing authorisation cannot be considered to be the first marketing authorisation, for the purpose of that provision, where it covers a new therapeutic

application of an active ingredient, or of a combination of active ingredients, and that active ingredient or combination has already been the subject of a marketing authorisation for a different therapeutic application.

[Signatures]