Court of Justice EU, 9 July 2020, Santen

PATENT LAW

Authorisation for a therapeutic application of a product cannot be regarded as the first authorization where another authorisation was granted previously for a different therapeutic application of the same product:

- **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.**

Source: **ECLI:EU:C:2020:34**

Court of Justice EU, 9 July 2020
(K. Lenaerts, R. Silva de Lapuerta, J.-C. Bonichot, M. Vilaras, E. Regan, M. Safjan, S. Rodin, P.G. Xuereb, T. von Danwitz, D. Šváby, F. Biltgen)
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,
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 sub

stance 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.

OPINION OF ADVOCATE GENERAL PITRUZZELLA
delivered on 23 January 2020 (1)
Case C-673/18
Santen SAS
v
Directeur général de l'Institut national de la propriété industrielle
(Request for a preliminary ruling from the Cour d'appel de Paris (France))
(Reference for a preliminary ruling — Proprietary medicinal products — Supplementary protection certificate for medicinal products — Patent law — Products containing the same active ingredient which have obtained successive marketing authorisations for different holders — Scope of the judgment in Neurim Pharmaceuticals (1991) (C-130/11) — Concepts of 'different application' and 'application within the limits of the protection conferred by the basic patent')

1. Just a few months since the judgment in Abraxis Bioscience was delivered, (2) the Court has once again been asked, this time by the Cour d'appel de Paris (Court of Appeal, Paris, France), to clarify the scope of its judgment of 19 July 2012, Neurim Pharmaceuticals (1991), (3) in which, adopting a teleological interpretation of Article 3(d) of Regulation (EC) No 469/2009, (4) it opened up the possibility of obtaining a supplementary protection certificate for medicinal products ('SPC') in respect of new applications of old active ingredients.

2. Whilst the question of the scope of the Neurim judgment remained just below the surface in the Abraxis judgment, even though the Court was invited by several intervening governments and Advocate General Saugmandsgaard Øe (5) to reverse the principles established by that judgment, in the present case the Cour d'appel de Paris expressly asks the Court to explain the conditions for the application of that judgment and to clarify whether its scope should be confined only to the situation at issue in the main proceedings which led to the judgment, namely where the old active ingredient has been the subject of a first marketing authorisation (MA) as a veterinary medicinal product and a second MA as a medicinal product for human use, or whether it should be seen as having a broader scope. (6)

3. Created by Regulation (EEC) 1768/92, (7) which Regulation No 469/2009 codifies, the SPC is a 'sui generis right', (8) the aim of which is to grant pharmaceutical patent holders, under certain conditions, a form of supplementary protection making it possible to defer beyond the expiry of the patent the time from which the invention protected by the patent enters the public domain and its marketing is subject to competition. The reason for the creation of the SPC is that in the pharmaceutical sector the period of effective protection conferred by patents is insufficient to cover the investment put into the research because the patent holder cannot exploit its invention economically between the date when the patent application is filed and

the date when the MA for the medicinal product incorporating that invention is granted. (9)

I. Legal framework

4. Article 1(a) to (c) of Regulation No 469/2009 provides:

'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'.

5. Under Article 2 of that regulation, which defines its scope, '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 (10) 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 (11) may, under the terms and conditions provided for in this Regulation, be the subject of a certificate'.

6. Article 3 of the regulation reads as follows: *'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 2001/83/EC or Directive 2001/82/EC, as appropriate;

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

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

7. Under Article 4 of Regulation No 469/2009, *'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'*.

II. The dispute in the main proceedings, the questions referred for a preliminary ruling and the procedure before the Court

8. Santen SAS (*'Santen'*) is a pharmaceutical laboratory specialising in ophthalmology. It holds European patent No EP 057959306 (*'the basic patent at issue in the main proceedings'*), filed on 10 October 2005 and granted on 31 December 2008 under the title *'Ophthalmic oil-in-water type emulsion with stable positive zeta potential'*, comprising 27 claims. That patent expires on 11 October 2025. Santen obtained an MA issued by the European Medicines Agency (EMA) on 19 March 2015 for the medicinal product Ikervis, an emulsion (eye drops) which has the ciclosporin as its active ingredient and treats severe keratitis (12) in adult patients with dry eye disease that has not improved despite treatment with tear substitutes (*'the MA at issue in the main proceedings'*).

9. On 3 June 2015, on the basis of the basic patent and the MA at issue in the main proceedings, Santen filed an application for an SPC at the Institut National de la Propriété Intellectuelle (INPI) for a product called *'ciclosporine collyre en émulsion'* [*'ciclosporin eye drops, emulsion'*], which it subsequently renamed *'ciclosporin for use in the treatment of keratitis'* in response to observations by the INPI.

10. By a decision of 6 October 2017, the director of the INPI rejected that application on the ground that an MA had already been granted on 23 December 1983 for a medicinal product called *'Sandimmun'* that also had ciclosporin as its active ingredient and, accordingly, that the MA at issue in the main proceedings was not the first MA for the product covered by the SPC application for the purposes of Article 3(d) of Regulation No 469/2009 (*'the decision of the director of the INPI'*). The medicinal product Sandimmun was presented in the form of an oral solution and had several therapeutic indications, both in preventing the rejection of solid organ and bone marrow grafts and non-transplant indications including the treatment of endogenous uveitis. (13) In his decision, the director of the INPI stated that the requirements in the Neurim judgment, on which Santen relied to argue that the medicinal product Ikervis included a *'new application'* of ciclosporin enabling a SPC to be granted, seemed to him not to be satisfied since, first, the basic patent relied upon protected not only a new application of ciclosporin (claims 23 and 24),) but also and primarily an ophthalmic oil-in-water submicron type emulsion containing an active substance, including ciclosporin (claims 1 to 21, 25 and 26) and, furthermore, that it had not been shown that the medical application in the MA at issue in the main proceedings amounted to a *'new therapeutic application'* within the meaning of the Neurim case-law, compared with the proprietary product Sandimmun, since both concerned the treatment of inflammations in the field of ophthalmology.

11. Santen challenged the decision of the director of the INPI before the referring court, seeking annulment of that decision and, in the alternative, that a request for a preliminary ruling be made the Court in order to clarify whether Article 3(d) of Regulation No 469/2009 precludes the grant of an SPC in the circumstances of the case in the main proceedings.

12. According to Santen, the medicinal product Ikervis constitutes a different and new application of ciclosporin within the meaning of Neurim because: (i) none of the earlier formulations of the medicinal product Sandimmun is the oil-in-water emulsion claimed in the basic patent at issue in the main proceedings; (ii) the medicinal products Sandimmun and Ikervis do not have the same therapeutic indication and treat different diseases; (14) (iii) although in both instances ciclosporin has an anti-inflammatory function, amongst others, it is to treat different parts of the eye and different conditions; (iv) their posology and means of administration are different and the two proprietary medicines are not interchangeable.
13. Before the referring court, the director of the INPI explained that he aims to take a measured approach in applying the Neurim case-law. First, the basic patent must have the same scope as the MA relied upon and, therefore, that scope must be limited to the new medical use corresponding to the therapeutic indication in that MA. That is not the situation with the SPC application submitted by Santen, in which the basic patent protects both a product, that is to say an ophthalmic emulsion in which the active substance is ciclosporin (claim 21), and the use of that emulsion to prepare an ophthalmic composition to treat numerous eye diseases that are referred to expressly, including uveitis (claim 24). Second, the MA relied upon must relate to an indication within a new therapeutic scope, in the sense of a new proprietary medicinal product, compared with the earlier MA, or a medicinal product in which the active ingredient acts differently from how it acts in the medicinal product to which the first MA relates. No new medicinal use has been demonstrated in respect of the SPC application filed by Santen in so far as both MAs were for the treatment of inflammation of parts of the human eye, using the same mechanism of action of ciclosporin
14. The referring court notes that it is common ground that the SPC application filed by Santen meets the requirements set out in Article 3(a), (b) and (c) of Regulation No 469/2009. In contrast, as regards the requirement in Article 3(d), the parties disagree on the interpretation to be given to the concept of *'different application of the same product'* in the Neurim judgment and on the scope which the basic patent must have for the requirements for the grant of the SPC to be met in the situations covered by that judgment.
15. Against that background, by judgment of 9 October 2018, the Cour d'appel de Paris stayed the proceedings pending before it and referred the following questions for a preliminary ruling:
'1. Must the concept of a "different application" within the meaning of the [Neurim judgment] be interpreted strictly, that is to say:
– as 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 scope, in the sense of a new proprietary medical product, compared with the earlier marketing authorisation, or a medicinal product in which the active ingredient acts differently from how it acts in the medicinal product to which the first marketing authorisation 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 [Neurim judgment] mean that the scope of the basic patent must be the same as that of the marketing authorisation relied upon and, therefore, be limited to the new medical use corresponding to the therapeutic indication of that marketing authorisation?'
16. In the case to which this Opinion relates, written observations were submitted by Santen, the French, Hungarian and Netherlands Governments and the European Commission. Those interested parties, with the exception of the Hungarian Government, presented oral argument at the hearing held before the Court on 5 November 2019.

III. Analysis

17. Since, by its questions, the Cour d'appel de Paris asks the Court to clarify the scope of its Neurim judgment, I will begin by highlighting the content of that judgment and analysing its implications for the interpretation of Regulation No 469/2009, for its internal coherence and for the SPC system more generally. Then, given that the Court relied on an essentially teleological interpretation of that regulation in the judgment, I will go over its objectives, as apparent, in particular, from the travaux préparatoires. At the end of my analysis, I will conclude that the interpretation adopted by the Court in the Neurim judgment should be abandoned. It is therefore only in the alternative, in the event that the Court should not concur with that conclusion, that I will respond to the referring court's questions regarding the scope of the Neurim judgment.

A. The Neurim judgment

18. In the main proceedings which gave rise to the Neurim judgment, the Neurim Pharmaceuticals (1991) laboratory (*'Neurim'*) had challenged before the UK courts the rejection by the United Kingdom Intellectual Property Office of its SPC application for a melatonin-based medicinal product for human use called *'Circadin'*, indicated for treatment of insomnia. The ground for the rejection was that melatonin had already been the subject of an MA, granted for a veterinary medicinal product, Regulin, which was used for regulating the seasonal breeding activity of sheep. Regulin had been protected by a patent held by the company Hoechst which had expired in May 2007, before the MA was granted for Circadin on 28 June 2007. Neurim asserted, in essence, that since Regulation

No 469/2009 was intended to permit protection to be obtained supplementary to that conferred by the basic patent, an MA for a product that is not covered by that patent cannot prevent the grant of the SPC and that each patent must permit the grant of an SPC for the first MA falling within the scope of the basic patent. Concurring with the position taken by Neurim, the referring court (15) had referred five questions to the Court for a preliminary ruling.

19. Examining the first (16) and third questions together, (17) after it had noted the specific features of the case in the main proceedings in paragraph 17 of the grounds of the judgment, the Court stated, in paragraph 19, that those questions asked by the referring court were 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 [Regulation No 469/2009], and on the other, the basic patent referred to in Article 3(a) of that regulation'*. In paragraphs 22, 23 and 24 of the grounds of the judgment, the Court noted that the fundamental objective of Regulation No 469/2009 is *'to ensure sufficient protection to encourage pharmaceutical research'* and that the reason given for the adoption of the regulation was *'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'*. (18) In paragraph 24, the Court pointed out that it is apparent from paragraph 29 of the Explanatory Memorandum 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 Regulation [No 469/2009], enable an SPC to be granted'*. In paragraph 25, it concluded that *'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'*. In such a situation, according to the Court, *'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 Regulation [No 469/2009]'*. (19) On those grounds, the Court answered the first and third questions to the effect that *'Articles 3 and 4 of Regulation [No 469/2009] 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'*. (20) In accordance with that conclusion, the Court answered the second question concerning Article 13(1) of Regulation No 469/2009 (21) to the effect that that provision was 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'*. (22) Lastly, with regard to the fourth and fifth questions, the Court stated 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'*. (23)

20. In the Neurim judgment the Court therefore relied on an essentially teleological interpretation of Regulation No 469/2009 to conclude that the *'scope of protection of the basic patent'* constitutes the material criterion in assessing whether the *'product'* covered by the MA which serves as the basis for the SPC application has already been the subject of an earlier MA in the Member State where the application is made. This means, in essence, that an earlier MA granted for the same active ingredient (or the same combination of active ingredients) as that of the MA on which the SPC application is based may be considered to be *'the first MA of the product'* for the purposes of Article 3(d) of the regulation only if it is within the limits of the protection of the basic patent. In doing so, the Neurim judgment opened the path to obtaining an SPC for subsequent applications of a known active ingredient, a path which, by contrast, would be closed on a literal interpretation of that provision, as I will explain later in this Opinion.

21. Although the reasoning followed by the Court in the grounds of the Neurim judgment is linear and logical, the judgment nevertheless left a number of issues unresolved, which makes it difficult to ascertain its real scope.

22. First, as will be shown in greater detail below, the Neurim judgment is not consistent with the Court's earlier case-law on the concept of *'product'* within the meaning of Article 1(b) of Regulation No 469/2009, which begs the question whether it should be construed as an exception, applicable only in factual circumstances identical to those examined by the Court, (24) as would seem to be confirmed by its operative part, or whether it is broader in scope, as seems to be suggested, on the other hand, by the reasoning followed by the Court. I will say at the outset that, in my view, the Neurim judgment cannot be construed as an exception. That interpretation is precluded by the reasoning set out in paragraphs 22 to 26 of the judgment, which clearly transcends the factual context of the case in the main

proceedings being heard by the Court. Rather, in the Neurim judgment the Court gave an interpretation that introduces a major development in the SPC rules. 23. Second, assuming that the solution adopted in the Neurim judgment extends beyond the case of use in human medicine of a product which has been previously authorised only in the veterinary field, the meaning of the expressions *'new therapeutic application'*, *'new use'*, *'different application'* or *'other therapeutic indication'* which appear in the grounds of the judgment is not defined and opens the door to a number of possible interpretations, as is shown by the present request for a preliminary ruling. This has given rise to divergent practices in national patent offices, as is pointed out in the study produced for the Commission by the Max Planck Institute for Innovation and Competition, the final report from which, entitled *'Study on the Legal Aspects of Supplementary Protection Certificates in EU'*, was published in 2018 (*'the Max Planck study'*). Thus, of the offices which do not confine the application of the Neurim judgment to the case of a first veterinary MA and a second MA in human medicine, (25) some have recourse to it only in the case of a *'new medical indication'* (26) and others also in the case of a *'different application'*. (27) Furthermore, some offices (28) also grant an SPC in the case of type II variations, (29) unlike others, which do not consider such variations to be relevant. (30)

24. Lastly, it is not clearly established whether the teleological approach taken in the Neurim judgment in interpreting Article 3(d) of Regulation No 469/2009 should be extended to other provisions of the regulation a literal reading of which would lead to the protection conferred by the SPC being accorded a narrower scope.

B. The implications of the Neurim judgment on the system applicable to the SPC

1. The Neurim judgment and the concept of *'product'* within the meaning of Regulation No 469/2009

25. The concept of *'product'*, for the purposes of Article 1(b) of Regulation No 469/2009 defined as *'the active ingredient or combination of active ingredients of a medicinal product'*, forms the cornerstone of the SPC system. Its interpretation determines not only whether a patented invention can lead to an SPC being granted, (31) but also the scope of the protection conferred by it. (32) As Advocate General Jacobs stated in his Opinion in Pharmacia Italia, (33) an awareness of the distinction between the concepts of *'product'* and *'medicinal product'* is essential to a correct understanding of Regulation No 469/2009. The *'product'*, as defined, is the subject of patent protection, which the SPC seeks to extend, (34) while the medicinal product is the subject of the MA, which confers entitlement to the SPC (35). The regulation operates at the interface between patent protection of products and the MA of medicinal products: it seeks to extend the patent protection of products which are constituents of authorised medicinal products.

26. Before the Neurim judgment, the concept of *'product'* had been the subject of a number of decisions by the Court, three of which should be briefly recalled.

27. In the judgment in Pharmacia Italia, (36) which concerned the question whether an earlier MA granted for a veterinary medicinal product precluded the grant of an SPC relating to the same active ingredient authorised as a medicinal product for human use, the Court, in interpreting Article 19(1) of Regulation No 1768/92, (37) held, first, that *'the decisive factor for the grant of the certificate is not the intended use of the medicinal product'* and, second, that *'the purpose of the protection conferred by the certificate relates to any use of the product as a medicinal product without any distinction between use of the product as a medicinal product for human use and as a veterinary medicinal product'*. (38)

28. In the judgment in Massachusetts Institute of Technology (*'the MIT judgment'*), (39) the Court was asked to rule on whether the concept of *'combination of active ingredients of a medicinal product'* within the meaning of Article 1(b) of Regulation No 1768/92 includes *'a combination of two substances, only one of which has therapeutic effects of its own for a specific indication, the other rendering possible a pharmaceutical form of the medicinal product which is necessary for the therapeutic efficacy of the first substance for that indication'*. (40) Before answering that question in the negative, the Court stated, first, that the concept of *'product'* must be understood to mean *'active ingredient'* (or *'active substance'*) in the strict sense (41) and, second, that, in the absence of any definition of the latter notion in Regulation No 1768/92, the meaning and scope of those terms had to be determined by considering the general context in which they are used and their usual meaning in everyday language. (42) In paragraph 21 of the judgment, the Court expressly held that the *'pharmaceutical form of the medicinal product'* does not form part of the definition of *'product'*, even though, as is stated later in paragraph 27, that pharmaceutical form is necessary for the therapeutic efficacy of the active ingredient. (43)

29. Lastly, in the order in Yissum, (44) the Court ruled on whether the concept of *'product'* within the meaning of Article 1(b) of Regulation No 1768/92 includes a second medical application of a known active ingredient. The facts in the main proceedings that gave rise to that order have strong similarities with those in the main proceedings in the present case. The Yissum Research and Development Company of the Hebrew University of Jerusalem (*'Yissum'*) had applied to the UK Patent Office for an SPC for a combination containing the active ingredient *'calcitriol'* for use in topical treatment of skin disorders. The application had been refused on the basis of Article 3(d) of Regulation No 1768/92 on the ground that the MA on which Yissum was relying was not the first such MA for that product as a medicinal product, as required by that provision. Two other medicinal products containing different formulations of the same active ingredient and used to treat different pathologies (renal failure and osteoporosis) had already been authorised on the basis of different patents. The question referred for a preliminary ruling did not, however, concern the interpretation of Article 3(d) of Regulation No 1768/92, but of Article 1(b) of that

regulation, and the referring court wished to know what was meant by *'product'* in that article *'in a case in which the basic patent protects a second medical application of a therapeutic agent …'* and whether *'the application of the therapeutic agent play[ed] any part'* in that definition for the purpose of the regulation. As the answer to this question could, according the Court, be clearly inferred from the MIT judgment, it simply held that the concept of *'product'* within the meaning of the regulation *'cannot include the therapeutic use of an active ingredient protected by a basic patent'*. (45)

30. At the time when the Court received the reference for a preliminary ruling which led to the Neurim judgment, there was therefore a line of settled case-law establishing a narrow interpretation of the concept of *'product'*. By interpreting Article 3(d) of Regulation No 469/2009 in such a way that the concept of *'first MA'* is divorced from the concept of *'product'* within the meaning of Article 1(b) of the regulation and connected with the concept of *'basic patent'*, for the purposes of Article 1(c), the Neurim judgment effectively circumvented that case-law, without, however, invalidating it, and introduced an artificial separation between two provisions of Regulation No 469/2009 sharing a functional link — the first defining the concept used in the second (46) — and broke down the schematic coherence of the regulation, which is founded on the pivotal role played by the concept of *'product'*. In doing so, the Court also confirmed an approach that was expressly contrary to that developed a few years earlier in the order in Yissum.

31. Following the Neurim judgment, the Court confirmed both the narrow interpretation of the concept of *'product'* in Article 1(b) of Regulation No 469/2009 (47) and — albeit only in obiter dicta — the approach adopted in that judgment for new therapeutic applications of an old active ingredient, (48) thus perpetuating the contradiction introduced into case-law and the system of that regulation.

32. The Abraxis judgment attempted to mitigate this contradiction by reaffirming the narrow interpretation of the concept of *'product'* within the meaning of Article 1(b) of Regulation No 469/2009 (49) and by restoring the link between that provision and Article 3(d) of the regulation. Thus, in paragraph 35 of that judgment, the Court ruled that *'only the authorisation in respect of the first medicinal product placed on the market, consisting of the product concerned, may be regarded as the first marketing authorisation within the meaning of Article 3(d) of Regulation No 469/2009, as defined in Article 1(b) of that regulation'*. (50) While affirming an interpretation of Article 3(d) of Regulation No 469/2009 different to and incompatible with that adopted in the Neurim judgment, the Abraxis judgment did not reverse that interpretation, as had been suggested, in essence, by Advocate General Saugmandsgaard Øe in his Opinion, but relegated it to being an *'exception to the narrow interpretation'* of that provision. (51)

33. As I have already mentioned in point 22 of this Opinion, I do not think that the Neurim judgment can be construed as an exception or that the inconsistency in case-law created by it can be resolved by restricting its scope such that it is reduced to a kind of empty shell. Doing so would betray the spirit and letter of that judgment, without eliminating any contradiction within the Court's case-law. The Court is therefore required in the present case to make a clear choice either to reverse the Neurim judgment or to widen the fine mesh of the concept of *'product'* currently applied in the case-law.

2. The Neurim judgment and the literal interpretation of Article 3(d) of Regulation No 469/2009

34. In accordance with the settled case-law of the Court, in interpreting a provision of EU law it is necessary to consider its wording, its origin, its context and the objectives pursued by the legislation of which it forms part. (52) However, the Court has also held that a teleological interpretation cannot go as far as affirming a reading of the provision at issue that is contrary to its wording.(53) As was also pointed out by Advocate General Saugmandsgaard Øe, (54) through a teleological interpretation the Neurim judgment stretched the clear wording of Article 3(d) of Regulation No 469/2009.

35. That provision sets out the fourth of the conditions to which the grant of the SPC is subject and stipulates that the MA referred to in point (b) of that article must be *'the first authorisation to place the product on the market as a medicinal product'*. Its wording refers to the concepts of *'product'*, *'authorisation to place on the market'* and *'first authorisation to place the product on the market'*. As regards the concept of *'product'*, it refers, in accordance with Article 1(b) of Regulation No 469/2009, only to the active ingredient protected by the basic patent which is the subject of the MA submitted in support of the SPC application and not the application of that active ingredient included in the claims in the basic patent. As regards the concept of *'authorisation to place on the market'*, whilst it is clear that this refers to the MA obtained for the active ingredient protected by the basic patent which is relied upon in support of the SPC application, it is equally clear that that MA does not necessarily have to be the first MA for the product for the purposes of Article 3(d) of Regulation No 469/2009 and that it is for the national patent office concerned to ascertain whether or not there is an earlier MA for that product. As regards the third concept, lastly, there is nothing in the wording of the provision to suggest that only an MA within the limits of the protection conferred by the basic patent or only the first MA permitting the patent to be exploited economically can be considered to be the *'first authorisation to place the product on the market'* within the meaning of that provision.

36. Based on the literal wording of Article 3(d) of Regulation No 469/2009, the *'first authorisation to place the product on the market'* is therefore the chronologically earliest MA to have been granted in the Member State concerned for the active ingredient which is the subject of the SPC application. The addition of a further criterion, besides the chronological order, whereby the first MA within the limits of the protection conferred by the basic patent is the first authorisation to

place the product on the market, would be contrary to the clear wording of that provision. (55)
37. The more or less strict nature of the condition set out in Article 3(d) of Regulation No 469/2009 does not therefore depend on the existence of a link between the patent and the first MA for the purposes of that provision, but on the latitude accorded to the concept of *'product'* within the meaning of Article 1(b) of the regulation. In this connection, I note that it would be possible in theory to achieve the result sought by the Neurim judgment, namely to permit the grant of an SPC for a second medical application of an old active ingredient, without departing from a literal interpretation of Article 3(d) of that regulation, provided, however, that the concept of *'product'* is interpreted as also including that scenario.

3. The Neurim judgment and the schematic coherence of Regulation No 469/2009

38. Because it is not possible reconcile the narrow interpretation of the concept of *'product'* within the meaning of Article 1(b) of Regulation No 469/2009 with the reading of Article 3(d) of that regulation adopted in the Neurim judgment, the Court's case-law contains at present a contradiction which undermines the schematic coherence of the regulation and whose effects are liable to spread beyond the application of the condition set out in that provision.
39. First, the teleological approach adopted by the Court in the Neurim judgment may also be applied to Article 3(c) of Regulation No 469/2009, the purpose of which is to avoid the same product being the subject of a number of successive SPCs, with the risk of the overall duration of protection under Article 13 of the regulation being exceeded. (56) This question is currently the subject of a reference for a preliminary ruling made by the Patents and Market Court of Appeal, Stockholm, Sweden, (57) which asks, in essence, whether or not the purpose of stimulating research into new therapeutic uses of known products, underlying the Neurim judgment, inter alia, (58) can justify an applicant who has previously been granted an SPC in respect of a product protected as such by a patent in force, being granted a certificate for a new use of the product in a case in which the new use constitutes a new therapeutic indication which is specifically protected by a new basic patent.
40. Second, the interpretation of the concepts of *'product'* and *'first authorisation to place the product on the market'* derived from the reading of Article 3(d) of Regulation No 469/2009 adopted in the Neurim judgment necessarily has repercussions on other fundamental provisions of that regulation. That is the case, as is expressly stated in the Neurim judgment, (59) with Article 13 of that regulation, which lays down the mechanism for calculating the term of the SPC from the first MA in the European Union in order to permit the simultaneous termination of any SPC granted for the same product. (60) The same holds for Article 4 of the regulation, which determines the subject matter of the protection conferred by the SPC, stating that it extends 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'*, and Article 5, which concerns the effects of the SPC, according to which an SPC granted in connection with a product which has obtained authorisation to be placed on the market as a medicinal product confers, *'upon the expiry of the patent, the same rights as were conferred by the basic patent in relation to the product, within the limits of the protection conferred by the basic patent, as provided for in Article 4 of Regulation [No 469/2009]'*. (61) In the cases envisaged in the Neurim judgment where an SPC is granted for a new use of a known active ingredient, the concept of *'product covered by the MA'* which appears in Article 4 must necessarily be interpreted as referring only to the new use of the active ingredient, (62) with the consequence that it is by reference to that new use, identified as a *'product'*, that both the subject matter and the effects of the SPC for the purposes of those provisions should be delimited, which would not appear to be consistent with the wording of Article 4 and seems to complicate the application of the test based on Article 5 of that regulation. (63)
41. Lastly, the grounds of the Neurim judgment are also capable of being applied to cases where the subject matter of the basic patent is not a new use of an old product but a new process to obtain a known product or a new combination containing a known product. A transposition of this case-law, which is theoretically possible, would enlarge the sphere of application of an interpretation of Article 3(d) of Regulation No 469/2009 that stretches the wording of that provision and would also be contrary to the position taken by the Court in the BASF judgment, (64) with regard to process patents, and in the MIT judgment, with regard to combination patents. (65)

C. The Neurim judgment and the teleological interpretation of Regulation No 469/2009

42. After analysing the difficulties of application to which the Neurim judgment has given rise, it must be ascertained whether the interpretation adopted by the Court in that judgment is justified in the light of the objectives of Regulation No 469/2009, as apparent in particular from the travaux préparatoires for that regulation.
43. It is clear from of the Explanatory Memorandum (66) and the preamble to Regulation No 469/2009 that, by its adoption, the Community legislature was, in essence, pursuing the four main objectives described below.

1. Preventing the creation of obstacles to the free movement of medicinal products within the internal market

44. First, in accordance with its legal basis, which is Article 95 EC, Regulation No 469/2009 was intended to approximate the laws of the Member States in order to establish a uniform system in relation to the conditions for grant, scope, term and validity of the SPC in order to prevent the heterogeneous development of national laws, which could affect the functioning of the internal market by creating obstacles to the free movement of medicinal products within it (recital 7 of Regulation No

469/2009 and paragraph 18 et seq. of the Explanatory Memorandum).

2. Encouraging pharmaceutical research

45. Second, Regulation No 469/2009 seeks to encourage pharmaceutical research by providing for protection to supplement that conferred by the patent, the effective duration of which is reduced because of the time required to obtain an MA before being able to begin to exploit the patent commercially and to cover the investment put into the research (recitals 3 and 4 of Regulation No 469/2009, paragraph 2 of the Explanatory Memorandum). (67) The need to make up for this lack of protection which penalises pharmaceutical research (recital 5 of Regulation No 469/2009) is linked with two different socio-economic objectives: to preserve the *'decisive role in the continuing improvement in public health'* (68) played by such research (recital 2 of Regulation No 469/2009, paragraph 1 of the Explanatory Memorandum) and to reduce the risk of research centres situated in the Member States relocating to countries that offer greater protection (recital 6 of the regulation) and that medicinal products, especially those that are the result of long, costly research, will not continue to be developed in Europe (recital 3 of Regulation No 469/2009). In this regard, paragraph 6 of the Explanatory Memorandum also mentions maintaining the competitiveness of European industry, especially in the face of competition from the United States and Japan, which already have legislation on patent term restoration.

46. The question of what kind of research is encouraged by Regulation No 469/2009 and what results of that research fall within the scope of the protection offered by the regulation lies at the heart of the questions which the Court is being asked to answer in the present case. It must be stated that, as the authors of the Max Planck study assert, Regulation No 469/2009 presents some ambiguities in this regard. (69)

47. Thus, first, illustrating the characteristics of the envisaged system, paragraph 12 of the Explanatory Memorandum states that the proposal for a regulation *'is not confined to new products only'*, that *'a new process for obtaining the product or a new application of the product may also be protected by a certificate'* and that *'all research, whatever the strategy or final result, must be given sufficient protection'*. In the same vein, commenting on the expression *'product protected by a patent'*, in order to specify what types of invention may serve as a basis for a certificate, the Explanatory Memorandum reiterates, in paragraph 29, that *'the proposal (for a regulation) does not provide for any exclusions'* and that *'all pharmaceutical research, provided that it leads to a new invention that can be patented, whether it concerns a new product, a new process for obtaining a new or known product, a new application of a new or known product or a new combination of substances containing a new or known product, must be encouraged, without any discrimination'*. The preamble of Regulation No 469/2009 also does not distinguish between research into (new or known) products, processes for obtaining products or applications relating to new or old products, as all these kinds of research can play a role in the improvement of public health and run the risk of relocation if there is a lack of protection. Similarly, Article 1 of Regulation No 469/2009 defines the concept of *'basic patent'* 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'*.

48. Second, as is stated in the Max Planck study, several passages in the Explanatory Memorandum refer to the need to protect *'innovative firms'* (70) and state that the envisaged system is intended to apply only to *'new medicinal products'*. (71) While I cannot concur with the conclusion reached in that study, namely that where the Explanatory Memorandum uses the expression *'new medicinal products'*, it actually refers to *'active ingredients'*, and thus to the concept of *'product'* as defined in the proposal for a regulation, (72) the fact remains that the Explanatory Memorandum shows that the Commission clearly intended to restrict the application of the regulation to innovative and *'research-intensive'* proprietary medicinal products. (73) The amendments made to the proposal for a regulation during the legislative procedure confirm this reading. (74) Moreover, the very purpose of Regulation No 469/2009, according to its preamble, is to make up for the lack of protection conferred by the patent on account of the erosion of the patent term due to the length of the authorisation procedure. Such a procedure is longer, as a general rule, in the case of medicinal products containing active ingredients not yet placed on the market, which require the submission of full dossiers in support of the MA application concerning both the efficacy and the safety of the medicinal products. (75) This is also suggested by the EU legislature's choice to establish the concept of *'product'*, in the strict sense of active ingredient, (76) as the cornerstone of the system introduced by Regulation No 469/2009, on the one hand, and by the wording of Article 3 of the regulation, itself centred on this concept, on the other.

49. The idea that any pharmaceutical research resulting in a patentable invention, even where it relates to an already marketed product, should be able to benefit from the supplementary protection offered by the SPC undoubtedly inspired the interpretation adopted in paragraph 25 of the Neurim judgment, (77) which is based on the parts of the Explanatory Memorandum mentioned in point 47 of this Opinion. (78)

50. However, the contrary is stated, this time explicitly, in the Abraxis judgment, where, referring to the parts of the Explanatory Memorandum mentioned in point 48 of this Opinion, (79) the Court ruled, in paragraph 37, that *'the 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'*. (80)

51. Paragraph 25 of the Neurim judgment and paragraph 37 of the Abraxis judgment are clearly contradictory. The Court is required, among other things, to resolve this conflict, knowing that confirming the teleological interpretation of Regulation No 469/2009 in paragraph 37 of the Abraxis judgment means nullifying the interpretation on which the approach taken in paragraph 25 of the Neurim judgment is based.
52. For my part, I consider that, rather than persevering with the exegesis of a document — the Explanatory Memorandum — which, on the relevant point here, is not very clear, in defining the subject matter of the protection granted by Regulation No 469/2009 and the scope of that protection, reference should be made to the wording of the provisions and the broad logic of that regulation, which militate in favour of limiting the scope of the regulation to cases where the SPC application relates to a not yet marketed active ingredient and to a manufacturing process or therapeutic use of such an active ingredient. Even if that is not the case of all parts of the Explanatory Memorandum, several of them confirm this interpretation.
53. That interpretation is reinforced after examining the third objective pursued by Regulation No 469/2009.
54. Before moving on to that examination, however, it is necessary to respond briefly to certain arguments raised by Santen regarding the extent of the objective of promotion of pharmaceutical research pursued by Regulation No 469/2009. According to Santen, the regulation is unquestionably intended to encourage research into any innovation, including formulations, and not to discriminate between research into new active substances and research into known substances. It asserts, in the first place, that a clear distinction must be made between the development of a single product by a single holder of an MA with a view to new formulations or new indications and situations of the kind that gave rise to the Neurim judgment, where a new formulation of an old active ingredient, allowing treatment of a disease which could not previously be treated with that active ingredient, is developed with high risk, long after the first authorisation of that active ingredient, by a different and independent pharmaceutical laboratory. I would point out in this regard, first, that it is apparent from paragraph 11 of the Explanatory Memorandum that new formulations are a priori excluded from the scope of the proposal for a regulation, (81) second, that neither the Explanatory Memorandum nor the proposal for a regulation or Article 3 of Regulation No 469/2009 distinguish according to whether the new therapeutic indication or new process to obtain an already authorised product were developed by the holder of the first MA or by another laboratory and, third, that, as is stated in paragraph 34 of the Neurim judgment, the approach taken by the Court in that judgment disregards any consideration concerning *'the determination of the proprietors of the authorisations, patents, or the application for the SPC'*. In the second place, Santen asserts that interpreting Regulation No 469/2009 to the effect that the new use of an old active ingredient can give entitlement to an SPC only where the active ingredient has not yet been authorised would unduly restrict the scope of the regulation, contrary to the intentions of the Community legislature. I note in this regard that, whilst paragraph 29 of the Explanatory Memorandum states that even though research into new uses must be encouraged, it is only when all of the conditions laid down by the proposal for a regulation are fulfilled that the result of the research may be granted an SPC. It cannot therefore be inferred from this one paragraph 29 of the Explanatory Memorandum that the Community legislature also intended to include new applications of already authorised active ingredients within the scope of the proposal for a regulation. Nor is that intention reflected in the wording of the relevant provisions of Regulation No 469/2009.

3. Creating a uniform system based on simple, transparent rules

55. The proposal for a regulation advocated a simple, transparent system which could easily be applied by all the parties concerned. (82) As it was for national patent offices to grant the SPC, so as not to place an excessive burden on them the Commission opted for a system in which the examination of SPC applications is based on objective data that are easy to verify. (83) Although practice shows that some stages of that examination may entail even very complex assessments, (84) it is nevertheless necessary in the examination only to establish the existence of a twofold link between the patent and the product, on the one hand, and between the product and the MA, on the other, and to check the existence of an earlier SPC or MA relating to the same product. National patent offices are not required to assess the value of the invention covered by the patent or of the investment needed to develop it. As far as the Community legislature was concerned, a set of simple rules based on objective criteria would have contributed to the harmonisation of the Community SPC system, limiting the number of divergent national decisions and increasing predictability and legal certainty for patent holders. (85) In the MIT judgment, furthermore, the Court itself stressed the need to avoid introducing elements of legal uncertainty into the application of Regulation No 469/2009 in the form of insufficiently precise tests so as not to prejudice the objective of harmonisation pursued by it. (86)
56. It cannot be denied that the Neurim judgment runs counter to the objective described above in so far as it incorporates vague concepts into the system of Regulation No 469/2009 (*'new therapeutic application' 'new use'*, *'different application'* of the same product), which are amenable to a number of interpretations, as the present case clearly shows, and, depending on the preferred interpretation, may entail complex and subjective assessments by national patent offices.

4. Achieving a correct balance of the interests at stake

57. It is clear both from the preamble of Regulation No 469/2009 and from the Explanatory Memorandum (87) that, while the main objective of the regulation is to extend the duration of the protection of pharmaceutical patents and to avoid the development of heterogeneous national rules in this area, that objective must be

balanced with a number of competing political, economic and social interests. The holder of such a patent has a monopoly over the sale of the medicinal products covered by the patent, which increases its chances of recovering the sums that it has invested in research, but delays the market entry of generics and raises the price of medicinal products, to the detriment of patients and national social security systems. The rules concerning the scope, term and conditions for grant of an SPC strike a delicate balance between those conflicting interests. However, the Neurim judgment shifted that balance in favour of pharmaceutical laboratories.

D. Interim conclusion

58. In the Neurim judgment, the Court gave a teleological interpretation of Regulation No 469/2009. That interpretation undoubtedly lends flexibility to the SPC system and, in all likelihood, responds more fully to the current needs of pharmaceutical research, which seem to be different from those which led to the adoption of Regulation No 1768/92. There is no doubt that the development of subsequent medical uses of known substances plays a significant role in the context of these changes, a large proportion of the pharmaceutical research being focused on that sector at present, as Santen points out in its written observations. (88) In addition, the interpretation adopted in the Neurim judgment permits sufficient legal protection to be granted to any innovation that increases the therapeutic efficacy of known active ingredients or uses them to treat new pathologies, in keeping with the objective of the continuing improvement in public health which is also among those pursued with the creation of the SPC. (89)

59. Nevertheless, as we have seen, the interpretation of Articles 3(d), and Articles 4 and 13 of Regulation No 469/2009 adopted in the Neurim judgment departs from the wording of those provisions and does not seem to find strong support in the travaux préparatoires for that regulation or to strike the balance of the interests at stake envisaged by the Community legislature when the SPC was created. The rules which reflect this balance, relating to the concept of *'product'*, the conditions for grant, the subject matter and the term of the SPC have remained unchanged since the adoption of Regulation No 1768/92, even though Regulation No 469/2009 was recently amended. (90) The schematic incoherence described, created by case-law, must therefore be resolved by case-law itself. This case gives the Court an opportunity to do so.

60. The unifying role of the Court is of paramount importance in the interpretation of Regulation No 469/2009, given the national character of the SPC and the lack of harmonisation of patent law, which fosters an often discordant application of the regulation by national patent offices. Similarly, in a sector as complex and sensitive as the pharmaceutical sector, it is important to be particularly vigilant in ensuring the coherence of case-law and in guaranteeing the highest possible level of legal certainty for the different economic operators concerned. Regulation No 469/2009 relates to a highly technical field, and its adoption required a number of interests to be taken into account and balanced and entailed delicate economic and social policy choices. That is why favouring a teleological reading of the regulation, which, while having the advantage of protecting and encouraging other forms of pharmaceutical research, departs from the clear wording of its provisions, which reflects the balance between the different interests at stake desired by the Community legislature and upheld by the EU legislature, does not seem to be the way forward.

61. Accordingly, in the light of all the above considerations, I agree with Advocate General Saugmandsgaard Øe in his Opinion in Abraxis Bioscience (C-443/17, EU:C:2018:1020), that the Court should abandon the *'scope of protection of the patent test'* introduced in the Neurim judgment and return to a literal interpretation of Article 3(d) of Regulation No 469/2009. It is for the EU legislature and not the Court to decide whether, and to what extent, the benefit of the SPC should be extended to the development of subsequent pharmacological or medical applications.

62. As regards the method to be used to make such a reversal, I take the view that it is not a satisfactory option to *'marginalise'* the Neurim judgment, confining its scope only to cases of a first veterinary MA and a second MA for a medicinal product for human use, which are statistically very rare. First, as I stated above, that judgment does not lend itself to being interpreted as an exception, the application of which is strictly limited to the factual circumstances of the main proceedings which gave rise to it. Second, such marginalisation would not eliminate the contradictions that currently exist in the Court's case-law or their impact on the schematic coherence of the law governing SPCs. I therefore consider it preferable to follow the path taken in the Abraxis judgment, relying, mutatis mutandis, on the analysis contained in paragraphs 24 in 40 thereof. In that part of the grounds of the Abraxis judgment, proceeding from a summary of the case-law on the concept of *'product'* within the meaning of Article 1(b) of Regulation No 469/2009, the Court arrived at a *'narrow interpretation'* of Article 3(d) of the regulation, which, in itself, is incompatible with the reasoning adopted by the Court in the Neurim judgment. Although in the Abraxis judgment the Court did not go as far as reversing the Neurim judgment, merely concluding that that judgment did not, in any event, refer to cases of a new formulation of a known product, (91) it must, in my view, take this step in its forthcoming judgment.

63. I therefore suggest that the Court answer the questions referred for a preliminary ruling by the Cour d'appel de Paris to the effect that Article 3(d) of Regulation No 469/2009, read in conjunction with Article 1(b) of that regulation, must be interpreted as meaning that the MA referred to in Article 3(b) of the regulation, relied upon in support of an SPC application relating to a different and new application of an old active ingredient, cannot be considered to be the first MA of the product concerned as a medicinal product

where that active ingredient has already been the subject of an authorisation as such.

64. If, on the other hand, the Court were to decide to confirm the Neurim judgment, on the basis of the reasoning set out in point 58 of this Opinion, it would have either to reconsider the concept of *'product'* within the meaning of Article 1(b) of Regulation No 469/2009 employed in the order in Yissum in respect of subsequent applications of existing active ingredients or to nullify the interpretation of Article 3(d) of the regulation given in paragraphs 32 to 39 of the Abraxis judgment. (92) For reasons relating to respect for both the wording of that provision and the schematic coherence of Regulation No 469/2009, I prefer the first option. The following remarks are made only in the alternative, should the Court decide to confirm the Neurim judgment and to clarify its scope in response to the questions asked by the referring court.

E. In the alternative: the questions referred

1. The first question

65. By its first question, the referring court asks the Court, in essence, whether the concept of a *'different application'* within the meaning of the Neurim judgment must be interpreted strictly or broadly. The court puts forward different possible interpretations lying between two extremes: one limiting the scope of the concept only to the situation where an application for human use follows a veterinary application, the other interpreting it according to the same criteria as for assessing the patentability of the invention, that is to say, as also including different formulations, posologies and/or means of administration. (93)

66. For reasons which have already been explained in part, neither of these extremes seems to be consistent with the logic underlying the Neurim judgment. On the one hand, as I have stated several times, nothing in the grounds of that judgment, in the light of which the operative part should be read, permits its scope to be limited only to the situation where an application for human use follows a veterinary application. (94) On the other hand, neither the terminology used in paragraphs 25 and 26 of that judgment (95) nor the reasoning set out by the Court — which infers from the objectives and history of Regulation No 469/2009 that holders of patents protecting new applications of old active ingredients are entitled to an SPC — give reason to consider that the Court also had in view situations where such a patent related only to minor changes to known applications of that active ingredient, such as different formulations, posologies and/or means of administration, changes which were, moreover, expressly excluded from the scope of the proposal for a regulation. (96)

67. The scope of the Neurim judgment, if the Court decides to confirm it, must therefore be identified between the two extremes analysed above. In my view, two situations should be considered to be covered by that judgment. The first is a new therapeutic application, namely the situation where the invention protected by the patent serving as the basis for the SPC application permits a new disease to be treated. (97) If the Court decided to accept this criterion for interpreting the Neurim judgment, it would have to reverse the MIT judgment. The second situation, envisaged by the Commission in its written observations, (98) is where the old active ingredient exerts a *'pharmacological, immunological or metabolic action'* of its own which is different from that previously known. Where there is such new action, the old active ingredient would, in essence, be treated as a new product. (99)

68. As the French Government stated in its written observations and at the hearing, it is true that the criteria proposed above complicate the examination of SPC applications to be conducted by national patent offices. However, I would not overstate those difficulties. The offices should be equipped to resolve questions connected with the application of those criteria and, as the Commission correctly asserted at the hearing, it would be for the SPC applicant to provide the necessary proof to demonstrate the new therapeutic indication or the new action of the active substance or known combination, otherwise the application will be rejected.

69. On the basis of the above considerations, I propose, in the alternative, that the Court answer the first question to the effect that Article 3 of Regulation No 469/2009 must be interpreted as meaning that the grant of an SPC for a different application of an active ingredient for which an MA has been granted in the Member State concerned, within the meaning of the Neurim judgment, requires that the MA which serves as the basis for the SPC application covers a new therapeutic indication of the active ingredient or relates to a use of the active ingredient in which it exerts a new pharmacological, immunological or metabolic action of its own.

2. The second question

70. By its second question, the referring court asks the Court, in essence, how the expression *'application within the limits of the protection conferred by the basic patent'* which appears in the Neurim judgment should be interpreted. It asks, in particular, whether that expression means that the basic patent must be the limited to the new medical use corresponding to the therapeutic indication of the MA on which the SPC application is based. It is clear from the order for reference that the INPI interprets and applies the Neurim judgment in this way.

71. It must be stated that, as Santen asserts, there is nothing in the Neurim judgment to permit the conclusion desired by the INPI. When the Court states in that judgment that the different application of the known active ingredient must be within the limits of the protection conferred by the basic patent, it simply re-characterises the criterion employed in paragraph 26 of that judgment, according to which it is the MA of the first medicinal product authorised for *'a therapeutic use corresponding to that protected by the patent relied upon for the purposes of the application for the SPC'* that constitutes the first MA of that product for the purposes of Article 3(d) of Regulation No 469/2009.

72. Having said that, the concern underlying the positions of the INPI and the French Government of preventing a situation where the grant of an SPC for a

different application of an old product might delay the time when the active ingredient as such enters the public domain or where the scope of that SPC extends, in accordance with Article 4 of Regulation No 469/2009, to other uses of the product as a medicinal product protected by the basic patent and authorised before the expiry of the certificate is entirely justified. I would observe in that regard that the Neurim judgment itself states that the scope of such an SPC could, in any event, cover only the new use of the old active ingredient, as protected by the basic patent and covered by the MA which serves as the basis for the SPC application. Under no circumstances can the scope of that SPC extend to the active ingredient as such or other uses of the active ingredient. This follows from paragraph 25 of the Neurim judgment and the fact that that judgment also interpreted Article 4 of Regulation No 469/2009, which defines the subject matter of the SPC. Consequently, where an SPC relating to a different application of an old active ingredient is granted, the *'product'* covered by the MA for the corresponding medicinal product protected by the SPC in accordance with Article 4 is not the *'active ingredient'* itself but the *'different application of that ingredient'* which is within the limits of the protection conferred by the basic patent. (100) Thus, assuming that the SPC application made by Santen fulfils the criteria set out in the answer to the first question, which must be ascertained by the referring court, the SPC would cover only the application *'ciclosporin for the treatment of keratitis'*.

73. In its written observations, the Commission doubts that such application of the active ingredient *'ciclosporin'* is part of the invention covered by the basic patent at issue in the main proceedings. In this regard, as the Commission itself observes, I note that the referring court proceeds from the premise that the condition laid down in Article 3(a) of Regulation No 469/2009 is fulfilled (or at least the observation that such a premise is not disputed) and does not therefore ask questions on this matter. The Court is thus not required to take a position. In any event, the question whether the Commission's doubts are justified relates to the application of the provisions of Regulation No 469/2009 and not their interpretation. The referring court must therefore assess whether the new application of *'ciclosporin'* upon which the SPC application made by Santen relies falls within the scope of the basic patent in the main proceedings, using the guidance contained in the Court's case-law and in particular the Teva judgment, (101) which summarised the criteria for the application of the condition laid down in Article 3(a) of that regulation.

74. On the basis of the above considerations, I propose, in the alternative, that the Court answer the second question to the effect that Article 4 of Regulation No 469/2009 must be interpreted as meaning that, where the SPC relates to a different application of an old active ingredient, the concept of *'product'* within the meaning of that provision designates only that application and does not extend to the active ingredient as such or other applications of it.

IV. Conclusion

75. In the light of all the above considerations, I suggest that the Court give the following answers to the Cour d'appel de Paris (France):

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, read in conjunction with Article 1(b) of that regulation, must be interpreted as meaning that the marketing authorisation referred to in Article 3(b) of the regulation, relied upon in support of an application for a supplementary protection certificate relating to a different and new application of an old active ingredient, cannot be considered to be the first marketing authorisation of the product concerned as a medicinal product where that active ingredient has already been the subject of an authorisation as such.

In the alternative, if the Court decided to interpret the Neurim judgment, I suggest that the Court answer the questions asked by the Cour d'appel de Paris as follows:

1. Article 3 of Regulation No 469/2009 must be interpreted as meaning that the grant of a supplementary protection certificate for a different application of an active ingredient for which a previous marketing authorisation has been granted in the Member State concerned, within the meaning of the judgment of 19 July 2012, Neurim Pharmaceuticals (1991), (C-130/11, EU:C2012:489), requires that the marketing authorisation which serves as the basis for the application for a supplementary protection certificate covers a new therapeutic indication of the active ingredient or relates to a use of the active ingredient in which it exerts a new pharmacological, immunological or metabolic action of its own.

2. Article 4 of Regulation No 469/2009 must be interpreted as meaning that, where the supplementary protection certificate relates to a different application of an old active ingredient, the concept of "product" within the meaning of that provision designates only that application and does not extend to the active ingredient as such or other applications of it.

1 Original language: French.

2 Judgment of 21 March 2019, Abraxis Bioscience (C-443/17, EU:C:2019:238, *'the Abraxis judgment'*).

3 C-130/11, EU:C:2012:489, *'the Neurim judgment'*.

4 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 151, p. 1). Regulation No 469/2009 was amended, with effect from 1 July 2019, by Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 (OJ 2019 L 153, p. 1). The amendments do not affect the provisions whose interpretation is sought in this reference for a preliminary ruling.

5 Opinion of Advocate General Saugmandsgaard Øe in Abraxis Bioscience (C-443/17, EU:C:2018:1020).

6 It should be noted that the written procedure in the present case was closed before the Court delivered the Abraxis judgment. The parties and interested parties which submitted written observations in the present case

were invited by the Court to comment on the consequences of that judgment for the purposes of the answers to the questions referred for a preliminary ruling by the Cour d'appel de Paris.

7 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).

8 This definition of SPC can be found in the Explanatory Memorandum which led 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 (*'the proposal for a regulation'*) (OJ 1990 C 114, p. 10) (*'the Explanatory Memorandum'*).

9 Similar reasons led the Community legislature to adopt Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products (OJ 1996 L 198, p. 30).

10 OJ 2001 L 311, p. 67.

11 OJ 2001 L 311, p. 1.

12 Inflammation of the cornea, the front part of the eye.

13 Inflammation of some or all of the uvea, the middle part of the eye.

14 The referring court states that it is not disputed that, while both medicinal products relate to the treatment of inflammation of parts of the eye in humans, these are different diseases, affecting different parts of the eye.

15 The Court of Appeal (England & Wales) (Civil Division) summarised the dispute before it as follows: *'In short, commercially, medically and legally there is a vast expanse of clear blue water between the parties'* products and legal rights. None of the work done by Hoechst helped Neurim at all — it may indeed have hindered them because the regulator would naturally have been concerned about possible side effects.'

16 This question was worded as follows: *'In interpreting Article 3 of [Regulation No 469/2009], 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?'*(emphasis added).

17 The third question reads as follows: *'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?'*

18 Paragraph 23 includes a reference to the judgments of 24 November 2011, Medeva (C-322/10, EU:C:2011:773, paragraphs 30 and 31), and Georgetown University and Others (C-422/10, EU:C:2011:776, paragraphs 24 and 25).

19 Paragraph 26 of the Neurim judgment.

20 Paragraph 27 of the grounds and paragraph 1 of the operative part of the Neurim judgment.

21 Under Article 13(1) of Regulation No 469/2009 *'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.'*

22 Paragraph 31 of the grounds and paragraph 2 of the operative part of the Neurim judgment.

23 Paragraph 35 of the grounds and paragraph 3 of the operative part of the Neurim judgment.

24 In paragraph 43 of the Abraxis judgment, the Court held that the Neurim judgment introduced an *'exception to the narrow interpretation of Article 3(d)'* of Regulation No 469/2009.

25 According to the information provided by the Max Planck study, a strict interpretation of the Neurim judgment is adopted by the Netherlands and Portuguese patent offices (see paragraph 11.3.1.4, p. 229 and 230). The French Government takes the same line in the present case.

26 Namely, when the active ingredient is applied for a new population of patients and treats a new disease.

27 Namely, in the absence of a new therapeutic application.

28 For example, the Austrian and United Kingdom offices (see the Max Planck study, paragraph 11.3.1.4, p. 229 and 230).

29 According to the definition given by the European Medicines Agency (EMA), type II variation corresponds to a *'major change to a marketing authorisation that may have a significant impact on the quality, safety or efficacy of a medicine, but does not involve a change to the active substance, its strength or the route of administration. Type II variations require a formal approval'* (see https://www.ema.europa.eu/en/glossary/type-ii-variation).

30 For example, the Spanish office (see the Max Planck study, paragraph 11.3.1.4, p. 229 and 230).

31 See Article 3 of Regulation No 469/2009.

32 It is in relation to the concept of *'product'* that Article 4 of Regulation No 469/2009 defines the subject matter of the protection conferred by the SPC.

33 C-31/03, EU:C:2004:278, point 38.

34 The SPC is intended to protect the *'product'* covered by the MA and not the medicinal product as such (see judgment of 24 November 2011, Medeva (C-322/10, EU:C:2011:773, paragraph 37)).

35 See judgment of 12 June 1997, Yamanouchi Pharmaceutical (C-110/95, EU:C:1997:291, paragraph 26).

36 Judgment of 19 October 2004 (C-31/03, EU:C:2004:641, *'the Pharmacia Italia judgment'*).

37 That article provided as a transitional measure that a certificate could be granted for any product, that is to say, any active ingredient or combination of active ingredients of a medicinal product, provided that on the date of entry into force of the regulation, namely 2 January 1993, the product is protected by a valid basic patent, and the first marketing authorisation was

obtained for the product as a medicinal product in the Community after 1 January 1985 (a different date was set for some Member States).

38 Paragraph 20 of the Pharmacia Italia judgment (emphasis added).

39 Judgment of 4 May 2006 (C-431/04, EU:C:2006:291).

40 It should be noted that in the case in the main proceedings which gave rise to the MIT judgment, the German Patent and Trade Mark Office had rejected the SPC application filed by MIT for the active ingredient *'carmustine'* when not in combination with other substances under Article 3(d) of Regulation No 1768/92, as that active ingredient had already been authorised for many years (see, in particular, Opinion of Advocate General Léger in Massachusetts Institute of Technology (C-431/04, EU:C:2005:721, point 22 and footnote 16)).

41 Paragraph 21 of the MIT judgment.

42 Paragraph 17 of the MIT judgment.

43 In his Opinion in the case giving rise to the judgment in MIT (C-431/04, EU:C:2005:721), Advocate General Léger had suggested that the Court answer in the affirmative. Disqualifying from classification as a *'combination of active ingredients'* a composition comprising an active ingredient and an excipient in the specific case where the excipient is necessary for the therapeutic efficacy of the active ingredient was not, in his view, consistent either with the broad logic of the regulation of which it formed part or, above all, with the objectives pursued by the Community legislature.

44 Order of 17 April 2007, (C-202/05, EU:C:2007:214, *'the order in Yissum'*)

45 See paragraphs 15 and 18 of the order in Yissum (emphasis added). In paragraph 19, the Court noted that the same interpretation could also be inferred from the Pharmacia Italia judgment.

46 There is no indication that the concept of *'product'* in Article 1 of Regulation No 469/2009 differs from that on which Article 3 of the regulation is based (see, by analogy, judgment of 10 May 2001, BASF, C-258/99, EU:C:2001:261, paragraph 24).

47 See, in the same vein as the MIT judgment, order of 14 November 2013, Glaxosmithkline Biologicals and Glaxosmithkline Biologicals, Niederlassung der Smithkline Beecham Pharma (C-210/13, EU:C:2013:762, paragraphs 27 to 32), in which the Court explicitly stated in paragraph 44 that *'the Court did not [in the Neurim judgment] cast doubt on the principle that Article 1(b) of Regulation No 469/2009 is to be interpreted narrowly, as held in the [MIT judgment], to the effect that the term "product" cannot cover a substance which does not correspond to the definition of "active ingredient" or that of "combination of active ingredients"'*. See, in the same vein, the Abraxis judgment, paragraph 44.

48 See judgment of 12 December 2013, Georgetown University (C-484/12, EU:C:2013:828, paragraphs 28 and 38).

49 See Abraxis judgment, paragraphs 24 to 31.

50 The Court referred in this regard to the judgment of 24 November 2011, Medeva, C-322/10, EU:C:2011:773. I note, incidentally, that that judgment seems to offer neither compelling support for the interpretation of Article 3(d) of Regulation No 469/2009 adopted in the Abraxis judgment nor, above all, a precedent precluding the interpretation of that article adopted in the Neurim judgment. Paragraph 40 of that judgment, to which the Court refers in the Abraxis judgment, states that *'only the authorisation in respect of the first medicinal product placed on the European Union market comprising, among its active ingredients, the combination of the two active ingredients identified in the wording of the claims of the patent'* (emphasis added) may be regarded as the first MA for the product as a medicinal product for the purposes of that article. In my view, it cannot be clearly inferred from this passage that an MA relating to a different use of an old active ingredient identified in the basic patent cannot constitute a first MA for the purposes of the abovementioned article. The same holds for the judgment of 10 May 2001, BASF (C-258/99, EU:C:2001:261, paragraph 28), interpreting Article 3(d) of Regulation No 1610/96, which is highlighted in the Opinion of Advocate General Saugmandsgaard Øe in Abraxis Bioscience (C-443/17, EU:C:2018:1020) (point 31) as a precedent precluding the interpretation adopted in the Neurim judgment. It is true that in that BASF judgment the Court held that a new plant protection product did not constitute a new *'product'* within the meaning of that provision where it differed from a plant protection product granted an earlier marketing authorisation only in the proportion of active ingredient to impurities contained in the respective products, which proportion resulted from the application of a process covered by the basic patent relied upon in support of the SPC application, which therefore precluded the grant of the SPC applied for on the basis of that basic patent, on the ground that the MA for the new plant protection product was not the first granted for the product at issue. However, the Court stated that this was the case in particular since the two substances in question, aside from their identical chemical compound, had *'the same general or specific action against harmful organisms or on plants, parts of plants or plant products'* (see, inter alia, paragraphs 27 and 28, emphasis added).

51 Opinion of Advocate General Saugmandsgaard Øe in Abraxis Bioscience (C-443/17, EU:C:2018:1020).

52 See, to that effect, judgment of 31 May 2018, Hassan (C-647/16, EU:C:2018:368, paragraph 40 and the case-law cited).

53 See, to that effect, judgments of 23 March 2000, Met-Trans and Sagpol (C-310/98 and C-406/98, EU:C:2000:154, paragraph 32), and of 15 September 2016, Mc Fadden (C-484/14, EU:C:2016:689, paragraphs 68 to 70). See also Opinion of Advocate General Cosmas in Schlebusch (C-273/98, EU:C:2000:78, point 45).

54 See Opinion of Advocate General Saugmandsgaard Øe in Abraxis Bioscience (C-443/17, EU:C:2018:1020), in particular point 32.

55 A similar conclusion was also reached by Advocate General Trstenjak in his Opinion in Neurim

Pharmaceuticals (C-130/11, EU:C:2012:268, point 23), while suggesting that the Court employ a teleological interpretation of Article 3(d) of Regulation No 469/2009.

56 See judgment of 3 September 2009, AHP Manufacturing (C-482/07, EU:C:2009:501, paragraph 42), and paragraph 36 of the Explanatory Memorandum.

57 Case C-354/19, Novartis, pending.

58 The referring court also cites the judgment of 23 January 1997, Biogen (C-181/95, EU:C:1997:32, paragraph 27), and Article 3(2) of Regulation No 1610/96, as interpreted by the Court in the judgment of 3 September 2009, AHP Manufacturing (C-482/07, EU:C:2009:501, paragraphs 25 and 26).

59 See paragraphs 30 and 31 and paragraph 2 of the operative part of the Neurim judgment.

60 As Advocate General Jacobs states in his Opinion in Spain v Council (C-350/92, EU:C:1995:64, point 44), that uniformity is probably the most significant result of the SPC.

61 Accordingly, as the Court explains in the judgment of 24 November 2011, Medeva (C-322/10, EU:C:2011:773, paragraph 39), *'if, during the period in which the patent was valid, the patent holder could oppose, on the basis of his patent, all use or certain uses of his product in the form of a medicinal product consisting of such a product or containing it, the SPC granted in relation to that product would confer on the holder the same rights for all uses of the product, as a medicinal product, which were authorised before the expiry of the certificate.'*

62 As is clear, moreover, from paragraph 25 of the Neurim judgment; see also point 72 of this Opinion.

63 See footnote 61.

64 Judgment of 10 May 2001 (C-258/99, EU:C:2001:261, paragraph 28).

65 See paragraph 31 and the operative part of the MIT judgment. In that judgment the Court did not accept, in essence, that the combination of a new excipient with a known active substance could be eligible for the grant of an SPC if this combination results in a new medicinal product in which the therapeutic effects of the active ingredient are defined and controlled by the additional substance.

66 See the citation in footnote 8 of this Opinion.

67 In the Explanatory Memorandum, the period between the filing of the patent application for a new medicinal product and its being made available to patients is calculated as being 12 years on average, the effect of which is to reduce exclusivity under the patent to eight years (paragraph 2).

68 Emphasis added.

69 See the Max Planck study, paragraph 2.1.3.1, p. 14.

70 See, for example, paragraph 3 of the Explanatory Memorandum, where the Commission also makes reference to the greater protection provided to *'high-technology medicinal products'* by Council Directive 87/21/EEC of 22 December 1986 amending Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ 1987 L 15, p. 36).

71 See, for example, paragraph 11 of the Explanatory Memorandum, which states that *'[the] proposal for a Regulation … concerns only new medicinal products. It does not involve granting a certificate for all medicinal products that are authorised to be placed on the market. … Minor changes to the medicinal product such as a new dose, the use of a different salt or ester or a different pharmaceutical form will not lead to the issue of a new certificate'*, paragraph 24, in which the Commission explains that the repercussions of the future regulation on health and social security costs are limited given that the system does not apply to *'all patented medicinal products placed on the market, but only to those which consist in new medicinal products'*, or paragraph 36. See, in the same vein as the abovementioned paragraph 11, the Explanatory Memorandum for the proposal for Regulation (EC) Regulation of the European Parliament and of the Council concerning the creation of a supplementary protection certificate for plant protection products [COM(94) 579 final, paragraph 68].

72 Why would the Commission have used the word *'médicament'* (*'medicinal product'*) in the expression *'médicament nouveau'* (*'new medicinal product'*) throughout the Explanatory Memorandum to refer to an *'active substance'*, when the proposal for a regulation employs a different term for this concept, namely *'produit'* (*'product'*, Article 1(a) and, in the same vein, paragraph 11 of the Explanatory Memorandum)? In my view, that expression should therefore be understood rather as a generic reference to innovative medicinal products. This conclusion is confirmed by the link between paragraph 11, where the Commission uses the expression *'new medicinal products'* and paragraph 12 of the Explanatory Memorandum, where the expression *'new products'* is used.

73 See, inter alia, paragraph 24 of the Explanatory Memorandum, where it is stated that *'each year, only about 50 new medicinal products are authorised worldwide'* and that *'it is these that are covered by the proposal for a [regulation]'*.

74 That is the case in particular with the amendments concerning Article 1, in which the definition of the concept of *'product'* was narrowed by separating it from that of *'medicinal product'* and the concept of *'product protected by a patent'* was replaced by *'basic patent'*.

75 See, to that effect, the Max Planck study, paragraph 2.1.3.2, p. 19.

76 See the Explanatory Memorandum, paragraph 28.

77 This approach is inferred, moreover, from the elements of the travaux préparatoires mentioned in point 47 of this Opinion.

78 See paragraph 24 of the Neurim judgment.

79 As discussed in points 52 to 55, 66 and 69 of the Opinion of Advocate General Saugmandsgaard Øe in Abraxis Bioscience (C-443/17, EU:C:2018:1020).

80 Emphasis added.

81 See, to that effect, the Abraxis judgment; see also order of 14 November 2013, Glaxosmithkline Biologicals and Glaxosmithkline Biologicals, Niederlassung der Smithkline Beecham Pharma (C-210/13, EU:C:2013:762, paragraph 29).

82 See paragraph 16 of the Explanatory Memorandum.
83 Ibid.
84 That is often the case where it is to be determined whether the product is *'protected by a patent'*, as is required by Article 3(a) of Regulation No 469/2009; see, in this regard, judgment of 25 July 2018, Teva UK and Others (C-121/17, EU:C:2018:585).
85 See paragraph 16 of the Explanatory Memorandum.
86 MIT judgment, paragraphs 28 and 29.
87 See, in particular, recital 10 of Regulation No 469/2009 and paragraphs 24 and 25 of the Explanatory Memorandum.
88 It should be stated, however, that before the amendment, on 29 November 2000, of Article 54(5) of the European Patent Convention (EPC 1973), which was signed at Munich on 5 October 1973 and entered into force on 7 October 1977, the patentability of second medical indications had already been recognised in 1984 in a decision of the Enlarged Board of Appeal of the European Patent Office and had therefore been able to be taken into account by the EU legislature in the drafting of Regulation No 1768/92 (see the Max Planck study, paragraph 11.3.1.6, p. 234).
89 See, to that effect, Opinion of Advocate General Léger in Massachusetts Institute of Technology (C-431/04, EU:C:2005:721, point 47 et seq.).
90 Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products (OJ 2019 L 153, p. 1), amended Article 5 of Regulation No 469/2009, introducing the exception known as the *'manufacturing waiver'* in favour of producers of generics.
91 See paragraph 43 of the Abraxis judgment.
92 In this second scenario, the Neurim judgment could be interpreted as an application by analogy of Regulation No 469/2009 to situations comparable to those covered by the regulation, namely where the new use of the old active ingredient claimed by the SPC applicant represents a major innovation, resulting from long, costly research. See, for such application, judgment of 12 December 1985, Krohn (165/84, EU:C:1985:507).
93 Under Article 54(4) and (5) of the European Patent Convention (see footnote 88 of the present Opinion), second medical uses of a known substance or composition, if they do not form part of the state of the art, are patentable, including, in the practice of the European Patent Office, where the use claimed is a new dosage, a new regimen for administration or a new subgroup of patients that can be treated. In such a case, the substance or composition is protected only within the limits of the use claimed; see the Max Planck study, paragraph 5.5, p. 67.
94 Paragraph 25 points in the opposite direction.
95 Those paragraphs refer consistently to the *'therapeutic' 'application'* or *'indication'* of the active ingredient.
96 See paragraph 11 of the Explanatory Memorandum.
97 It is conceivable that a new therapeutic use of this kind is made possible by a new formulation of the active substance. That situation, which differs from the one examined by the Court in the Abraxis judgment, where the therapeutic use of the new formulation was the same, should also be covered by the Neurim judgment, in my view, as excluding new formulations in such a situation would amount to an arbitrary application of my proposed criterion for interpreting that judgment.
98 It is interesting to note that before the Court, the Commission has always supported a flexible interpretation of the conditions set out in Article 3 of Regulation No 469/2009, in particular where the application of Article 3(d) was directly or indirectly concerned. That was so in the cases giving rise to the judgments in Neurim and Abraxis, in the case giving rise to the order in Yissum, as well as in present case.
99 See judgment of 15 January 2015, Forsgren (C-631/13, EU:C:2015:13, paragraphs 25, 27 and 47).
100 The *'product'* covered by the MA within the meaning of Article 3(b) of Regulation No 469/2009 and the judgment of 16 September 1999, Farmitalia (C-392/97, EU:C:1999:416, paragraphs 19 to 22) should be understood in the same way.
101 Judgment of 25 July 2018, Teva UK and Others (C-121/17, EU:C:2018:585).