Court of Justice EU, 21 March 2019, Abraxis Bioscience

PATENT LAW

Marketing authorisation relied on in support of an application for a SPC concerning a new formulation of an old active ingredient, cannot be regarded as being the first marketing authorisation for the product concerned as a medicinal product in the case where that active ingredient has already been the subject of a marketing authorisation as an active ingredient

- **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 that regulation, relied on in support of an application for a supplementary protection certificate concerning a new formulation of an old active ingredient, cannot be regarded as being the first marketing authorisation for the product concerned as a medicinal product in the case where that active ingredient has already been the subject of a marketing authorisation as an active ingredient.**

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Court of Justice EU, 21 March 2019
(T. von Danwitz, K. Jürimäe (Rapporteur), C. Lycourgos, E. Juhász, C. Vajda)
JUDGMENT OF THE COURT (Fourth Chamber)
21 March 2019 (*)
(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 granting — Grant of first authorisation to place the product on the market as a medicinal product — Authorisation covering a product as a medicinal product constituting a new formulation of a known active ingredient)
In Case C‑443/17,
REQUEST for a preliminary ruling under Article 267 TFEU from the High Court of Justice (England & Wales), Chancery Division (Patents Court), made by decision of 16 March 2017, received at the Court on 24 July 2017, in the proceedings
Abraxis Bioscience LLC
v
Comptroller General of Patents,
THE COURT (Fourth Chamber),
composed of T. von Danwitz, President of the Seventh Chamber, acting as President of the Fourth Chamber, K. Jürimäe (Rapporteur), C. Lycourgos, E. Juhász and C. Vajda, Judges,
Advocate General: H. Saugmandsgaard Øe,
Registrar: L. Hewlett, Principal Administrator,
having regard to the written procedure and further to the hearing on 21 June 2018,
after considering the observations submitted on behalf of:
– Abraxis Bioscience LLC, by R. Meade QC and J. Antcliff, Solicitor,
– the United Kingdom Government, by Z. Lavery and D. Robertson, acting as Agents, and by B. Nicholson, Barrister,
– the Czech Government, by M. Smolek, J. Vláčil and A. Kasalická, acting as Agents,
– the Hungarian Government, by M.Z. Fehér, G. Koós and R. Kissné Berta, acting as Agents,
– the Netherlands Government, by M.L. Noort, M.K. Bulterman, C.S. Schillemans, M.H.S. Gijzen and J.M. Hoogveld, acting as Agents,
– the Polish Government, by B. Majczyna, acting as Agent,
– the European Commission, by N. Yerrell and J. Samnadda, acting as Agents,
after hearing **the Opinion of the Advocate General** at the sitting on 13 December 2018,
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 Abraxis Bioscience LLC (‘*Abraxis*’) and the United Kingdom’s Comptroller General of Patents concerning the rejection of an application for the grant of a supplementary protection certificate (‘*SPC*’) for a medicinal product marketed under the name ‘*Abraxane*’.
Legal context
3 Recitals 3 to 5 and 7 to 10 of Regulation No 469/2009 state as follows:
‘*(3) Medicinal products, especially those that are the result of long, costly research will not continue to be developed in the [European Union] 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.
(5) This situation leads to a lack of protection which penalises pharmaceutical research.

...
(7) A uniform solution at [EU] 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 [European Union] 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 [European Union].
(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.'

4 Article 1 of that regulation 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 an [SPC];
...'

5 Article 2 of that regulation provides:

'*Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Directive 2001/83/EC 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 a certificate.*'

6 Article 3 of that regulation states:

'*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.'

7 Article 4 of Regulation No 469/2009 provides:

'*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].*'

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

8 Abraxis is a pharmaceutical company which markets, under the name '*Abraxane*', a medicinal product indicated for the treatment of certain cancers.

9 Abraxane contains a substance which Abraxis calls '*nab-paclitaxel*', being a combination of nanoparticles of paclitaxel coated with albumin and protected by European Patent EP 0 961 612. In that substance, the albumin and the paclitaxel are closely linked in such a way that they pass the cell membrane as a single entity. Nab-paclitaxel thus demonstrates greater efficacy than earlier formulations of paclitaxel for the treatment of certain cancerous tumours.

10 Abraxane was granted a marketing authorisation ('*MA*') in 2008 by the European Medicines Agency (EMA). Prior to the date on which that MA was granted for that medicinal product, paclitaxel had been marketed in another form by other companies under previous MAs.

11 Abraxis applied for an SPC on the basis of the basic patent at issue and the MA granted for Abraxane. By decision of 26 August 2016, the Comptroller General of Patents turned down that application on the ground that it did not comply with Article 3(d) of Regulation No 469/2009. It held that, although that provision permits the grant of an SPC for a new and inventive therapeutic use of an old active ingredient, its scope does not extend to a new and inventive formulation of an old active ingredient.

12 Abraxis appealed against that decision to the High Court of Justice (England & Wales), Chancery Division (Patents Court). It argues before that court that the condition laid down in Article 3(d) of Regulation No

469/2009 is met in the case of Abraxane in the light of the solution arrived at by the Court in the **judgment of 19 July 2012, *Neurim Pharmaceuticals (1991)* (C-130/11, EU:C:2012:489)**.

13 As it took the view that the scope of that judgment was not clear and that, therefore, the interpretation of Article 3(d) of that regulation was not obvious in the case of a new or inventive formulation of an old active ingredient, the High Court of Justice (England & Wales), Chancery Division (Patents Court), decided to stay the proceedings and to refer the following question to the Court of Justice for a preliminary ruling:

'*Is Article 3(d) of Regulation [No 469/2009] to be interpreted as permitting the grant of an SPC where the [MA] referred to in Article 3(b) [of that regulation] is the first [MA] within the scope of the basic patent to place the product on the market as a medicinal product and where the product is a new formulation of an old active ingredient?*'

The request for the oral procedure to be reopened

14 By a letter lodged at the Court Registry on 31 January 2019, Abraxis requested that the oral procedure be reopened pursuant to Article 83 of the Rules of Procedure of the Court of Justice.

15 In support of its request, Abraxis submits, in essence, that the Advocate General based his Opinion on arguments which were not debated between the parties and that, in his Opinion, he proposed a departure from the case-law resulting from the **judgment of 19 July 2012, *Neurim Pharmaceuticals (1991)* (C-130/11, EU:C:2012:489)**, or a limitation of that case-law solely to the factual circumstances giving rise to that judgment, which goes beyond the preliminary question asked by the referring court without taking into account its specificity.

16 In that regard, it is a matter of settled case-law that the Court may, of its own motion, on a proposal from the Advocate General, or at the request of the parties, order the reopening of the oral procedure under Article 83 of its Rules of Procedure if it considers that it lacks sufficient information or that the case must be decided on the basis of an argument which has not been debated between the parties. By contrast, neither the Statute of the Court of Justice of the European Union nor the Rules of Procedure make provision for the parties to submit observations in response to the Advocate General's Opinion (judgment of 23 January 2018, F. ***Hoffmann-La Roche and Others*, C-179/16, EU:C:2018:25,** paragraph 39 and the case-law cited).

17 In the present case, although Abraxis's observations are submitted as a response to certain points of the Advocate General's Opinion, it follows from the case-law cited in the preceding paragraph that there is no provision in the texts governing the procedure before the Court for the lodging of such observations.

18 In addition, after hearing the Advocate General, the Court finds that it has sufficient information to answer the question submitted by the referring court and that all the arguments necessary for the determination of the present case have been debated between the parties.

19 The request for the oral procedure to be reopened must therefore be rejected.

Consideration of the question referred

20 By its question, the referring court asks, in essence, whether 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 that regulation, relied on in support of an application for an SPC concerning a new formulation of an old active ingredient, may be regarded as being the first MA for the product concerned as a medicinal product, when that active ingredient has already been granted an MA as an active ingredient.

21 At the outset, it should be noted that, as is clear from the order for reference, the dispute in the main proceedings concerns an application for an SPC, the subject of which is a new formulation of an old active ingredient, paclitaxel, in the form of nanoparticles coated with albumin which acts as a carrier for paclitaxel. According to the information provided by the referring court, that new formulation, called '*nab-paclitaxel*', allows the active ingredient to exercise its therapeutic effects with an increased efficacy. It is marketed as a medicinal product under the mark '*Abraxane*'. That medicinal product was subject to an MA which is the first MA coming within the scope of the basic patent covering that new formulation. The referring court also states that paclitaxel had already, prior to the grant of the MA in respect of Abraxane, been marketed under other MAs.

22 It is against that background that the question referred for a preliminary ruling by the referring court must be understood.

23 In order to answer that question, it is necessary, in the first place, to determine whether Article 1(b) of Regulation No 469/2009 must be interpreted as meaning that a new formulation of an old active ingredient, which, such as nab-paclitaxel, consists of that active ingredient and a carrier linked together in the form of nanoparticles permitting that active ingredient to exercise its therapeutic effects with increased efficacy, may be regarded as being a product that is distinct from the product consisting solely of the same active ingredient.

24 In that regard, it is important to note that that provision states that the term '*product*' means the active ingredient or combination of active ingredients of a medicinal product.

25 According to the Court's settled case-law, 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. In this case, it is generally accepted in pharmacology that the term 'active ingredient' does not include substances forming part of a medicinal product which do not have an effect of their own on the human or animal body (**order of 14 November 2013, *Glaxosmithkline Biologicals and Glaxosmithkline Biologicals,***

***Niederlassung der Smithkline Beecham Pharma*, C-210/13, EU:C:2013:762**, paragraphs 27 and 28 and the case-law cited).

26 In that regard, 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 (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), itself repealed and replaced by Regulation No 469/2009, indicates that the term '*product*' is understood to mean an active substance 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.

27 The Court has inferred from this that the pharmaceutical form of the medicinal product, to which an excipient may contribute, does not form part of the definition of '*product*', which is understood to mean an '*active substance*' or '*active ingredient*' in the strict sense. Whether a substance without any therapeutic effect of its own is necessary for the therapeutic efficacy of the active ingredient cannot, in this case, be regarded as a sufficiently precise test (**order of 14 November 2013, *Glaxosmithkline Biologicals and Glaxosmithkline Biologicals, Niederlassung der Smithkline Beecham Pharma*, C-210/13, EU:C:2013:762**, paragraph 29 and the case-law cited).

28 Accordingly, a substance which does not have any therapeutic effect of its own and which is used to obtain a certain pharmaceutical form of a medicinal product is not covered by the concept of '*active ingredient*' which is used to define the term '*product*' (**order of 14 November 2013, *Glaxosmithkline Biologicals and Glaxosmithkline Biologicals, Niederlassung der Smithkline Beecham Pharma*, C-210/13, EU:C:2013:762**, paragraph 30 and the case-law cited).

29 Consequently, first, the alliance of such a substance with a substance which does have therapeutic effects of its own cannot give rise to a '*combination of active ingredients*' within the meaning of Article 1(b) of Regulation No 469/2009. Second, the fact that the substance without any therapeutic effect of its own renders possible a pharmaceutical form of the medicinal product necessary for the therapeutic efficacy of the substance which does have therapeutic effects cannot invalidate that interpretation (**order of 14 November 2013, *Glaxosmithkline Biologicals and Glaxosmithkline Biologicals, Niederlassung der Smithkline Beecham Pharma*, C-210/13, EU:C:2013:762**, paragraphs 31 and 32 and the case-law cited).

30 Those considerations apply equally to a substance which, such as the albumin in the main proceedings, acts as a carrier of the active ingredient, according to the indications listed in the request for a preliminary ruling referred to in paragraph 21 of the present judgment. Since such a carrier does not have any therapeutic effects of its own – this being a matter which must, however, be verified by the referring court –, it cannot be regarded as being an active ingredient within the meaning of Article 1(b) of Regulation No 469/2009 even if it allows the active ingredient with which it is associated to exercise its therapeutic effect more effectively. Therefore, even the alliance of such a carrier with another substance which does have therapeutic effects of its own cannot give rise to a combination of active ingredients within the meaning of that provision.

31 It follows from the foregoing that Article 1(b) of Regulation No 469/2009 must be interpreted as meaning that a new formulation of an old active ingredient, which, such as nab-paclitaxel, consists of that active ingredient and a carrier which has no therapeutic effect on its own linked together in the form of nanoparticles, cannot be regarded as being a product distinct from the product consisting solely of that active ingredient even if such a formulation allows that active ingredient to exercise its therapeutic effect with increased efficacy.

32 In the second place, it is appropriate to determine whether an MA granted for a new formulation of an old active ingredient, such as nab-paclitaxel, may be regarded as being the first MA granted for that product as a medicinal product within the meaning of Article 3(d) of Regulation No 469/2009, in the case where that MA is the first MA to come within the scope of protection of the basic patent concerned.

33 In that regard, it must be pointed out that, according to that provision, one of the conditions to which the grant of an SPC is made subject is that, in the Member State in which the SPC application is submitted and at the date of that application, the MA obtained in respect of the product which was the subject of that application must be the first MA for that product as a medicinal product.

34 As the Advocate General noted, in essence, in point 30 of his Opinion, in the light of the definition of the scope of '*product*', as is clear from the Court's settled case-law, a literal interpretation of Article 3(d) of Regulation No 469/2009 presupposes that the first MA for the product as a medicinal product within the meaning of that provision means the first MA for a medicinal product incorporating the active ingredient or the combination of active ingredients at issue.

35 According to such an interpretation, 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 MA within the meaning of Article 3(d) of Regulation No 469/2009, as defined in Article 1(b) of that regulation (see, to that effect, judgment of 24 November 2011, ***Medeva*, C-322/10, EU:C:2011:773**, paragraph 40).

36 It should be added that, with regard to the objective of Regulation No 469/2009, it is clear from the wording of recitals 3 to 5 and 9 thereof, as the Advocate General observed in point 50 of his Opinion, that the SPC regime has the purpose of compensating for the lack of protection conferred by a patent with respect to

covering the investment put into research concerning new medicinal products and, therefore, of encouraging that research. However, it follows from recital 10 of that regulation that the legislature intended to achieve that objective so as to take into account all the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector.

37 That finding, which supports a narrow interpretation of Article 3(d) of Regulation No 469/2009, is confirmed by the Explanatory Memorandum of 11 April 1990 to the Proposal for a Regulation, referred to in paragraph 26 of the present judgment, the effect of which is, as the Advocate General observed in points 52 to 55, 66 and 69 of his Opinion, 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.

38 Such an objective would be jeopardised if, in order to fulfil the condition set out in Article 3(d) of Regulation No 469/2009, it were possible to take into account, in respect of a new formulation of an old active ingredient, solely the first MA to be covered by the scope of the basic patent protecting that new formulation and to disregard an MA which had been granted previously in respect of the same active ingredient in another formulation.

39 Furthermore, such an interpretation of Article 3(d) of Regulation No 469/2009 would risk leading to legal uncertainty and inconsistencies as to the circumstances in which an SPC may be obtained, as it would be difficult to determine in which specific circumstances an MA granted in respect of a new formulation of an old active ingredient may be covered by that provision.

40 Consequently, an MA granted for a new formulation of an old active ingredient, such as nab-paclitaxel, cannot be regarded as being the first MA granted for that product as a medicinal product within the meaning of Article 3(d) of Regulation No 469/2009, when that active ingredient has already been the subject of an MA.

41 The case-law arising from the **judgment of 19 July 2012, *Neurim Pharmaceuticals (1991)* (C‑130/11, EU:C:2012:489**) cannot call into question such an interpretation. In 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 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 SPC application.

42 However, the Court did not, in that judgment, cast doubt on the narrow interpretation of the notion of '*product*', referred to in Article 1(b) of that regulation, according to which that scope cannot cover a substance which does not correspond to the definition of an '*active ingredient*' or to that of a '*combination of active ingredients*' (see, to that effect, **order of 14 November 2013, *Glaxosmithkline Biologicals and Glaxosmithkline Biologicals, Niederlassung der Smithkline Beecham Pharma,* C‑210/13, EU:C:2013:762**, paragraph 44).

43 Moreover, it should be noted that the exception to the narrow interpretation of Article 3(d) of that regulation, as held in the **judgment of 19 July 2012, *Neurim Pharmaceuticals (1991)* (C‑130/11, EU:C:2012:489**), does not, in any event, refer to cases of a new formulation of the product at issue. That exception cannot, therefore, in any event, be relied on in the case of an MA granted for a new formulation of an active ingredient which has already been the subject of an MA, even if the MA for that new formulation was the first to come within the scope of the basic patent relied on in support of the SCP application for that new formulation.

44 Consequently, the answer to the question referred is 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 that regulation, relied on in support of an application for an SPC concerning a new formulation of an old active ingredient, cannot be regarded as being the first MA for the product concerned as a medicinal product in the case where that active ingredient has already been the subject of an MA as an active ingredient.

Costs

45 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Fourth Chamber) hereby rules:

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 that regulation, relied on in support of an application for a supplementary protection certificate concerning a new formulation of an old active ingredient, cannot be regarded as being the first marketing authorisation for the product concerned as a medicinal product in the case where that active ingredient has already been the subject of a marketing authorisation as an active ingredient.

OPINION OF ADVOCATE GENERAL SAUGMANDSGAARD ØE

delivered on 13 December 2018 (1)

Case C‑443/17

Abraxis Bioscience LLC

v
Comptroller General of Patents
(Request for a preliminary ruling from the High Court of Justice (England & Wales), Chancery Division (Patents Court), United Kingdom)
(Reference for a preliminary ruling — Medicinal products — Supplementary protection certificate — Regulation (EC) No 469/2009 — Conditions for granting — Article 3(d) — Concept of '*first authorisation to place the product on the market as a medicinal product*' — Marketing authorisation for a medicinal product constituting a new formulation, protected by a basic patent, of a previously authorised active ingredient — Non-compliance with the condition laid down in Article 3(d))

I. Introduction

1. In its request for a preliminary ruling, the High Court of Justice (England & Wales), Chancery Division (Patents Court), United Kingdom) seeks from the Court an interpretation of Article 3(d) of Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products. (2)

2. This request was made in the context of a dispute between the company Abraxis Bioscience LLC ('*Abraxis*') and the Comptroller General of Patents, Designs and Trademarks ('*the Comptroller*'). Abraxis is seeking from the national court the annulment of the Comptroller's decision to reject the supplementary protection certificate ('*SPC*') application made by Abraxis for a combination of substances containing the active ingredient paclitaxel in the form of nanoparticles bound to albumin. Abraxis calls that combination of substances '*nab-paclitaxel*' and markets it under the name of Abraxane.

3. In accordance with the SPC regime provided for by Regulation No 469/2009, if the commercial exploitation of a patent is delayed because of the regulatory procedures required to obtain marketing authorisation ('*marketing authorisation*', '*authorisation to place on the market*' or '*MA*') for a medicinal product incorporating the invention protected by the patent, the holder of that patent is permitted to enjoy an additional period of exclusivity on the expiry of the patent. That period of exclusivity compensates, at least in part, for the erosion of the period of effective exploitation of the exclusivity conferred by the patent. (3)

4. The grant of an SPC is subject, in the Member State in which it is sought, to compliance with the conditions laid down in Article 3 of Regulation No 469/2009. First of all, the '*product*' — the concept of which is defined in Article 1(b) of that regulation as '*the active ingredient or combination of active ingredients of a medicinal product*' — must be protected by a '*basic patent*'. (4) Next, a valid marketing authorisation for the product must have been granted in accordance with the EU rules. (5) Article 3(d) of that regulation requires that that marketing authorisation be '*the first authorisation to place the product on the market as a medicinal product*'. Finally, the product must not have already been the subject of an SPC. (6)

5. In the present case, the active ingredient in Abraxane, paclitaxel, had already been marketed under other brand names for use in eliminating cancer cells pursuant to earlier marketing authorisations. Nab-paclitaxel is a new formulation of that active ingredient and has the same use. That formulation is protected by the basic patent relied upon by Abraxis in support of its SPC application, it being understood that the protection conferred by that patent does not extend to paclitaxel as such.

6. In that context, the national court asks the Court, in essence, whether the condition set out in Article 3(d) of Regulation No 469/2009 is fulfilled where, although the marketing authorisation relied upon in support of the SPC application is for an active ingredient which has already been granted an earlier marketing authorisation, that earlier marketing authorisation did not concern the new formulation — protected by the basic patent and covered by the marketing authorisation of the applicant for the SPC — of that active ingredient.

7. The national court invites the Court, by that question, to clarify the scope of its judgment in *Neurim Pharmaceuticals (1991)* (7) ('*Neurim*'). As I shall recall in more detail in my analysis, (8) the Court held therein that that condition is fulfilled when the marketing authorisation at issue, even if it is not the first marketing authorisation for the active ingredient concerned, is the first to cover the new therapeutic use — protected by the basic patent — of that active ingredient. The national court seeks to ascertain whether the points of principle set out in that judgment also mean that Article 3(d) of Regulation No 469/2009 does not preclude the grant of an SPC where the marketing authorisation relied upon is the first to fall within the scope of a basic patent protecting the new formulation, for a known therapeutic use, of a previously authorised active ingredient.

8. At the end of my analysis, I shall propose that the Court answer in the negative the question referred.

II. Legal framework

9. As is apparent from recital 1 of Regulation No 469/2009, that regulation was adopted with a view to codifying Regulation (EEC) No 1768/92, (9) which had been substantially amended several times. The following provisions of Regulation No 469/2009 reproduce the content of the equivalent provisions of Regulation No 1768/92.

10. Article 1 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 [an SPC];
…'
11. Article 2 of that regulation provides that '*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 [(10)] … or Directive 2001/82/EC [(11)] … may, under the terms and conditions provided for in this Regulation, be the subject of a certificate*'.
12. Article 3 of that regulation 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.'
13. According to Article 4 of Regulation No 469/2009, '*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]*'.
14. Article 5 of that regulation states that '*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*'.

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

15. Abraxis markets, under the name Abraxane, a medicinal product indicated for the treatment of certain breast, pancreatic and lung cancers. That medicinal product contains the active ingredient paclitaxel in the form of nanoparticles coated with albumin. Albumin is a protein which acts as a carrier for paclitaxel. Abraxis calls the combination of substances thus formulated '*nab-paclitaxel*', the term also used in the order for reference for the sake of convenience.
16. Nab-paclitaxel is protected by European patent (UK) No EP 0 961 612, entitled '*Protein stabilised pharmacologically active agents and their use*' ('*the basic patent*'). Claim Nos 1, 32 and 33 of the basic patent are worded as follows:

'*1. A composition comprising particles of a solid or liquid, substantially water insoluble pharmacologically active agent, coated with protein, wherein the average diameter of said particles is less than 200 [nanometres], wherein said protein coating has free protein associated therewith, and wherein a portion of said pharmacologically active agent is contained within said protein coating and a portion of said pharmacologically active agent is associated with said free protein.*'
'*32. A composition according to any one of claims 1 to 22 for use in eliminating cancer cells, wherein said composition is cremophor free and said pharmacologically active agent is an antineoplastic.*'
'*33. A composition according to claim 32, wherein said antineoplastic is paclitaxel and said protein is albumin.*'
17. Abraxane is the subject of Marketing Authorisation EU/1/07/428/001, granted in 2008 by the European Medicines Agency (EMA). Prior to the granting of that marketing authorisation, paclitaxel had already been marketed by other undertakings, under the brand names Paxene and Taxol, pursuant to earlier marketing authorisations. Nab-paclitaxel demonstrates greater efficacy than traditional formulations of paclitaxel for the treatment of certain cancerous tumours. Nab-paclitaxel also has some benefits in terms of patient tolerance. It is common ground that the development of Abraxane has required lengthy and expensive research, with the result that the marketing authorisation for that medicinal product was obtained a particularly long time after the application for the patent was filed.
18. Abraxis applied for an SPC on the basis of the basic patent and the marketing authorisation for Abraxane. By decision of 26 August 2016, the Comptroller rejected that application on the grounds that, as that marketing authorisation was not the first marketing authorisation for paclitaxel, the condition set out in Article 3(d) of Regulation No 469/2009 was not fulfilled. That authority considered that, although that provision, as interpreted by the Court in *Neurim*, does not preclude the grant of an SPC on the basis of the first marketing authorisation covering a new and inventive *therapeutic* use of an active ingredient that had already been the subject of an earlier marketing authorisation, it does preclude the grant of an SPC on the basis of the first marketing authorisation covering a new and inventive *formulation* of that active ingredient for a known therapeutic use.
19. Abraxis appealed against that decision to the High Court of Justice (England & Wales), Chancery Division (Patents Court). In its appeal, that company maintains that the condition laid down in Article 3(d) of Regulation No 469/2009 is fulfilled according to the principles set out in Neurim.
20. Moreover, Abraxis points out that SPCs for nab-paclitaxel have been granted in nine Member States (Denmark, Greece, Spain, France, Italy, Luxembourg, Austria, Portugal and Finland) and rejected in two Member States (Sweden and the United Kingdom). Nab-paclitaxel is also the subject of pending SPC

applications in three Member States (Germany, Ireland and the Netherlands), as well as in Switzerland.

21. The national court has doubts as to the scope of *Neurim* and, accordingly, as to the interpretation of Article 3(d) of Regulation No 469/2009. In those circumstances, that court decided to stay the proceedings and to refer the following question to the Court for a preliminary ruling:

'*Is Article 3(d) of Regulation No 469/2009 to be interpreted as permitting the grant of an SPC where the marketing authorisation referred to in Article 3(b) [of that regulation] is the first authorisation within the scope of the basic patent to place the product on the market as a medicinal product and where the product is a new formulation of an old active ingredient?*'

22. Abraxis, the United Kingdom Government, the Czech, Hungarian, Netherlands and Polish Governments and the European Commission have submitted written observations to the Court.

23. Abraxis, the Netherlands Government and the Commission were represented at the hearing held on 21 June 2018.

IV. Analysis

A. Preliminary considerations

24. The conditions to which the grant of an SPC is made subject under Article 3 of Regulation No 469/2009 highlight the links between the SPC and the basic patent, on the one hand, and the marketing authorisation, on the other hand. The present case provides the Court with an opportunity to clarify any possible links between the basic patent and the marketing authorisation relied upon in support of the SPC application. More specifically, this case raises the question of whether Article 3(d) of that regulation refers to the '*the first authorisation to place the product on the market as a medicinal product*' without further qualification, or to the first marketing authorisation covering the product as a medicinal product *and falling within the scope of the protection conferred by the basic patent*.

25. In that regard, while a literal reading of that provision leads to the first of those interpretations (Section 1), the Court departed from that reading in *Neurim* (Section 2). Although the case giving rise to that judgment had a very specific factual background, the reasoning adopted by the Court does not necessarily appear to be restricted to contexts of that kind. This reference for a preliminary ruling invites the Court to examine the scope of that judgment and the resulting implications in a situation such as that at issue in the main proceedings (Section 3).

1. The literal interpretation of Article 3(d) of Regulation No 469/2009 read in conjunction with Article 1(b) of that regulation

26. For the purposes of a coherent interpretation of the provisions of Regulation No 469/2009, the terms used in Article 3(d) of that regulation must be read by reference to the definitions in Article 1 thereof. In particular, the concept of '*product*' means, in accordance with Article 1(b) of that regulation, '*the active ingredient or combination of active ingredients of a medicinal product*'.

27. According to settled case-law beginning with *Massachusetts Institute of Technology*, (12) the concept of '*active ingredient*', within the meaning of that provision, excludes those constituents of a medicinal product which do not have any therapeutic effects of their own on the body, (13) such as excipients. (14) The latter, even when necessary for the therapeutic efficacy of a substance which has therapeutic effects of its own, do not constitute '*active ingredients*'. (15) Nor does the combination of an excipient and such a substance give rise to a '*combination of active ingredients*'. (16)

28. In the present case, the order for reference states that the national court considered, contrary to what Abraxis maintained before that court, that nab-paclitaxel does not constitute either an active ingredient distinct from paclitaxel or a combination of active ingredients comprising paclitaxel and albumin (since that carrier protein has, according to that court, no therapeutic effects of its own on the body). The question referred to the Court is therefore based on the premiss that, in accordance with the abovementioned case-law, paclitaxel is the only active ingredient in Abraxane. (17)

29. As is clear from the order in *Yissum*, (18) the concept of '*product*' is also independent of the therapeutic use concerned: an active ingredient (or a combination of active ingredients) remains one and the same '*product*' regardless of its therapeutic uses. In accordance with *Pharmacia Italia*, (19) nor is the definition of '*product*' influenced by the species (whether an animal species or humans) for which the product is intended.

30. In the light of that definition of '*product*', as set out in Article 1(b) of Regulation No 469/2009, a literal interpretation of Article 3(d) of that regulation presupposes, as the Court expressly found in *Medeva*, (20) that the '*first authorisation to place the product on the market as a medicinal product*', within the meaning of that provision, means the first marketing authorisation for a medicinal product incorporating the active ingredient or combination of active ingredients at issue. According to that reading, an SPC can therefore be obtained only on the basis of the first marketing authorisation covering an active ingredient or a combination of specific active ingredients.

31. The Court, moreover, interpreted in the same way Article 1(8) and Article 3(d) of Regulation (EC) No 1610/96 concerning the creation of a supplementary protection certificate for plant protection products, (21) the content of which reproduces, in the plant protection products sector, the content of Article 1(b) and Article 3(d) of Regulation No 469/2009. Thus, in *BASF*(22) the Court found, first of all, that the concept of '*product*' used in Article 3 of Regulation No 1610/96 is equivalent to the concept of '*product*' as defined in Article 1(8) of that regulation. The Court next held that a new plant protection product did not constitute a new '*product*' within the meaning of those provisions 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. (23) Accordingly, Article 3(d) of Regulation No 1610/96 precluded the grant of the SPC applied for on the basis of that basic patent and the marketing authorisation for the new plant protection product, on the ground that that marketing authorisation was not the first granted for the product at issue. (24)

2. The teleological interpretation of Article 3(d) of Regulation No 469/2009 adopted in Neurim

32. In *Neurim*, however, the Court replaced the literal interpretation of Article 3(d) of Regulation No 469/2009 with a teleological reading based, in essence, on the consideration that the that regulation is intended to encourage not only research into new active ingredients or new combinations of active ingredients, but also other types of inventive activities in the field of medicinal products. (25)

33. The case giving rise to that judgment concerned the issue of whether an SPC could be obtained on the basis of the marketing authorisation for a medicinal product, Circadin, which contained an unpatented active ingredient (the natural hormone melatonin) that formed part of a medicinal product already granted a marketing authorisation, Regulin. Although Circadin was intended for the treatment of insomnia in humans, Regulin was used to regulate the reproductive cycle of sheep. Circadin fell within the scope of a patent protecting both the use of melatonin for the new therapeutic indication at issue and the new formulation of melatonin with a view to such use. (26)

34. The Court held that an SPC could be granted on the basis of that patent and the marketing authorisation for Circadin since, although it was not the first marketing authorisation relating to melatonin, it was the first marketing authorisation covering that active ingredient *for a therapeutic use falling within the scope of the protection conferred by the basic patent*. Indeed, '*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]*' (27) (that test is referred to below as the '*the scope of protection of the basic patent test*'). In accordance with Articles 4 and 5 of that regulation, the protection conferred by the SPC is therefore limited to the new use which is the subject of the basic patent and does not extend to melatonin as such. (28)

35. In the situation brought to the attention of the Court, the new use protected by the basic patent concerned a therapeutic indication in human medicine of a product already covered by an earlier marketing authorisation for a therapeutic indication in a separate therapeutic area as a veterinary medicinal product. The grounds and the operative part of *Neurim* refer, for their part, in general terms to the possibility of obtaining an SPC on the basis of the first marketing authorisation relating to a new therapeutic '*application*' or '*use*' — protected by the basic patent — of a previously authorised product. (29)

36. As noted by the national court, the Court has not specified, in particular, whether the logic underlying the test set out in that judgment means that an SPC may be granted where the marketing authorisation at issue is the first to fall within the scope of a basic patent protecting the new formulation, for a known therapeutic use (in the present case, eliminating cancer cells), (30) of a product which is already the subject of a marketing authorisation covering that use.

37. *Neurim* also raises certain questions concerning the relationship between the concept of new therapeutic '*application* or '*use*', within the meaning of that judgment, and patent law. In that regard, as I shall indicate below, (31) the second (and subsequent) therapeutic '*uses*', or '*applications*', of known substances which may be patented under the Convention on the Grant of European Patents, signed at Munich on 5 October 1973, as amended in 2000 ('*the European Patent Convention*' or '*EPC*'), are not limited to the uses of a known product for a new therapeutic indication. They also include applications of such a product for a known therapeutic indication whose novelty lies, for example, in the dosage or the route of administration. It is not certain that in *Neurim* the Court intended to attribute such a broad meaning to the concept at issue. (32)

38. Moreover, the difficulties relating to the interpretation of that judgment are exacerbated because neither that judgment nor the preceding Opinion of Advocate General Trstenjak (33) referred to the pre-existing case-law concerning the concept of '*product*' within the meaning of Article 1(b) of Regulation No 469/2009. However, *Neurim* is difficult to reconcile with that case-law and, in particular, with the order in *Yissum* (34) and, in the event that the test set out therein applies where the basic patent protects the new formulation of a known active ingredient for a known therapeutic use, with *Massachusetts Institute of Technology*. (35)

39. Although the questions referred by the national courts concerned the interpretation of Article 1(b) of Regulation No 469/2009, it is clear from those two judgments that the national disputes giving rise to the references for a preliminary ruling concerned the application of Article 3(d) thereof. The SPC applications were rejected on the ground that the marketing authorisations relied upon in support of those applications were not the first marketing authorisations for the products concerned. (36) If the Court had found that the scope of protection of the basic patent test applied in situations such as those at issue in those disputes, in order to resolve those disputes the Court would have had to rule that, in spite of the strict interpretation given of the concept of '*product*' within the meaning of Article 1(b) of that

regulation, (37) an SPC could be granted on the basis of a broad interpretation of Article 3(d) thereof. (38)

40. Subsequent to *Neurim*, the Court, in the order in *Glaxosmithkline Biologicals and Glaxosmithkline Biologicals, Niederlassung der Smithkline Beecham Pharma*, (39) confirmed the interpretation of the concept of '*product*' within the meaning of Article 1(b) of Regulation No 469/2009 adopted in *Massachusetts Institute of Technology*, (40) and stated that *Neurim* had not called it into question. In *Forsgren*, (41) the Court again recalled that interpretation, while emphasising that the SPC regime is intended to cover the cost of research leading to the discovery of new '*products*'. However, the Court did not specifically address the question of whether an SPC may be obtained when the relevant marketing authorisation covers the new formulation — protected by the basic patent — of a known active ingredient (whether or not that formulation permits a new therapeutic use). (42)

41. In those circumstances, the relationship between, on the one hand, Article 1(b) of Regulation No 469/2009 and the line of case-law relating thereto and, on the other hand, Article 3(d) of that regulation and *Neurim* requires clarification. In that connection, an independent study by the Max Planck Institute, commissioned by the Commission, (43) which is referred to in the Commission's proposal for revision of Regulation No 469/2009 adopted in 2018, (44) highlights that *Neurim* has given rise to differing interpretations as between the Member States. Those divergences could explain, at least in part, why, as is clear from the order for reference, some of the Member States have approved and some have rejected the SPC applications for Abraxane. (45)

3. The issue in the present case

42. In determining whether Article 3(d) of Regulation No 469/2009 precludes the grant of an SPC for the new and inventive formulation of a previously authorised active ingredient intended for a known therapeutic use of that active ingredient, the Court will have the opportunity to resolve the contradictions between the above-mentioned lines of case-law. It will have to clarify how they can coexist harmoniously or, where appropriate, indicate whether certain judgments have been, or should be, reversed. In that regard, the interested parties have proposed several distinct approaches.

43. First, Abraxis considers that the reasoning adopted in *Neurim* justifies the conclusion that the condition set out in Article 3(d) of that regulation is fulfilled whenever the marketing authorisation for a medicinal product incorporating a product which is already the subject of an earlier marketing authorisation is the first to fall within the scope of the protection conferred by the basic patent. That interpretation would open the way for the grant of an SPC for, inter alia, any new and inventive formulation of a known active ingredient covered by a new marketing authorisation.

44. If it adopted that approach, the Court would, in my view, be rejecting the approach adopted in *Massachusetts Institute of Technology* (46) and the order in *Yissum*. (47) Moreover, the scope of protection of the basic patent test, if it were extended by analogy to the plant protection products sector, would call into question the reasoning followed in *BASF*. (48)

45. Secondly, the United Kingdom Government and the Commission in its written observations propose limiting the applicability of that test to situations where the marketing authorisation at issue is the first to cover a *new therapeutic use* protected by the basic patent. (49) That option would entail the abandonment of the approach previously adopted by the Court in situations of the kind at issue in the order in *Yissum*. (50)

46. Thirdly, the Czech and Netherlands Governments take the view that the approach adopted in *Neurim* should be confined even more narrowly. According to them, that approach is justified only in situations where the marketing authorisation concerned is the first to cover a therapeutic indication of the product in *human* medicine, when the earlier marketing authorisations relating to the product concern another therapeutic indication in *veterinary* medicine. The Polish Government essentially shares the view that the principles set out in that judgment covered a very specific situation and cannot be applied automatically in all cases where an SPC is applied for on the basis of a patent protecting a new therapeutic use of an old active ingredient.

47. A fourth approach could be to abandon the scope of protection of the basic patent test in order to return to a literal interpretation of Article 3(d) of Regulation No 469/2009 in all situations. The Hungarian Government, although it has not expressly taken a position on the scope of *Neurim*, suggests that the question referred should be answered in the negative on the basis of such a literal interpretation.

48. For the reasons set out below, I shall indicate my preference for the last of those approaches and, in the alternative, for the third approach.

B. Rejection of the scope of protection of the basic patent test

49. As I have already stated, a textual interpretation of Article 3(d) of Regulation No 469/2009, read in conjunction with Article 1(b) thereof, implies that an SPC application must be rejected where the marketing authorisation at issue is not the first marketing authorisation for the product as a medicinal product, irrespective of whether or not that marketing authorisation is the first to fall within the scope of the protection conferred by the basic patent. (51) Although the provisions of the regulation must be interpreted in consideration not only of their wording but also the general scheme and objectives of the system established by that regulation, (52) according to settled case-law, the Court has no power to depart from the clear and precise wording of a provision of EU legislation. (53) That applies in particular where, as in the present case, the analysis of the objectives and context of the provision at issue and of the regulation of which the provision forms part support the literal interpretation.

1. Examination of the preamble and travaux préparatoires

50. According to recitals 3, 4, 5 and 9 of Regulation No 469/2009, the SPC regime has the purpose of compensating for the lack of protection conferred by a patent with respect to covering the investment put into research concerning new medicinal products and, therefore, of encouraging that research. Recitals 7 and 8 of that regulation add that a uniform solution to that problem should be provided for at European Union level in order to prevent a heterogeneous development of national laws which would create obstacles to the proper functioning of the internal market. (54)

51. Recital 10 of Regulation No 469/2009 emphasises that the legislature intended to achieve that objective so as to take into account in a balanced way all the interests involved in the '*complex and sensitive*' sector of medicinal products. Those interests include those of pharmaceutical companies, those of manufacturers of generic medicinal products and, at the place where those competing interests converge, the interests of patients and sickness insurance funds. (55)

52. The condition set out in Article 3(d) of that regulation actually forms part of the effort to strike such a balance between the interests involved by limiting the benefit of the SPC to products placed on the market for the first time as medicinal products. In that regard, the Explanatory Memorandum (56) seems to me to indicate that the research which the establishment of the SPC regime was intended to encourage is that leading to the first marketing, as a medicinal product, of an active ingredient or combination of active ingredients. (57)

53. In particular, paragraph 11 of the Explanatory Memorandum reads as follows: '*The proposal for a Regulation therefore 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. Only one certificate may be granted for any one product, a product being understood to mean an active substance in the strict sense. 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*'. (58)

54. That point seems to echo the first subparagraph of paragraph 6 of the Explanatory Memorandum, which states: '*Over about the last 10 years there has been a fall in the number of molecules of European origin that have reached the research and development stage …*' The second subparagraph of paragraph 5 of that document had, in that regard, emphasised the risks associated with the research and development activities necessary for the commercial exploitation of new active substances: '*Out of a total of about 10 000 substances synthesised by a research laboratory, a few hundred will be selected for the filing of patents out of which only one to three will actually be authorised to be placed on the market*'. (59)

55. Moreover, paragraph 35 of the Explanatory Memorandum states: '*It occurs very often that one and the same product is successively granted several authorisations to be placed on the market, namely each time a modification is made affecting the pharmaceutical form, dose, composition, indications, etc. In such a case, only the first authorisation for the product to be placed on the market in the Member State in which the application is presented is taken into account for the purposes of the proposal for a Regulation …*' The third subparagraph of paragraph 36 of that document goes on to clarify that '*although one and the same product may be the subject of several patents and several authorisations to be placed on the market in one and the same Member State, the supplementary protection certificate will only be granted for that product on the basis of a single patent and a single authorisation to be placed on the market, namely the first chronologically given in the State concerned*'. (60)

56. Abraxis relies, however, on paragraph 11, already cited, and on paragraphs 12 and 29 of the Explanatory Memorandum in support of an alternative teleological reading, according to which Regulation No 469/2009 seeks to stimulate all pharmaceutical research giving rise to an invention which is patented and incorporated into a medicinal product that has been granted a new marketing authorisation. Abraxis states that, according to *Neurim*, (61) that general consideration provides, where a previously authorised product is covered by a new marketing authorisation for a use falling within the scope of the protection conferred by the basic patent, justification for granting that product an SPC the scope of which will be limited to that of that patent. The concept of '*use*', or '*application*', within the meaning of that judgment, covers any type of invention without distinction, whether it concerns a formulation, a manufacturing process or a therapeutic indication of a known product. Consequently, Article 3(d) of Regulation No 469/2009 does not preclude the grant of an SPC for the new formulation, intended for a known therapeutic use, of an active ingredient already covered by an earlier marketing authorisation.

57. In my view, that argument does not stand up to a detailed analysis of the Explanatory Memorandum as a whole and of the paragraphs on which Abraxis relies in particular.

58. *In the first place*, paragraph 29 of that document states: '*The purpose of the expression "product protected by a patent" is to specify what types of invention may be used as a basis for a certificate. The proposal does not provide for any exclusions. In other words, 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, and must be able to be given a supplementary certificate of protection provided that all of the conditions governing the application of the proposal for a Regulation are fulfilled (my empahasis).*'

59. Understood in its entirety, that paragraph reflects, it seems to me, the principle that the concept of '*basic patent*' defined in Article 1(c) of Regulation No 469/2009, which is referred to by Article 3(a) thereof, or of '*patent*' within the meaning of Article 2 is not limited to patents which protect a product as such. That concept includes patents relating to a process for the manufacture of a known product or to an application of it. (62) Accordingly, the scope of that regulation, as defined in Article 2 thereof, does not exclude a product which, without being patented as such, is covered by a patent which protects an invention relating to a process to obtain that product or an application of it. The condition laid down in Article 3(a) of that regulation is also fulfilled in such a situation. However, the SPC may only be granted provided that the other conditions set out in that article are fulfilled. They include the condition, in Article 3(d) of that regulation, that the marketing authorisation relied upon in support of the SPC application must be the first marketing authorisation for the product at issue.

60. It is also to that effect that paragraph 12 of the Explanatory Memorandum should be understood, in that it states: '*The proposal is not confined to new products only. A new process for obtaining the product or a new application of the product may also be protected by a certificate. All research, whatever the strategy or final result, must be given sufficient protection.*' (63)

61. In that regard, I would note that, although patent law is not harmonised at EU level, (64) all the Member States have acceded to the European Patent Convention. (65) This makes it possible to patent, inter alia, '*substances or combinations of substances*', without those substances or combinations being limited to active ingredients and combinations of active ingredients(66) Moreover, Article 54(4) and Article 54(5) of the EPC provide for the patentability, respectively, of the first therapeutic uses of known substances and the second therapeutic uses (or subsequent therapeutic uses) of such substances. (67)

62. According to the case-law of the European Patent Office (EPO), the concept of '*use*' (for which the term '*application*' is used as a synonym), (68) within the meaning of Article 54(5) of the EPC, does not refer only to the use of a known product for a new therapeutic indication. That concept also covers applications of such a product for a known therapeutic indication when other features of those applications are new and inventive, for example, the dosage or route of administration. (69)

63. In my view, Article 3(d) of Regulation No 469/2009 nevertheless precludes the grant of an SPC on the basis of a patent protecting a second therapeutic application of a known product or a new formulation of that product for a therapeutic application already covered by an earlier marketing authorisation. By definition, the known product covered by such a patent is not a product placed on the market for the first time for the purposes of that provision. Although the condition set out in Article 3(a) of that regulation could, in principle, be fulfilled in such a situation, the condition provided for in Article 3(d) of that regulation is not fulfilled.

64. Abraxis points out, however, that Article 54(5), as currently worded, was added to the European Patent Convention only at the time of its 2000 revision, that is to say after the adoption of Regulation No 1768/92. Abraxis infers from this that inventions relating to the second and subsequent therapeutic uses of known products should now also benefit from the protection of the SPC regime in order to reflect that change. (70) That argument does not convince me, since such inventions were already regarded as patentable in accordance with the EPO case-law established as early as 1984. (71) That development was therefore not a new contextual factor which the legislature failed to anticipate when adopting Regulation No 1768/92 or, *a fortiori*, Regulation No 469/2009. As noted by the United Kingdom Government, the order in *Yissum*(72) had previously also concerned a situation in which the basic patent protected the second therapeutic use of a known active ingredient.

65. In short, paragraphs 12 and 29 of the Explanatory Memorandum mean that any patent which protects either a product as such, or a manufacturing process or an application of a known product, may be relied upon as a basic patent in support of an SPC application. It cannot, however, be extrapolated from this that any invention protected by such a patent may be covered by an SPC where the marketing authorisation relied upon for that purpose, although it is the first to fall within the scope of the protection conferred by the patent, is not the first marketing authorisation for the product at issue.

66. *In the second place*, paragraph 11 of the Explanatory Memorandum, read as a whole, is, in my view, intended to make clear that such changes to the medicinal product do not justify the grant of an SPC in that they do not modify the active ingredients and thus do not lead to the creation of a new product. This is particularly true of changes in relation to obtaining a new salt, ester or other derivative of the active ingredient — which constitute different forms of the '*active moiety*' of that active ingredient. (73) That consideration also underlies the case-law of the Court according to which an SPC covering an active ingredient also protects the derivatives of that active ingredient provided that they are protected by the basic patent, (74) it being understood that those derivatives are not then considered to be distinct active ingredients. However, in the event that the derivative obtained itself constitutes a new active ingredient which is the subject of a specific patent, an SPC could be granted for that derivative.

67. It is, in my opinion, from that perspective that it is necessary to understand recital 14 of Regulation No 1610/96, which Abraxis relies upon in order to establish the validity of the scope of protection of the basic patent test. That recital — which according to recital 17 of that regulation is also valid for the interpretation in particular of Article 3 of Regulation

No 469/2009 — states that '*the issue of a certificate for a product consisting of an active substance does not prejudice the issue of other certificates for derivatives (salts and esters) of the substance, provided that the derivatives are the subject of patents specifically covering them*'.

68. Indeed, a reading of recital 14 of Regulation No 1610/96 in the light of Article 1(8) and Article 3(d) of that regulation highlights that an SPC may be granted only on the basis of the first marketing authorisation covering an active ingredient or combination of specific active ingredients. (75) In those circumstances, that recital can be understood only as meaning that a derivative of an active ingredient already covered by an SPC may, where that derivative is specifically claimed by a patent, be the subject of another SPC, in so far as it is itself considered to be a new and distinct active ingredient. (76) That recital in no way suggests that any new formulation of a previously authorised active ingredient may be the subject of an SPC provided that it is covered by a basic patent.

69. It follows from all the foregoing considerations that the intention of the legislature, in establishing the SPC regime, was to protect not all pharmaceutical research sufficiently innovative to give rise to the grant of a patent and the marketing of a new medicinal product, but only research leading to the placing on the market for the first time of an active ingredient or a combination of active ingredients as a medicinal product. That research must be encouraged whatever its purpose, regardless of whether it concerns the product itself or a process to obtain or therapeutic use of that product.

2. Other considerations of a teleological and contextual nature

70. The approach adopted by the legislature inevitably denies the protection of an SPC to certain inventions, such as the formulation of nab-paclitaxel, which, although they concern a previously authorised product, constitute genuine therapeutic advances (77) and are subject to a considerable erosion of the effective duration of the patent by reason of the procedures to be carried out before commercial exploitation is possible. (78) In my view, however, that finding does not justify the creation by judicial decision of a test departing from the wording of Article 3(d) of Regulation No 469/2009 and from the intention of the legislature, on the basis of a different conception of the way in which it is appropriate to pursue the objectives of stimulating innovation and striking a balance between all the interests involved in the field of medicinal products. The following considerations strengthen my conviction in that regard.

71. *In the first place*, the actual impact of the SPC regime on innovation requires delicate economic assessments involving the consideration of a multiplicity of factors. (79) In that regard, although the argument put forward by Abraxis is based on the premiss that extending the scope of the protection conferred by the SPC would necessarily favour research into innovative medicinal products in the European Union, the accuracy of that premiss is disputed.

72. In particular, according to some recent studies, the grant of SPCs on the basis of marketing authorisations for medicinal products comprising active ingredients which have all been previously authorised may amplify a tendency, observed in the pharmaceutical industry, to concentrate research efforts on safer and more marginal innovations ('*incremental innovations*') rather than on risky innovations leading to real therapeutic breakthroughs ('*fundamental innovations*'). (80)

73. Moreover, the authors of the Max Planck Report argue that the decline in the research and development of new molecules in Europe, which the introduction of the SPC regime was aimed at remedying, was due to the particularly risky nature of those activities and the onerous nature of the pre-clinical tests and clinical trials necessary for the first placing on the market of an active ingredient. In the light of those factors, the effective duration of the patent was insufficient to ensure the continued profitability of that type of activity. However, the existence of such a market failure has not been documented as regards the research and development of new therapeutic applications of known active ingredients. (81)

74. Without taking any position in that debate, which would be beyond the scope of my duties, the existence of such a debate induces me to exercise prudence before drawing general conclusions on the adequacy or otherwise of the system adopted by the legislature with the objective of encouraging pharmaceutical research within the European Union.

75. *In the second place*, and in any event, it must be borne in mind that, by adopting the SPC regime, the legislature intended to achieve that objective in a manner which struck a balance between all the interests involved. That intention resulted in a general compromise between those various interests, under which *certain* patented inventions, namely those leading to the first placing on the market of an active ingredient or a combination of active ingredients as a medicinal product, may benefit from an SPC. Only the legislature has the power to change the weighting of the interests involved if it considers that, in the current context, the balance sought is no longer maintained by the system in place, in the light of developments in the pharmaceutical research sector.

76. Moreover, the compromise made by the legislature under the SPC regime is part of a broader legislative framework providing for varies types of incentives for research into new medicinal products. They include, in addition to intellectual property rights, legislative incentives such as the protection of data derived from pre-clinical tests and clinical trials (82) as well as the market exclusivity conferred by a marketing authorisation. (83)

77. *In the third place*, paragraph 16 of the Explanatory Memorandum states that the legislature intended to create a simple, transparent system which could easily be applied by the national patent offices responsible for granting SPCs. The rule that only the first marketing

authorisation for the product may be relied upon in support of an SPC application contributes to the pursuit of that objective. As, in essence, the United Kingdom Government, the Hungarian and Netherlands Governments, and also the Commission, have pointed out, to place on the national patent offices the burden of verifying whether the earlier marketing authorisations for the product fall within the scope of the protection conferred by the basic patent would depart from the logic governing that system.

78. *In the fourth place*, the literal interpretation of Article 3(d) of Regulation No 469/2009 cannot be dismissed on the basis of the objective of compensating for the delay in the commercial exploitation of a patented invention on account of the procedures necessary to obtain a marketing authorisation.

79. I would point out in that regard that a medicinal product containing a new active ingredient or a new combination of active ingredients must be authorised at the end of the procedure based on Article 8(3) of Directive 2001/83. (84) That procedure involves the submission of a full application for marketing authorisation, including the results of pre-clinical tests and clinical trials establishing the efficacy and safety of that medicinal product. (85) However, the marketing authorisation for a medicinal product which contains an active ingredient or a combination of active ingredients included in a reference medicinal product (when it does not constitute a generic of the latter medicinal product) (86) may be obtained at the end of the '*hybrid*' procedure provided for in Article 10(3) of that directive. That procedure allows the applicant for marketing authorisation, upon the expiry of the period of protection of the data derived from the pre-clinical tests and clinical trials provided in the submission of a marketing authorisation dossier for the reference medicinal product, to use those data without demonstrating independently the effectiveness and safety of the active ingredient. The applicant need then himself produce only the results of pre-clinical tests and clinical trials covering the changes made to the medicinal product at issue — concerning, in particular, the formulation or the therapeutic indications — by comparison with the reference medicinal product. (87)

80. However, certain medicinal products, such as Abraxane, containing a new formulation of a known active ingredient differ to such an extent from other medicinal products containing that active ingredient that their authorisation is subject to the procedure laid down in Article 8(3) of Directive 2001/83. (88) In the light of that consideration, Abraxis submits that the objective referred to in point 78 of this Opinion justifies conferring on the new formulation of a known active ingredient the protection of an SPC where the placing on the market of a medicinal product containing that formulation required the grant of a new marketing authorisation under the same conditions as a medicinal product containing a new active ingredient.

81. Both the wording of Article 3(d) of Regulation No 469/2009 and the case-law of the Court prevent me from concurring with that view. Indeed, that provision does not set out any criterion relating to the type of procedure followed for the purpose of obtaining a marketing authorisation. In accordance with that wording, the Court held in *Neurim* that Article 8(3) of Directive 2001/83, the subject matter of which is purely procedural, cannot affect the assessment of the substantive conditions which are laid down by Regulation No 469/2009. (89) Accordingly, the scope of Article 3(d) of that regulation does not depend on whether or not a full application for marketing authorisation has been required.

82. However, since the placing on the market of medicinal products containing a new product, within the meaning of Article 1(b) of Regulation No 469/2009, unlike the placing on the market of medicinal products consisting of new formulations of previously authorised products, *necessarily* requires the submission of a complete marketing authorisation dossier, that fact may help to explain the legislative choice to confine the benefit of the SPC to products placed on the market for the first time. In that regard, as is apparent from *Synthon*, (90) the protection conferred by the SPC is intended to offset the time taken to obtain a marketing authorisation, which requires '*long and demanding testing of the safety and efficacy of the medicinal product concerned*'. According to that explanation, the legislature sought to promote basic innovation, which requires particularly risky research and the commercial exploitation of which entails a particularly onerous authorisation procedure, while ensuring the simplicity and transparency of the SPC regime. To that end, the legislature used the fact that the active ingredient or combination of active ingredients was new as a '*proxy*' to demonstrate the existence of such innovation. (91)

83. From that perspective, although the authorisation of certain new formulations of known products is itself also subject to the procedure based on Article 8(3) of Directive 2001/83, the exclusion of the benefit of the SPC for such inventions appears to be inherent both in striking the overall balance sought by the legislature between the interests involved and in the functioning of the SPC regime, which the legislature intended to be simple and predictable.

84. It is ultimately for the legislature, if it deems it appropriate, to modify the system so as to protect all patented inventions whose commercial exploitation requires the submission of a full application for marketing authorisation under that provision, or even to favour more generally all research leading to the placing on the market of a medicinal product incorporating for the first time a patented invention. Likewise, it is solely within the discretion of the legislature to choose the approach to be adopted in order to implement such a modification and, in particular, the provision or provisions of Regulation No 469/2009 which should be amended for that purpose. I note in that regard that, in the context of the ongoing review procedure, the Commission has not proposed any amendment to Article 3 or Article 1(b) of that regulation. (92)

3. Preliminary conclusion

85. Having regard to all the foregoing considerations, I take the view that neither the objectives pursued by Regulation No 469/2009 nor its context supports an interpretation which departs from the wording of Article 3(d).

86. That finding leads me to propose the abandonment of the scope of protection of the basic patent test and a return to a literal interpretation of Article 3(d) of Regulation No 469/2009, in the light of Article 1(b) of that regulation. I am of the view that the restrictive reading by the Court, in its settled case-law, of the concept of 'product', within the meaning of Article 1(b) of that regulation, cannot be circumvented by means of a broad interpretation of the concept of 'first authorisation to place the product on the market as a medicinal product', within the meaning of Article 3(d) of that regulation.

87. My proposal means, inter alia, that the latter provision precludes the grant of an SPC in a situation, such as that at issue in the main proceedings, where the marketing authorisation relied upon in the SPC application, although the first to fall within the scope of a basic patent protecting the new formulation of a known active ingredient, is not the first marketing authorisation for that active ingredient.

88. In the alternative, and in the event that the Court does not wish to adopt such an approach, I shall examine below the options which might allow it to limit the application of the scope of protection of the basic patent test to specific situations.

C. The possibility, in the alternative, of limiting the application of the scope of protection of the basic patent test

89. *In the first place*, the United Kingdom Government and the Commission, in its written observations, take the view, in essence, that the scope of protection of the basic patent test applies where the invention protected by the patent at issue concerns a *new therapeutic use* of a known product. (93) Such a factual background characterised the cases which gave rise to *Neurim* and to the order in *Yissum*. (94) On the other hand, Article 3(d) of Regulation No 469/2009 precluded the grant of an SPC in situations where, as in particular in the case giving rise to *Massachusetts Institute of Technology* (95) or in the case in the main proceedings, the marketing authorisation at issue is the first to fall within the scope of a basic patent which protects a new formulation of a known product for a known therapeutic use of that product.

90. In the light of the foregoing, that interpretation remains at odds with the wording and objectives of Regulation No 469/2009. Moreover, the interested parties have not presented arguments capable of justifying a distinction between, on the one hand, inventions relating to a new therapeutic use of an already authorised active ingredient (where appropriate, in a new formulation) and, on the other hand, inventions relating to a new formulation of such an active ingredient for a known therapeutic use. I am also struggling to find such arguments.

91. First of all, neither the wording of the regulation nor the Explanatory Memorandum suggests that the legislature intended to favour research into new therapeutic applications for a known active ingredient over research into new formulations of such an active ingredient already covered by a marketing authorisation which enhance its efficacy or safety for known therapeutic indications. (96)

92. Next, it is difficult to justify and apply such a distinction from the perspective of patent law. Indeed, I would point out that under the European Patent Convention, as interpreted by the EPO, any new formulation of a known active ingredient, as well as any second or subsequent therapeutic application of such an active ingredient, whether or not it permits a new therapeutic indication, is capable of being patented. (97)

93. Lastly, it cannot be presumed, without a more in-depth examination of an economic and scientific nature, that the merits and risks associated with research and development concerning a new therapeutic use of a known active ingredient would exceed, in general at least, those involved in the research and development of a new formulation of such an active ingredient intended to improve its efficacy or safety for known therapeutic indications. (98) In particular, applications for marketing authorisation covering a new formulation of a previously authorised product, a new therapeutic indication for that product or a combination of both may, in principle at the very least, benefit from the hybrid procedure provided for in Article 10(3) of Directive 2001/83. (99)

94. *In the second place*, the Czech and Netherlands Governments have proposed confining the scope of *Neurim* to the specific cases in which the marketing authorisation relied upon in the SPC application, although not the first to cover the active ingredient at issue, is the first marketing authorisation for that active ingredient for the therapeutic use protected by the basic patent *and as a human medicinal product*.

95. In support of that line of argument, the Netherlands Government submits that the first placing on the market of a human medicinal product containing a given active ingredient, even though it has already been authorised as a veterinary medicinal product, necessarily requires the submission of a marketing authorisation dossier similar to that of a human medicinal product containing an active ingredient that has never been authorised.

96. In my opinion, on the one hand, that approach is not in keeping with the wording of the provisions of Regulation No 469/2009. Indeed, as the Court has already found in *Pharmacia Italia*, (100) that regulation does not distinguish in principle between marketing authorisations granted for human medicinal products and those for veterinary medicinal products. (101) In particular, the definition of 'medicinal product' in Article 1(a) of the regulation includes substances that can be administered to humans or to animals. Similarly, Article 2 of Regulation No 469/2009 provides that the regulation applies without distinction to any product protected by a patent and subject to an administrative

authorisation procedure under either Directive 2001/83 or Directive 2001/82. However, the legislature did not consider it appropriate to provide, in Article 3(d) of Regulation No 469/2009, that the marketing authorisation relied upon in support of the SPC application must be the first marketing authorisation covering the product at issue for a given (human or animal) population.

97. Moreover, the fact that the grant of the marketing authorisation relied upon in support of the SPC application required the submission of a complete dossier under Article 8(3) of Directive 2001/83 is not, I would point out, a decisive criterion for the purpose of the grant of an SPC. That fact is, at most, one of the reasons capable of explaining the choice of the legislature to restrict the benefit of the SPC to active ingredients or combinations of active ingredients placed on the market for the first time. (102)

98. However, in the alternative, and in the event that the Court does not adopt the principal interpretation which I have put forward, the interpretation advocated by the Czech and Netherlands Governments has certain advantages which lead me to propose that it be endorsed by the Court.

99. First, the regulatory argument put forward by the Netherlands Government seems to me, in spite of its limits, to be relevant in the light of the objective, pursued by Regulation No 469/2009, of compensating for the erosion of the protection conferred by a patent by reason of the length of the authorisation procedures for a new medicinal product constituting a basic innovation.

100. In that connection, I would point out that Directive 2001/83 does not permit use of the hybrid procedure on the basis of a reference veterinary medicinal product. (103) Consequently, the first placing on the market of a human medicinal product containing a particular active ingredient, even when that active ingredient is already authorised for veterinary use, is always subject to the submission of a full application for marketing authorisation under Article 8(3) of that directive. It therefore involves the same procedures as those required for the first placing on the market of a medicinal product composed of an active ingredient that has never been authorised for veterinary or human use, which is not necessarily the case with the first marketing authorisation covering a new therapeutic indication of a product previously authorised as a human medicinal product.

101. Moreover, where an invention leads to the first placing on the market of a product for a particular therapeutic indication and as a human medicinal product, it does not seem unreasonable to me to consider that that invention may, in principle, be regarded as a basic therapeutic advance. Thus, although the legislature did not specifically envisage the particular, and probably exceptional, kind of situations at issue in *Neurim*, the pursuit of the objectives referred to by that regulation would imply that the benefit of the SPC extends to such situations.

102. Secondly, that solution would promote the coherence of the Court's case-law by allowing *Neurim* to coexist alongside the judgments relating to the interpretation of the concept of 'product', within the meaning of Regulation No 469/2009, and the order in *Yissum*. (104)

103. That order covers situations in which the first marketing authorisation for an active ingredient concerns a therapeutic indication in human medicine and the second marketing authorisation for that active ingredient, although the first to cover a new therapeutic use protected by the basic patent, also relates to a human medicinal product. Those situations are, according to the interpretation of the Czech and Netherlands Governments, excluded from the scope of the test set out in *Neurim*. Article 3(d) of Regulation No 469/2009 therefore precludes the grant of an SPC in such situations.

104. I would add, for the sake of completeness, that *Pharmacia Italia*, (105) in which the Court refused to establish the intended use of the medicinal product as the decisive factor for the grant of an SPC, dealt with a situation in which both the first marketing authorisation for the active ingredient at issue, which covers a veterinary medicinal product, and the second marketing authorisation for that active ingredient, which concerns a human medicinal product, fall within the scope of the *same* basic patent protecting that active ingredient as such. In that situation, as has been emphasised by Abraxis and by the United Kingdom Government, the application of the scope of protection of the basic patent test would in any event lead to the rejection of the SPC application.

105. In the light of those considerations, I propose that the Court, in the alternative, hold that the scope of protection of the basic patent test applies only where a product previously authorised pursuant to Directive 2001/82 for a therapeutic indication in veterinary medicine is subsequently granted a marketing authorisation under Directive 2001/83 for a new therapeutic indication in human medicine. In such a situation, Article 3(d) of Regulation No 469/2009 does not preclude the grant of an SPC on the basis of that marketing authorisation, provided it is the first to fall within the scope of the protection conferred by the basic patent relied upon in support of the SPC application.

V. Conclusion

106. In the light of all the foregoing considerations, I propose that the Court give the following answer to the question referred by the High Court of Justice (England & Wales), Chancery Division (Patents Court), United Kingdom:

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 precludes the grant of such a certificate where the marketing authorisation relied upon in support of the application for a supplementary protection certificate under Article 3(b) of that regulation is not the first marketing authorisation for

the active ingredient or combination of active ingredients at issue as a medicinal product. This is so even in a situation, such as that at issue in the main proceedings, where the marketing authorisation relied upon is the first to cover the formulation protected by the basic patent relied upon in support of the application for a supplementary protection certificate under Article 3(a) of that regulation.

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(1) Original language: French.
(2) Regulation of the European Parliament and of the Council of 6 May 2009 (OJ 2009 L 152, p. 1).
(3) In accordance with Article 13 of Regulation No 469/2009, the term of the protection conferred by the SPC is equivalent to the period which elapsed between the date on which the application for the patent was lodged and the date of the first authorisation to place the product on the market in the European Union, reduced by a period of five years, it being understood that the duration of the SPC may not, in any event, exceed five years.
(4) Article 3(a) of Regulation No 469/2009.
(5) Article 3(b) of Regulation No 469/2009.
(6) Article 3(c) of Regulation No 469/2009.
(7) Judgment of 19 July 2012 (C‑130/11, EU:C:2012:489).
(8) See points 32 to 35 of this Opinion.
(9) Council Regulation of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ 1992 L 182, p. 1).
(10) Directive 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).
(11) Directive 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).
(12) Judgment of 4 May 2006 (C‑431/04, EU:C:2006:291, paragraph 25).
(13) See, also, order of 14 November 2013, *Glaxosmithkline Biologicals and Glaxosmithkline Biologicals, Niederlassung der Smithkline Beecham Pharma* (C‑210/13, EU:C:2013:762, paragraphs 28 to 30), and judgment of 15 January 2015, Forsgren (C‑631/13, EU:C:2015:13, paragraphs 23 to 25). The latter judgment stated that the therapeutic effect which a substance must produce on the body in order to be considered to be an '*active ingredient*' consists in '*a pharmacological, immunological or metabolic action of its own*'. The concept of '*active ingredient*' within the meaning of Article 1(b) of Regulation No 469/2009 thus corresponds to that of '*active substance*' as defined in Article 1(3a) of Directive 2001/83.
(14) Article 1(3b) of Directive 2001/83 defines the concept of '*excipient*' as '*any constituent of a medicinal product other than the active substance and the packaging material*'. In accordance with section 3.2.2.1 of Part 1 of Annex I to that directive, that concept includes adjuvants (see order of 14 November 2013, *Glaxosmithkline Biologicals and Glaxosmithkline Biologicals, Niederlassung der Smithkline Beecham Pharma* (C‑210/13, EU:C:2013:762, paragraphs 36 and 37)).
(15) See judgment of 4 May 2006, Massachusetts Institute of Technology (C‑431/04, EU:C:2006:291, paragraph 27), and order of 14 November 2013, Glaxosmithkline Biologicals and Glaxosmithkline Biologicals, Niederlassung der Smithkline Beecham Pharma (C‑210/13, EU:C:2013:762, paragraphs 29 and 30).
(16) See judgment of 4 May 2006, *Massachusetts Institute of Technology* (C‑431/04, EU:C:2006:291, paragraph 26), and order of 14 November 2013, *Glaxosmithkline Biologicals and Glaxosmithkline Biologicals, Niederlassung der Smithkline Beecham Pharma* (C‑210/13, EU:C:2013:762, paragraph 31).
(17) See judgment of 13 January 2017, [2017] EWHC 14 (Pat), paragraphs 55 to 59, annexed to the order for reference.
(18) Order of 17 April 2007 (C‑202/05, EU:C:2007:214, paragraph 18).
(19) Judgment of 19 October 2004 (C‑31/03, EU:C:2004:641, paragraph 20). In that judgment, the Court interpreted the concept of '*first [marketing authorisation] in the Community*' for the purposes of the transitional provision set out in Article 19(1) of Regulation No 1768/92. The Court held, referring to Article 1(b) and Article 3 of that regulation, that that transitional provision covered, without distinction, any marketing authorisation granted for a human or veterinary medicinal product. Accordingly, it precluded the grant in a Member State, on the basis of the marketing authorisation for a human medicinal product, of an SPC for an active ingredient already covered by the marketing authorisation for a veterinary medicinal product granted in another Member State before the date laid down in that transitional provision.
(20) Judgment of 24 November 2011 (C‑322/10, EU:C:2011:773, paragraph 40). See, also, the Opinion of Advocate General Trstenjak in *Neurim Pharmaceuticals (1991)* (C‑130/11, EU:C:2012:268, point 27), and, to that effect, judgment of 19 October 2004, *Pharmacia Italia* (C‑31/03, EU:C:2004:641, paragraph 19).
(21) Regulation of the European Parliament and of the Council of 23 July 1996 (OJ 1996 L 198, p. 30).
(22) Judgment of 10 May 2001 (C‑258/99, EU:C:2001:261, paragraph 24).
(23) Judgment of 10 May 2001, BASF (C‑258/99, EU:C:2001:261, paragraph 10 and paragraphs 27 to 29).
(24) Judgment of 10 May 2001, BASF (C‑258/99, EU:C:2001:261, paragraphs 36 and 37).
(25) See *Neurim*, paragraphs 22 to 24. See, also, the Opinion of Advocate General Trstenjak in *Neurim Pharmaceuticals (1991)* (C‑130/11, EU:C:2012:268, points 48 to 51).

(26) *Neurim*, paragraphs 12 to 15 and paragraphs 25 and 26. See, also, the Opinion of Advocate General Trstenjak in *Neurim Pharmaceuticals (1991)* (C‑130/11, EU:C:2012:268, point 7).
(27) *Neurim*, paragraph 26.
(28) *Neurim*, paragraph 24 and 25.
(29) *Neurim*, paragraphs 24 to 27.
(30) In that regard, Abraxis argues that the marketing authorisation for nab-paclitaxel includes a new therapeutic indication, namely the treatment of certain pancreatic cancers, which is not covered by the marketing authorisation for the medicinal products containing paclitaxel in another formulation (the remaining therapeutic indications of those medicinal products and Abraxane overlap). In my view, that fact, assuming it to be true, is irrelevant for the purposes of answering the question referred for a preliminary ruling in so far as, first, the basic patent does not contain any claim relating to the use of nab-paclitaxel in the treatment of pancreatic cancer. That patent refers, as is apparent in particular from claim 32, only to the use of that formulation in eliminating cancer cells — which constitutes a known therapeutic use of paclitaxel. Secondly, the answer I shall propose will not depend, in any event, on whether or not the new formulation of the active ingredient at issue makes use for a new therapeutic indication possible.
(31) See points 61 and 62 of this Opinion.
(32) The meaning of '*new therapeutic application*' within the meaning of the judgment in *Neurim* and its link with patent law is the subject of a request for a preliminary ruling from the Cour d'appel de Paris (Court of Appeal, Paris) (France) of 9 October 2018 (pending Case C-673/18).
(33) Opinion in *Neurim Pharmaceuticals (1991)* (C‑130/11, EU:C:2012:268).
(34) Order of 17 April 2007 (C‑202/05, EU:C:2007:214). It is apparent from paragraph 5 of that order that the basic patent at issue protected a combination which contained a previously authorised active ingredient and was intended for use in connection with a new therapeutic indication.
(35) Judgment of 4 May 2006 (C‑431/04, EU:C:2006:291). Paragraph 6 of that judgment reveals that the basic patent relied upon in the SPC application protected the alliance, for the treatment of brain tumours, of an excipient and an active ingredient already authorised for such use.
(36) See judgment of 4 May 2006, *Massachusetts Institute of Technology* (C‑431/04, EU:C:2006:291, paragraph 10), and order of 17 April 2007, *Yissum* (C‑202/05, EU:C:2007:214, paragraph 8).
(37) The Court did not adopt the teleological interpretation of Article 1(b) of Regulation No 469/2009 proposed by Advocate General Léger in his Opinion in *Massachusetts Institute of Technology* (C‑431/04, EU:C:2005:721, points 52 to 62). He had argued, in essence, that the purpose of that regulation is to protect any medicinal product that is the result of long, costly research. In his view, the combination of the active ingredient and the excipient at issue, conferring on the former new properties in terms of efficacy and safety, represented a '*major therapeutic advance*', so that it would have been '*regrettable [if it] were not protected in the same way as research into active ingredients alone*'.
(38) According to settled case-law, the Court may interpret provisions to which no reference is made in the wording of the questions referred for a preliminary ruling, with a view to providing an answer which will be of use to the national court. See, in particular, judgment of 19 September 2018, *González Castro* (C‑41/17, EU:C:2018:736, paragraph 54 and the case-law cited).
(39) Order of 14 November 2013 (C‑210/13, EU:C:2013:762, paragraph 44).
(40) Judgment of 4 May 2006 (C‑431/04, EU:C:2006:291, paragraphs 17 to 19 and paragraphs 21 to 29).
(41) Judgment of 15 January 2015 (C‑631/13, EU:C:2015:13, paragraphs 23, 26 and 52).
(42) The case which gave rise to the order of 14 November 2013, *Glaxosmithkline Biologicals and Glaxosmithkline Biologicals, Niederlassung der Smithkline Beecham Pharma* (C‑210/13, EU:C:2013:762, paragraphs 9 and 10) concerned two SPC applications, one relating to an adjuvant alone, the other relating to a vaccine composed of an active ingredient and that adjuvant. In the case which gave rise to the judgment of 15 January 2015, *Forsgren* (C‑631/13, EU:C:2015:13, paragraph 13), an SPC was sought on the basis of a patent protecting Protein D as such. The national courts asked whether such substances or combinations of substances constituted '*products*' within the meaning of Article 1(b) of Regulation No 469/2009. That said, it was not ruled out that, in any event, the SPC applications should have been granted if Article 3(d) of that regulation had been interpreted as referring to the first marketing authorisation covering the product as a medicinal product *and* falling within the scope of the protection conferred by the basic patent.
(43) *Study on the Legal Aspects of Supplementary Protection Certificates in the EU*, Final report published in 2018 ('*the Max Planck Report*'), available online at: https://publications.europa.eu/en/publication-detail/-/publication/6845fac2-6547-11e8-ab9C‑01aa75ed71a1/language-en/format-PDF/source-search, pp. 163 to 168 and pp. 229 and 230.
(44) Proposal for a Regulation of the European Parliament and of the Council of 28 May 2018 amending [Regulation No 469/2009], COM(2018) 317 final.
(45) However, it is too early to draw conclusions as to the interpretation of *Neurim* in each of the nine Member States in which Abraxis has obtained an SPC. That outcome could also be attributed to the fact that, because the procedural elements of the SPC regime have not been harmonised in their entirety, certain national patent offices do not of their own motion

verify compliance with the condition provided for in Article 3(d) of Regulation No 469/2009. See, in that regard, Max Planck Report, pp. 493 and 494, and Mejer, M., *25 years of SPC protection for medicinal products in Europe: Insights and challenges*, May 2017, available online at: https://ec.europa.eu/docsroom/documents/26001, pp. 4 and 13.

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

(47) Order of 17 April 2007 (C‑202/05, EU:C:2007:214). See points 38 and 39 of this Opinion.

(48) Judgment of 10 May 2001 (C‑258/99, EU:C:2001:261). See point 31 of this Opinion.

(49) At the hearing, the Commission seemed to have abandoned this view, proposing, in essence, to apply the test of the scope of the protection of the patent also when the patent at issue protects a new formulation of a known product which enables it to exercise new '*therapeutic effects*'.

(50) Order of 17 April 2007 (C‑202/05, EU:C:2007:214).

(51) See point 30 of this Opinion.

(52) See, by analogy, judgment of 3 September 2009, *AHP Manufacturing* (C-482/07, EU:C:2009:501, paragraph 27).

(53) See, in particular, judgments of 23 March 2000, *Met-Trans and Sagpol* (C‑310/98 and C‑406/98, EU:C:2000:154, paragraph 32); of 8 December 2005, *ECB v Germany* (C‑220/03, EU:C:2005:748, paragraph 31); and of 26 October 2006, *European Community* (C‑199/05, EU:C:2006:678, paragraph 42).

(54) As the Court found in the judgment of 13 July 1995, *Spain v Council* (C‑350/92, EU:C:1995:237, paragraph 34), at the time Regulation No 1768/92 was adopted, provisions establishing an SPC for medicinal products existed in two Member States and were at the draft stage in another Member State. As stated in recital 6 of Regulation No 469/2009, the creation of the SPC system also fulfilled the objective of ensuring within the European Union a level of protection of pharmaceutical research results no lower than that afforded in third countries. In that regard, paragraphs 6 and 15 of the Explanatory Memorandum of the Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products of 11 April 1990 (COM(90) 101 final) ('*the Explanatory Memorandum*'), which formed the basis for the adoption of Regulation No 1768/92, were evidence of the willingness to adapt EU legislation to that of the United States of America and Japan, where provision was already made for a regime to extend the duration of a patent. Other third States have since established comparable regimes.

(55) See the Opinion of Advocate General Trstenjak in *Neurim Pharmaceuticals (1991)* (C‑130/11, EU:C:2012:268, point 41).

(56) See footnote 54 of this Opinion.

(57) See, also, to that effect, judgment of 15 January 2015, *Forsgren* (C‑631/13, EU:C:2015:13, paragraph 52), cited in point 40 of this Opinion.

(58) The second subparagraph of paragraph 24 of the Explanatory Memorandum states: '*Each year, only about 50 new medicinal products are authorised worldwide. It is these that are covered by the proposal for a [Regulation].*'

(59) See, also, paragraph 31 of the Explanatory Memorandum to the Proposal for a European Parliament and Council Regulation (EC) concerning the creation of a supplementary protection certificate for plant protection products, 9 December 1994 (COM(94) 579 final).

(60) See, by analogy, paragraph 68 of the Explanatory Memorandum to the Proposal for a European Parliament and Council Regulation (EC) concerning the creation of a supplementary protection certificate for plant protection products, 9 December 1994 (COM(94) 579 final), which is referred to in paragraph 23 of the judgment of 4 May 2006, *Massachusetts Institute of Technology* (C‑431/04, EU:C:2006:291). See, also, to that effect, the second subparagraph of paragraph 46 and paragraph 56(1) of the Explanatory Memorandum.

(61) *Neurim*, paragraphs 24 to 27.

(62) Article 1(b) of the Proposal for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products, of 11 April 1990 (COM(90) 101 final) provided that any patent covering a product as such, a process to obtain it or an application of it or *a combination of substances* (that is to say a formulation) *containing the product* could give rise to the grant of an SPC. However, the definition of basic patent set out in Article 1(c) of Regulation No 1768/92 and Regulation No 469/2009 no longer refers to patents protecting the formulation of a product. In that regard, I would observe that a patent covering the formulation of a known product for a new and inventive therapeutic use is already included in the category of '*patents for applications*'. A new formulation of a known product for a known therapeutic use cannot, for its part, benefit from the protection of an SPC in so far as Article 3(d) of Regulation No 469/2009 precludes this in any event (see point 63 of this Opinion).

(63) In the same vein, the fourth subparagraph of paragraph 28 of the Explanatory Memorandum states that the basic patent may cover '*the active ingredient, the process by which the medicinal product is obtained, or an application or use of the medicinal product*'.

(64) See, to that effect, judgment of 25 July 2018, *Teva UK and Others* (C‑121/17, EU:C:2018:585, paragraph 31).

(65) See point 37 of this Opinion.

(66) A new formulation containing a known active substance constitutes a patentable '*combination of substances*' in accordance with the general criteria set out in Article 52(1) of the EPC. Indeed, although Article 53(c) the EPC excludes the patentability of methods of therapeutic treatment, that exception does

not cover '*substances or compositions*' for use in those methods. In that context, '*substances or compositions*' are not limited to substances which have a therapeutic effect of their own on the body or to combinations of such substances. See, to that effect, the decision of the Enlarged Board of Appeal of the EPO of 5 December 1984, *Pharmuka* (G-6/83, EP:BA:1984:G000683.19841205, paragraphs 10 and 20) and the decision of the Board of Appeal of the EPO of 12 January 2012, *Coloplast A/S* (T‑1099/09, EP:BA:2012:T109909.20120112, paragraph 4.3).

(67) Article 54(4) and (5) of the EPC thus qualifies the exception to the patentability of methods of therapeutic treatment provided for in Article 53(c) of that convention. As regards the patentability of second or subsequent therapeutic uses prior to the amendment of the EPC in 2000, see point 64 of this Opinion.

(68) See the EPO's explanations of the case-law of the Boards of Appeal, subsection concerning the patentability of '*Second (or further) medical use*', available online at: https://www.epo.org/law-practice/legal-texts/html/caselaw/2016/e/clr_i_c_7_2.htm. See, also, case-law cited in footnotes 69 and 71 of this Opinion.

(69) Decision of the Enlarged Board of Appeal of the EPO of 19 February 2010, *Abbott Respiratory LLC*, (G-2/08, EP:BA:2010:G000208.20100219, paragraph 5.10.3, 5.10.9 and 6.1). See, also, EPO Guidelines for Examination, subsection concerning '*Therapeutic uses pursuant to Art. 54(5)*', available online at: https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_vi_7_1_2.htm. According to those guidelines, Article 54(5) of the EPC covers any uses of a substance or composition based '*not only on the treatment of a different disease but also on the treatment of the same disease by a different therapeutic method differing for example in the dosage, administration regime, group of subjects or route of administration*'.

(70) That argument was also put forward by Advocate General Trstenjak in point 49 of her Opinion in *Neurim Pharmaceuticals (1991)* (C‑130/11, EU:C:2012:268).

(71) Decisions of the Enlarged Board of Appeal of the EPO of 5 December 1984, *Eisai* (G-5/83, EP:BA:1984:G000583.19841205) and *Pharmuka* (G-6/83, EP:BA:1984:G000683.19841205). That body held that it was possible to patent so-called '*Swiss-type*' claims, relating to the application of a substance or combination of substances in the manufacture of a medicinal product for a new and inventive therapeutic use.

(72) Order of 17 April 2007 (C‑202/05, EU:C:2007:214, paragraphs 11 and 20).

(73) According to its common meaning, '*active moiety*' means the molecule responsible for the physiological or pharmacological action of the chemical substance, to the exclusion of the appended portions of the molecule, which define it as a salt, an ester or other non-covalent derivative. That concept is relevant in relation to active ingredients taking various forms as salts, esters or other derivatives.

(74) See judgment of 16 September 1999, *Farmitalia* (C‑392/97, EU:C:1999:416, paragraphs 18 to 22). The same approach underlies recital 13 of Regulation No 1610/96, which states that '*the certificate confers the same rights as those conferred by the basic patent*', and that '*consequently, where the basic patent covers an active substance and its various derivatives (salts and esters), the certificate confers the same protection*'.

(75) See point 31 of this Opinion. According to settled case-law, the preamble to an EU act has no binding legal force and cannot be relied on as a ground for derogating from the actual provisions of that act. See judgments of 19 November 1998, *Nilsson and Others* (C‑162/97, EU:C:1998:554, paragraph 54); of 12 May 2005, *Meta Fackler* (C‑444/03, EU:C:2005:288, paragraph 25); and of 10 January 2006, *IATA and ELFAA* (C‑344/04, EU:C:2006:10, paragraph 76).

(76) The question as to the conditions under which the derivative of an active ingredient must in itself be considered to be a distinct active ingredient has not been addressed by the Court. Various approaches are conceivable. In particular, on the one hand, it could be argued that a derivative protected as such by a patent must necessarily be considered to be a new active ingredient. On the other hand, it has been argued that a derivative constitutes a new active ingredient within the meaning of the EU rules concerning SPCs in the same way as within the meaning of the EU rules on the placing on the market of medicinal products. See von Morze, H., '*SPCs and the "Salt" Problem No 2*', *Intellectual Property Quarterly*, No 4, 2010, pp. 375 and 376. See, also, to that effect, judgment of the Bundespatentgericht (Federal Patent Court, Germany) of 5 September 2017, 14 W (pat) 25/16, paragraph 5. In that regard, Article 10(2)(b) of Directive 2001/83 provides that the different salts, esters and other derivatives of an active ingredient are to be considered to be the same active ingredient unless they differ significantly in properties with regard to safety or efficacy. See, also, Commission, '*The rules governing medicinal products in the European Union*', *Notice to Applicants, Volume 2A, Procedures for marketing authorisation, Chapter 1*, June 2018 ('*the Notice to applicants for marketing authorisation*'), p. 32.

(77) As is clear from the Assessment Report for Abraxane adopted by the EMA's Committee for Medicinal Products for Human Use ('*the CHMP*'). (EMEA/47053/2008, p. 3), the marketing authorisation for that medicinal product was granted following the centralised authorisation procedure on the basis of Article 3(2)(b) of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1), on the ground that the medicinal product was a therapeutically significant innovation.

(78) As stated in the Assessment Report for Abraxane adopted by the CHMP (EMEA/47053/2008, p. 3), the authorisation procedure for Abraxane involved a full

application for marketing authorisation under Article 8(3) of Directive 2001/83.

(79) Those issues were the subject of a study commissioned by the Commission and authored by Copenhagen Economics, entitled *Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe*, the final report of which was published in May 2018 and is available online at: https://ec.europa.eu/health/sites/health/files/human-use/docs/pharmaceuticals_incentives_study_en.pdf.

(80) See Technopolis Group, *Effects of supplementary protection mechanisms for pharmaceutical products*, final report published on 15 June 2018, available online at: http://www.technopolis-group.com/report/effects-of-supplementary-protection-mechanisms-for-pharmaceutical-products/, pp. 87 to 90 and pp. 156 and 157. See, also, de Boer, R. W., *Supplementary protection certificate for medicinal products: An assessment of European regulation*, Vrije Universiteit Amsterdam, study commissioned by the Ministerie van Volksgezondheid, Welzijn en Sport (Ministry of Health, Well-being and Sport, Netherlands), available online at: http://www.spcwaiver.com/files/Netherlands_SPC_assessment.pdf, pp. 36 and 44 to 46.

(81) Max Planck Report, pp. 237 and 238 and pp. 630 and 631.

(82) According to the first subparagraph of Article 10(1) of Directive 2001/83, '*the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 6 for not less than eight years in a Member State or in the [the European Union]*'. Article 10(5) of that directive provides for an additional year of data protection in the event of the submission of an application for authorisation of a new therapeutic indication for which significant pre-clinical or clinical studies have been carried out. With regard to medicinal products authorised following the centralised procedure established by Regulation No 726/2004, Article 14(11) of that regulation grants an additional year of data protection if, in the first eight years of market exclusivity, the marketing authorisation holder obtains an authorisation for a new therapeutic indication with a significant clinical benefit in comparison with existing therapies.

(83) The second subparagraph of Article 10(1) of Directive 2001/83 provides that '*a generic medicinal product authorised pursuant to this provision shall not be placed on the market until ten years have elapsed from the initial authorisation of the reference product*'. The fourth subparagraph of that provision provides for an additional year of market exclusivity where, in the first eight years of market exclusivity, the marketing authorisation holder obtains an authorisation for a new therapeutic indication bringing a significant clinical benefit in comparison with existing therapies.

(84) For medicinal products containing a new combination of active ingredients used separately in the composition of previously authorised medicinal products, Article 10b of Directive 2001/83 requires that the results of pre-clinical tests and clinical trials relating to that combination are to be provided in accordance with Article 8(3)(i) of that directive. The scientific references relating to each individual active ingredient need not be provided. See, also, Notice to applicants for marketing authorisation, p. 38.

(85) See Annex I, second part, of Directive 2001/83.

(86) The authorisation procedure for a generic medicinal product, known as the '*abridged procedure*', is provided for in Article 10(1) of Directive 2001/83.

(87) See Notice to applicants for marketing authorisation, pp. 33 and 34.

(88) See footnote 78 of this Opinion.

(89) *Neurim*, paragraph 33.

(90) Judgment of 28 July 2011 (C‑195/09, EU:C:2011:518, paragraph 47).

(91) See, to that effect, inter alia, Max Planck Report, p. 238.

(92) Proposal for a Regulation of the European Parliament and of the Council of 28 May 2018 amending [Regulation No 469/2009], COM(2018) 317.

(93) The United Kingdom Government and the Commission have not indicated whether, in their view, the scope of protection of the basic patent test applies when the new 'therapeutic use' protected by the patent designates the use of the product for a new therapeutic indication or, more broadly, when any new therapeutic use within the meaning of Article 54(5) of the SPC is at issue (see points 61 and 62 of this Opinion). Given that those interested parties have not referred to the broad concept of '*therapeutic use*' within the meaning of that provision, I take their position to be an endorsement rather of the first of those approaches.

(94) Order of 17 April 2007 (C‑202/05, EU:C:2007:214).

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

(96) See point 52 et seq. of this Opinion.

(97) See points 61 and 62 of this Opinion.

(98) On the one hand, therapeutic indications of a medicinal product relate to various situations, including the treatment of illnesses, symptoms or groups of specific patients. The development of a new therapeutic indication for a medicinal product may or may not, depending on the case, bring a significant benefit in comparison with existing therapies (see footnotes 82 and 83 of this Opinion). On the other hand, as the facts in the main proceedings illustrate, certain new formulations of an already authorised active ingredient, in particular in the nano-medicinal product sector, considerably improve, in terms of safety of efficacy, the treatment of the same pathologies as those treated by means of existing formulations of that active substance. Moreover, a new formulation of a known product, protected by a patent for a very general therapeutic application, without the patent specifically mentioning the use for specific therapeutic indications,

may be used for therapeutic indications not covered by the earlier marketing authorisation for the product. According to Abraxis, that is the case for nab-paclitaxel inasmuch as the marketing authorisation for Abraxane mentions, amongst its therapeutic indications, the treatment of pancreatic cancer (an indication which, I note, is not specifically referred to in the basic patent, claim 32 of which covers the formulation in question for any '*use in eliminating cancer cells*').

(99) See points 79 and 80 of this Opinion.

(100) Judgment of 19 October 2004 (C‑31/03, EU:C:2004:641, paragraphs 18 to 20).

(101) See, also, to that effect, the Opinion of Advocate General Jacobs in *Pharmacia Italia* (C‑31/03, EU:C:2004:278, points 49 and 50).

(102) See points 78 to 83 of this Opinion.

(103) The opposite is not true: the applicant for a marketing authorisation for a veterinary medicinal product containing an active ingredient used in the composition of a human medicinal product authorised under Directive 2001/83 may refer to certain data provided in the application for marketing authorisation for the latter medicinal product (see Annex I, Title I, point C, of Directive 2001/82).

(104) Order of 17 April 2007 (C-202/05, EU:C:2007:214).

(105) Judgment of 19 October 2004 (C-31/03, EU:C:2004:641, paragraphs 11 and 20).