Reports of Cases

JUDGMENT OF THE COURT (Eighth Chamber)

15 January 2015*

(Reference for a preliminary ruling — Medicinal products for human use — Supplementary protection certificate — Regulation (EC) No 469/2009 — 'Active ingredient' — Pneumococcal conjugate vaccine — Paediatric use — Carrier protein — Covalent binding)

In Case C-631/13,

REQUEST for a preliminary ruling under Article 267 TFEU from the Oberster Patent- und Markensenat (Austria), made by decision of 28 August 2013, received at the Court on 2 December 2013, in the proceedings

Arne Forsgren

v

Österreichisches Patentamt,

THE COURT (Eighth Chamber),

composed of C. Toader, acting as President of the Eighth Chamber, E. Jarašiūnas and C.G. Fernlund (Rapporteur), Judges,

Advocate General: Y. Bot,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

— A. Forsgren, by D. Alge, Patentanwalt,

— the European Commission, by F. Bulst and G. Braun, acting as Agents,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

* Language of the case: German.

Judgment

1 This reference for a preliminary ruling concerns the interpretation of Article 1(b) and Article 3(a) and (b) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ 2009 L 152, p. 1).

2 The request has been made in proceedings between Mr Forsgren and the Österreichisches Patentamt (Austrian Patent Office) regarding the grant of a supplementary protection certificate ('the SPC').

Legal context

3 Article 1 of Regulation No 469/2009, entitled 'Definitions', is worded as follows:

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

(a) "medicinal product" means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;

(b) "product" means the active ingredient or combination of active ingredients of a medicinal product;

(c) "basic patent" means a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;

(d) "certificate" means the supplementary protection certificate;

…'

4 Article 2 of that regulation, entitled 'Scope', provides:

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

5 Under Article 3 of Regulation No 469/2009, entitled 'Conditions for obtaining a certificate':

'A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:

(a) the product is protected by a basic patent in force;

(b) a valid authorisation to place the product on the market [("a marketing authorisation")] 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 a certificate;

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

6 Article 4 of Regulation No 469/2009, entitled 'Subject-matter of protection', is worded as follows:

'Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.'

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

7 As can be seen from the documents placed before the Court, Mr Forsgren is the proprietor of a European patent (EP0594610B1; 'the basic patent') relating to 'Protein D – an IgD-binding protein of *Haemophilus influenzae*'.

8 Protein D is present in a pneumococcal vaccine for paediatric use named 'Synflorix'. The marketing of that product was authorised by Commission Decision C(2009) 2563 of 30 March 2009 granting marketing authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council for 'Synflorix — Pneumococcal polysaccharide conjugate vaccine (adsorbed)', a medicinal product for human use (OJ 2009 C 101, p. 3; 'the Synflorix marketing authorisation').

9 It can be seen from the wording of the marketing authorisation for Synflorix, in the version applicable at the material time, and, in particular, from the summary of the product characteristics set out in Annex I thereto that Synflorix is a vaccine composed of 10 pneumococcal polysaccharide serotypes which are conjugated to carrier proteins and adsorbed on to aluminium phosphate. In eight of those serotypes, Protein D is the carrier protein. The therapeutic indications set out in the marketing authorisation are as follows: 'Active immunisation against invasive disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae* in infants and children from 6 weeks up to 2 years of age'. Annex I to the marketing authorisation for Synflorix states that the excipients of that vaccine are sodium chloride and water for injections.

10 On 24 September 2009, Mr Forsgren applied to the Österreichisches Patentamt for an SPC for Protein D. That application was refused on the ground that Protein D was just an excipient.

11 The Board of Appeal of the Österreichisches Patentamt upheld that decision. The Board noted the therapeutic effect of Protein D against the *Haemophilus influenzae* bacterium. However, it found that Protein D was not present as such in Synflorix, but was covalently bonded to other active ingredients. Consequently, Protein D may not be authorised as a medicinal product within the meaning of Regulation No 469/2009.

12 Mr Forsgren lodged an appeal with the Oberster Patent- und Markensenat (Supreme Patent and Trade Mark Adjudication Tribunal; or 'the referring court') against the decision of the Board of Appeal of the Österreichisches Patentamt. He submits that Protein D has a therapeutic effect of its own and that, in a number of Member States, SPCs have been granted in relation to that product.

13 In its order for reference, the Oberster Patent- und Markensenat states that:

— Protein D is protected by a basic patent;

— no SPC has been granted in relation to that substance;

— a marketing authorisation has been granted in relation to Synflorix;

— Protein D present in Synflorix has two independent effects:

— as a vaccine against a middle ear inflammation caused by non-typable *Haemophilus influenzae* bacteria; and

— as an adjuvant to the substances effective against pneumococci (pneumococcal polysaccharides).

14 The referring court is of the opinion that the grant of an SPC depends only on whether Protein D may be regarded as an active ingredient of the medicinal product Synflorix. That court doubts that this is the case, for two reasons.

15 First of all, the referring court is uncertain whether the fact that Protein D is covalently bound to other substances precludes in all events the grant of an SPC. Unlike the circumstances in the cases which gave rise to the judgments in *Medeva* (C-322/10, EU:C:2011:773) and *Georgetown University and Others* (C-422/10, EU:C:2011:776), the active ingredient in relation to which the SPC was requested in the case before the referring court is present in the authorised medicinal product not alongside other active ingredients, but covalently bound to other active ingredients. In view of that molecular bond, the medicinal product contains a substance which differs from that in the basic patent.

16 According to the referring court, given that even the smallest of changes in a molecule can significantly alter its effects, *a fortiori*, the same is true where another substance is covalently bound thereto. That is possibly not the case here, however, inasmuch as Protein D, notwithstanding the covalent binding, has an independent immunogenic effect with respect to *Haemophilus influenzae*. In those circumstances, the referring court is inclined to find that an SPC may also be granted for an active ingredient protected by a basic patent where that active ingredient is present in the medicinal product only as part of a covalent bond with other substances.

17 Secondly, the referring court has doubts as to whether the fact that no marketing authorisation has been granted with respect to Protein D precludes the grant of an SPC. It is uncertain whether the marketing authorisation for Synflorix also covers Protein D for the purposes of the application of Article 3(b) of Regulation No 469/2009, since that authorisation only covers Protein D as a carrier protein and expressly mentions that there is no evidence of an independent effect as a vaccine against *Haemophilus influenzae*.

18 The referring court is uncertain whether, as a carrier protein, Protein D can give rise to the grant of an SPC. On the basis of the judgment in *Massachusetts Institute of Technology* (C-431/04, EU:C:2006:291), the referring court is of the opinion that the grant of an SPC is all the more unlikely since Protein D permits only the administration of an active ingredient.

19 The referring court also doubts that Protein D could give rise to the grant of an SPC, in the light of its enhancement of the effects of pneumococcal polysaccharides. That court is of the opinion that, since such an adjuvant effect is not covered by the wording of the marketing authorisation, that fact also precludes the grant of an SPC, independently of the Court's answer to the request for a preliminary ruling in the case which gave rise to the order in *Glaxosmithkline Biologicals and Glaxosmithkline Biologicals, Niederlassung der Smithkline Beecham Pharma* (C-210/13, EU:C:2013:762).

20 In those circumstances, the Oberster Patent- und Markensenat decided to stay proceedings and to refer to the Court the following questions for a preliminary ruling:

‘1. Under Article 1(b) and Article 3(a) and (b) of [Regulation No 469/2009], provided that the other conditions are met, may [an SPC] be granted for an active ingredient protected by a basic patent (in this case, Protein D) where that active ingredient is present in a medicinal product (in this case, Synflorix) as part of a covalent (molecular) bond with other active ingredients but none the less retains an effect of its own?

2. If Question 1 is answered in the affirmative:

(a) Under Article 3(a) and (b) of [Regulation No 469/2009], may [an SPC] be granted for the substance protected by the basic patent (in this case, Protein D) where that substance has a therapeutic effect of its own (in this case, as a vaccine against the *Haemophilus influenzae* bacterium) but the marketing authorisation for the medicinal product does not relate to that effect?

(b) Under Article 3(a) and (b) of [Regulation No 469/2009], may [an SPC] be granted for the substance protected by the basic patent (in this case, Protein D) where the marketing authorisation describes that substance as a ‘carrier’ for the actual active ingredients (in this case, pneumococcal polysaccharides), where the substance, as an adjuvant, enhances the effect of those substances, but where that effect is not expressly mentioned in the marketing authorisation for the medicinal product?’

Consideration of the questions referred

Question 1

21 By its first question, the referring court asks, in essence, whether Articles 1(b) and 3(a) of Regulation No 469/2009 must be interpreted as precluding the possibility that an active ingredient can give rise to the grant of an SPC on the sole ground that the active ingredient is covalently bound to other active ingredients forming part of a medicinal product.

22 Article 2 of Regulation No 469/2009 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 particular, in Directive 2001/83, may, under the terms and conditions provided for in that regulation, be the subject of an SPC.

23 ‘[P]roduct’ is defined in Article 1(b) of Regulation No 469/2009 as ‘the active ingredient or combination of active ingredients of a medicinal product’. However, the term ‘active ingredient’ is not defined in that regulation. That term also appeared in Article 1(b) of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ 1992 L 182, p. 1), which was repealed by Regulation No 469/2009, and a question relating to that provision has already been referred to the Court. The Court held on that occasion that it is generally accepted in pharmacology that the term ‘active ingredient’ does not cover substances forming part of a medicinal product which do not have an effect of their own on the human or animal body (see judgment in *Massachusetts Institute of Technology*, EU:C:2006:291, paragraph 18).

24 That interpretation was subsequently reproduced, in essence, by the EU legislature. Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 (OJ 2011 L 174, p. 74) amended Article 1 of Directive 2001/83 to the effect that the term ‘active substance’ — which must be understood as meaning ‘active ingredient’ (judgment in *Massachusetts Institute of Technology*,

EU:C:2006:291, paragraph 21) — is defined therein as 'any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis'.

25 It follows that the term 'active ingredient', for the purposes of applying Regulation No 469/2009, concerns substances producing a pharmacological, immunological or metabolic action of their own. Since Regulation No 469/2009 does not draw any distinction according to whether an active ingredient is covalently bound with other substances, it is not appropriate to exclude, on that ground, the grant of an SPC for such an active ingredient.

26 On the other hand, the Court has held that a substance which has no therapeutic effect of its own and which is used to obtain a certain pharmaceutical form of the medicinal product is not covered by the term 'active ingredient' and, consequently, cannot give rise to the grant of an SPC (judgment in *Massachusetts Institute of Technology*, EU:C:2006:291, paragraph 25).

27 The answer to the question whether a substance which is part of a medicinal product is an active ingredient within the meaning of Article 1(b) of Regulation No 469/2009 depends, therefore, on whether that substance has a pharmacological, immunological or metabolic action of its own, independently of any covalent binding with other active ingredients.

28 Accordingly, the answer to Question 1 is that Articles 1(b) and 3(a) of Regulation No 469/2009 must be interpreted as not precluding, in principle, the possibility that an active ingredient can give rise to the grant of an SPC where the active ingredient is covalently bound to other active ingredients which are part of a medicinal product.

Question 2(a)

29 By part (a) of its second question, the referring court asks, in essence, whether Article 3(b) of Regulation No 469/2009 precludes the grant of an SPC for an active ingredient whose therapeutic effect does not fall within the therapeutic indications covered by the wording of the marketing authorisation.

30 Mr Forsgren submits that the fact that a marketing authorisation does not expressly cover the use of an active ingredient for its own therapeutic effect does not preclude the grant of an SPC. Any answer to the contrary would fail to have proper regard for the aim of Regulation No 469/2009. Mr Forsgren submits that Protein D, aside from its action as a carrier protein, was used in Synflorix on account of its capacity to confer protection against infections caused by *Haemophilus influenza*. It is itself immunogenic and has a credible and specific therapeutic effect. The fact that the marketing authorisation for Synflorix does not mention that therapeutic effect is irrelevant. There is nothing in Regulation No 469/2009 to suggest such an obligation. Moreover, since the wording of a marketing authorisation may be amended over time, establishing a link between the SPC and the wording of the marketing authorisation would raise considerable practical difficulties.

31 The European Commission contends that, in order for an SPC to be granted, the marketing authorisation procedure for the product covered by the basic patent must have been successfully completed. In the absence of such a marketing authorisation, there is no reason for an extension of the term of the protection conferred by the patent. The Commission adds that the system established under Regulation No 469/2009 is intended to establish some simplicity and some transparency. That objective would not be achieved if the competent authority were required to verify by reference to sources other than the marketing authorisation whether the substance at issue is an active ingredient.

32 In that regard, it should be borne in mind that the grant of an SPC requires fulfilment of the four cumulative conditions set out in Article 3 of Regulation No 469/2009. That provision provides, in essence, that an SPC can be granted only if, at the date of the application, the product is protected by a basic patent in force and has not already been the subject of a certificate. In addition, that product must have been granted a marketing authorisation as a medicinal product which is still valid, in accordance with Directive 2001/83 or Directive 2001/82, as appropriate; and, lastly, that authorisation must be the first in relation to that product as a medicinal product.

33 It is also important to note that the SPC is designed to re-establish an adequate period of effective protection of the basic patent by permitting the holder to enjoy an additional period of exclusivity on the expiry of that patent, which is intended to compensate, at least in part, for the delay to the commercial exploitation of his invention by reason of the time which has elapsed between the date on which the application for the patent was filed and the date on which the first marketing authorisation in the European Union was granted (judgment in *Eli Lilly and Company*, C-493/12, EU:C:2013:835, paragraph 41 and the case-law cited).

34 It follows from the foregoing that, unless it has been granted a marketing authorisation as a medicinal product, a patented product may not give rise to the grant of an SPC.

35 In addition, Article 4 of Regulation No 469/2009 provides that the protection conferred by the certificate is to extend only to the product covered by the marketing authorisation 'for any use of the product as a medicinal product that has been authorised before the expiry of the certificate'. That provision implies that the use of a product which has not been authorised, as a medicinal product, by the marketing authorisation may not be covered by an SPC (see, to that effect, judgment in *Medeva*, EU:C:2011:773, paragraph 37). Consequently, an active ingredient whose therapeutic effects do not fall within the therapeutic indications for which a marketing authorisation was granted may not give rise to the grant of an SPC.

36 In that regard, the Court has held, in essence, that the protection conferred on a medicinal product by an SPC may be relied upon in order to oppose the marketing of a medicinal product containing the same active ingredient together with another active ingredient — after noting that those medicinal products had been authorised for the same therapeutic indication (see orders in *Novartis*, C-442/11, EU:C:2012:66, paragraphs 20 to 22, and *Novartis*, C-574/11, EU:C:2012:68, paragraphs 18 to 20).

37 As was pertinently noted by the referring court, the wording of Annex I to the marketing authorisation for Synflorix makes it clear that the therapeutic indications for which Synflorix was authorised are restricted to 'active immunisation against invasive disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae* in infants and children from 6 weeks up to 2 years of age'; that annex further states that 'there is insufficient evidence that Synflorix provides protection against … non-typeable *Haemophilus influenzae*'. It should further be noted that the European Public Assessment Report prepared by the European Medicines Agency ('EMEA') as part of the assessment of the application for a marketing authorisation for Synflorix (Assessment report for Synflorix, procedure No EMEA/H/C/000973; 'the European Public Assessment Report') states in that regard that '[s]ince the claim for protection against [acute otitis media] caused by non-typeable *H. influenzae* at this stage is not supported by clinical data there is no need for an assay of the protein D content in the specification at the level of the drug product.'

38 It therefore appears that, since no trial or data concerning the therapeutic effects of Protein D against *Haemophilus influenzae* was integrated into the marketing authorisation procedure, that procedure was not able to delay the commercial use of the basic patent. In such circumstances, the grant of an SPC is contrary to the aim pursued by Regulation No 469/2009, which is to offset, at least in part, the delay to the commercial use of a patented invention on account of the time needed for the first marketing authorisation in the European Union to be granted.

39 Accordingly, the answer to Question 2(a) is that Article 3(b) of Regulation No 469/2009 must be interpreted as precluding the grant of an SPC for an active ingredient whose effect does not fall within the therapeutic indications covered by the wording of the marketing authorisation.

Question 2(b)

40 By part (b) of its second question, the referring court asks whether Article 3(b) of Regulation No 469/2009 must be interpreted as precluding the grant of an SPC for a product referred to in the marketing authorisation of a paediatric vaccine as the carrier protein of an active ingredient, on the ground that that protein, as an adjuvant, enhances the effect of an active ingredient, without that effect being expressly mentioned in the marketing authorisation.

41 The Commission submits that, in the case which gave rise to the order in *Glaxosmithkline Biologicals and Glaxosmithkline Biologicals, Niederlassung der Smithkline Beecham Pharma* (EU:C:2013:762), the Court has already answered that question and has confirmed that a substance which has no therapeutic effect — such as an adjuvant — may not be regarded as a product within the meaning of Regulation No 469/2009.

42 It should be noted, however, that the wording of the marketing authorisation for Synflorix, in particular Annex I thereto, and pages 8, 13 and 14 of the European Public Assessment Report show that, in that medicinal product, aluminium phosphate is used as an adjuvant for adsorption purposes and that sodium chloride and water for injections are used as excipients. Notwithstanding the verifications to be carried out by the referring court, it therefore follows from the wording of the marketing authorisation for Synflorix, the validity of which has not been called into question, that Protein D is used in that medicinal product neither as an excipient nor as an adjuvant.

43 In those circumstances, the answer to Question 2(b) cannot, therefore, be inferred from the order in *Glaxosmithkline Biologicals and Glaxosmithkline Biologicals, Niederlassung der Smithkline Beecham Pharma* (EU:C:2013:762, paragraph 45), in which the Court held that Article 1(b) of Regulation No 469/2009 must be interpreted as meaning that, just as an adjuvant is not covered by the definition of 'active ingredient' within the meaning of that provision, so a combination of two substances, one of which is an active ingredient having therapeutic effects of its own, while the other, an adjuvant, enhances those therapeutic effects while having no therapeutic effect of its own, does not fall within the definition of 'combination of active ingredients' within the meaning of that provision.

44 Moreover, it should be noted that, under the terms of Article 1 of the marketing authorisation for Synflorix, that product is a pneumococcal polysaccharide conjugate vaccine (adsorbed). According to point 2.2 of the European Public Assessment Report, the 10 active substances in that medicinal product are the pneumococcal polysaccharide serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F, each of those polysaccharides being conjugated to a carrier protein (D, TT or DT).

45 In view of the foregoing, and in order to be in a position to answer Question 2(b) in a manner which may be useful to the referring court for the purposes of the decision to be given in the main proceedings, it is necessary to reformulate it in the light of the foregoing considerations and to consider that, by that question, the referring court is seeking, in essence, to establish whether a carrier protein conjugated to a pneumococcal polysaccharide used in a vaccine for paediatric use may be regarded as a 'product' within the meaning of Regulation No 469/2009, that is to say, as an 'active ingredient or combination of active ingredients of a medicinal product'.

46 Mr Forsgren observes that Protein D contributes to the induction of a specific immune response to the pneumococcal polysaccharides to which it is conjugated. That protein should, consequently, as a carrier protein, be considered to be an independent active ingredient. In that regard, Mr Forsgren relies on an analogy with the situation of safeners brought before the Court in *Bayer CropScience*

(C-11/13, EU:C:2014:2010). Consequently, Mr Forsgren suggests answering Question 2(b) to the effect that an SPC may be granted in relation to a substance referred to in the marketing authorisation as a carrier protein.

47 In that regard, it follows from paragraph 25 above that the term 'active ingredient', for the purposes of applying Regulation No 469/2009, relates to substances which produce a pharmacological, immunological or metabolic action of their own. It is thus apparent from the introduction to the European Public Assessment Report that unconjugated polysaccharide vaccines are not appropriate for the purpose of inducing an immunogenic response and memory in children of less than two years. On the other hand, according to the same report, where polysaccharide antigens are conjugated with a carrier protein, they may induce such effects.

48 In the light of those considerations, it is appropriate to establish whether a carrier protein used in a medicinal product, which does not have an immunogenic effect of its own that is covered by the wording of the marketing authorisation, may be categorised as an 'active ingredient' where, conjugated with a polysaccharide antigen by means of a covalent binding, it produces such an effect.

49 It must be stated that there is nothing in Regulation No 469/2009 that explicitly settles the matter.

50 Nor, contrary to the assertions made by Mr Forsgren, does an analogy with the judgment in *Bayer CropScience* (EU:C:2014:2010) make it possible to settle the question definitively. In the case which gave rise to that judgment, the issue, in essence, was whether a safener which was part of a plant protection product and which was combined with a herbicidal active substance could be considered to be a 'product' within the meaning of Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products (OJ 1996 L 198, p. 30) and, on that basis, give rise to the grant of an SPC. The Court answered that question in the affirmative, where that substance has a toxic, phytotoxic or plant protection action of its own, which may in particular be the case when acting on the metabolism of a plant.

51 It is appropriate, consequently, to refer to the fundamental objective of Regulation No 469/2009, which is to ensure sufficient protection to encourage pharmaceutical research, which plays a decisive role in the continuing improvement in public health (judgment in *Georgetown University and Others*, EU:C:2011:776, paragraph 24 and the case-law cited).

52 In addition, as can be seen in particular from subparagraphs 4 and 5 of paragraph 28 of the Explanatory Memorandum to the Proposal for a Council Regulation (EEC) of 11 April 1990, concerning the creation of a supplementary protection certificate for medicinal products [COM(90) 101 final], the protection conferred by an SPC is largely intended to cover the cost of research leading to the discovery of new 'products'.

53 In the light of the wording and purpose of Regulation No 469/2009, it must be held that Article 1(b) of that regulation does not permit an 'active ingredient' to be categorised as a carrier protein conjugated with a polysaccharide antigen by means of a covalent binding, unless it is established that it produces a pharmacological, immunological or metabolic action of its own. Ultimately, it is for the referring court to determine, in the light of all the facts of the dispute on which it is required to rule, whether, on the basis of those criteria, Protein D, conjugated with pneumococcal polysaccharides which form part of Synflorix, produces a pharmacological, immunological or metabolic action of its own, and whether that effect falls within the therapeutic indications covered by the wording of the marketing authorisation.

54 In view of all the foregoing, the answer to Question 2(b) is that Article 1(b) of Regulation No 469/2009 must be interpreted as meaning that a carrier protein conjugated with a polysaccharide antigen by means of a covalent binding may be categorised as an 'active ingredient' within the meaning of that

provision only if it is established that it produces a pharmacological, immunological or metabolic action of its own which is covered by the therapeutic indications of the marketing authorisation, a matter which it is for the referring court to determine, in the light of all the facts of the dispute in the main proceedings.

Costs

55 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 (Eighth Chamber) hereby rules:

1. **Articles 1(b) and 3(a) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as not precluding, in principle, the possibility that an active ingredient can give rise to the grant of a supplementary protection certificate where the active ingredient is covalently bound to other active ingredients which are part of a medicinal product.**

2. **Article 3(b) of Regulation No 469/2009 must be interpreted as precluding the grant of a supplementary protection certificate for an active ingredient whose effect does not fall within the therapeutic indications covered by the wording of the marketing authorisation.**

   Article 1(b) of Regulation No 469/2009 must be interpreted as meaning that a carrier protein conjugated with a polysaccharide antigen by means of a covalent binding may be categorised as an 'active ingredient' within the meaning of that provision only if it is established that it produces a pharmacological, immunological or metabolic action of its own which is covered by the therapeutic indications of the marketing authorisation, a matter which it is for the referring court to determine, in the light of all the facts of the dispute in the main proceedings.

[Signatures]