Court of Justice EU, 12 December 2013, Eli Lilly v HGS

PATENT - SPC

SPC possible on condition that active ingredient is covered by a functional formula that is identified in the claims of the patent

- **that Article 3(a) of Regulation No 469/2009 must be interpreted as meaning that, in order for an active ingredient to be regarded as 'protected by a basic patent in force' within the meaning of that provision, it is not necessary for the active ingredient to be identified in the claims of the patent by a structural formula. Where the active ingredient is covered by a functional formula in the claims of a patent issued by the EPO, Article 3(a) of that regulation does not, in principle, preclude the grant of an SPC for that active ingredient, on condition that it is possible to reach the conclusion on the basis of those claims, interpreted inter alia in the light of the description of the invention, as required by Article 69 of the EPC and the Protocol on the interpretation of that provision, that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question, which is a matter to be determined by the referring court.**

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Court of Justice EU, 12 December 2013

(M. Ilešič, C.G. Fernlund, A. Ó Caoimh, C. Toader (Rapporteur) and E. Jarašiūnas)

JUDGMENT OF THE COURT (Third Chamber)

12 December 2013(*)

"Medicinal products for human use – Supplementary protection certificate – Regulation (EC) No 469/2009 – Article 3 – Conditions for obtaining such a certificate – Concept of a 'product protected by a basic patent in force' – Criteria – Wording of the claims of the basic patent – Precision and specificity – Functional definition of an active ingredient – Structural definition of an active ingredient – European Patent Convention"

In Case C‑493/12,

REQUEST for a preliminary ruling under Article 267 TFEU from the High Court of Justice (England and Wales), Chancery Division (Patents Court) (United Kingdom), made by decision of 24 October 2012, received at the Court on 5 November 2012, in the proceedings

Eli Lilly and Company Ltd

v

Human Genome Sciences Inc.,

THE COURT (Third Chamber),

composed of M. Ilešič, President of the Chamber, C.G. Fernlund, A. Ó Caoimh, C. Toader (Rapporteur) and E. Jarašiūnas, Judges,

Advocate General: N. Jääskinen,

Registrar: L. Hewlett, Principal Administrator

having regard to the written procedure and further to the hearing on 12 September 2013,

after considering the observations submitted on behalf of:

– Eli Lilly and Company Ltd, by A. Waugh QC, T. Mitcheson, Barrister, and M. Hodgson, Solicitor,

–Human Genome Sciences Inc., by M. Tappin QC, J. Antcliff and P. Gilbert, lawyers,

–the United Kingdom Government, by J. Beeko, acting as Agent, and C. May, Barrister,

– the French Government, by D. Colas and S. Menez, acting as Agents,

–the Latvian Government, by I. Kalniņš and I. Ņesterova, acting as Agents,

– the European Commission, by F.W. Bulst and J. Samnadda, acting as Agents,

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

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Article 3 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 Eli Lilly and Company Ltd ('Eli Lilly') and Human Genome Sciences Inc. ('HGS'), directed at preventing HGS from obtaining any supplementary protection certificate ('SPC') on the basis of the basic patent held by HGS and a marketing authorisation ('MA') which Eli Lilly is intending to apply for, and indeed obtain, to place a medicinal product containing an antibody which it has produced and developed on the market.

Legal context

European Union law

3 Recitals 4, 5, 9 and 10 in the preamble to Regulation No 469/2009 read as follows:

'(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.

[…]

(9) The duration of the protection granted by the certificate should be such as to provide adequate

effective protection. For this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of 15 years of exclusivity from the time the medicinal product in question first obtains authorisation to be placed on the market in the Community.

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

4 Article 1 of Regulation No 469/2009, headed 'Definitions', provides as follows:

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

(a) "medicinal product" means any substance or combination of substances presented for treating or preventing disease in human beings ... ;

(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 [SPC];

[...]'

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

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

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

(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC [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)] [...] ;

(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.'

The European Patent Convention

6 Under the heading 'Extent of protection', Article 69 of the Convention on the Grant of European Patents, signed in Munich on 5 October 1973, in the version applicable at the material time in the main proceedings ('the EPC'), provides as follows:

'(1) The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims.

(2) For the period up to grant of the European patent, the extent of the protection conferred by the European patent application shall be determined by the claims contained in the application as published. However, the European patent as granted or as amended in opposition, limitation or revocation proceedings shall determine retroactively the protection conferred by the application, in so far as such protection is not thereby extended.'

7 Article 1 of the Protocol on the Interpretation of Article 69 of the EPC, which forms an integral part of the convention in accordance with Article 164(1) thereof, provides as follows:

'Article 69 should not be interpreted as meaning that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Nor should it be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties.'

8 Article 83 of the EPC provides as follows:

'The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.'

9 Article 84 of the EPC states that '[t]he claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description.'

United Kingdom law

10 Section 60 of the United Kingdom Patents Act 1977 ('UK Patents Act 1977'), headed 'Meaning of infringement', is worded as follows:

'(1) Subject to the provisions of this section, a person infringes a patent for an invention if, but only if, while the patent is in force, he does any of the following things in the United Kingdom in relation to the invention without the consent of the proprietor of the patent, that is to say:

(a) where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;

[...]

(2) Subject to the following provisions of this section, a person (other than the proprietor of the patent) also infringes a patent for an invention if, while the patent is in force and without the consent of the proprietor, he supplies or offers to supply in the United Kingdom a person other than a licensee or other person entitled to work the invention with any of the means, relating to an essential element of the invention, for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those

means are suitable for putting, and are intended to put, the invention into effect in the United Kingdom.'

11 The other relevant provisions of the UK Patents Act 1977 provide as follows:

'Section 125 – Extent of invention

(1) For the purposes of this Act an invention for a patent for which an application has been made or for which a patent has been granted shall, unless the context otherwise requires, be taken to be that specified in a claim of the specification of the application or patent, as the case may be, as interpreted by the description and any drawings contained in that specification, and the extent of the protection conferred by a patent or application for a patent shall be determined accordingly.

[...]

(3) The Protocol on the Interpretation of Article 69 of the European Patent Convention (which Article contains a provision corresponding to subsection (1) above) shall, as for the time being in force, apply for the purposes of subsection (1) above as it applies for the purposes of that Article.

[...]

Section 130 – Interpretation

[...]

(7) Whereas by a resolution made on the signature of the Community Patent Convention the governments of the Member States of the European Economic Community resolved to adjust their laws relating to patents so as (among other things) to bring those laws into conformity with the corresponding provisions of the European Patent Convention, the Community Patent Convention and the Patent Cooperation Treaty, it is hereby declared that the following provisions of this Act, that is to say, sections 1(1) to (4), 2 to 6, 14(3), (5) and (6), 37(5), 54, 60, 69, 72(1) and (2), 74(4), 82, 83, 100 and 125, are so framed as to have, as nearly as practicable, the same effects in the United Kingdom as the corresponding provisions of the European Patent Convention, the Community Patent Convention and the Patent Cooperation Treaty have in the territories to which those Conventions apply.'

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

12 HGS is the holder of European Patent (UK) No 0 939 804 ('HGS's patent'), which was filed on 25 October 1996, issued on 17 August 2005 by the European Patents Office ('EPO') and is due to expire on 25 October 2016. The patent relates to the discovery of a new protein, namely Neutrokine alpha (α). The patent discloses and claims, inter alia, that protein. It is apparent from the patent claims that the patent also relates to antibodies that bind specifically to that protein. Neutrokine-α acts as an intercellular mediator in inflammation and immune response, so that too much or too little of that protein is associated with diseases of the immune system. Thus, antibodies that bind specifically to Neutrokine-α may inhibit its activity and be useful in the treatment of autoimmune diseases.

13 Claims 13, 14 and 18 of HGS's patent are worded as follows:

'13. An isolated antibody or portion thereof that binds specifically to:

(a) the full length Neutrokine-α polypeptide (amino acid sequence of residues 1 to 285 of SEQ ID No: 2); or

(b) the extracellular domain of the Neutrokine-α polypeptide (amino acid sequence of residues 73 to 285 of SEQ ID No: 2).

14. The antibody or portion thereof of claim 13 which is selected from the group consisting of:

(a) a monoclonal antibody;

[...]

18. A pharmaceutical composition comprising ... the antibody or portion thereof of any one of claims 13 to 17 and, optionally, a pharmaceutically acceptable carrier.'

14 Eli Lilly wishes to market a pharmaceutical composition which may be used in the treatment of autoimmune diseases. That composition contains as its active ingredient an antibody that binds specifically to Neutrokine-α, which Eli Lilly refers to as LY2127399 (now also known as Tabalumab). According to the referring court, Eli Lilly recognises that if it marketed that composition before the expiry of HGS's patent, antibody LY2127399 would infringe claim 13 of that patent.

15 The referring court concludes from this that antibody LY2127399 is an antibody as defined in claim 13 of HGS's patent, namely an isolated antibody or portion thereof which binds specifically to Neutrokine-α polypeptide. Any pharmaceutical composition containing LY2127399 is therefore a pharmaceutical composition as defined in claim 18 of that patent and is therefore protected by that claim.

16 Eli Lilly brought an action before the referring court for a declaration that any SPC relying, for its legal basis, on HGS' patent and based on an MA for a medicinal product containing LY2127399 would be invalid. It argues in that regard that that antibody is not covered by a 'basic patent' within the meaning of Article 3 of Regulation No 469/2009, in so far as claim 13 of HGS's patent is too broadly drafted for it to be possible for that antibody to be regarded as being 'specified', for the purpose of the test set out in Case **C-322/10 Medeva [2011] ECR I-12051**, in the wording of the claims of that patent. Indeed, that claim, which refers to *'an isolated antibody or portion thereof that binds [...] to the full-length Neutrokine-α polypeptide [...] or the extracellular domain of the Neutrokine-α polyeptide'*, does not provide any description of the antibody in question, in particular as regards the specific primary antibody sequence, and fails to disclose any functional information as to which Neutrokine-α epitopes it is claimed the antibody binds or which neutralising activity it is claimed it exerts.

17 Thus, according to Eli Lilly, in order for an SPC to be granted on the basis of HGS's patent, the patent would have to contain a structural definition of the

active ingredients and the claims would have to be significantly more specific.

18 Claim 13 of HGS's patent is broadly worded, covering a large number of antibodies. However, as Eli Lilly observed before the referring court, in other patent applications filed by HGS relating to the antibody that binds to Neutrokine-α, HGS's claims were more specifically and precisely worded, clearly specifying an antibody in terms of its primary amino acid sequence. Thus, European Patent No 1 294 769, filed on 15 June 2001 and relied on by HGS in support of the SPC application submitted on 10 January 2012 for the product BENLYSTA (belimumab), which obtained an MA for the European Union on 13 July 2011, refers to an antibody based on the amino acid sequence of the variable heavy chain and the variable light chain of HGS's monoclonal antibody to Neutrokine-α. Moreover, Divisional Patent Nos 10165 182.2 and 10185 178.0 of European Patent No 1 294 769 also contained specific claims of that kind.

19 On the other hand, in HGS's patent at issue in the main proceedings, the antibody is defined functionally, but not structurally, the definition thus covering an unknown number of otherwise unspecified antibodies. This is the broadest way of claiming an antibody. Furthermore, the specification for that patent does not contain any example of an antibody having been made or tested. Finally, nor does that patent contain any structural description of antibodies which might function as therapeutic antibodies.

20 In response, HGS claims that an SPC could be validly granted on the basis of its basic patent and any MA granted for a medicinal product containing LY2127399. It points out that its patent has been found to be valid by both the Board of Appeal of the EPO in decision T-18/09 of 21 October 2009 and by the courts of the United Kingdom, namely the Supreme Court, by judgment of 2 November 2011, and the Court of Appeal, by judgment of 5 September 2012. Those judicial bodies found, inter alia, that the claims of that patent are novel, inventive, susceptible of industrial application and sufficient, that is to say, HGS's patent discloses the claimed inventions clearly and completely enough for them to be performed by a person skilled in the art.

21 According to HGS, that patent uses standard forms of claim that are routinely granted by the EPO in cases involving patents for new proteins and antibodies that bind to them. It is standard practice that antibodies binding to previously unidentified proteins are considered novel and inventive. That justifies broad antibody per se protection being obtained where the basic patent contains claims which expressly refer to 'an antibody capable of binding to [the novel protein]'. As observed by the referring court, patent law therefore recognises that claims, such as claim 13 of HGS's patent, to antibodies that specifically bind to a novel protein are valid and, even though they cover multiple antibodies, they provide an appropriate and justified level of protection for the invention. In such a case, the inventor has discovered a novel target protein and, for the first time, has enabled those skilled in the art to produce the protein and the antibodies which bind to that target protein. It is recognised by European patent law that it is neither appropriate nor necessary to require such inventors to provide a more specific, structural definition of the antibodies in their claims.

22 For those reasons, HGS contends that an SPC may be validly granted to it on the basis of its basic patent and any future MA obtained by Eli Lilly for LY2127399. HGS states that the criteria proposed by Eli Lilly – to the effect that a structural definition is necessary in order for a product to be regarded as being protected by a basic patent within the meaning of Article 3(a) of Regulation No 469/2009 – fails to take account of the fact that claims to an antibody defined functionally are usually accepted by the EPO and routinely used in support of SPC applications.

23 In those circumstances, the High Court of Justice (England and Wales), Chancery Division (Patents Court) decided to stay proceedings and refer the following questions to the Court for a preliminary ruling:

'(1) What are the criteria for deciding whether "the product is protected by a basic patent in force" in Article 3(a) of Regulation [No 469/2009]?

(2) Are the criteria different where the product is not a combination product, and if so, what are the criteria?

(3) In the case of a claim to an antibody or a class of antibodies, is it sufficient that the antibody or antibodies are defined in terms of their binding characteristics to a target protein, or is it necessary to provide a structural definition for the antibody or antibodies, and if so, how much?'

Consideration of the questions referred

24 By its three questions, which it is appropriate to consider together, the referring court asks, in essence, whether Article 3(a) of Regulation No 469/2009 must be interpreted as meaning that, in order for an active ingredient to be regarded *as 'protected by a basic patent in force'* within the meaning of that provision, the active ingredient must be identified in the claims of the patent by a structural formula, or whether the active ingredient may also be considered to be protected where it is covered by a functional formula in the patent claims.

25 In that context, in the absence of case-law from the Court specifically concerning that aspect of the protection of a single active ingredient, the referring court is uncertain whether the criteria for determining whether a *'product is protected by a basic patent in force'* within the meaning of Article 3(a) of Regulation No 469/2009 are different when the 'product', within the meaning of Article 1(b) of the regulation, is a single active ingredient, as opposed to a combination of active ingredients.

26 Whereas HGS maintains that a product may be regarded as being identified in the claims of a basic patent and thus protected by the patent where the product is identified by means of a functional formula or definition, including an indication that it forms part of a specific therapeutic class, Eli Lilly is of the view

that, in order to enjoy such protection, the active ingredient must be adequately identified and described in the descriptions and claims of the basic patent, which is not the case in the main proceedings. Accordingly, Eli Lilly submits that, in this case, in the light of Article 3(a) of Regulation No 469/2009, the active ingredient tabalumab, which it has developed, is neither identified nor 'protected' by HGS's patent, in spite of the fact that, during the lifetime of that patent, it cannot place that active ingredient on the market without infringing HGS's patent.

27 The French and Latvian Governments and the European Commission are also essentially of that view. The Latvian Government states, in particular, that even though the use of a functional definition or formula of an active ingredient is not in itself an obstacle to the grant of an SPC, in order for an active ingredient to be regarded as being protected by a basic patent in force, it is none the less still necessary for the active ingredient to be defined more specifically in the descriptions of the patent, so that it may be clearly identified. Where appropriate, the holder of such a patent should specify his invention in subsequent patents, in particular divisional patents.

28 The French Government is of the view that, for the purpose of the application of Article 3(a) of Regulation No 469/2009, inspiration should be drawn from the rules of the EPC, in particular Articles 69 and 83 of that convention, and the Protocol on the interpretation of Article 69 of the convention. Of greatest importance is the fact that, in the light of the description of the invention in the basic patent, the claims of that patent should unambiguously refer to the active ingredient for which an SPC is sought. Where necessary, it is for the patent holder to characterise more precisely one or more selected antibodies in subsequent patents which are sufficiently precise to enable an SPC to be granted on that basis.

29 The Commission acknowledges that to insist upon a literal reference to the active ingredient in the claims of a basic patent would be unduly restrictive. However, that institution is of the view that, for a competent person and on the basis of the general knowledge of a person skilled in the art, it should be immediately evident from the claims of a basic patent that the active ingredient for which an SPC is sought is actually claimed by that patent. For the purposes of the application of Article 3(a) of Regulation No 469/2009, inspiration should be sought, inter alia, from the criteria established by the EPO regarding the admissibility of corrections to be made to European patents.

30 In that regard, it should be noted that, under European law as it applied at the material time in the main proceedings, provisions concerning patents had not been made the subject of any kind of harmonisation at European Union level or of any approximation of laws (see **Medeva, paragraph 22 and the case-law cited**), although, since that time, Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection (OJ 2012 L 361, p. 1) and the Agreement on a Unified Patent Court (OJ 2013 C 175, p. 1), which may be applicable in the future, pursuant to Article 3(b) of that agreement, to SPCs granted on the basis of Regulation No 469/2009, have been adopted.

31 Since no harmonised European Union patent rules are applicable in the main proceedings, the extent of the protection conferred by a basic patent can be determined only in the light of the non‑European Union rules governing patents (**Medeva, paragraph 23 and the case-law cited**).

32 It must be borne in mind that the rules for determining what is protected by a basic patent for the purpose of Article 3(a) of Regulation No 469/2009 are those relating to the extent of the invention covered by such a patent, such as the rules laid down in the main proceedings in section 125 of the UK Patents Act 1977. Where the patent in question has been granted by the EPO, those rules are also the rules laid down in the EPC and Protocol on the Interpretation of Article 69 of that convention.

33 On the other hand, as is apparent from the response given by the Court to questions 1 to 5 in the case which gave rise to the judgment **in Medeva**, for the purpose of determining whether a product is 'protected by a basic patent in force' within the meaning of Article 3(a) of Regulation No 469/2009, recourse may not be had to the rules governing infringement proceedings, such as, in the main proceedings, those laid down in section 60 of the UK Patents Act 1977.

34 By finding that Article 3(a) of Regulation No 469/2009 precludes the grant of an SPC relating to active ingredients which are not specified in the claims of a basic patent (see **Medeva, paragraph 25**, and the orders in Case **C-630/10 University of Queensland and CSL [2011] ECR I‑12231, paragraph 31**, and Case C-6/11 Daiichi Sankyo [2011] ECR I‑12255, paragraph 30), the Court emphasised the key role played by the claims for the purpose of determining whether a product is protected by a basic patent within the meaning of that provision.

35 The importance of those claims is also borne out by the second subparagraph of paragraph 20 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), which, in so far as concerns what is *'protected by the basic patent'*, refers expressly and solely to the claims of the basic patent. The importance of such claims is also confirmed by recital 14 in the preamble to 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), which refers, with regard to the issue of an SPC in the field of plant protection, to the need for '*products'* to be *'the subject of patents specifically covering them*' (see Medeva, paragraph 27).

36 In the main proceedings, it is common ground that the active ingredient tabalumab, namely LY2127399, is

not expressly named in the claims of HGS's patent. Moreover, it would appear that it is not otherwise specified in the descriptions or specifications of that patent and cannot, therefore, be identified as such.

37 With regard to the fact that the marketing of that active ingredient by Eli Lilly during the lifetime of HGS's patent would constitute an infringement of the patent, it is clear, in the light of what has been stated at paragraphs 32 and 33 above, that that is not a crucial factor, for the purpose of granting an SPC on the basis of Regulation No 469/2009, in particular Article 3(a) of that regulation, in the determination of whether that active ingredient is protected by that patent.

38 It should be recalled that, in accordance with the case-law cited at paragraph 34 above, an active ingredient which is not identified in the claims of a basic patent by means of a structural, or indeed a functional definition cannot, in any event, be considered to be protected within the meaning of Article 3(a) of Regulation No 469/2009.

39 With regard to the question whether the use of a functional definition may alone be sufficient, it should be noted that Article 3(a) of Regulation No 469/2009 does not, in principle, preclude an active ingredient which is given a functional definition in the claims of a patent issued by the EPO being regarded as protected by the patent, on condition that it is possible to reach the conclusion on the basis of those claims, interpreted inter alia in the light of the description of the invention, as required by Article 69 of the EPC and Protocol on the interpretation of that provision, that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question.

40 With regard to the requirements laid down by the EPC, it should, however, be noted that the Court does not have jurisdiction to interpret the provisions of that convention, since, unlike the Member States, the European Union has not acceded to the convention. The Court cannot, therefore, provide further guidance to the referring court concerning the manner in which it is determine the extent of the claims of a patent issued by the EPO.

41 Moreover, it should be recalled that the SPC is designed simply to re‑establish a sufficient 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 MA in the European Union was granted (Case **C-229/09 Hogan Lovells International [2010] ECR I-11335, paragraph 50**; Case C-443/12 Actavis Group PTC and Actavis UK [2013] ECR I‑0000, paragraph 31; and Case C‑484/12 Georgetown University [2013] ECR I‑0000, paragraph 36).

42 As stated in recital 4 in the preamble to Regulation No 469/2009, the purpose of that additional period of exclusivity is to encourage research and, to that end, it is designed to ensure that the investments put into such research are covered.

43 In the light of the objective of Regulation No 469/2009, the refusal of an SPC application for an active ingredient which is not specifically referred to by a patent issued by the EPO relied on in support of such an application may be justified – in circumstances such as those in the main proceedings and as observed by Eli Lilly – where the holder of the patent in question has failed to take any steps to carry out more in-depth research and identify his invention specifically, making it possible to ascertain clearly the active ingredient which may be commercially exploited in a medicinal product corresponding to the needs of certain patients. In such a situation, if an SPC were granted to the patent holder, even though – since he was not the holder of the MA granted for the medicinal product developed from the specifications of the source patent – that patent holder had not made any investment in research relating to that aspect of his original invention, that would undermine the objective of Regulation No 469/2009, as referred to in recital 4 in the preamble thereto.

44 In the light of the foregoing considerations, the answer to the questions referred is that Article 3(a) of Regulation No 469/2009 must be interpreted as meaning that, in order for an active ingredient to be regarded as 'protected by a basic patent in force' within the meaning of that provision, it is not necessary for the active ingredient to be identified in the claims of the patent by a structural formula. Where the active ingredient is covered by a functional formula in the claims of a patent issued by the EPO, Article 3(a) of that regulation does not, in principle, preclude the grant of an SPC for that active ingredient, on condition that it is possible to reach the conclusion on the basis of those claims, interpreted inter alia in the light of the description of the invention, as required by Article 69 of the EPC and the Protocol on the interpretation of that provision, that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question, which is a matter to be determined by the referring court.

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 (Third Chamber) hereby rules:

Article 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 meaning that, in order for an active ingredient to be regarded as 'protected by a basic patent in force' within the meaning of that provision, it is not necessary for the active ingredient to be identified in the claims of the patent by a structural formula. Where the active

ingredient is covered by a functional formula in the claims of a patent issued by the European Patents Office, Article 3(a) of that regulation does not, in principle, preclude the grant of a supplementary protection certificate for that active ingredient, on condition that it is possible to reach the conclusion on the basis of those claims, interpreted inter alia in the light of the description of the invention, as required by Article 69 of the Convention on the Grant of European Patents and the Protocol on the interpretation of that provision, that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question, which is a matter to be determined by the referring court.