Court of Justice EU, 12 December 2013, Actavis v Sanofi

PATENT LAW

Situation differs from Biogen and AHP Manufacturing: namely whether such a patent may permit its holder to obtain more than one SPC

- **However, the main proceedings concern a different situation.** They entail a situation in which the same patent may be regarded as protecting a number of products within the meaning of Article 3(a) of Regulation No 469/2009, thus raising a different question from those referred in, inter alia, the cases which gave rise to the decisions in **Biogen** and **AHP Manufacturing**, namely whether such a patent may permit its holder to obtain more than one SPC.

No new SPC possible in case the holder of a patent each time he places a medicinal product on the market containing a (1) principle active ingredient, protected by the basic patent and (2) another active ingredient which is not protected by the patent

- **However, in circumstances such as those in the main proceedings, even if the condition laid down in Article 3(a) of Regulation No 469/2009 were satisfied, for the purpose of the application of Article 3(c) of that regulation, it cannot be accepted that the holder of a basic patent in force may obtain a new SPC, potentially for a longer period of protection, each time he places on the market in a Member State a medicinal product containing, on the one hand, the principle active ingredient, protected as such by the holder's basic patent and constituting, according to the statements of the referring court, the core inventive advance of that patent, and, on the other, another active ingredient which is not protected as such by that patent.**

31 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 his 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, and **Georgetown University**, paragraph 36).

32 In the main proceedings, Sanofi's patent, which protects the active ingredient irbesartan as such within the meaning of Article 3(a) of Regulation No 469/2009, has already enabled its holder to obtain an SPC relating to that active ingredient. Moreover, it is common ground that hydrochlorothiazide, an active ingredient that is a member of a class of diuretics, is not protected as such by that patent or indeed by any other patent.

Basic objective of Regulation No 469/2009 is to compensate for the delay to the marketing of what constitutes the core inventive advance that is the subject of the basic patent

It should be recalled that the basic objective of Regulation No 469/2009 is to compensate for the delay to the marketing of what constitutes the core inventive advance that is the subject of the basic patent, namely, in the main proceedings, irbesartan. In the light of the need, referred to in recital 10 in the preamble to that regulation, to take into account all the interests at stake, including those of public health, if it were accepted that all subsequent marketing of that active ingredient in conjunction with an unlimited number of other active ingredients, not protected as such by the basic patent but simply referred to in the wording of the claims of the patent in general terms, such as, in the case of the patent in the main proceedings, 'beta-blocking compound', 'calcium antagonist', 'diuretic', 'non-steroidal anti-inflammatory' or 'tranquilizer', conferred entitlement to multiple SPCs, that would be contrary to the requirement to balance the interests of the pharmaceutical industry and those of public health as regards the encouragement of research within the European Union by the use of SPCs.

Source: **curia.europa.eu**

Court of Justice EU, 12 December 2013

(M. Ilešič, C.G. Fernlund, A. Ó Caoimh, C. Toader (Rapporteur), 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 – Successive marketing of two medicinal products containing, wholly or partially, the same active ingredient – Combination of active ingredients, one of which has already been marketed in the form of a medicinal product with a single active ingredient – Whether it is possible to obtain a number of certificates on the basis of the same patent and two marketing authorisations)

In Case C-443/12,

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 21 September 2012,

received at the Court on 3 October 2012, in the proceedings
Actavis Group PTC EHF,
Actavis UK Ltd,
v
Sanofi,
intervening party:
Sanofi Pharma Bristol-Myers Squibb SNC,
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:
– Actavis Group PTC EHF, by R. Meade QC, I. Jamal, Barrister, and C. Balleny, Solicitor,
– Sanofi and Sanofi Pharma Bristol-Myers Squibb SNC, by D. Alexander QC, S. Moore and S. Rich, Solicitors,
– 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 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 Actavis Group PTC EHF and Actavis UK Ltd (together, 'Actavis'), the claimants in the main proceedings, and Sanofi and Sanofi Pharma Bristol-Myers Squibb SNC (together, 'Sanofi') concerning the validity of the supplementary protection certificate ('SPC') obtained by Sanofi for the medicinal product CoAprovel.

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 ["MA"] 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.'

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.'

7 Article 5 of Regulation No 469/2009, entitled 'Effects of the certificate', provides as follows:

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

8 Article 13 of Regulation No 469/2009, entitled 'Duration of the certificate', states, inter alia, that *'[t]he certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the Community, reduced by a period of five years'*.

United Kingdom law

9 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.'

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

10 Sanofi is the proprietor of European Patent No 0454511 ('Sanofi's patent'). It is apparent from the description of that patent that the invention which it covers relates, inter alia, to a family of compounds which includes the antihypertensive active ingredient irbesartan. The description also refers to pharmaceutical compositions containing a combination of active ingredients, one of which is a compound in accordance with the invention, whereas the other ingredient or ingredients may be a beta-blocking compound, a calcium antagonist, a diuretic, a non-steroidal anti-inflammatory or a tranquiliser.

11 Claims 1 to 7 of the basic patent are based on solely irbesartan, or on one of its salts. Claim 20 of the patent relates to a pharmaceutical composition containing irbesartan in association with a diuretic. However, no specific diuretic is named in claim 20 or in the description of the basic patent.

12 An application for that patent was made to the European Patent Office on 20 March 1991 and the patent was granted on 17 June 1998. The patent expired on 20 March 2011.

13 On the basis of that basic patent and MAs granted on 27 August 1997 in respect of the medicinal product Aprovel, which contains irbesartan as its single active ingredient and is used principally to treat primary hypertension, Sanofi obtained its first SPC for that active ingredient on 8 February 1999. That certificate expired on 14 August 2012.

14 Similarly on the basis of its basic patent but, on this occasion, MAs granted on 15 October 1998 in respect of the medicinal product CoAprovel, comprising a combination of irbesartan and a diuretic, namely hydrochlorothyiazide, which is used to treat primary hypertension, Sanofi obtained a second SPC relating to the irbesartan–hydrochlorothiazide combination. That certificate was granted on 21 December 1999 and expired on 14 October 2013.

15 It is apparent from the summary of the European Public Assessment Report (EPAR) of the European Medicines Agency that '[t]he combination of the two active ingredients has an additive effect, reducing the blood pressure more than either medicine alone'. It follows that the curative properties of that combination of active ingredients corresponds to the total therapeutic effect that would otherwise be obtained by separate administration of Aprovel and hydrochlorothiazide. In that regard, the summary states that '[t]he studies of … Aprovel used with hydrochlorothiazide as separate tablets were used to support the use of CoAprovel', so that that combination does not have any new therapeutic effect when compared with the effects obtained as a result of those two active ingredients being used separately.

16 Actavis intends to market generic versions of Aprovel and CoAprovel. As a generic medicinal product corresponding to CoAprovel would infringe the protection conferred on the irbesartan-hydrochlorothiazide combination of active ingredients by the second SPC granted to Sanofi, Actavis brought proceedings before the referring court challenging the validity of that SPC.

17 In support of its application, Actavis contends, first, that the second SPC obtained by Sanofi for the combination of irbesartan and hydrochlorothiazide is invalid, in so far as that combination is not protected by the basic patent within the meaning of Article 3(a) of Regulation No 469/2009, since that combination of active ingredients is not expressly specified or identified in the wording of any of the claims of that patent. Sanofi, on the other hand, submits that that combination is specified or identified in claim 20 of its patent, which states that the patent relates to a combination of irbesartan and a diuretic. Hydrochlorothiazide is nothing other than a diuretic.

18 Second, Actavis argues that the second SPC is invalid in the light of Article 3(c) of Regulation No

469/2009, given that the 'product', within the meaning of that provision, has already been the subject of an initial SPC. Sanofi, on the other hand, submits, inter alia, that there has been no infringement of that provision, since the first SPC and the MAs granted for Aprovel were obtained in respect of the single active ingredient irbesartan, whereas the second SPC and the MAs for CoAprovel were obtained for a different product, namely the combination of irbesartan and hydrochlorothiazide.

19 The referring court states that those arguments raise issues concerning the interpretation of, first, Article 3(a) of Regulation No 469/2009 and, second, Article 3(c) and (d) of that regulation, which have been considered by the Court in the judgments in **Case C-322/10 Medeva [2011] ECR I-12051**, and **Case C-422/10 Georgetown University and Others [2011] ECR I-12157**, and the orders in Case C-518/10 Yeda Research and Development Company and Aventis Holdings [2011] ECR I-12209, **Case C-630/10 University of Queensland and CSL [2011] ECR I-12231,** and Case C-6/11 Daiichi Sankyo [2011] ECR I-12255.

20 However, the referring court considers that it is not possible for it to resolve the dispute in the main proceedings on the basis of those earlier rulings.

21 First, it considers that the answers given by the Court in those earlier rulings, which related, inter alia, to the criteria to be applied for the purpose of determining whether a product is protected by a 'basic patent' within the meaning of Article 3(a) of Regulation No 469/2009, did not provide a clear test which may be applied to facts such as those in the main proceedings.

22 According to the referring court, that analysis is confirmed by the fact that a number of national courts have given divergent rulings in cases similar to that in the main proceedings. Thus, in its decision of 10 August 2012 in Case Sanofi v Sandoz, the tribunal de grande instance de Paris (Regional Court, Paris) (France) considered, as contended by Actavis in the main proceedings, that claim 20 of Sanofi's patent did not specify or identify hydrochlorothiazide as part of a combination with irbesartan. On the other hand, the Landgericht Düsseldorf (Regional Court, Düsseldorf) (Germany) and the Rechtbank's-Gravenhage (District Court, The Hague) (the Netherlands) took the view that that combination was identified in claim 20 of Sanofi's patent. For the High Court of Justice (England and Wales), Chancery Division (Patents Court), which suggests an answer to this question, the key factor is whether the active ingredient or combination of active ingredients in question constitutes the core inventive advance embodied by the basic patent.

23 Second, the referring court considers that the question whether, in **Medeva** and **Georgetown University** and Others, the Court intended to change the case-law on the interpretation of Article 3(c) of Regulation No 469/2009 remains unsettled. The referring court is of the view that it is not possible to determine, on the basis of those decisions, whether the Court of Justice now considers that that provision precludes the grant of more than one SPC per 'basic patent' within the meaning of Article 1 of that regulation, regardless of the number of products claimed in that patent, or whether it remains of the view that there can be only one SPC per 'product' and per 'basic patent', as held in **Case C-181/95 Biogen [1997] ECR I-357**, and **Case C-482/07 AHP Manufacturing [2009] ECR I-7295**.

24 The referring court observes in that regard that, whereas the Netherlands Patent Office has adopted the interpretation of **Medeva** and **Georgetown University** and Others, to the effect that it prohibits the grant of more than one SPC per patent, regardless of the number of products claimed in the patent, the United Kingdom Intellectual Property Office has taken the view in the main proceedings that two SPCs may be granted to Sanofi on the basis of a single 'basic patent' within the meaning of Article 1 of Regulation No 469/2009, since those SPCs are for two different products claimed in the basic patent.

25 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) In a situation in which multiple products are protected by a basic patent in force, does Regulation [No 469/2009], and in particular Article 3(c), preclude the proprietor of the patent being issued a certificate for each of the products protected?'

Consideration of the questions referred

Question 2

26 By its second question, which it is appropriate to examine first of all, the referring court asks, in essence, whether, in circumstances such as those in the main proceedings, in which, on the basis of a patent protecting an innovative active ingredient and an MA for a medicinal product containing that ingredient as the single active ingredient, the holder of that patent has already obtained an SPC for that active ingredient, Article 3(c) of Regulation No 469/2009 must be interpreted as precluding the holder of that patent from obtaining, on the basis of that same patent but an MA for a different medicinal product containing that active ingredient in combination with another active ingredient which is not protected as such by the patent, a second SPC relating to that combination of active ingredients.

27 It is true that the Court has held, in a situation in which a 'product' within the meaning of Article 1 of Regulation No 469/2009 is protected by a number of basic patents in force, which may belong to different patent holders and may be patents for that product, patents for processes by which the product is obtained or patents relating to an application of the product, that, under Article 3(c) of that regulation, each of those

patents may confer entitlement to an SPC but that only one certificate may be granted for each basic patent (see **Biogen**, paragraph 28, and **AHP Manufacturing**, paragraphs 22 and 23). In such a situation, the type of patent held, as the case may be, by each of those proprietors will affect the protection that may be obtained if an SPC is granted, since, for a patent protecting a product as such, the protection conferred by the SPC will cover that product, whereas for a patent protecting a process by which a product is obtained, that protection will extend only to the process by which that product is obtained or, if the law applicable to such a patent so provides, possibly to the product directly obtained by that process (see the order in **Queensland University** and CSL, paragraph 39) and, for a patent relating to a new therapeutic application of an active ingredient, known or otherwise, the protection conferred by the SPC will not cover the active ingredient as such but only the new use of that product (Case C‑130/11 Neurim Pharmaceuticals (1991) [2012] ECR, paragraph 25).

28 However, the main proceedings concern a different situation. They entail a situation in which the same patent may be regarded as protecting a number of products within the meaning of Article 3(a) of Regulation No 469/2009, thus raising a different question from those referred in, inter alia, the cases which gave rise to the decisions in **Biogen** and **AHP Manufacturing**, namely whether such a patent may permit its holder to obtain more than one SPC.

29 In that regard, it is possible, on the basis of a patent which protects several different 'products', to obtain several SPCs in relation to each of those different products, provided, inter alia, that each of those products is 'protected' as such by that 'basic patent' within the meaning of Article 3(a) of Regulation No 469/2009, in conjunction with Article 1(b) and (c) of that regulation (Case C‑482/12 **Georgetown University** [2013] ECR, paragraph 30).

30 However, in circumstances such as those in the main proceedings, even if the condition laid down in Article 3(a) of Regulation No 469/2009 were satisfied, for the purpose of the application of Article 3(c) of that regulation, it cannot be accepted that the holder of a basic patent in force may obtain a new SPC, potentially for a longer period of protection, each time he places on the market in a Member State a medicinal product containing, on the one hand, the principle active ingredient, protected as such by the holder's basic patent and constituting, according to the statements of the referring court, the core inventive advance of that patent, and, on the other, another active ingredient which is not protected as such by that patent.

31 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 his 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, and Georgetown University, paragraph 36**).

32 In the main proceedings, Sanofi's patent, which protects the active ingredient irbesartan as such within the meaning of Article 3(a) of Regulation No 469/2009, has already enabled its holder to obtain an SPC relating to that active ingredient. Moreover, it is common ground that hydrochlorothiazide, an active ingredient that is a member of a class of diuretics, is not protected as such by that patent or indeed by any other patent.

33 In accordance with Article 5 of Regulation No 469/2009, an SPC granted in connection with a product confers, upon the expiry of the basic patent, the same rights as were conferred by that patent in relation to the product, within the limits of the protection conferred by the basic patent, as provided for in Article 4 of the regulation. Accordingly, if, during the period in which the patent was valid, the patent holder could oppose, on the basis of his patent, the use or certain uses of his product in the form of a medicinal product consisting of such a product or containing it, the SPC granted in relation to that product would confer on the holder the same rights for all uses of the product, as a medicinal product, which were authorised before the expiry of that certificate (see the judgments in **Medeva**, paragraph 39, and **Georgetown University** and Others, paragraph 32, and the orders in **University of Queensland** and CSL, paragraph 34, and Daiichi Sankyo, paragraph 29).

34 Thus, in the main proceedings, since it is common ground that, during the period in which the first SPC was valid, Sanofi was entitled to oppose, on the basis of its basic patent, the use or certain uses of irbesartan in the form of a medicinal product consisting of such a product or containing it, the SPC (now expired) granted for that product also conferred on Sanofi the same rights for all uses of the product, as a medicinal product, which were authorised before the expiry of that certificate.

35 It follows that that first SPC permitted Sanofi to oppose the marketing of a medicinal product containing irbesartan in combination with hydrochlorothiazide for a similar therapeutic use to that of Aprovel, so that if one of that pharmaceutical laboratory's competitors had marketed a medicinal product similar to CoAprovel for similar therapeutic use, Sanofi would have been able to oppose the marketing of such a product by invoking its SPC for irbesartan (see, to that effect, with regard to the use of the active ingredient valsartan and hydrochlorothiazide, the orders of 9 February 2012 in Case C‑442/11 Novartis, paragraph 23, and Case C‑574/11 Novartis, paragraph 20).

36 In such a situation, Article 13 of Regulation No 469/2009 dictates that, upon expiry of the initial SPC, the holder thereof may no longer, in connection with the basic patent used as the basis for the grant of the SPC, oppose the marketing by third parties of the active ingredient which was the subject of the protection conferred by that SPC. This means that, after that date,

it must be possible for third parties to place on the market not only medicinal products consisting of the formerly protected active ingredient but also any medicinal product containing that active ingredient in combination with another active ingredient that is not protected as such by the basic patent or any other patent.

37 Moreover, with regard to the second SPC granted in the main proceedings, the possibility cannot be ruled out that, under national law which provides a degree of protection against indirect infringement, an SPC relating to the irbesartan-hydrocholorothiazide combination may permit the holder to oppose the marketing of a medicinal product containing the active ingredient irbesartan, as a single active ingredient or in combination with another active ingredient. In such a situation, the second SPC may in fact confer upon its holder, albeit partially and indirectly, further protection for irbesartan, extending de facto the protection it enjoyed as a result of the grant of the first SPC relating to that active ingredient, under the conditions referred to at paragraph 35 above. Thus, in view of the consequences of it being granted, in terms of the extension of protection, the situation outlined above confirms that an SPC such as the second SPC at issue in the main proceedings cannot be issued.

38 Similarly, if, in circumstances such as those in the main proceedings, the medicinal product CoAprovel had obtained MA before Aprovel, which would have enabled its proprietor to obtain an SPC either, in the light of paragraph 34 of **Medeva**, for irbesartan alone, or for the irbesartan-hydrochlorothiazide combination, and MA had subsequently been obtained for Aprovel, that could not have secured a second SPC for irbesartan, in view of the condition laid down in Article 3(c) of Regulation No 469/2009.

39 Sanofi's argument that the placing on the market of a medicinal product such as CoAprovel entails additional research costs and clinical and pre-clinical trials for the patent holder, which justify the grant of a second SPC in respect of the irbesartan-hydrochlorothiazide combination, is not such as to call into question the interpretation advocated in this judgment.

40 Bearing in mind the objective of Regulation No 469/2009, as referred to at paragraph 31 above – namely, to compensate the patent holder for the delay to the commercial exploitation of his invention by providing him with an additional period of exclusivity – first, the grant of the first SPC in respect of the single active ingredient irbesartan has already afforded the holder such compensation and, second, the objective of that regulation is not to compensate the holder fully for the delay to the marketing of his invention or to compensate for such delay in connection with the marketing of that invention in all its possible forms, including in the form of combinations based on that active ingredient.

41 It should be recalled that the basic objective of Regulation No 469/2009 is to compensate for the delay to the marketing of what constitutes the core inventive advance that is the subject of the basic patent, namely, in the main proceedings, irbesartan. In the light of the need, referred to in recital 10 in the preamble to that regulation, to take into account all the interests at stake, including those of public health, if it were accepted that all subsequent marketing of that active ingredient in conjunction with an unlimited number of other active ingredients, not protected as such by the basic patent but simply referred to in the wording of the claims of the patent in general terms, such as, in the case of the patent in the main proceedings, 'beta-blocking compound', 'calcium antagonist', 'diuretic', 'non-steroidal anti-inflammatory' or 'tranquilizer', conferred entitlement to multiple SPCs, that would be contrary to the requirement to balance the interests of the pharmaceutical industry and those of public health as regards the encouragement of research within the European Union by the use of SPCs.

42 It follows that, in such a situation, Article 3(c) of Regulation No 469/2009 precludes a patent holder from obtaining, on the basis of one and the same basic patent, more than one SPC in connection with irbesartan, since such SPCs would in fact be connected, wholly or in part, with the same product (see, to that effect, with regard to plant protection products, **Case C-258/99 BASF [2001] ECR I-3643, paragraphs 24 and 27**). On the other hand, if a combination consisting of an innovative active ingredient in respect of which an SPC has already been granted and another active ingredient, which is not protected as such by the patent in question, is the subject of a new basic patent within the meaning of Article 1(c) of that regulation, the new patent could, in so far as it covered a totally separate innovation, confer entitlement to an SPC for that new combination that is subsequently placed on the market.

43 In the light of the foregoing considerations, the answer to the second question referred is that, in circumstances such as those in the main proceedings, where, on the basis of a patent protecting an innovative active ingredient and an MA for a medicinal product containing that ingredient as the single active ingredient, the holder of that patent has already obtained an SPC for that active ingredient entitling him to oppose the use of that active ingredient, either alone or in combination with other active ingredients, Article 3(c) of Regulation No 469/2009 must be interpreted as precluding that patent holder from obtaining – on the basis of that same patent but a subsequent MA for a different medicinal product containing that active ingredient in conjunction with another active ingredient which is not protected as such by the patent – a second SPC relating to that combination of active ingredients.

Question 1

44 In view of the answer given to Question 2, to the effect that a second SPC, such as that at issue in the main proceedings, may not be granted to Sanofi for the irbesartan-hydrochlorothiazide combination, irrespective of whether that combination was protected as such by the basic patent within the meaning of

Article 3(a) of Regulation No 469/2009, there is no need to answer Question 1.

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:

In circumstances such as those in the main proceedings, where, on the basis of a patent protecting an innovative active ingredient and a marketing authorisation for a medicinal product containing that ingredient as the single active ingredient, the holder of that patent has already obtained a supplementary protection certificate for that active ingredient entitling him to oppose the use of that active ingredient, either alone or in combination with other active ingredients, Article 3(c) 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 precluding that patent holder from obtaining – on the basis of that same patent but a subsequent marketing authorisation for a different medicinal product containing that active ingredient in conjunction with another active ingredient which is not protected as such by the patent – a second supplementary protection certificate relating to that combination of active ingredients.

* Process language: English.