TO THE PRESIDENT AND MEMBERS OF THE COURT OF JUSTICE OF THE EUROPEAN UNION

WRITTEN OBSERVATIONS

submitted pursuant to Article 23 of the Statute of the Court of Justice by the European Commission represented by Mr Friedrich Wenzel Buist and Ms Julie Samnadda, members of its Legal Service, acting as agents with an address for service in Luxembourg at the office of Mr. A. Aresu also a member of the Commission's Legal Service, Bureau F3/907, Bâtiment BECH, 5 Rue A Weicker, L-2721 Luxembourg, who consent to service by e-Curia

in Case C-443/12

a request for a preliminary ruling by the High Court of Justice, Chancery Division (Patents Court) (United Kingdom) pursuant to Article 267 of the TFEU in proceedings between

Actavis Group Pte EHF
Actavis UK Limited
and
Sanofi Pharma
and
Sanofi Pharma Bristol-Myers Squibb SNC

1. **The legal context**

1. **EU law**


2. The second to tenth recitals of the Regulation provide:

   "[...]"

   (2) Pharmaceutical research plays a decisive role in the continuing improvement in public health.

   (3) Medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research.

   (4) At the moment, the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research.

   (5) This situation leads to a lack of protection which penalises pharmaceutical research.

   (6) There exists a risk of research centres situated in the Member States relocating to countries that offer greater protection.

   (7) A uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly affect the functioning of the internal market.

   (8) Therefore, the provision of a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which marketing authorisation has been granted is necessary. A regulation is therefore the most appropriate legal instrument.

   (9) The duration of the protection granted by the 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.

[...]”.

3. Article 1 of the Regulation provides:

"Definitions

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 the Regulation provides:

"Scope

Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use 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 may, under the terms and conditions provided for in this Regulation, be the subject of a certificate."
5. Article 3 of the Regulation provides:

"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 as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;

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

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

1.1. European Patent Convention

6. Under the heading ‘Extent of Protection’, Article 69 of the Convention on the Grant of European Patents, signed on 5 October 1973, in the amended version applicable at the time of the facts in the main proceedings ("the European Patent Convention"), 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 European Patent Convention, 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 123 of the European Patent Convention signed on 5 October 1973, in the amended version applicable at the time of the facts in the main proceedings ("the European Patent Convention") provides1, in relevant part:

"[...]

(2) The European patent application or European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed.

(3) The European patent may not be amended in such a way as to extend the protection it confers."

1.2. Law governing the patent

9. The patent in question is a European (UK) No 0 454 511 ("the Patent"). Accordingly, the law governing the patents would be both the European Patent Convention and in addition, where applicable, the UK Patent Acts 1977.

2. THE MAIN PROCEEDINGS AND THE REFERENCE FOR A PRELIMINARY RULING

10. This is a reference dated 21 September 2012 ("Order for Reference") from the High Court of Justice Chancery Division (Patents Court) ("the Referring Court") in proceedings between Actavis Group PTC EHF, Actavis UK Limited, the principal claimants ("Actavis") and Sanofi, the defendants ("Sanofi") Sanofi is the proprietor of the Patent entitled "N-substituted heterocycle derivatives, their preparation, compositions containing them" which covers an antihypertensive drug whose international non-proprietary name is irbesartan. The Patent expired on 20 March 2011.

11. The facts, arguments of the parties and the opinion of the Referring Court are as set out in the judgment of the Referring Court of 20 September 2012 [2012] EWHC 2545 (Pat) which forms part of the Order for Reference. The Referring Court also

directed that its judgment in *Novartis Pharmaceuticals UK Ltd v Medimmune Ltd* [2012] EWHC 18 (Pat) should be appended to the Order for Reference.

### 2.1. The supplementary protection certificates

12. Sanofi obtained two supplementary protection certificates under different marketing authorisations.

13. On 27 August 1997, irbesartan was authorised under market authorisation EU/1/97/046/001-009 and Sanofi obtained Supplementary Protection Certificate GB98/037 for "[irbesartan] optionally in the form of one of its salts" ("the Irbesartan SPC"). Sanofi applied for the Irbesartan SPC on 1 October 1998, it was granted on 8 February 1999 and expired on 14 August 2012. Sanofi marketed Irbesartan under the trade mark Aprovei.

14. On 15 October 1998, Sanofi obtained marketing authorisation EU/1/98/086/001-006 for a fixed dose combination of irbesartan and hydrochlorothiazide ("HCTZ"). Sanofi, therefore, also obtained Supplementary Protection Certificate GB99/008 for "[irbesartan] optionally in the form of one of its salts and hydrochlorothiazide" ("the Combination SPC").

15. Sanofi applied for the Combination SPC on 12 March 1999, and it was granted on 21 December 1999 and will expire on 14 October 2013. Sanofi markets the Combination SPC under the trade mark CoAprovel.

### 2.2. The dispute before the Referring Court

16. As both the patent in question and the Irbesartan SPC have expired, Actavis intends to market a generic version of both Aprovei and CoAprovel. It is common ground that the Actavis's generic version of CoAprovel will infringe the Combination SPC.

17. The dispute, therefore, concerns a challenge to the validity of Sanofi's Combination SPC by Actavis on two grounds. These grounds raise issues of interpretation of Article 3(a) and Article 3(c) of the Regulation. The Referring Court did not consider that any issue pertaining to Article 3(d) of the Regulation needed to be referred, although Article 3(d) was raised in argument in the course of the proceedings.
18. In relation to Article 3(a) of the Regulation, Actavis contends that the Combination SPC is not "protected by a basic patent in force" within the meaning of Article 3(a) because the Combination SPC does not fall within the scope of the Patent. Actavis's arguments are summarised at paragraph 59 of the Order for Reference.

19. In response, Sanofi argues in essence that the combination is specified/identified and so falls within the scope of the Patent, as claimed. Sanofi's arguments are summarised at paragraphs 65 and 94 of the Order for Reference.

20. In relation to Article 3(c), Actavis argues that as there is a previous supplementary protection certificate namely the Irbesartan SPC which was granted under the Patent, in the light of this Court's case law in Case C-322 Medeva BV v Comptroller-General of Patents, Designs and Trade Marks [2011] ECR I-0000 ("Medeva") at paragraph 41, the Combination SPC should not have been granted. Actavis's arguments are summarised at paragraphs 78 and 93 of the Order for Reference.

21. In response, Sanofi contends that prior to Medeva, it was clear from the case law of the Court that when a basic patent covers several products for every product an SPC could be obtained on the basis that one SPC per "product" per basic patent would be permitted. In their view, Medeva does not change Case C-181/95 Biogen Inc v SmithKline Biological SA [1997] ECR 1-357 ("Biogen"), paragraph 28. Sanofi's arguments are summarised at paragraph 94 of the Order for Reference.

22. In support of their arguments in relation to Article 3(a) and Article 3(c) respectively, both parties refer to various judgments and decisions of national courts and patent offices, following this Court's ruling in Medeva.

2.3. The view of the Referring Court

23. In relation to Article 3(a) of the Regulation, the Referring Court considers that there is a lack of clarity in this Court's judgment in Medeva. In particular, the Referring Court is of the view that Medeva lays down no criteria which national jurisdictions can apply as a matter of EU law. In particular, guidance is sought from the Court as to the criteria which should be applied for "what is protected by the basic patent" within the meaning of Article 3(a) of the Regulation. In the absence of such further clarification which would enable future disputes to be resolved there will continue to be divergent rulings of national courts and patent offices and further references to
this Court. These divergences are summarised at paragraph 73 of the Order for Reference.

24. This leads the Referring Court to suggest its own test at paragraph 76 of the Order for Reference whereby for the purposes of Article 3(a) "[w]here the product is a combination of active ingredients, the combination, as distinct from one of them, must embody the inventive advance of the basic patent". Such a test would not be dependent on the wording of the claim of the basic patent as drafted. In the view of the Referring Court, this test would meet the objective of the Regulation which is to encourage "invention in the field of medicinal products."

25. The Commission infers from the Referring Court's reasoning that if the suggested test of "inventive advance" were adopted by the Court and applied in the present case, this would lead to the conclusion that an application for an SPC in the present case would meet the requirements of Article 3(a). However, the Referring Court does not state this expressly.

26. As far as Article 3(c) is concerned, the Referring Court considers that Medeva paragraph 41 casts doubt on this Court's earlier case law notably Biogen at paragraphs 26-28 and AHP. According to the Referring Court, prior to Medeva, the Court's jurisprudence had been interpreted as follows:

"These two cases [Biogen and AHP] clearly establish that it is possible to obtain one SPC per basic patent per product where there were multiple patents covering one product. Prior to Medeva it was generally thought that by parity of reasoning, it was also possible to obtain one SPC per product per basic patent where one patent covered multiple different medicinal products" (paragraph 83 of the Order for Reference).

27. In the view of the Referring Court, if the effect of Medeva, paragraph 41 is to cast doubt on or even overturn earlier case law, it would henceforth no longer be possible to interpret Article 3(c) in a manner which would allow for one SPC per product per basic patent.

28. In addition, the Referring Court suggests that a proper interpretation of Article 3(c) depends on Article 3(a) being "correctly interpreted" (paragraph 95 of the Order for Reference). The Referring Court advocates that Article 3(c) should be dependent on the scope of Article 3(a) and in particular its suggested test of the "inventive
advance". With this approach, if the active ingredient (or combination of active ingredients) embodies the inventive advance of the patent then one SPC may be granted in respect of that product and that patent. If the patent protects two products, because the patent discloses and claims two inventively distinctive active ingredients (or combination of active ingredients) then one SPC may be granted in respect of each product and hence two SPCs in respect of that patent (paragraph 95 of the Order for Reference).

3. THE QUESTIONS REFERRED

1. What are the criteria for deciding whether "the product is protected by a basic patent in force" in Article 3(a) of Regulation 469/2009/EC ("the Regulation")?

2. In a situation in which multiple products are protected by a basic patent in force, does the Regulation, and in particular Article 3(c), preclude the proprietor of the patent being issued a certificate for each of the products protected?

4. PRELIMINARY REMARKS

29. In the period 2010-2012, there have been a number of references on the scope of Article 3 of the Regulation.


31. In relation to the First Question, the Commission agrees that further clarification from this Court would appear to be desirable. Such clarification might also avoid further references to this Court on essentially similar issues. The Commission would respectfully suggest that the Court may choose to continue with the approach to
Article 3(a) which began with Case C-392/97 *Farmitalia* [1999] ECR I-5553 ("Farmitalia"), paragraph 26 which acknowledges that national patent law has not been harmonised. Alternatively, the Court might wish to consider an interpretation of Article 3(a) which builds on the approach that the Court began in *Medeva*, paragraphs 24, 25 and 26 and give greater precedence to Union law and the harmonisation sought to be achieved with the Regulation notwithstanding that national patent law itself has not been harmonised.

32. In relation to the Second Question, as to the Referring Court’s reasons for making the reference, the Commission is of the view that the Referring Court has misinterpreted *Medeva*, paragraph 41 which does not have the effect as stated at paragraph 96 of the Order for Reference. Nevertheless, the Commission considers that the factual circumstances of the application for an SPC in the present case, do call for clarification of the scope of Article 3(c) of the Regulation as neither *Medeva* nor *Biogen* deals with a similar situation.

5. **ANALYSIS OF THE QUESTIONS REFERRED FOR A PRELIMINARY RULING**

5.1. **First Question**

33. The First Question relates to the interpretation of Article 3(a) of the Regulation. It appears that the same question is once again being asked in Case C-493/12 (*Eli Lilly*) currently pending before the Court.

34. The Referring Court seeks further clarification as to the precise meaning of the words "specified" or "identified" appearing in the Court's judgments in those cases. As a preliminary remark, the Commission would like to point out that the difference in formulation of the responses given by the Court in those cases ("specified" vs "identified" in the English and "figurant" vs "mentionné" in the French translation) is without significance. Indeed, this difference does not appear e.g. in the German translations of the judgments in question, which consistently use the term "genannt").

35. The Commission had advocated different responses in its observations on the referrals mentioned above than what the Court decided, but had come to the same result *in casu*.
36. The complexity of the situation appears to result from the challenge of delineating precisely which aspects of Article 3(a) of the Regulation are for Union law and which, given the lack of harmonisation of patent law at Union level, are a matter for national law.

Analysis on the basis of Farmitalia

37. The Commission is of the view that on the basis of Farmitalia, the line is to be drawn as follows. The Court held in Farmitalia paragraph 27 and confirmed inter alia in Medeva, paragraph 23 and Yeda, paragraph 35, that "the extent of patent protection can be determined only in the light of the non-Community rules which govern patents" (Farmitalia, ibid.).

38. At the same time, the Regulation establishes, as the Court confirmed, inter alia, in Medeva, paragraph 24, "a uniform solution at European Union level by creating a SPC which may be obtained by the holder of a national or European patent under the same conditions in each Member State. It thus aims to prevent the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the European Union and thus directly affect the establishment and functioning of the internal market".

39. There is a certain tension between this objective and the aforementioned lack of harmonisation of patent law. This tension is embodied in the Regulation's approach not only to prolong, within certain limits, the protection accorded by national (or European) patents, but also to make – by virtue of its Article 3(a) – the grant of an SPC dependent on the protection already in place.

40. The Court may wish to maintain an approach based solely on Farmitalia. However, the Court would have to properly delineate the question which the national authority which grants SPCs should examine in order to determine whether an application for an SPC fulfils Article 3(a) of the Regulation.

41. The question to be asked is what product is protected by the basic patent in force which is relied upon in the SPC application. The Regulation does, however not stop here. As a matter of Union law, it further regulates what this question consists of more specifically. In order to achieve, to the extent possible, "a uniform solution at
European Union level", this question aims at establishing, as the Court has repeatedly held, which active ingredients are specified (or identified) in the wording of the claims of the basic patent. The question does not aim at establishing what would infringe the patent. The Commission agrees with the Referring Court that on a proper reading of Medeva the Court rejected the infringement test. In the view of the Commission, the Court was right to do so.

42. Nevertheless, Union law does not govern how one establishes what is specified or identified in the wording of the claims of the patent. This is where the application of national law begins. The difficulty of the Referring Court seems to stem from an uncertainty as to what rules of national law governing the basic patent it should apply in the context of the Regulation.

43. At least as far as patents granted under the European Patent Convention are concerned, as is the case in the main proceedings, the present reference provides an opportunity to clarify which rules of national law – in the sense of non-Union law – should be applied.

44. In the view of the Commission, in the context of the European Patent Convention, the relevant rule is Article 69. The European Patent Office's Enlarged Board of Appeal has held as follows in its decision of 11 December 1989, Case G 2/88, emphasis added) in the context of a decision on the interpretation of Article 123(3) EPC:

"Article 123(3) EPC provides that "The claims of the European patent may not be amended ... in such a way as to extend the protection conferred [...]"

3.3 Question (i) asks in particular how far should the national laws of Contracting States relating to infringement be considered, when deciding upon admissibility under Article 123(3) EPC. [...] [T]he protection conferred by a patent is to be determined by interpretation of the terms of the claims, and the rights of the patent proprietor flow from the protection which is conferred. There is a clear distinction between the protection which is conferred and the rights which are conferred by a European patent, however. The protection conferred by a patent is determined by the terms of the claims (Article 69(1) EPC) [...] In this connection, Article 69 EPC and its Protocol are to be applied, both in
proceedings before the EPO and in proceedings within the Contracting States, whenever it is necessary to determine the protection which is conferred. In contrast, the rights conferred on the proprietor of a European patent (Article 64(1) EPC) are the legal rights which the law of a designated Contracting State may confer upon the proprietor, for example, as regards what acts of third parties constitute infringement of the patent, and as regards the remedies which are available in respect of any infringement. In other words, in general terms, determination of the "extent of the protection conferred" by a patent under Article 69(1) EPC is a determination of what is protected, in terms of category plus technical features; whereas the "rights conferred" by a patent are a matter solely for the designated Contracting States, and are related to how such subject-matter is protected. It follows that when deciding upon the admissibility of any amendment to the claims of a patent which is proposed in opposition proceedings (whether or not such amendment involves a change of category of claim), what has to be considered and decided is whether the subject-matter which is protected by the claims, as defined by their categories in combination with their technical features, is extended. It is not necessary to consider the national laws of the Contracting States in relation to infringement when making such a decision, however.

4. When considering whether a proposed amendment to the claims is such as to extend the protection conferred, a first step must be to determine the extent of protection which is conferred by the patent before the amendment: it is necessary to be quite clear as to what is the protection conferred by the patent without amendment, before one can decide whether a proposed amendment is such as to extend it. Determination of the extent of protection has to be carried out in accordance with Article 69(1) EPC and its Protocol, which provides a guide to the manner in which the technical features of the claim are to be interpreted. The Protocol was adopted by the Contracting States as an integral part of the EPC in order to provide a mechanism for harmonisation of the various national approaches to the drafting and interpretation of claims [...]. The central role of the claims under the EPC would clearly be undermined if the protection and consequently the rights conferred within individual designated Contracting States varied widely as a result of purely national traditions of claim interpretation; and the Protocol was added to the EPC as a supplement primarily directed to
providing an intermediate method of interpretation of claims of European patents throughout their life, as a compromise between the various national approaches to interpretation and determination of the protection conferred ("... so as to combine a fair protection for the patentee with a reasonable degree of certainty for third parties"). The object of the Protocol is clearly to avoid too much emphasis on the literal wording of the claims when considered in isolation from the remainder of the text of the patent in which they appear; and also to avoid too much emphasis upon the general inventive concept disclosed in the text of the patent as compared to the relevant prior art, without sufficient regard also to the wording of the claims as a means of definition. This approach to interpretation of claims must be adopted by the EPO when determining the protection conferred for the purpose of Article 123(3) EPC.

45. With this approach, which preserves the approach in *Farmitalia*, the situation could be summarised as follows: Union law regulates which specific question needs to be answered for the purposes of Article 3(a) of the Regulation. The criteria to be applied in a given case in order to answer that question would be taken from national law. The way the Union law question is phrased for the purposes of the application of national law would make it clear, however, that these criteria are not those which determine when a patent is infringed, but those that "national" law provide for in establishing the extent of protection of the patent in question. National law may be the European Patent Convention as in the present case.

46. While these criteria may require a difficult examination in practice, which is not conducive to the aim of providing an easily applicable SPC system (compare paragraph 16 of the Explanatory Memorandum (COM(90)101 final and also below), it would appear that this is the inevitable consequence of the basic structure of Article 3(a) of the Regulation and its reliance on national patent law with all its complexities.

47. However, the "inventive advance test" proposed by the Referring Court would be even more difficult to apply. Requiring the literal mentioning of the active ingredient would, obviously, be an easier test, but – besides other drawbacks – this could also be difficult to reconcile with an approach based on *Farmitalia* given that the Court
has interpreted Union law as not providing for an exhaustive harmonisation of what is protected by the basic patent.

48. If the Court wishes to maintain an approach based on Farmitalia, the Commission would propose the following answer to the First Question:

"Article 3(a) of Regulation (EC) No 469/2009 does not preclude the competent industrial property office of a Member State from granting an SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent relied on in support of the SPC application which is to be established in accordance with the rules governing the basic patent that determine the scope of protection."

Re-defining the boundary between national and Union law in Article 3(a)

49. However, the Commission would invite the Court to consider an alternative approach which would have the effect of further "Unionising" Article 3(a) and re-define the boundary between Union and national law without impugning national patent law. For the purposes of Article 3(a) of the Regulation, what is protected by a patent could be determined uniformly on the basis of Union law, while the rights flowing from that protection are determined by national law in accordance with Articles 4 and 5 of the Regulation. By holding in Medeva, paragraph 24 that the active ingredient must be "specified" in the patent claim, the Court could be said to have already moved in this direction and paragraph 24 of Medeva could be read as a counter-point to paragraph 23 i.e. as if it had been preceded by an implicit "However, ".

50. The following arguments could be invoked in support of such an approach. According to settled case-law, the need for a uniform application of European Union law and the principle of equality require that the terms of a provision of European Union law which make no express reference to the law of the Member States for the purpose of determining its meaning and scope must normally be given an independent and uniform interpretation throughout the European Union (see, in particular, Case C-327/82 Ekro [1984] ECR 107, paragraph 11; Case C-287/98 Linster [2000] ECR I-6917, paragraph 43; Case C-5/08 Infopaq International
51. The text of the Regulation does not define "protected by a basic patent in force", nor does it contain any reference to national laws as regards the meaning to be applied to those terms.

52. The Regulation's objective of establishing a uniform solution at European Union level by creating a SPC which may be obtained by the holder of a national or European patent under the same conditions in each Member State (see paragraph 38 above) would also seem to support a uniform interpretation of the term "protected by a basic patent in force".

53. When determining what this uniform interpretation would consist of, the Court should take account of the Regulation's objective of creating an SPC system that is readily applicable in practice. This objective is described in more detail in paragraph 16 of the Explanatory Memorandum (COM(90)101 final) which states: "The proposal for a Regulation provides for a simple, transparent system which can easily be applied by the parties concerned. It therefore does not lead to excessive bureaucracy. There is no need for any new administrative body and the patents offices should be able to implement the procedure for granting the certificate without an excessive burden being placed on their administrations. [...] Examination of the conditions to be fulfilled for the certificate to be granted involves the use of objective data that are easy to verify." This policy goal is also reflected in Recital 8 of the preamble to the Regulation.

54. Against this background, whether an active ingredient is specified in a patent claim should be established on the basis of a test which is comparatively easy to apply, in practice. A literal reference to the active ingredient in question would seem unduly restrictive. However, an appropriate way forward could be a test based on whether it is immediately evident to a skilled person using the common general knowledge on the date of filing of the application for the patent² from the wording of the claim that the active ingredient in question is claimed by the patent. This would be the test that

² Compare http://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_vii_3_1.htm
the national patent office would apply in assessing the application for an SPC under Article 3(a).

55. This test is inspired by the test applied by the European Patent Office, when deciding the admissibility of corrections of European patents. Common general knowledge can come from various sources. The reference to the "date of filing" is the date the application for the patent is filed in the patent office and is, generally speaking, the relevant date for determining the effective date for the grant of protection and for the assessment of the patentability conditions.

56. In practice, this would mean that for the purposes of Article 3(a) of the Regulation read in the light of Medeva, paragraph 28, an active ingredient would be "specified (emphasis added) in the wording of the claim of the basic patent relied on in support of the SPC application" where it is immediately evident to a skilled person from the wording of the claim that the active ingredient is claimed by the patent on the date of filing of the application for the patent using the common general knowledge of a skilled person.

57. The Commission would respectfully advocate this approach for present purposes and the Commission would suggest the following response:

Article 3(a) of Regulation (EC) No 469/2009 precludes the competent industrial property office of a Member State from granting an SPC relating to any active ingredient which is not specified in the wording of the claims of the basic patent relied on in support of the SPC application. An active ingredient is specified for these purposes where it is immediately evident from the wording of the claims to a skilled person that the active ingredient is claimed by the patent.

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3 See Rule 139 ("Correction of errors in documents filed with the European Patent Office") of the Implementing Regulations to the EPC: "Linguistic errors, errors of transcription and mistakes in any document filed with the European Patent Office may be corrected on request. However, if the request for such correction concerns the description, claims or drawings, the correction must be obvious in the sense that it is immediately evident that nothing else would have been intended than what is offered as the correction."

4 Compare http://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_vii_3_1.htm
5.2. The Second Question

58. The Second Question relates to the interpretation of Article 3(c) of the Regulation and should, in the view of the Commission, be answered in the negative. In essence, the Second Question concerns whether Article 3 (c) should be interpreted to allow for "one SPC per product per basic patent" as opposed to "one SPC per patent".

59. The Commission will first deal with the Referring Court's reasoning as to why it considered it necessary to refer Article 3(c). The Referring Court considers that the problem of interpretation stems from this Court's judgment in Medeva (paragraph 79 of the Order for Reference) summarised above. This in turn has led to certain decisions and judgments of national authorities and courts which interpret Medeva as a departure from previous case law (paragraph 92 of the Order for Reference).

60. As far as any perceived link between this Court's judgment in Medeva and Article 3(c) of the Regulation is concerned, the Commission considers that there is no such link. Neither Medeva nor Biogen concerned cases where the same patent protected several products. The Court did not rule on Article 3(c) in Medeva, paragraph 41 when it referred to the judgment of Biogen, paragraph 28. The reference to Biogen was an obiter comment. Article 3(c) of the Regulation was not the subject of the reference in Medeva. In any event, the situation in the case at hand is not the one addressed in paragraph 41 of Medeva ("where a patent protects a product" as opposed to several products).

61. Nor does the attention given to Article 3(c) of the Regulation by the Advocate-General in her opinion in Medeva change or impact on the Court's obiter comment in Article 3(c), in any way. It should be noted that the Court did not seem to adopt the Advocate General's line of reasoning in its judgment.

Literal Interpretation

62. In the view of the Commission, the wording of Article 3(c) of the Regulation would support an approach based on "one SPC per product per patent". This becomes apparent if one takes as the point of departure, the definition in Article 1(b) of the Regulation which defines "product" as "the active ingredient or combination of active ingredients of a medicinal product". If one replaces the word "product" in
Article 3(c) of the Regulation with the text of the definition itself, the text of Article 3(c) would then stipulate that *the active ingredient* in the singular (emphasis added) or the *combination of active ingredients* in the plural (and with emphasis added) of the medicinal product in question has not already been the subject of an SPC. The application for an SPC would have to be assessed on the basis of whether it concerns a single active ingredient ("the first option") or a combination of active ingredients ("the second option"). Therefore, the text of Article 3(c) itself of the Regulation addresses the following situations:

-a single active ingredient;

-a combination of active ingredients.

63. If the application for an SPC invokes only one active ingredient i.e. the marketing authorisation relied on for the purposes of satisfying the requirement of Article 3(b) of the Regulation covers only one of the active ingredients protected by the patent), then it is the first option which would have to be applied. If the SPC application invokes several active ingredients, then the second option of Article 3(c) applies. The situation where a patent protects a combination of active ingredients is thus specifically addressed in Article 3(c) of the Regulation.

64. If a patent protects both i.e. an active ingredient plus a combination of active ingredients, one would still need to establish for the purposes of an application for an SPC whether the particular application concerns a single active ingredient or a combination of active ingredients i.e. the first or the second option.

65. However, for the purposes of Article 3(c), an SPC is not precluded from being granted simply because *an SPC* (emphasis added) has previously been granted under the basic patent. It follows from the text of Article 1(b) read together with Article 3(c) that an SPC that has been granted for a single active ingredient under the first option does not preclude the grant of an SPC for a combination of active ingredients under the second option. The Commission is also of the view that the previous grant of an SPC for either a single or a combination of active ingredients under the first or second option respectively also does not preclude the grant of another SPC provided the "product" in either case is different. Therefore, in the present case, on the basis of a purely literal interpretation of Article 3(c) of the Regulation, the question for the
granting authority would be whether the particular combination of active ingredients has already been the subject of an SPC.

**Purposive Interpretation**

66. In *Medeva*, the Court confirmed that the fundamental objective of the Regulation is to ensure sufficient protection to encourage pharmaceutical research, which plays a decisive role in the continuing improvement in public health. Given that the period of effective protection under the patent is considered to be insufficient to cover the investment put into pharmaceutical research, the Regulation thus seeks to make up for that insufficiency by creating a SPC for medicinal products (*Medeva*, paragraphs 30 and 31). The Court also held that if the holder of "a basic patent relating to an innovative active ingredient or an innovative combination of active ingredients were to be refused an SPC on the ground that, in the commercial version of the medicinal product which places that active ingredient or that combination on the market for the first time, the active ingredient or the combination coexists in the medicinal product alongside other active ingredients or combinations which have other therapeutic purposes and may or may not be protected by another basic patent in force, the fundamental objective of Regulation No 469/2009, which is to ensure sufficient protection to encourage pharmaceutical research and play a decisive role in the continuing improvement in public health, could be undermined" (*ibid.*, paragraph 34, emphasis added).

67. Against this background, it could indeed appear attractive, from the point of view of a purposive interpretation, to make the grant of a second SPC on the basis of one and the same patent dependent on whether the active ingredient or combination of active ingredients in question embodies "the inventive advance of the patent" (as the Referring Court suggests e.g. in paragraph 95 of the Order for Reference) or constitutes "inventively distinct products" from those for which an SPC has already been granted (as Actavis puts it at paragraph 93 of the Order for Reference).

68. However, such an approach to Article 3(c) of the Regulation would appear to be very difficult indeed to apply in practice as it would seem to require a full blown investigation as to the state of the art at the time of the patent application and/or the inventive step reflected by the claim in question.
Furthermore, it would seem inconsistent to apply the "inventive advance" test only
to a subsequent i.e. a second or third application for an SPC under a patent and not
to the initial application i.e. first application for an SPC under a patent. If one took
the "inventive advance" criterion seriously, one would need to require the first
application for an SPC to also satisfy the "inventive advance" test. This shows,
however, what the "inventive advance" test truly means, namely a (re-)examination
of certain patentability requirements with regard to the basic patent.

This can be illustrated by the following example. If one took the view in the present
case that the true inventive advance in the present case was not in the invention of
irbesartan but in the invention of the chemical compound as claimed in independent
claim 1, no SPC for a single active ingredient ("mono-SPC") should have been
granted on that basis even if Sanofi had applied only for the mono SPC. However,
there does not seem to be any basis in the Regulation for refusing such a mono-SPC
had this been the only one applied for by Sanofi. The Regulation extends, within the
limits of its Article 4, the duration of patent protection without stipulating that the
product protected by the relevant claim of the basic patent has to satisfy a distinct
heightened standard of innovativeness. Rather, the Regulation accepts the basic
patent as it is. The SPC is merely accessory in nature.

While the practice of optimising the term of protection which is criticised by the
Advocate General Trstenjak in her Opinion in Medeva (paragraph 100) would
indeed seem to run counter to the objective of the Regulation, the Referring Court
correctly points out that there can be cases where the patent discloses and claims
"distinct inventions" (paragraph 87 of the Order for Reference). Whilst it would, as
stated above, serve the purpose of the Regulation best to define a criterion which
would help to differentiate between patents which claim "distinct inventions", and
thus should qualify for several SPCs, and those which claim only variations of
essentially the same invention, and thus do not, the Commission does not see how
such a criterion could be defined.

In addition, any such criterion would be difficult to reconcile with the wording of the
Regulation which has introduced the notion of "product" to ensure that only true
improvement is rewarded by an SPC. Whilst the Commission notes that from the
Court's case law (Case C-431/04 MIT, [2006] ECR 1-4089 paragraphs 17-23;
confirmed in C-202/05 Yissum [2007] ECR 1-2839 paragraph 17) that "product" must be strictly defined to achieve this objective, it now appears that such a strict interpretation may not be enough to prevent excessive prolongations of protection for parts of patents (in this case the combination of irbesartan and a diuretic). As stated above, there does, however, not seem to be any solution to this problem in the Regulation.

Systematic Interpretation

73. Following the interpretation of Articles 4 and 5 of the Regulation by the Court in Case C-442/11 Novartis AG v Actavis UK Ltd [2012] ECR 1-0000 one might consider the argument that the patent holder has no legitimate interest in the combination SPC as he could prevent the marketing of all medicinal products consisting of a combination of active ingredients already on the basis of the mono SPC which he would simply need to obtain first. Leaving aside the limits set by Article 4, this presupposes that the mono-SPC would be granted first which depends on a variety of factors not all of which are within the control of the patent owner, including the respective length of the authorisation process for the medicinal product containing only one active ingredient and the one for the medicinal product containing the combination. In this respect, the Commission would draw the Court's attention to Article 7(1) of the Regulation in accordance with which the application for a certificate must be lodged within six months of the grant of the marketing authorisation.

6. CONCLUSION

74. The Commission submits that the Court should answer the questions of the Referring Court as follows:

First Question: "Article 3(a) of Regulation (EC) No 469/2009 precludes the competent industrial property office of a Member State from granting an SPC relating to any active ingredient which is not specified in the wording of the claims of the basic patent relied on in support of the SPC application. An active ingredient is specified for these purposes where it is immediately evident from the wording of the claims to a skilled person that the active ingredient is claimed by the patent."
Second Question: "Article 3(c) of Regulation (EC) No 469/2009 does not preclude the proprietor of the patent being issued a certificate for each of the products protected in a situation in which multiple products are protected by a basic patent in force."

Friedrich Wenzel BULST
Agent for the Commission

Julie SAMNADDA
The Registrar  
Court of Justice  
of the European Union  
L-2925 Luxembourg  

Dear Sir,  

Subject: Case C-443/12 –  
Actavis Group PTC EHF e.a. v Sanofi  

The Commission would like to submit a corrigendum to its written observations presented in the case caption. The phrase "does not preclude" should be replaced with "preclude". Paragraph 48 would therefore read as follows:  

"48. If the Court wishes to maintain an approach based on Farmitalia, the Commission would propose the following answer to the First Question:  

"Article 3(a) of Regulation (EC) No 469/2009 precludes the competent industrial property office of a Member State from granting an SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent relied on in support of the SPC application which is to be established in accordance with the rules governing the basic patent that determine the scope of protection."  

Yours faithfully,  

Julie SAMNADDA  
Friedrich Wenzel BULST  
Agents of the Commission