EUROPEAN COMMISSION

ORIGINAL

Brussels, 29 June 2011
sj.a(2011)776202

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 Bulst 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

in Case C-130/11

A request for a preliminary ruling by the Court of Appeal (England and Wales) (pursuant to Article 267 of the TFEU in proceedings between

Neurim Pharmaceuticals (1991) Limited

and

Comptroller-General of Patents

on the interpretation of Council Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificates for medicinal products (OJ 16.6.2009, L 152, p. 1)

A. THE LEGAL CONTEXT

EU law

1. Council 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) which codifies Council Regulation (EEC) No. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ 1992, L 182, p. 1). ("the Regulation").

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."

6. Article 4 of the Regulation provides:

"Subject matter of protection

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 7 of the Regulation provides:

"Application for a certificate

1.The application for a certificate shall be lodged within six months of the date on which the authorisation referred to in Article 3(b) to place the product on the market as a medicinal product was granted.

2.Notwithstanding paragraph 1, where the authorisation to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within six months of the date on which the patent is granted.
[...]"

Law governing the patent

8. The patent in question is a European patent. Accordingly, the law governing the patents would be both the European Patent Convention and in addition, where applicable, the UK Patent Acts 1977.

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

9. This reference from the Court of Appeal (England and Wales) ("the Referring Court") concerns an appeal by Neurim Pharmaceuticals (1991) Limited ("Neurim") against a judgement of the lower court, the High Court (Patents) which upheld the decision of the Comptroller-General of Patents ("the Comptroller") in which the Comptroller refused an application for a supplementary protection certificate ("SPC") under the Regulation ([2010] EWHC 976 (Pat)). The reason for the refusal by the Comptroller was that the marketing authorisation relied upon by Neurim was not the first authorisation to place the product on the market as a medicinal product. In the course of the appeal, the Referring Court decided that the question which was the relevant marketing authorisation for present purposes was not *acte clair* and decided to refer the matter to this Court and issue an order to that effect ("Order for Reference").The facts are as described in the Order for Reference (paragraphs 3-5).

The basic patent

10. There is one "basic patent" relied upon in support of Neurim's SPC application and it is a European Patent – EP (UK) No. 0 518 468 ("the Neurim Patent"). The scope of the patent is described as "Melatonin containing compositions" in other words "compositions that contain melatonin" for "use in correcting a melatonin deficiency or distortion in the plasma melatonin level and profile in a human subject." The patent was applied for on 23 April 1992. The Neurim Patent is described at paragraphs 3 and 4 of the order for Reference and also at paragraphs 1, 13 of the judgment of the lower court.

The marketing authorisations

11. The Neurim Patent is supported by a marketing authorisation granted by a Commission decision of 28 June 2007 following the opinion of the Committee for Medicinal Products for Human Use of the European Medicines Agency and which allows Neurim to sell their patented composition and for which Neurim uses a trade mark "Circadin" ("the Circadin MA").

12. In its application for an SPC, Neurim relied on the Circadin MA as the first authorisation to place the product on the market in the United Kingdom within the meaning of Article 3 (d) of the Regulation.

13. However, the Comptroller objected to the application on the basis that the Circadin MA was not the "relevant first MA." The Comptroller had identified another marketing authorisation which was earlier in time (and granted in 2001 or even earlier) for a product containing melatonin for use in sheep and sold under the trade mark "Regulin" ("the Regulin MA") (see paragraph 3 (7) of the Order for Reference).

14. The Regulin MA is for a yellow cylindrical implant whose active ingredient is melatonin. The Regulin MA was the subject of another patent owned by Hoechst EP 0 246 910 ("Hoechst Patent") for a method of regulating the seasonal breeding activity of animals. It would appear from the Order for Reference that in the view of the Referring Court "neither the "Hoechst patent nor the subject matter of the Regulin MA fell within the scope of the Neurim Patent" (paragraph 4 of the Order for Reference).

The Comptroller's arguments

15. The Comptroller's rejection of the application rests on the simple premise that as the active ingredient of both the Circadin MA and the Regulin MA is melatonin, the "product" in question is therefore melatonin and the first authorisation to place the product on the market as a medicinal product is therefore the Regulin MA for the purposes of the Regulation. The Neurim MA is not the first, so Neurim's application for an SPC must fail on the ground that it does not comply with Article 3(d) of the Regulation.

16. The Comptroller, however, considered that Neurim's application for an SPC could have successfully relied on the Regulin MA but then it would have been an SPC of "zero scope" (Paragraph 10 of the Order for Reference). This is because in the view of the Comptroller, there is a distinction between the conditions for grant provided under Article 3 and the effect of grant, including scope (provided under Articles 4 and 5 of the Regulation). The Comptroller relies on certain decisions of this Court namely Case C-31/03 *Pharmacia* [2004] ECR I-100001, case C-431/04 *MIT* [2006] ECR I-4089 and Case C-202/05 *Yissum* [2007] ECR I-2839 (paragraphs 11-13 of the Order for Reference).

Neurim's contention

17. Neurim's contention is equally simple in that it asserts that a marketing authorisation for a medicinal product that is not the subject of the protection accorded by the basic patent is irrelevant (paragraphs 15-27 of the Order for Reference). The patents in question namely that of Hoechst on the one hand and that of Neurim on the other hand, do not overlap in scope and neither do the respective marketing authorisations.

18. In making this assertion, as to the difference in scope of protection conferred by the respective basic patents of Hoechst and Neurim, Neurim's argument is based principally on a teleological interpretation of the Regulation and the "fundamental objective" of the Regulation. Neurim relies on a different set of judgments of this Court to that of the Comptroller namely *AHP* Case C-482/07 ECR 2009 I-0000, Case C-229/09 *Hogan Lovells* judgment of 11 November 2010 [not yet reported] and Case C- 181/95 *Biogen* [1997] ECR I-00357 (paragraphs 16, 19 and 26 of the Order for Reference).

19. The Court of Appeal is of the view that Neurim's arguments are correct insofar as their arguments support the fundamental objective of the Regulation which is to promote investment in research (paragraphs 28-30).

C. THE QUESTIONS REFERRED

20. The Referring Court raises the following questions:

" 1. In interpreting Article 3 of Regulation 469/2009 ("the SPC Regulation") when a marketing authorisation (A) has been granted for a medicinal product comprising an active ingredient, is Article 3(d) to be construed as precluding the grant of an SPC based on a later marketing authorisation (B) which is for a different medicinal product comprising the same active ingredient where the limits of the protection conferred by the basic patent do not extend to placing the product the subject of the earlier MA on the market within the meaning of Article 4?

2. If the grant of the SPC is not precluded, does it follow that in interpreting Article 13(1) of the SPC Regulation, "the first authorisation to place the product on the market in the Community" needs to be an authorisation to place a medicinal product on the market within the limits of the protection conferred by the basic patent within the meaning of Article 4?

3. Are the answers to the above questions different if the earlier marketing authorisation has been granted for a veterinary medicinal product for a particular indication and the later marketing authorisation has been granted for a medicinal product for human use for a different indication?

4. Are the answers to the above questions different if the later marketing authorisation required a full application for marketing approval in accordance with Article 8 (3) of Directive 2001/83/EC (formerly a full application under Article 4 of Directive 65/65/EEC)?

5. Are the answers to the above questions different if the product covered by authorisation (A) to place the corresponding medicinal product on the market is within the scope of protection of a different patent which belongs to a different registered proprietor from the SPC applicant? "

Preliminary remarks

21. This reference is another in a series of references from the High Court and the Court of Appeal of England and Wales (United Kingdom) since 2010 on the conditions for obtaining an SPC under Article 3 of the Regulation. On 12 May 2011, the hearing took place before this Court on the earliest of these references in joined cases C-322/10 Medeva BV ("Medeva") and C-422/10 Georgetown University ("Georgetown"). Observations have been submitted in Case C-518/10 Yeda ("Yeda") and also Case C-630/10 University of Queensland ("Queensland"). These references all concern the interpretation of Article 3(a) and (b) of the Regulation.

22. This reference, on the other hand, concerns Article 3(d). However, in the view of the Commission, despite the fact that the questions in the Order for Reference are aimed at Article 3(d), that provision should not be considered in isolation of the other provisions of Article 3. In particular, Article 3(b) needs to be considered not least because there is a specific reference in the text of subparagraph (d) to subparagraph (b). In addition, the notion of "product" which is common to subparagraphs (a)-(d) in the view of the Commission also underlies any interpretation of Article 3(d).

23. In addition, the first two questions are also framed by reference to Article 4 which concerns the scope of protection conferred by an SPC, once granted.

Conditions for obtaining an SPC generally

24. As the Commission stated in Medeva and as the Referring Court acknowledges, the conditions for obtaining a certificate as set out in Article 3 (a)-(d) of the Regulation are cumulative. If any condition is not fulfilled, the SPC will not be granted (paragraph 6 of the Order for Reference).

25. Before analysing the appropriate test for determining whether or not a product is protected by a basic patent in force for the purposes of Article 3(a) of the Regulation, the Commission wishes to point out that Article 3(a) of the Regulation is not concerned with the marketing authorisation. The reference to "product" which is made in paragraphs (a) and (b) (but also (c) and (d)) of Article 3 must be read in the light of the general framework of Article 3 of the Regulation and in particular in the light of the overall scheme and objectives of the system of which it is a part (see to this effect by way of comparison Case C-482/07 AHP Manufacturing BV v BIE [2009] ECRI-7295, paragraph 27).

26. The Commission considers that the reference to the term "product" as it appears in paragraphs (a) to (d) of Article 3 is to the product which is the subject of the SPC application in question and this must be defined by reference to Article 1(b) of the Regulation.

27. Article 3(a) of the Regulation requires that, at the date of the SPC application, the "product" which is the subject of the application is protected by a basic patent in force. The Commission considers that Article 3(a) of the Regulation is, therefore, concerned with the correlation between the product which is the subject of the SPC application and the product which is the subject of the patent.

28. Article 3(b) of the Regulation requires that, at the date of the SPC application, a valid authorisation to place the product which is the subject of the application on the market has been obtained. The Commission considers that Article 3(b) of the Regulation is, therefore, concerned with the correlation between the product which is the subject of the SPC application and the product for which the marketing authorisation is granted.

29. The questions referred aim essentially at establishing whether there is a link between the marketing authorisation referred to in Article 3(b) and (d) as well as the marketing authorisation referred to in Article 13(1) of the Regulation and the basic patent referred to in Article 3(a).

30. The Commission assumes for the purposes of these observations that the condition set out in Article 3(a) is satisfied in the main proceedings and it is on that basis that the Commission makes these observations.

First Question

Interpretation of Article 3(d) of the Regulation

Wording of Article 3(d) of the Regulation

31. Article 3(d) concerns the relevant marketing authorisation. The text of Article 3(d) refers back to Article 3(b). Article 3(b) itself refers to the two separate administrative authorisation regimes for the grant of a marketing authorisation for a medicinal product namely the regime for veterinary medicinal products and that of medicinal products for human use "as appropriate" or "suivant le cas" in the French version of the Regulation. These separate regimes are more expressly set out in Article 2 which concerns the scope of the Regulation.

32. Both Article 3(b) and 3 (d) use the word "authorisation" without any further specification and without reference to the basic patent mentioned in Article 3(a). Article 3(d) does, however, contain a reference to the "product" as do subparagraph (b), (c) and (d). The term "product" is defined in Article 1(b) of the Regulation as "the active ingredient or combination of active ingredients of a medicinal product".

33. However, the reference to "first authorisation" in Article 3(d) is not qualified in any way. Therefore, a strictly literal interpretation of Article 3(d) might, at first sight, support the position taken by the Comptroller and suggest that the answer to the First Question should be in the affirmative. However, in the view of the Commission a contextual and purposive interpretation of the Regulation point in a different direction.

The context in which Article 3(d) of the Regulation occurs

34. The Referring Court has framed this question, so as to create a link between the conditions set out in Article 3 and the provisions on the scope of protection set out in Article 4.

35. The Commission observes that, as the Comptroller also contends, there is, indeed, a distinction to be made between the conditions for grant of a SPC as set out in Article 3 and the effect of the grant of an SPC as set out in Article 4. Of itself, it is not necessary to determine the scope of protection afforded by the SPC under Article 4 in order to assess whether an application for an SPC meets the conditions set out in Article 3. That being said, it is submitted that there is some merit in construing Article 3 of the Regulation in conjunction with Article 4 of the Regulation.

36. Article 4 describes the subject matter of protection conferred by an SPC once granted and provides that such protection "extends 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". This protection must, however, remain, "within the limits of the protection conferred by the basic patent".

37. The reference to the protection accorded by the SPC extending "only to the product covered by the authorisation to place the *corresponding medicinal product*" (emphasis added) in the text of Article 4 is of assistance in this respect in interpreting Article 3(d). It is submitted that the limitation of the protection

conferred by the SPC to that of the basic patent would be devoid of purpose if the goods which fall within the scope of the patent do not relate at all to the goods which fall within the marketing authorisation. The basic patent delineates the parameters of protection or as the text of Article 4 states it is "[w]ithin the limits of the protection conferred by the basic patent." That in itself is a reference to Article 3(a) of the Regulation.

38. For the avoidance of doubt, the Commission is not suggesting that construing Article 4 alongside the text of Article 3 and in particular subparagraph (d) espouses the adoption of the so called "infringement test" for the purposes of Article 3(a). On the contrary, Article 4 is limited to defining the subject matter of protection.

39. In addition, the Commission finds no merit in the Comptroller's assertion that Neurim could have relied instead on the Regulin MA with the result that it would have had a "zero scope" SPC. The question of "zero" type SPCs are currently before the Court in a very different context namely the temporal scope of an SPC. The reference in C-125/10 Merck is unlikely to shed any light on "zero scope" as it addresses the theory of zero or negative *term* SPCs (an approach which is not adopted by the Commission in its observations in that case), i.e. only the temporal but not the subject matter scope of an SPC.

40. It is therefore submitted that a contextual interpretation of Article 3(d) would support an answer to the first question in the negative.

Objective of the rules of which Article 3(d) of the Regulation forms part

41. The Court has pointed out in *AHP* "[r]egarding the objectives of Regulation No 1768/92, firstly, it must be noted that the fundamental objective of the Regulation, as set out in the first and second recitals in the preamble thereto, is to ensure sufficient protection to encourage pharmaceutical research, which plays a decisive role in the continuing improvement in public health (Case C-392/97 *Farmitalia* [1999] ECR I-5553, paragraph 19). In that regard, the third and fourth recitals in the preamble give as a reason for the adoption of the Regulation the fact that the period of effective protection under the patent is insufficient to cover the investment put into the pharmaceutical research. Regulation No 1768/92 thus seeks to make up for that insufficiency by creating an SPC for medicinal products. It seeks, in addition, to confer supplementary protection on the holders of national or European patents,

without instituting any preferential ranking amongst them (Biogen, paragraphs 26 and 27)" *(AHP* at paragraph 30, emphasis added).

42. This objective does not warrant a broad interpretation of the term "product". To prevent unmerited protection which is not justified by the investment into research which the Regulation intends to stimulate, the Court has pointed out in *MIT* that the term "product" requires a strict interpretation (paragraphs 17-23; and confirmed in *Yissum* at paragraph 17).

43. The present case does, however, concern research which is deserving of protection consistent with the rationale of the Regulation as Article 1(c) of the Regulation shows. Article 1(c) defines "basic patent" as "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" (emphasis added).

44. If one inserts the latter definition into Article 3(a), a certain tension becomes apparent. While Article 3(a) requires that the product be protected by a basic patent, the definition of "basic patent" is already fulfilled by "the application of a product". Article 1(c) therefore suggests that a basic patent may be designated for the purposes of an SPC application if the patent protects the application of the product for which the SPC is sought. Article 3(a), however, might be read to require more, namely that the product itself – and not only in its application – is protected by the designated patent. That interpretation would, however, void the last element of the definition of Article 1(c) of its *effet utile*. This last element is an important one, as §12 of the Explanatory Memorandum (COM(90) 101 final) accompanying the Commission's proposal of the regulation codified by the Regulation ("the Explanatory Memorandum") shows and §12 states the following:

> *"However, the proposal is not confined to new products only. A new process for obtaining the product or a new application of the product may also be protected by a certificate. All research, whatever the strategy for or final result, must be given sufficient protection."*

45. At the same time, the Regulation is concerned with avoiding the grant of successive SPCs for the same product. This does, however, not mean that there cannot be several SPCs for the same product. In *AHP,* the Court has held that Article 3(c) of

the Regulation, considered in the light of the second sentence of Article 3(2) of Regulation No 1610/96, must be interpreted as not precluding the grant of an SPC to the holder of a basic patent for a product for which, at the time the SPC application is submitted, one or more SPCs have already been granted to one or more holders of one or more other basic patents (Case C-482/07 AHP Manufacturing, paragraph 43). This judgment averts any risk of "evergreening" through successive SPCs as all these SPCs would end at the same point in time by virtue of Article 13 of the Regulation (Case C-127/00 *Hässle* ECR 2003 I-14781, paragraph 77) given that the duration of all these SPCs would be calculated on the basis of the same marketing authorisation. In the present case, an SPC for Neurim would expire at a different point in time than the one that would be granted to Hoechst. The question arises if this would amount to the grant of successive SPCs and an "evergreening" which would be contrary to the purpose of the Regulation. It is submitted that it would not do so, for the following reason.

46. The notion of "evergreening" is explained in §36 of the Explanatory Memorandum, which states:

> *"The certificate is designed to encourage research into new medicinal products [...]. However, it would not be acceptable, in view of the balance required between the interests concerned, for this total duration of protection for one and the same medicinal product to be exceeded. This might nevertheless be the case if one and the same product were able to be the subject of successive certificates. This calls for a strict definition of the product within the meaning of Article 2. If a certificate has already been granted for the active ingredient itself, a new certificate may not be granted for one and the same active ingredient whatever minor changes may have been made regarding other features of the medicinal product"* (emphasis added).

47. This extract from the Explanatory Memorandum shows that the Regulation is concerned with stimulating research into new *medicinal* products rather than products as such. The proxy it uses is the concept of product, as Advocate General Jacobs has explained in paragraph 38 of his opinion in *Pharmacia,* which serves as the "interface" between the basic patent (the duration of which is considered too short) and the marketing authorisation (the necessity of which is the reason for the short effective term of protection):

"The Regulation operates at the interface between patent protection of products and authorisation to market medicinal products: it seeks to extend the patent protection of products which are constituents of authorised medicinal products. An awareness of that context is essential to a correct understanding of the Regulation."

48. The Court held in *Yissum* (C-202/05, ECR 2007 I-2839 paragraphs 18, 20), very much in line with the Explanatory Memorandum's call for a strict interpretation, *"that the concept of 'product' cannot include the therapeutic use of an active ingredient protected by a basic patent"* and *"that Article 1(b) [...] is to be interpreted as meaning that in a case where a basic patent protects a second medical use of an active ingredient, that use does not form an integral part of the definition of the product"*.

49. The fact that SPCs are not granted for "medicinal products", but for "products", should, however, not deflect attention from the ultimate aim of stimulating research into medicinal products (not products as such) without evergreening the protection of such medicinal products through successive SPCs. Arguing in favour of an affirmative answer to the first question risks loses sight of that basic objective and elevates the proxy "product" to a more central role than it deserves. It is submitted that §36 strikes this balance quite well by referring to the situation in which *"a certificate has already been granted for the active ingredient itself"* (emphasis added) as precluding the grant of another certificate. In the present case, no certificate appears to have been granted for the active ingredient itself as the active ingredient itself is not even the subject of a patent (see paragraph 3 of the Order for Reference).

50. Clearly, in a situation in which an SPC has been granted for a product and there are only (minor) changes to the active ingredient or the use of that active ingredient, no further SPC should be granted as the Court in *Yissum* ruled and the Explanatory Memorandum states was the intention. However, if no SPC has been granted for an active ingredient itself at all, it would appear that the purposive interpretation of Article 3(d) of the Regulation (in light of Article 1(c) of the Regulation) which suggests that an SPC should be granted for a certain use thereof (*if* Article 3(a) is fulfilled, see paragraph 30 above). This should not lead to evergreening and would not jeopardise the legal certainty required in the application of Article 3 of the Regulation (see to this effect by way of comparison *MIT*, at paragraph 29).

51. The First Question should therefore only be answered in the negative provided that the basic patent in question clearly does not extend to the placing the product which is the subject of the earlier marketing authorisation on the market. As set out in paragraph 30 above, the reply should also clarify that the issue raised by the Referring Court is mute if the condition laid down in Article 3(a) of the Regulation is not satisfied.

52. It would appear that this approach is not at odds with the Court's judgment in *Pharmacia Italia* (Case C-31/03, ECR 2004 I-10001) as the latter concerned a case in which the designated patent appears to have read on the active ingredient of all the relevant medicinal products for which marketing authorisations had been granted (see AG Jacob's opinion in that case, paragraphs 23 and 24). This is not the case here.

Second Question

53. While the marketing authorisation referred to in Article 3(b) and (d) of the Regulation is the authorisation granted for the Member State in which the application is submitted, the marketing authorisation referred to in Article 13(1) is the first one for the Community (or EU as it is now), which is not necessarily the same (Case C-127/00 *Hässle*, paragraph 73). However, there appears to be no reason to also differentiate in substantive (as opposed to geographic) terms between the term marketing authorisation as used in Article 3 and in Article 13(1). The systematic and purposive interpretation of Article 3(d) undertaken in the context of the First Question above would be undermined, if the Second Question were not answered in the affirmative.

Third Question

54. There is nothing in the text of Article 3(b) and Article 3(d) to suggest that a marketing authorisation which has been granted under either authorisation regime for medicinal products (veterinary or human use) should or should not be taken into account in assessing which is the "first authorisation" within the meaning of Article 3(d). There is no general distinction in principle between the marketing authorisation regimes for medicinal products for human use human and veterinary medicinal products. For the reasons set out in the Court's judgment at paragraph 20 of *Pharmacia Italia* the answer to the Third Question must be in the negative.

Fourth Question

55. "Full application" means that the application consists of all the particulars and documents set out in Article 8(3) of Directive 2001/83/EC. In regulatory terms, a full application may not always be necessary. Directive 2001/83/EC establishes various derogations from the dossier requirements in Article 8(3). In principle, and leaving aside the possibility of a well-established medicinal use marketing authorisation, the first authorisation to place a product on the market will always be a full application. However, that does not exclude that subsequent marketing authorisation applications for the same/similar products are submitted on the basis of a full dossier as the conditions for an abridged procedure may not be fulfilled. Moreover, an application for a human medicinal product cannot refer to data contained in a dossier for a veterinary medicinal product and vice versa. Consequently, the necessity of submitting a full application under Article 8(3) is independent of any veterinary medicinal product containing the same active ingredient which may be already authorised for a medicinal product for human use.

56. This illustrates that the regulatory requirements under Directive 2001/83/EC to submit or not a full application follow very different considerations from those which are at the heart of the Regulation. They do not appear to have any relevance for the questions referred. The Fourth Question should therefore be answered in the negative.

Fifth Question

57. With its Fifth Question, the Referring Court seems to be exploring whether a negative answer to the First Question would need to rely on the insight that the Regulation confers supplementary protection on the holders of national or European patents *without instituting any preferential ranking amongst them* (see paragraph 41 above). As it would not do so, for the reasons set out above in response to the First Question, the Fifth Question ought to be answered in the negative.

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

"Question 1: Article 3(d) of Regulation (EC) No 469/2009 must be interpreted as not precluding the grant of a supplementary protection certificate based on a marketing authorisation (B) in a situation in which an earlier marketing

authorisation (A) has been granted for a medicinal product comprising an active ingredient which is for a different medicinal product comprising the same active ingredient where it is evident that the limits of the protection conferred by the basic patent within the meaning of Article 4 of the Regulation do not extend to the product which is the subject of the earlier marketing authorisation A, provided that all the other conditions of Article 3 of the Regulation are fulfilled and in particular that of Article 3(a). It is for the national court to make this assessment with reference to the rules that govern the patent.

Question 2 : In the light of the proposed response to Question 1, the reference to the first marketing authorisation to place the product on the market in the European Union in Article 13(1) of Regulation (EC) No 469/2009 must be interpreted as an authorisation to place a medicinal product on the market within the limits of the protection conferred by the basic patent within the meaning of Article 4.

This applies independently of whether:

- in case of Question 3, the earlier marketing authorisation A has been granted for a veterinary medicinal product and the later marketing authorisation B for medicinal product for human use;

-in the case of Question 4, the later marketing authorisation B required a full application for marketing approval in accordance with Article 8(3) of Directive 2001/83/EC;

- in the case of Question 5, the product covered by the earlier marketing authorisation A is within the scope of protection of a different patent which belongs to a different registered proprietor from the SPC applicant."

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