EUROPEAN COMMISSION

Brussels, 21 February 2014
sj.a(2014)459692
Court procedural documents

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 Ms Merete Clausen 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-577/13

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

(1) ACTAVIS GROUP PTC KHF
(a company incorporated under the laws of Iceland)
(2) ACTAVIS UK LIMITED

Claimants

and

BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG
(a company incorporated under the laws of Germany)

Defendant

concerning the interpretation 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 (codified version) OJ 16.6.2009 L152/1.

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

1. This is a request for a preliminary ruling by the High Court of Justice, Chancery Division, Patent Court (United Kingdom) ("the Referring Court"), in a dispute between Actavis Group PTC KHF and Acatavis UK Limited, ("the Claimants") on the one hand and Boehringer Ingelheim Pharma GMBH & Co. KG ("the Defendant") on the other hand. The order for reference dated 23 September 2014 sets out in its schedule, the questions referred, the agreed statement of facts, the preliminary view of the Referring Court and a summary of the arguments of the Claimants and the Defendant.

2. The present case concerns the interpretation of Article 3 and 13 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 product (codified version) OJ 16.6.2009 L152/1 ("the Regulation").

3. The dispute concerns a challenge to the validity of the supplementary protection certificate SPC/GB02/037 ("the Combination SPC") protecting the combination of two active ingredients, i.e. Telmisartan and hydrochlorothiazide ("the Combination Product"). The owner of that Combination SPC is the Defendant. The patent to which the Combination SPC applies is European Patent EP 0 502 314 which was designated as the basic patent in force for the territory of the UK for the purposes of Article 3(a) of Regulation.

4. As it appears from the agreed statement of facts in the schedule to the order, it is common ground that the basic patent in force was amended at the recommendation of the UK IPO following the initial submission of the application for the Combination SPC on 6 September 2002. This is summarised briefly below.

5. On 6 September 2002, the application for the SPC was first filed before the UK IPO. The UK IPO considered that the basic patent in force did not contain the claim(s) protecting the Combination Product. The UK IPO recommended to the Defendant that they amend the basic patent to insert a claim which would include the Combination Product. On 10 November 2003, the Defendants requested the

suspension of the procedure for the grant of the application for the Combination SPC.

6. On 20 November 2003, the Defendant applied to amend the basic patent. On 22 December 2003, the UK IPO agreed to suspend the application for the Combination SPC. On 10 November 2004, the UK IPO allowed the amendments to the patent. The procedure for the application for the Combination SPC began again, this time on the basis of the basic patent, as amended.

7. On 13 January 2005, the UK IPO granted the Combination SPC. On 30 January 2012, the basic patent, as amended, expired. The Combination SPC entered into force on 31 January 2012 and is due to expire on 30 January 2017.

8. There are two relevant marketing authorisations in this dispute. The first marketing authorisation is for the single active ingredient, telmisartan. This first marketing authorisation was the basis of an earlier supplementary patent certificate for the single active ingredient for which the basic patent was designated for the purposes of Article 3(a) and it served as the marketing authorisation for the purposes of Article 3(b) of the Regulation. The second marketing authorisation was for the Combination Product and formed the basis of the application for the Combination SPC.

9. The Claimants have challenged the validity of the Combination SPC on the basis that 'at the date of the application', the relevant product was not 'specified in the wording of the claims of the patent' and that at the date of the SPC application namely 6 September 2002, the basic patent "subject of the application for the Combination SPC did not contain claim 12, and none of the claims of the Patent specified the Combination Product in their wording" (paragraphs 1-2 of the Claimants' arguments).

10. The Defendant contends that "European and national legislation permit patents to be amended post-grant" and "where a patent can be permissibly amended by definition the protection it confers is not extended [i]t therefore follows that if, following amendment, the basic patent in force 'protects' the product for which the SPC is

sought then prior to amendment it must also have 'protected' that product" (paragraph 2 of the Defendants' arguments).

2. THE QUESTIONS REFERRED

1. (a) If a patent does not, upon grant, contain a claim that explicitly identifies two active ingredients in combination, but the patent could be amended so as to include such a claim could this patent, whether or not such an amendment is made, be relied upon as a "basic patent in force" for a product comprising those ingredients in combination pursuant to Article 3(a) of Regulation No 469/2006/EC ("the Regulation")?

   (b) Can a patent that has been amended after the grant of the patent and either (i) before and / or (ii) after grant of the SPC be relied upon as the "basic patent in force" for the purposes of fulfilling the condition set out in Article 3(a) of the Regulation?

   (c) Where an applicant applies for an SPC for a product comprised of active ingredients A and B in circumstances where

      (i) after the date of application for the SPC but before the grant of the SPC, the basic patent in force, being a European Patent (UK) (the "Patent") is amended so as to include a claim which explicitly identifies A and B;

      and

      (ii) the amendment is deemed, as a matter of national law, always to have had effect from the grant of the Patent;

      is the applicant for the SPC entitled to rely upon the Patent in its amended form for the purposes of fulfilling the Art 3(a) condition?

2. For the purposes of determining whether the conditions in Article 3 are made out at the date of the application for an SPC for a product comprised of the combination of active ingredients A and B, where (i) the basic patent in force includes a claim to a product comprising active ingredient A and a further claim to a product comprising the combination of active ingredients A and B and (ii) there is already an SPC for a product comprising active ingredient A ("Product X") is it necessary to consider whether the combination of active ingredients A and B is a distinct and separate invention from that of A alone ?

3. Where the basic patent in force "protects" pursuant to Article 3(a):

   (a) A product comprising active ingredient A ("Product X"); and

   (b) A product comprising a combination of active ingredient A and active ingredient B ("Product Y").

   And where:

   (c) An authorisation to place Product X on the market as a medicinal product has been granted;

   (d) An SPC has been granted in respect of Product X; and

   (e) A separate authorisation to place Product Y on the market as a medicinal product has subsequently been granted.

   Does the Regulation, in particular Articles 3(c), 3(d) and/or 13(1) of the Regulation preclude the proprietor of the patent being issued with an SPC in respect of Product Y? Alternatively, if an SPC can be granted in respect of Product Y, should its duration be assessed by reference to the grant of the authorisation for Product X or the authorisation for Product Y?

4. If the answer to question 1(a) is in the negative and the answer to question l(b)(i) is positive and the answer to question l(b)(ii) is negative, then in circumstances where:

   (i) in accordance with Art 7(1) Regulation, an application for an SPC for a product is lodged within six months of the date on which a valid authorisation to place that product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC;

   (ii) following the lodging of the application for the SPG, the competent industrial property office raises a potential objection to the grant of the SPC under Article 3(a) of the Regulation;

   (iii) following and in order to meet the aforesaid potential objection by the competent industrial property office, an application to amend the basic patent in force relied upon by the SPC applicant is made and granted;

   (iv) upon amendment of the basic patent in force, said amended patent complies with Article 3(a);

   does the SPC Regulation prevent the competent industrial property office from applying national procedural provisions to enable (a) suspension of the application for the SPC in order to allow the SPC applicant to apply to amend the basic patent, and (b) recommencement of said application at a

later date once the amendment has been granted, the said date of recommencement being

- after six months from the date on which a valid authorisation to place that product on the market as a medicinal product was granted but

- within six months of the date on which the application to amend the basic patent in force was granted?

3. PRELIMINARY REMARKS

11. The Commission considers that this reference may be decided by reasoned order on the basis of Article 99 of the Rules of Procedure of the Court as the answers can be clearly deduced from existing case law, in particular the recent judgment in Case C-443/12 *Actavis Group PTC EHF and Actavis UK Ltd v Sanofi,* Judgment of 12 December 2013 (not yet reported) *("C-443/12 Actavis").*

12. For the reasons set out below, it suffices, in the view of the Commission, to reply to the first part of Question 3. Question 2 could also be addressed for purposes of clarification but there is no need to reply to the remaining Questions 1 and 4. The Commission will, therefore, limit its analysis to the first part of Question 3 and examine it together with Question 2.

13. As the Referring Court acknowledges, Question 2 is in essence the same as that raised by Case C-322/10 *Medeva BV v Comptroller General of Patents, Designs and Trade Marks* ECR 2011 I-12051 ("*Medeva*") and the further judgments that followed *Medeva* in this field[1] including *Case C-443/12 Actavis.* However, the judgment in *C-443/12 Actavis* was handed down on 12 December 2013 after the Referring Court made the present reference on 22 September 2013.

14. It follows from the Court's judgment in *C-443/12 Actavis* that the holder of a patent is precluded from obtaining a supplementary protection certificate in circumstances

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[1] 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.

such as those in the main proceedings. In *C-443/12 Actavis,* the Court held that a supplementary protection certificate for a combination of active ingredients A and B cannot be granted where, first, there is already a supplementary protection certificate for a single active ingredient A and, second, the patent does not protect active ingredient B "as such" (ibid., paragraph 43). The Commission understands the use of the term "as such" to mean "in isolation", i.e. not in combination with any other active ingredient.

15. In its reasoning in *C-443/12 Actavis*, the Court seeks to prevent the likely reaction to this approach by patentees, namely to divide patents up and seek a separate patent for A + B, by introducing the notions "new basic patent" and "totally separate innovation" (ibid., para. 42). The Commission refers to paragraphs 62-72 of its observations in *C-443/12 Actavis* where it had stated its doubts as to the viability of a similar notion.

16. Assuming for the purposes of the present case that telmisartan is active ingredient A and hydrochlorothiazide is active ingredient B, *C-443/12 Actavis* shows that the combination SPC sought may not be granted, independently of whether hydrochlorothiazide was expressly identified in the Patent. Hydrochlorothiazide is simply not protected *as such* by the patent – neither before nor after the amendment. The questions regarding the relevance of the amendment and the duration of a supplementary protection certificate granted for a combination are, therefore, moot.

17. It also follows from the judgment in *C-443/12 Actavis* that it is not necessary to consider, in the present case, whether the combination of active ingredients A and B is a distinct and separate invention from that of A alone for the purposes of Question 2.

18. The Commission, therefore, only proposes to answer the first part of Question 3 and Question 2 in a single response as follows: the proprietor of the patent such as that at issue in the present case is precluded from obtaining a supplementary protection certificate in respect of Product Y where the factual circumstances set out in Question 3(a) – (e) apply.

4. CONCLUSION

Proposed response to the first part of Question 3 and Question 2:

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. It is, in circumstances such as those in the main proceedings, therefore, not necessary to consider whether the combination of active ingredients A and B is a distinct and separate invention from that of A alone.

19. In the light of that proposed reply, it follows that no reply is necessary to Questions 1 and 4.

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Agents for the Commission