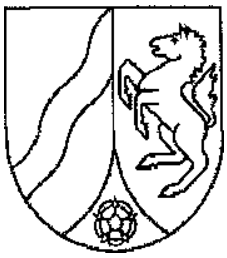


DÜSSELDORF DISTRICT COURT

DECISION

4b O 66/11

In the matter

Novartis AG, legally represented by its management, Lichtstraße 35, 4056 Basel, Switzerland,

Plaintiff,

- Attorneys of record: Law firm of Freshfields Bruckhaus Deringer, Feldmühleplatz 1, 40545 Düsseldorf, -

versus

1. **Actavis Deutschland GmbH & Co. KG,** Elisabeth-Selbert-Straße 1, 40764 Langenfeld,
2. **Actavis Ltd.,** BLB 016 B Bulebel Industrial Estate, ZTN 3000 Zejtun, Malta,

Defendants,

- Attorneys of record: Law firm of Gleiss Lutz, Bleichstraße 8 - 10, 40211 Düsseldorf, -

Presiding Judge Voß, Judge Dr. Rinken and Judge Dr. Reimnitz of Civil Chamber 4b of the Düsseldorf District Court, after hearing the parties, have found as follows on 8 November 2011:

I. The proceedings are being stayed.

II. The following question is being submitted to the Court of Justice of the European Union (CJEU) in accordance with Art. 267 TFEU to decide on how Articles 4 and 5 of Regulation (EC) No. 469/2009 should be interpreted:

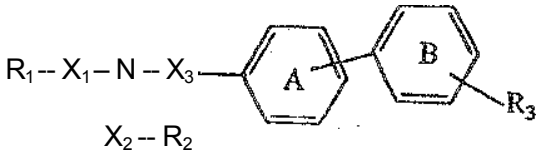
Should Articles 4 and 5 of Regulation (EC) No. 469/2009 be interpreted in such a way that the protection of a supplementary protection certificate, which has been granted for a single active ingredient (here: Valsartan), covers an embodiment comprising a combination of active ingredients (here: Valsartan + Hydrochlorothiazide) that contains such single active ingredient?

Reasons:

I.

1 Plaintiff is the holder of supplementary protection certificate DE 19 675 036 (hereinafter: "certificate in suit," cf. the register excerpt according to Exhibit FBD 8), which is based on patent EP 0 443 983 B1 (hereinafter: "basic patent," Exhibit FBD 6), which has been validated in Germany under patent number DE 59 107 440.

2 Until its expiry on 12 February 2011, claim 1 in conjunction with claim 26 of the basic patent protected the active ingredient known under the international non-proprietary name Valsartan. Dependent claim 26 of the basic patent specifies an acyl compound according to formula I of claim 1



as follows:

> "(S)-N-(1-Carboxy-2-methyl-prop-1-yl)-N-pentanoyl-N-[2'-(1H-tetrazol-5-yl)biphenyl-4-ylmethyl]-amine, in free form or in salt form."

3 Valsartan is an active ingredient from the group of AT1 antagonists, which is normally used in the treatment of high blood pressure and slight to medium-heavy cardiac insufficiency if a therapy with ACE blockers is unsuitable. The original product DIOVAN® is being sold since 1996 by one of Plaintiff's group companies. Combination products are also being sold apart from this single substance product, such as, for example, CODIOVAN® with the combination of active ingredients Valsartan and Hydrochlorothiazide, EXFORGE® with the combination of active ingredients Valsartan and Amlodipine, and EXFORGE®HCT with the combination of active ingredients Valsartan, Amlodipine and Hydrochlorothiazide. Plaintiff is also selling other branded products containing the single substance preparation and the aforementioned combinations of active ingredients.

4 In the period from 13 February 2011 to (and including) 13 November 2011, the product Valsartan is being protected by the certificate in suit, whereby protection for the period as of 14 May 2011 is based on an extension according to Regulation (EC) No. 1901/2006. The certificate in suit is further based on German Marketing Authorisations No. 36983.00.00 and 36983.01.00 for the single active ingredient Valsartan as medicinal product DIOVAN®. Unlike in other countries, Plaintiff did not file for a certificate in Germany for its combination of active ingredients "Valsartan + Hydrochlorothiazide" (hereinafter: "V + H") (cf. "Agreed Statement of Facts" according to Exhibit B 7).

5 Defendants belong to the international Actavis Group, whereby Defendant 1) is the German sales company and Defendant 2) is its Maltese production company.

6 In Germany, Actavis-Group PTC ehf., which is affiliated with Defendants, is the holder of the market authorisations for the combination medicinal product Valsartan-Actavis comp, comprising the active ingredients Valsartan and Hydrochlorothiazide in the following dosages (cf. excerpts from the AMIS database according to Set of Exhibits FBD 9; hereinafter: "contested embodiments"):

- Valsartan-Actavis 80 mg/2.5 mg coated tablets
- Valsartan-Actavis comp 160 mg/2.5 mg coated tablets and
- Valsartan-Actavis comp 160 mg/25 mg coated tablets.

7 Defendant 2) is specified as the manufacturer, along with Generikon Pharma GmbH; Defendant 1) is listed as the sole sales company.

8 In its letter dated 14 December 2010, Defendant 1) announced that it intends to sell the contested embodiments in Germany before the expiry of the certificate in suit. In preliminary injunction proceedings before the Chamber, Defendants were sentenced to cease and desist from selling the contested embodiments as requested, based on the certificate in suit (cf. Exhibits FBD 1, FBD 2).

9 Plaintiff holds the opinion that the certificate in suit would be violated if the announced market launch of the contested embodiments in Germany were to actually take place, for its extent of protection covers also generics comprising another active ingredient apart from Valsartan. The legal situation therefore should not be assessed differently than the legal situation in respect of the basic patent. This is supported both by the wording and by the classification of Articles 4 and 5 of Regulation (EC) No. 469/2009 dated 06 May 2009 (hereinafter: "SPC Regulation"): The protective effect of a protection certificate is similar to the protective effect of the basic patent; only the subject matter of protection is limited to the product that is covered by the authorisation. This kind of interpretation is also in line with the meaning and purpose of the protection certificate regulation, as expressed in the relevant recitals (3), (4) and (5).

10 By invoking the certificate in suit, Plaintiff is (basically) requesting also in these main proceedings that Defendants be sentenced to cease and desist from selling the contested embodiments within the Federal Republic of Germany.

11 Defendants, who have filed for the dismissal of the action, believe that the contested embodiments make no use of the teaching that is protected by the certificate in suit, arguing basically as follows: Art. 4 SPC Regulation limits the protection to medicinal products that

contain (only) the active ingredient according to the certificate or the combination of active ingredients according to the certificate. This kind of understanding is supported already by the grammatical interpretation of Articles 4, 5 SPC Regulation. A single active ingredient is a different product in terms of the SPC Regulation than a combination of active ingredients. The historic interpretation of the respective provisions would not lead to clear results, but certainly would not militate against Defendants' interpretation. With Art. 4 SPC Regulation, the European legislature passed a special law (*lex specialis*) as compared to Art. 5 SPC Regulation and patent law; i.e., when it comes to the protective scope of a certificate, nothing at all can be derived from the protective scope of "hypothetical patent claims." The purpose of the law also supports their interpretation because only their interpretation allows for an avoidance of inconsistencies within the SPC Regulation. One has to see, in particular, that Art. 3c) SPC Regulation excludes the granting of several certificates for one and the same product. This principle must not be bypassed through an expanded interpretation of a certificate that was granted for a different product. Otherwise, one would even be faced with illogical consequences as regards the term and the nullity of a certificate.

II.

1.

12 As is rightly undisputed between the Parties, the decision of the legal dispute depends solely on the answer to the question of law specified at the beginning under No. II. of the decision.

13 For, if the respective question of law were to be answered in the affirmative, Plaintiff would be entitled to the cease and desist claims brought against Defendant 1) and 2) under Sec. 16a, sentence 2, Sec. 139 (1) of the Patent Act, Art. 64 (1) EPC.

14 There is a risk of first infringement especially in light of the letter of Defendant 1) dated 14 December 2010, because it shows that Defendant 2) intends to supply Defendant 1) with the contested embodiments and that Defendant 1) intends to sell these medicinal products on the German market before the expiry of the protection term of the certificate in suit. In that case, Defendant 2), who is specified as the manufacturer in the authorisations under pharmaceutical law, would be liable for the infringement regardless of the fact that it is domiciled abroad, because it would deliberately and willingly contribute to the sale of the contested embodiments in Germany, fully aware of the certificate in suit and of the country of destination (cf. BGH, GRUR 2002, 599 – Radio clock I).

2.

15 The stipulations of the SPC Regulation that are to be interpreted in order to answer the relevant question of law read as follows:

> ***Art. 4***
>
> *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.*
>
> ***Art. 5***
>
> *Subject to the provisions of Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.*

3.

16 The Chamber is inclined to answer the submitted question of law in the same manner as Plaintiff did. The Chamber's opinion is based on the following considerations, taking into account the essential arguments presented by the Parties:

a)

17 While, according to its official heading, Art. 5 SPC Regulation governs the "effects of the certificate," Art. 4 SPC Regulation, according to its official heading, concerns the "subject matter of protection" of the supplementary protection certificate. I.e., Art. 4 SPC Regulation distinguishes between the "product," which in Art. 1b) is defined as "the active ingredient or the combination of active ingredients of a medicinal product," and the "medicinal product" (cf. the legal definition in Art. 1a) SPC Regulation). Only the subject matter of protection is limited to the product that is covered by the authorisation.

18 Art. 4 SPC Regulation uses three criteria to determine the subject matter of protection:

– First, it is clarified – quite declaratory – that the absolute limit is defined by the protective scope of the basic patent.

– Then, the product is identified in order to exclude such substances from the protected active ingredient that possibly constitute a further subject matter of protection of the basic patent. Various passages in the SPC Regulation, which make reference to the product identified in the authorisation, show that Art. 4 SPC Regulation is not about establishing a limitation to the specific authorised medicinal product: Art. 8 (1 b) and (1 c), Art. 9 (2 d), Art. 11 (1 d) SPC Regulation.

– Ultimately, Art. 4 SPC Regulation provides for a purpose-bound substance protection by limiting the subject matter of protection to authorised uses.

19 According to Art. 5 SPC Regulation, on the other hand, the effect of the protection certificate is aligned to the effects of the basic patent.

20 In the present case, the product covered by Art. 4 SPC Regulation is the active ingredient Valsartan protected by sub-claim 26, while other compounds falling under the claims of the basic patent can basically be manufactured without being limited by the protection certificate. In order to determine the extent of protection of the certificate in suit, one must fictitiously read the patent claims – that protect also other substances – as if specifying only the active ingredient Valsartan that is described in the certificate; this leads to a hypothetical patent claim which is product and purpose related (cf. Benkard/Grabinski, Patentgesetz, 10th edition, § 16a, marg. no. 38). In the present case, this means that the subject matter protected by the certificate in suit is "Valsartan in all approved uses as medicinal product." Given that according to Art. 5 SPC Regulation the effect of protection is aligned to the basic patent, the certificate in suit comprises all medicinal products that contain the active ingredient Valsartan – even if the latter is combined with other active ingredients. According to the principles under patent law, which according to Art. 5 SPC Regulation also apply to the certificate in suit, it is irrelevant from an infringement point of view whether or not a medicinal product shows other features apart from the active ingredient Valsartan; in particular, it does not mean that a medicinal product does not infringe a patent if it contains also one or more other active ingredients apart from Valsartan. Such additions might, at best, lead to a so-called dependent invention, which, however, from a patent law point of view, admittedly cannot be used to argue that no infringement of a patent has taken place (cf., e.g., BGH, GRUR 1992, 436 – Fixing device II). This principle is extended to supplementary protection certificates through Art. 5 SPC Regulation. The fact that the single active ingredient Valsartan is a different product than "V +

H" does not conflict with the view taken here: Art. 4 SPC Regulation has only one task – and that is to individualize the subject matter of protection. The extent of protection that applies to the product thus identified is then determined by Art. 5 SPC Regulation. I.e., Art. 5 SPC Regulation makes, in particular, no differentiation according to the criteria of whether the addition of yet another active ingredient is essential or immaterial.

21 If and in as far as Defendants claim that Art. 4 SPC Regulation is a special law (*lex specialis*) as compared to patent law and Art. 5 SPC Regulation, it must be countered that the provision in Art. 5 SPC Regulation regarding the effect of protection of the product is not eliminated by Art. 4 SPC Regulation, but that it rather determines the effects of protection based on its definition of subject matter of protection. This is also supported by the structure of the SPC Regulation: it would be at least very unusual if the lawmaker had mentioned in its text the allegedly special law provision of Art. 4 SPC Regulation before the allegedly general law provision in Art. 5 SPC Regulation.

22 A synopsis of the recitals pertaining to the SPC Regulation shows that an extension of patent protection is, in fact, supposed to be achieved in order to create a balance for the loss of effective patent protection (cf. Benkard/Grabinski, Patentgesetz, 10th edition, § 16a, marg. no. 9; cf. Schulte/Kühnen, Patentgesetz, 8th edition, § 16a, marg. no. 5). The patent holder is supposed to be compensated (at any rate partially, cf. Art. 13 (1) and (2) SPC Regulation) for the fact that marketing of the invention is subordinated to a marketing authorisation procedure in the interest of national health. The national German lawmaker had a similar understanding of the SPC Regulation when it introduced Sec. 16a of the Patent Act (cf. BT printed matter 12/3630, pg. 6, I. 1., Exhibit FBD 11).

23 Recital (3) of the SPC Regulation first emphasizes that medicinal products, especially those that are the result of long, costly research will not continue to be developed unless they are covered by favorable rules that provide for sufficient protection to encourage such research. The authors of the SPC Regulation then state in recital (4) that because of 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. As a consequence, this leads to a lack of protection which penalizes pharmaceutical research (cf. recital (5)) and to a risk of research centers situated in the EEA relocating to countries that offer greater protection (cf. recitals (6) and (7)). Because of this misbalance, the authors of the SPC Regulation consider it necessary to create a supplementary protection certificate for medicinal products that have been authorised (cf. recital (8)). In order to ensure sufficient, actual protection, the holder of both a patent and a certificate should be able to enjoy an

overall maximum of 15 years of exclusivity (cf. recital (9)). By emphasizing that the time of actual patent protection is reduced, it is expressed that it is the legislative intention of the SPC Regulation to give back (some of) the lost patent protection.

24 The limitation of the subject matter protected by a certificate in accordance with Art. 4 SPC Regulation is therefore to be interpreted such that it only serves to exclude "over-protection": In the event that the basic patent provides protection for further products or active ingredients that are not specifically included in the certificate, an exception is stipulated to the principle in Art. 5 SPC Regulation that the same scope of protection applies to both the basic patent and the certificate. When determining the subject matter protected by a certificate, the patent claims which potentially also protect further active ingredients shall fictitiously be considered as if naming only the active ingredient indicated in the certificate; as already explained hereinabove, Art. 4 SPC Regulation leads to a hypothetical patent claim, which is product-bound and purpose-bound. Compensation hence is not limited to an authorisation procedure for a specific medicinal product, but it is granted for the time period starting with the filing of the basic patent, during which a product according to the invention must not be sold (taking into account a maximum term of five years from the effective date of the certificate, Art. 13 (2) SPC Regulation).

25 Recital (10) in the SPC Regulation does not provide any reasons for a different interpretation. Since it states that "the protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product," this does not support Defendants' narrow interpretation of the subject matter protected by a certificate. This passage, too, shows the SPC Regulation's strict differentiation between the terms "product" and "medicinal product" (cf. hereinabove). In accordance with Art. 4 SPC Regulation, recital (10), too, confines protection to the product which obtained authorisation to be placed on the market as a medicinal product; however, this, too, should not be equated with the concept of a "pharmaceutically authorised product," which the SPC Regulation does not use.

26 In the opinion of the Chamber, Defendants' reference to marg. nos. 9, 13, 20 and 39 in the EC Commission's statement of grounds for a preliminary draft of the SPC Regulation (cf. Schennen, "The Extension of Patent Protection" (Die Verlängerung der Patentlaufzeit), 1993, pages 95 – 97, 102) does not support their opinion either. Marg. no. 39, in particular, confirms that Art. 4 SPC Regulation has the function of identifying those active ingredients from a multitude of active ingredients protected under a basic patent, which are to be also included in the subject matter protected by the certificate.

27 A supplementary protection certificate is not merely an extension of the patent protection term but is a protected right sui generis. However, this alone does not justify the conclusion that the stipulations in Art. 4 SPC Regulation (completely) replace the general principles under patent law. This view would not be in accordance with the recitals listed above. Moreover, Defendants' interpretation would also result in that the desired compensation for the loss of effective patent protection could be far too easily circumvented, which would contradict the protective purpose of the SPC Regulation (cf. European Court of Justice, GRUR Int. 2000, 69, 70 et seq. – Farmitalia). This would in turn have the consequence of economically undermining the protection granted by a certificate.

c)

28 Defendants may be right in that the individual ingredient Valsartan, on the one hand, and the combination "V + H," on the other, are two different products. They are, however, not only different in terms of the SPC Regulation (cf. the differentiation between "active ingredient" and "combination of active ingredients" in Art. 1b) SPC Regulation), but also in terms of patent law pursuant to Sec. 9, sentence 2, no. 1 of the Patent Act. Defendants' reference to the "Escitalopram" decision (BGH GRUR 2010, 123), where, based on the circumstances of the individual case, a racemic mixture was considered to be a different active ingredient or at least a different combination of active ingredients in relation to a single enantiomer, also does not provide an argument in Defendants' favor, since the circumstances of that case did not pertain to the situation of a "dependent invention." Thus, based on the necessary legal assessment considering the protective purpose of the SPC Regulation, this decision does not exclude "V + H" from falling under the protection of the certificate for the product Valsartan.

d)

29 To support their interpretation, Defendants have – albeit unsuccessfully – cited Art. 3c) SPC Regulation, which in their opinion provides for a prohibition of double protection. According to Art. 3 c) SPC Regulation, a certificate is granted only "if the product has not already been the subject of a certificate."

30 The Chamber is of the opinion that the stated stipulation results in nothing more than a ban on double granting – just as patent law also contains a prohibition of double granting, however there is still the possibility of so-called dependent inventions. Art. 3c) SPC Regulation simply wants to prevent the multiple issuing of one and the same certificate for

the benefit of the same applicant for one product protected by multiple patents. Such cases are feasible, e.g., when various uses or indications and synthesis processes are patented in addition to the active ingredient as such. This does not necessarily mean, however, that a certain subject matter of infringement cannot fall under the protective scope of two IP rights. Defendants' conclusion that, because the issuing of two certificates is not permitted for the identical product "A + B," this should mean that an extension of the protection of A to the combination of A + B would also be inadmissible, is not justified.

31 In as far as Defendants argue that the interpretation presented here also leads to an evasion of the calculation of the term (Art. 13 SPC Regulation) and of the grounds for invalidity (Articles 3, 15 (1a) SPC Regulation), we counter as follows:

32 Even under patent law, cases may exist where a dependent patent may prove invalid but where the subject matter of infringement continues to be subject to the prohibition derived from the basic patent.

33 As regards the possible threat of exceeding the statutory maximum term (of five years according to Art. 13 (2) SPC Regulation), the Chamber is of the opinion that the following solution could help resolve the issues presented by Defendants: should a certificate already have been in place for three years to protect the active ingredient A, so that according to the interpretation presented in this case it simultaneously creates protection for the combination A + B, this circumstance could be taken into consideration in the event of an application for a certificate for the combination of active ingredients A + B in the grant procedure in such a way, that the period of three years for which protection for the combination of active ingredients results already from the certificate for the single active ingredient is taken into consideration, meaning that the term of the newer certificate would have to be limited to a maximum of two years.

III.

34 The parties have informed the Chamber that proceedings between Plaintiff and Actavis UK Limited are pending before the Court of Justice of the European under docket

number C-442/11, which relate to the same question of law – in that case presented by the High Court.

Voß Dr. Rinken Dr. Reimnitz