Claim No HC 10 C04610

IN THE IN THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT

MR JUSTICE FLOYD

TUESDAY 12TH JULY 2011

B E T W E E N:

NOVARTIS AG
(a company incorporated in Switzerland)

Claimant

and

ACTAVIS UK LIMITED

Defendant

ORDER FOR REFERENCE OF QUESTIONS TO THE COURT OF JUSTICE OF THE EUROPEAN UNION

UPON hearing Counsel for the Claimant and for the Defendant

AND UPON the Court finding that, in order to give judgment in this case, it is necessary to resolve questions concerning the interpretation of European law and that it is appropriate to request the Court of Justice of the European Union (CJ) to give a preliminary ruling thereon

AND UPON the Claimant and the Defendant agreeing that the terms of the Consent Order of Master Bragge dated 12 January 2011 (including the Claimant's cross-undertaking) shall remain in place until the expiry of SPC/GB97/009 (as extended) or until after judgment at first instance in this action, whichever is earlier.

IT IS ORDERED THAT

1. The questions set out in the Schedule to this order be referred to the CJ for a preliminary ruling in accordance with Article 267 TFEU

2. All further proceedings in this action be stayed until the CJ has given its ruling on the said questions or until further order

3. The senior Master shall forthwith and without waiting for time to appeal against this order to expire transmit to the Registrar of the CJ pursuant to CPR 68 this Order and Schedule thereto

4. The costs are reserved

5. The parties shall have liberty to apply

SCHEDULE

REQUEST FOR PRELIMINARY RULING OF THE COURT OF JUSTICE OF THE EUROPEAN COMMUNITIES

Introduction

1. This dispute concerns the effects of a Supplementary Protection Certificate belonging to Novartis AG. The SPC in dispute is SPC/GB97/009 ("the SPC"). The product description of the SPC is "*Valsartan optionally in the form of a pharmaceutically acceptable salt*". The validity of the SPC and the designated basic patent for the SPC are not in dispute. The dispute is about the scope of the SPC. Actavis says that the SPC covers medicines, such as Diovan®, having valsartan as their only active ingredient but that it does not cover medicines, such as Co-Diovan®, which contains valsartan as an active ingredient, and also hydrochlorothiazide as an additional active ingredient. Novartis says that the SPC covers medicines which contain valsartan as the single active and medicines which contain valsartan in combination with one or more other active ingredients, including hydrochlorothiazide.

2. The dispute turns on the interpretation of Article 4 and Article 5 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) ("the Regulation").

3. The dispute began on 30 November 2010 when Actavis indicated its intention to launch a generic pharmaceutical comprising valsartan in combination with hydrochlorothiazide immediately after expiry of EP (UK) 0 443 983 (the "Patent"). Novartis issued proceedings against Actavis alleging that such a pharmaceutical would infringe the SPC. The trial of these proceedings took place on 12 July 2011. At the start of the trial, the court decided that the matter should be referred to the CJEU. In accordance with the directions from the court the parties summarised their submissions and prepared the agreed factual background set out below. The agreed factual background is in Section A, Novartis' submissions are summarised in Section B, and Actavis' submissions are summarised in Section C. The question referred is in Section D.

Relevant Community legislation

4. Articles 4 and 5 of the Regulation read as follows:

Article 4

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 expiry of the certificate.

Article 5

Effects of the certificate

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.

5. These Articles contain a number of terms that are defined in Article 1. The relevant definitions are as follows:

Article 1

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; ...

Section A - Factual background

6. Novartis is one of the world's largest research-based pharmaceutical companies. Actavis is in the business of developing, manufacturing and selling generic pharmaceuticals.

7. Valsartan is an angiotensin II receptor blocker and is primarily used in the treatment of high blood pressure (hypertension), but also in respect of congestive heart failure and post-myocardial infarction.

8. Novartis markets and sells a range of valsartan-containing medicinal products including Diovan and Co-Diovan. Diovan contains valsartan as the only active ingredient whereas Co-Diovan contains valsartan in combination with another active, hydrochlorothiazide. Hydrochlorothiazide is a diuretic which also has blood pressure reducing properties.

9. Novartis has a number of different marketing authorisations for Diovan and Co-Diovan in the UK. The first marketing authorisation for Diovan in the UK was granted in October 1996 and the first marketing authorisation for Co-Diovan in the UK was granted in January 2003. These UK marketing authorisations are summarised in the table below:

	Diovan	**Co-Diovan**
Active ingredients	Valsartan	Valsartan+hydrochlorothiazide
Approved Formulations	40mg, 80mg, 160mg capsules granted on 16 Oct 1996 40mg, 80mg, 160mg, tablets granted on 22 March 2002 and 320mg tablets granted on 17 Sept 2007 3mg/ml oral solution granted on 28 May 2010	80/12.5mg tablets granted on 29 Jan 2003 160/12.5mg and 160/25mg tablets granted on 23 June 2004

10. Co-Diovan is indicated for the treatment of hypertension. Patients are usually prescribed Co-Diovan when their blood pressure is not being effectively managed by Diovan alone.

11. The development and regulatory approval of Diovan for the treatment of hypertension was based on over 60 studies conducted in over 6000 patients, with the additional indications (heart failure and post myocardial infarction) approved on the basis of additional clinical studies in over 20,000 patients. Co-Diovan was authorised on the basis of at least 17 studies involving almost 10,000 patients in total. The approval of Co-Diovan relied in part on the developmental work undertaken for Diovan, including the data relating to the safety, pharmacokinetics and pharmacodynamics of valsartan, but also involved additional investment in order to study the safety and efficacy of the combination medicine as such. Further investment was also made to formulate Co-Diovan as a tablet instead of the capsule form originally used for Diovan.

12. Valsartan was protected by the Patent. This was the basic patent for the purposes of the SPC application pursuant to Article 3(a) of the Regulation. Claim 1 of the Patent was to a general chemical formula which comprised thousands of compounds including valsartan. Claim 26 was specifically directed to valsartan. There was no claim to valsartan in combination with hydrochlorothiazide, nor was the combination disclosed anywhere in the specification of the Patent. However a medicine containing valsartan and hydrochlorothiazide would infringe the Patent.

13. The SPC in this case was applied for by Novartis AG on 11 April 1997 and was granted by the UK IPO on 22 August 1997. The product which is the subject of the SPC is valsartan and the SPC is based on the UK marketing authorization for valsartan granted on 16 October 1996 (see above).

14. Novartis did not apply in the UK for a supplementary protection certificate for which the product description is valsartan and hydrochlorothiazide. Novartis did apply for and obtain in a number of other European jurisdictions supplementary protection certificates for which the product description is valsartan and hydrochlorothiazide.

15. The SPC came into force upon expiry of the Patent on 12 February 2011. Originally the SPC was due to expire on 12 May 2011. On 11 January 2011 Novartis was granted a six-month extension pursuant to the Paediatric Regulation. The certificate now expires on 12 November 2011.

Summary of submissions of the parties

Section B - Novartis' submissions

16. Novartis argue that Articles 4 and 5 of the Regulation must be considered together, not least because Article 5 is subject to the provisions of Article 4.

17. Article 4 is entitled "Subject matter of protection", and is effectively in three parts.

    (a) The first part ("Within the limits of protection conferred by the basic patent") makes it clear that the protection conferred by the certificate cannot be any greater than that conferred by the underlying patent. Thus for example, where a patent is to a process for synthesising an active ingredient, products made according to a different, non-infringing, process will not be within the scope of the patent nor the SPC for the active based on that patent.

    (b) The second part ("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") serves to limit the protected subject matter to the product that is the active within the medicinal product that has been authorised. Any other compounds protected by the patent will not fall within the scope of protection of the SPC. Thus, the basic patent might claim millions of compounds pursuant to a general chemical formula and yet the product might only be a single compound.

    (c) The third part ("and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate") limits the protection further to all uses of the product in medicinal products, provided that such medicinal products are authorised before expiry of the certificate. Non-medicinal uses of the product are not included within the subject matter of the SPC.

18. Applying Article 4 to the claims of the Patent in this case results in the following:

    (a) The basic patent is EP (UK) 0443983. It is a– patent which provides product protection as such, and is not limited to a process to obtain the products or any application of the products.

    (b) Whilst the Patent claims thousands of molecules *per se* by reference to a general chemical formula, only the product (within the meaning of Article 1(b) of

the Regulation) that is covered by the authorisation for a medicinal product forms the subject matter of the certificate, which in this case is valsartan.

(c) The SPC is limited to **any** use of valsartan as a medicinal product so long as the medicinal product has been authorised before the expiry of the certificate. For example authorised medicinal products containing valsartan include Diovan and Co-Diovan as set about in the table at paragraph [9] above.

19. Article 5 is headed "Effects of the certificate". It provides that, in relation to the subject matter of the certificate as defined by Article 4, the certificate shall confer on the holder the same rights as the patent.

20. Since it is a fundamental and uncontroversial principle of patent law that a patent for product A will be infringed by the unauthorised manufacture and/or sale of a medicinal product that contains active ingredients A + B in combination, an SPC for product A will also be infringed by the unauthorised manufacture and/or sale of a medicinal product that contains active ingredients A + B in combination.

21. In this case, since the Patent for valsartan is infringed by a medicinal product containing valsartan in combination with hydrochlorothiazide, on the basis of Article 5 it follows that the SPC for valsartan will also be infringed by a medicinal product that contains valsartan in combination with hydrochlorothiazide.

22. Novartis contend that their interpretation of Articles 4 and 5 as set out above is supported by the language of the Regulation. Of particular note, Article 4 states that:

(i) "*Within the limits of the protection conferred by the basic patent, the protection conferred by the certificate shall extend* ***only*** *to the product covered by the authorisation to place the corresponding medicinal product on the market* ..." (emphasis added). The word "only" relates back to the protection conferred by basic patent. It emphasises that the certificate only protects the particular product i.e. active ingredient contained within the medicinal product that has been authorised and does not also extend to all the other products that are protected by the basic patent;

(ii) "... *and for* ***any*** *use of the product as* ***a*** *medicinal product*" (emphasis added). The word "any" makes it clear that **all** authorised medicinal uses of

the product will fall within the scope of the certificate. This is reinforced by the word "a" in relation to medicinal product, which again emphasises that the protection conferred by the certificate is not limited to the product as used in the particular medicinal product relied on to obtain the certificate.

23. Novartis' interpretation is also supported by the overall scheme and objectives of the Regulation as set out in Recitals (2) – (6) and also in the Explanatory Memorandum in particular at paragraphs 1, 2, 5, 25 and 27. In particular, Novartis' interpretation is consistent with the primary aim of ensuring effective protection so as to encourage the investment into pharmaceutical research since the SPC confers protection on the product when used in any medicinal product that is authorised before expiry of the certificate, regardless of whether the product is the only active ingredient(s) or is present in combination with one or more other actives.

24. The medicinal product that contains two or more active ingredients in combination is invariably developed after the medicinal product that contains the single active ingredient and will rely at least in part on the research and development that went into bringing the single active to market. So in this case, any combination medicine containing valsartan would have to rely on the efforts (in terms of research and development, clinical trials, seeking marketing approval and so on) necessary for obtaining authorisation to sell the valsartan drug, and could not have occurred without the development of the valsartan drug. In short, the combination therapy stands on the shoulders of the monotherapy. It would therefore undermine the ability of Novartis to enjoy a period of effective protection sufficient to cover the investment put into research if a third party could market a valsartan-containing medicine whilst the SPC for valsartan is in force.

25. Any other interpretation would enable a third party to circumvent the protection conferred by a certificate for any particular product simply by combining it with another active ingredient and getting the combination approved after the basic patent has expired. This would enable the third party to exploit the product that is the subject of the certificate whilst avoiding the effects of the certificate itself. This in turn would result in the patentee failing to recoup the investment put into the underlying research and therefore being less able to reinvest in further research for the benefit of the Community at large. This is contrary to the primary aims and objectives of the Regulation.

26. Furthermore, if an SPC for a product did not also protect use of the product in combination with one or more other actives in a medicine there would be a serious disincentive on the part of the patentee to research and develop combination medicines at all, contrary to the interests of the Community public health.

27. Novartis contend that their interpretation of Articles 4 and 5 of the Regulation is also supported by the travaux préparatoires. They rely in particular on paragraphs 38 – 44 of the Explanatory Memorandum.

28. It is undisputed that an SPC is a *sui generis* right. It sits at the interface between the patent system and the regulatory system and its subject matter is defined by reference to them both. The consequence is that it confers the same rights and obligations as the basic patent pursuant to Article 5, but only in respect of products contained in authorized medicinal products pursuant to Article 4, and not in respect of any other products that were claimed in the patent.

29. The effect of Novartis' interpretation of the Regulation is that a medicinal product which contains a combination of active ingredients will infringe both the SPC for the single active and the SPC for the combination of actives. This is consistent with the scheme and purpose of the Regulation, and with the operation of intellectual property rights in general. In particular, one medicinal product may infringe:

    (a) two patents, for example a product patent and a formulation patent; and

    (b) the exclusive rights attaching to two sets of regulatory data, for example the regulatory data protection (RDP) for a medicinal product containing active A and the RDP for the medicinal product containing actives A and B.

30. This point should not be confused with the requirement under Article 3(c) of the Regulation that the product (i.e. the active ingredient or combination of active ingredients), which is the subject of the SPC application, has not already been the subject of a certificate. There is a difference between the subject of a certificate for the purposes of grant and the effect of the certificate once granted in terms of its scope of protection. In short, the scheme of the Regulation ensures against double granting but allows for protection by more than one SPC.

31. Actavis point out that Novartis did not apply for an SPC for valsartan + hydrochlorothiazide in the United Kingdom, but did so in certain other Member States and speculate about the reasons for this. Novartis contend that this is irrelevant to the question of interpretation of the Regulation. Whether Novartis has combination SPCs in every Member State, in some Member States or in no Member States, the interpretation of the Regulation must be the same.

32. Furthermore, Novartis rely on the decisions from courts in other Member States which have adopted the same interpretation of Articles 4 and 5 of the Regulation and in particular decisions from Germany, France, Austria, Norway and Sweden. Only the Belgian Court has decided the point differently.

33. In addition Actavis' submissions in Section C below repeatedly seek to characterise Novartis' case. Novartis do not accept those characterisations.

Section C - Actavis' submissions

34. Supplementary protection certificates were introduced by Council Regulation 1768/92 to provide an extended period of protection for patented pharmaceutical products which had been granted a marketing authorisation pursuant to the regulatory scheme for such products originally introduced by Council Directive 65/65/EEC and now governed by Council Directive 2001/83/EEC. Regulation 1768/92 has been amended on several occasions and has now been repealed and replaced by a consolidated version, Council Regulation 469/2009 with effect from 6/5/2009.

35. Supplementary protection certificates are granted nationally pursuant to the provisions of Regulation 469/2009 and provide *sui generis* rights defined thereunder in relation to products which are both protected by a basic patent and the subject of a marketing authorisation in the Member State in which they are granted.

36. The specific conditions which must be satisfied for the grant of an SPC are as follows:

    (a) The product the subject of the SPC must be protected by a basic patent in force in the Member State in question (Article 3(1)(a)).
    (b) There must be an authorisation to place the product on the market as a medicinal product in that Member State (Article 3(1)(b)).
    (c) The application for the SPC must be made within 6 months of the grant of the foregoing marketing authorisation (Article 7(1)).
    (d) The foregoing marketing authorisation must be the first marketing authorisation for that product in the Member State in question (Article 3(1)(d)).

37. It is clear from these requirements that an SPC may only be granted for a specific product which is both protected by a basic patent and the subject of a marketing authorisation in the Member State in which the SPC is sought. Further, the SPC may be granted only on the basis of the first marketing authorisation for that product in that Member State.

38. In order to determine precisely the nature of the qualifying requirements, it is necessary to establish the meaning of the term "product" as used in Article 3 of Regulation 469/2009. The "product" which is the subject of an SPC is defined by Article 1(b) of Regulation 468/2009 as meaning:

"the active ingredient or combination of active ingredients of a medicinal product".

A medicinal product is defined in Article 1(a) as meaning:

> "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 animals."

39. It is clear from these definitions that the "product" which is the subject of an SPC is only the specific "active ingredient" or "combination of active ingredients" which is contained in an identified medicinal product. It is this "product" which must be protected by the basic patent relied upon and which must be the subject of a marketing authorisation. Each different "active ingredient" or "combination of active ingredients" will, thus, for this purpose, be a different "product". If the position were otherwise, an SPC could not be granted for a combination product at all: see paragraph 41 below.

40. This interpretation is confirmed by reference to the terms of Article 3(1)(b) which requires as a condition for the grant of an SPC that there is "a valid authorisation to place the product on the market as a medicinal product". Such authorisation can only be given for a specific active ingredient or combination of active ingredients. Accordingly, the product which is the subject of an SPC can only be that specific ingredient or combination of ingredients.

41. The interpretation is further confirmed by the requirement of Article 3(1)(d) that the marketing authorisation of Article 3(1)(b) be the first such authorisation for that product. If a combination of active ingredients were to be treated as being the same product as any of the individual active ingredients therein, the marketing authorisation for the combination could never be the first marketing authorisation for a product: there would always be an earlier marketing authorisation for one of the individual active ingredients. The reference to a "combination of active ingredients" in the definition of "product" in Article 1(b) would be otiose. Such a combination could never be a "product" capable of being the subject of a "first marketing authorisation" for the purposes of Article 3(1)(d).

42. Thus, separate SPCs may be granted for a single active ingredient or a combination of active ingredients including that single active ingredient provided that those single active ingredients and combinations of active ingredients are each protected by a basic patent and the subject of an appropriate marketing authorisation in the member state concerned. Equally, as explained below, if a patentee wishes to obtain protection for a combination product under an SPC, he must obtain an SPC specific to that combination product.

43. The foregoing interpretation of the definition of "product" in Article 1(b) and the impact of Article 3(1)(b) are supported by a series of decisions of the Court of Justice in Cases C-31/03 *Pharmacia Italia*, C-431/04 *MIT* and C-202/05 *Yissum*. In particular, in *MIT* the Court ruled that it was not possible to grant an SPC for a combination of active ingredients unless each individual ingredient identified in the SPC was shown to have therapeutic activity. Accordingly, an SPC for a combination of active ingredients could not be granted where one of the components in question was an excipient, albeit an excipient which affected the way in which the active ingredient took effect: see paragraphs 14-26 of the judgment in *MIT*.

44. The Court in that case referred in paragraph 23 of its judgment in support of its conclusions to the Explanatory Memorandum to the Proposal for a European Parliament and Council Regulation of 9 December 1994 concerning the creation of a supplementary protection certificate for plant protection products which states that:

> " - *it would not be acceptable, in view of the balance required between the interests concerned, for the total duration of protection granted by the SPC and the patent for one and the same product to be exceeded;*
> - *that might be the case if one and the same product were able to be the subject of several successive SPCs;*
> - *that calls for a strict definition of the product;*
> - *if an SPC has already been granted for the active substance itself, a new SPC may not be granted for that substance, whatever changes may have been made regarding other features of the plant protection product (use of a different salt, different excipients, different presentation, etc.);*
> - *in conclusion, it should be noted that, although one and the same substance may be the subject of several patents and several marketing authorisations in one and the same Member State, the SPC will be granted only on the basis of*

a single patent and a single authorisation, namely the first granted in the Member State concerned."

45. That memorandum and Regulation 1610/96 which resulted therefrom are specifically stated therein to be relevant to the interpretation of the corresponding requirements of Regulation 1768/92, now succeeded by Regulation 469/2009. This statement by the Commission is accordingly directly applicable to the present case and was so applied by the Court in *MIT*.

46. It follows from the above Explanatory Memorandum that only one SPC may be granted to cover any single product (whether that product comprises a single active ingredient or a combination of more than one active ingredient). Unless, as noted above, each individual active ingredient and each specific combination of active ingredients is a distinct product, an SPC could never be granted for a combination of active ingredients (at least not where any of the individual ingredients had previously been marketed alone). In order for it to be possible to grant an SPC for a combination of active ingredients, the combination must be a different product from its individual components. This is consistent with the definition of product in Article 1(b) of Regulation 469/2009 and the use of that term in Article 3.

47. An SPC is therefore specific to the product for which it is granted, namely the individual active ingredient or combination of active ingredients specified therein.

48. Novartis agrees that "valsartan" and "valsartan and hydrochlorothiazide together" are separate and distinct "products" as defined by Article 1(b) of Regulation 469/2009. This is undoubtedly the correct interpretation of the definition. Thus, two separate SPCs may be granted for these two separate "products". Despite this, Novartis argues that one of these two separate SPCs (that for valsartan) should be interpreted so that the product of the other (valsartan and hydrochlorothiazide together) infringes it. Consequently, Novartis interprets the meaning of the term "product" in Articles 3 and 4 of Regulation 469/2009 differently. For the reasons set out below, this cannot be correct.

Consistent interpretation of "product" in Regulation 469/2009

49. The meaning of the term "product" as used in Regulation 469/2009 must be consistent throughout the Regulation. Not only is this logically and linguistically sound, it is a

requirement that the CJEU has itself imposed when interpreting the Regulation. Thus, in Case C-127/00, *Hassle v Ratiopharm*, the CJEU stated expressly that the term "first authorisation to place on the market" must be given the same interpretation wherever it appears in the Regulation: see §57. It is clear from the analysis of the Court in that case that the reasoning applies with equal force to any other specific terminology used in the Regulation. Indeed, where a term is defined, it is plain that the definition applies throughout the Regulation and must be applied in the same way at each point where the term appears.

50. Thus, turning to the terms in which the protection conferred by an SPC is defined by Article 4 of Regulation 469/2009 we see that it reads as follows:

> *Article 4*
>
> ***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.*

51. It is clear from Article 4 that the protection given by an SPC "*extends only to the product covered by the authorisation to place the corresponding medicinal product on the market*". This must be the same "product" as that for which an SPC may be granted under Article 3. The definition of the term must be applied in the same way when interpreting Article 4 as when interpreting Article 3. Consequently, according to Article 4, an SPC protects only the particular "product" for which it was granted. It does not extend to another product for which a separate SPC could be granted and for which, if protection is wanted, should be sought.

52. It follows that where there is a different product containing a different combination of active ingredients from that specified in the SPC, it is outside the scope of the protection given by the SPC. The provisions of Article 4 reflect the terms of recital (10) to Regulation 469/2009 which is in substantially the same terms:

> "The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product."

Article 4: *"and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate"*

53. Novartis argues that there is a difference between the subject matter of the SPC under Article 4 and the extent of protection that it gives under Article 5. Novartis says that, consequent to the provisions of Article 5, the scope of protection given by an SPC should be interpreted as if the SPC were a patent claim: it extends to all formulations and applications of the product, in this case valsartan. In this way the SPC is said to cover valsartan alone and valsartan in combination with other active ingredients, such as hydrochlorothiazide. Novartis construes the "subject matter" of the SPC under Article 4 without reference to the "product description" for which the SPC is granted under Article 3. The effect of Novartis' argument is that the meaning applied to the term "product" in articles 3 and 4 is different. For the reasons stated above, that cannot be correct. Novartis' argument ignores this difficulty, concentrating on Articles 4 and 5 as if they appeared in isolation.

54. Further, the Regulation makes clear that the scope of an SPC is not to be interpreted as a patent claim. The final words of Article 4 ensure the SPC covers further medical applications of the product which is the subject of the SPC in addition to those included in the first marketing authorisation. This allows medical indications and applications which are subsequently added to the authorised uses for a particular product (as defined by Article 1(b)) to be included within the scope of the SPC. Otherwise, they would be excluded. It does not affect the subject matter of the SPC.

55. This limitation makes clear that the SPC is to cover only medicinal uses of the "product" and nothing else. It is not to cover other uses of the "product" or a separate and distinct "product".

56. Although the SPC was granted based on three initial marketing authorisations to valsartan dated 16 October 1996, subsequent marketing authorisations for valsartan fall within the scope of the SPC.

57. This is made clear by the wording of Article 4 "*and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate*". These words would be unnecessary if the scope of the SPC was to be interpreted as a patent claim. This is clearly set out at paragraph 13 and paragraphs 39 to 42 of the Proposal for a Council Regulation presented by the Commission on 11 April 1990 in relation to

the proposal to introduce a supplementary protection certificate scheme (COM(90) 101 final) (the Explanatory Memorandum).

58. Novartis points to Article 5 of the Regulation in support of its interpretation of Article 4. Article 5 provides that

> "*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.*"

59. Novartis says that to "confer the same rights as conferred by the basic patent" the SPC must have the same scope as a patent claim. The argument is misconceived. First, it fails to take account of the definition of "product". Second, if it were right, Article 4 would be redundant. All that would be required would be Article 5 saying that an SPC confers the same rights as the basic patent. Third, it conflicts with Article 4 properly understood: see above. Article 5 is in truth directed at a different target: basic patents which have use (or other) limitations in their claims. The object of Article 5 is to ensure that the protection provided by the SPC does not extend in any respect beyond that given by the basic patent. Thus, if the claims of the basic patent are limited to particular medical uses, then so is the SPC. That will be so, even if the marketing authorisation on which the SPC is based extends beyond those uses. Thus, properly understood, both Articles 4 and 5 are complementary limiting provisions defining the scope of the SPC.

An SPC is a *sui generis* right

60. There is no reason why the protection conferred by an SPC should be interpreted as a patent claim, such that an SPC for a product containing a single active ingredient should extend to other products containing combinations of active ingredients. If the patentee wants to obtain SPC protection for a product containing the combination of active ingredients, all he has to do is to apply for and obtain an SPC for that combination. An SPC is not a patent right, it is a *sui generis* right. There is no basis for treating an SPC as if it were a patent right.

61. Novartis says that this approach conflicts with the underlying objective of the SPC scheme. Actavis contend that this argument is unfounded. A patentee's ability to obtain an SPC is limited by two factors: the protection conferred by the basic patent

over the product (as defined) and the product (as defined) for which he has obtained a marketing authorization. The SPC scheme requires that both are present for the grant of an SPC. If they are, the patentee is entitled to an SPC for the product which he has invented and marketed. If not, he is not. A patentee can have no complaint that he does not have SPC protection if (a) his basic patent does not protect the product in issue, (b) he has not obtained a marketing authorisation for that product or (c) he has simply not sought an SPC for the product. Actavis says that Novartis' argument is an attempt to extend the scope of an SPC to one or more of these situations. It is illegitimate.

62. That an SPC is a distinct right was made clear at the creation of the right. At paragraphs 9, 20, 31 and 38 of the Explanatory Memorandum there is reference to the SPC right as a *sui generis* right.

Marketing authorisation upon which the SPC is based

63. The conclusion that an SPC for a product containing a single active ingredient covered a different product containing that active ingredient in combination with another active ingredient would have another surprising consequence. An SPC can only be granted for a product for which there is a marketing authorization. If the SPC granted on the basis of a marketing authorization for a product containing a single active ingredient covered different products containing that active ingredient in combination with another active ingredient, it would extend to products which cannot be marketed under the marketing authorization on whose existence it is based. This plainly cannot have been the intention of the legislature and is accordingly wrong.

64. Further confirmation that the understanding of the effect of Article 4 set out above is correct may be derived from paragraphs 13, 20, 28, 31, 36 and 39-42 of the Explanatory Memorandum. In particular, paragraph 40 of the Explanatory Memorandum makes clear that the SPC is to cover all authorised medical uses of a particular product whether or not the subject of the first marketing authorisation for that product. It is implicit in this formulation that the SPC does not cover uses of a different product.

65. It follows from this that if a patentee wishes to obtain protection for a combination therapy consisting of two or more active ingredients, then he must seek an SPC for each combination of active ingredients he wishes to protect. Should he not do so, then

the SPC for the product comprising the single active ingredient does not cover the combination.

Application of the legal framework to the present case

66. In the present case the SPC was granted for valsartan. It was not granted for a combination of valsartan and hydrochlorothiazide. Not in dispute between the parties is that the two are separate and distinct "products". Novartis has sought and obtained SPCs for both valsartan alone and the combination of valsartan and hydrochlorothiazide in a number of EU member states: see §4 above. This is only possible if these are two different products for the purposes of Article 3 of the Regulation. If they were the same product, the second SPC would necessarily be invalid.

67. As explained above, if they are two different products for the purposes of Article 3, then they are two different products for the purposes of Article 4. Accordingly, the SPC covers only products containing valsartan as their only active ingredient. It does not cover other products, such as one containing the combination of valsartan and hydrochlorothiazide. Thus, the SPC does not prevent the marketing by Actavis of a medicinal product containing a combination of valsartan and hydrochlorothiazide. There is no UK SPC covering the combination of valsartan and hydrochlorothiazide. Such a product is therefore free for Actavis to market following the expiry of the Patent.

68. It is clear from the patentee's evidence in this case that Novartis took a "business" decision not to seek an SPC for the combination of valsartan and hydrochlorothiazide in the UK. It took a different decision in other member states. Having chosen not to seek protection for the combination product (which its evidence shows is of minor commercial importance), it can have no complaint that it has no protection against competition for the combination product following the expiry of the basic patent.

Section D - Questions referred under Article 234 EC

69. In view of the need for a consistent and certain approach to questions of interpretation of the Regulation, the High Court of Justice, pursuant to Article 234 TFEU, requests the Court of Justice of the European Union to make a preliminary ruling on the following question of European Union Law:

Where a supplementary protection certificate has been granted for a product as defined by Regulation (EC) No 469/2009 for an active ingredient, are the rights conferred by that certificate pursuant to Article 5 of the Regulation in respect of the subject matter as defined in Article 4 of the Regulation infringed:

(i) by a medicinal product that contains that active ingredient (in this case valsartan) in combination with one or more other active ingredients (in this case hydrochlorothiazide); or

(ii) only by a medicinal product that contains that active ingredient (in this case valsartan) as the sole active ingredient?

Claim No HC 10 C04610

IN THE IN THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT

MR JUSTICE FLOYD

TUESDAY 12TH JULY 2011

B E T W E E N:

NOVARTIS AG
(a company incorporated in Switzerland)

Claimant

and

ACTAVIS UK LIMITED

Defendant

ORDER FOR REFERENCE OF QUESTIONS TO THE COURT OF JUSTICE OF THE EUROPEAN UNION

Bristows
100 Victoria Embankment
London EC4Y 0DH
Ref: 354/BDC/06401 0112
Tel: 020 7400 8000; Fax: 020 7400 8050
Solicitors for the Claimant

Bird & Bird LLP
15 Fetter Lane
London EC4A 1JP
JYJ/MJH/ACTGR.0072
Tel: 020 7415 6000; Fax: 020 7415 611
Solicitors for the Defendant