

SPCs AND COMBINATION PRODUCTS – INFRINGEMENT ISSUES

Philippe de Jong, Altius, Brussels (philippe.dejong@altius.com)

A BIT OF BACKGROUND

1. Supplementary protection certificates ('SPCs') for medicinal products are governed by Regulation 469/2009 concerning the supplementary protection certificate for medicinal products ("the SPC-Regulation"). The SPC-Regulation is a consolidation of Regulation 1768/92 (the old SPC-Regulation) and Regulation 1901/06/EEC (the Paediatric Regulation).

2. Despite the title of the SPC-Regulation, an SPC is not granted for a medicinal product, but for a product. A product can be part of a medicinal product, but does not necessarily coincide with that medicinal product. This follows clearly from the separate definitions given to both terms in Article 1 of the SPC-Regulation.

A "medicinal product" is defined in Article 1(a) as "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".

A "product" is defined in Article 1(b) as "the active ingredient or combination of active ingredients of a medicinal product".

3. The rights of the proprietor of an SPC are governed by Articles 5 and 4 (in that order) of the SPC-Regulation.

Article 5 determines the "effects" of the certificate. It states 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*". The essence of this provision is that the proprietor of an SPC has the same rights and obligations as the proprietor of the basic patent, i.e. has the exclusive right to perform the same exhaustive list of reserved acts (manufacturing, offering for sale, ...). This has been confirmed by the ECJ.¹ Under patent law, if a patent is granted for a specific active ingredient, this ingredient enjoys absolute protection and the patent holder has the right to prohibit any third party not having its consent from commercially using any medicinal product containing that active ingredient. Pursuant to Article 5 of the SPC-Regulation, when an SPC is granted for that active ingredient (the "product"), the proprietor of the SPC for that product has the same right.

The only difference between the two protection systems, lies in Article 4 of the SPC-Regulation ("*subject to the provisions of Article 4*"), which, according to its title, determines the "subject matter of protection", but also the scope of protection of the SPC, as will be discussed below.

According to Article 4 of the SPC-Regulation, the protection conferred by a certificate "*shall [, within the limits of the protection conferred by the basic patent,] extend only to the product covered by the authorization to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorized before the expiry of the certificate*".

¹ "...the certificate [confers] the same rights as those conferred by the basic patent, with the result that, where the basic patent covers an active substance and its various derivatives (salts and esters), the certificate confers the same protection" (ECJ, 16 September 1999, C-392/97, *Farmitalia*, § 20 www.curia.eu).

4. Under this provision, the particular question arises whether medicinal products containing two or more active ingredients can fall within the scope of protection of an SPC for a product consisting of only one active ingredient.

To make the discussion more comprehensive, Article 4 of the SPC-Regulation can be broken down into the following three parts:

- a first part: “*within the limits of the protection conferred by the basic patent*”;
- a second part: “*the protection conferred by a certificate shall extend only to the product covered by the authorization to place the corresponding medicinal product on the market*”; and
- a third part: “*and for any use of the product as a medicinal product that has been authorized before the expiry of the certificate*”.

“WITHIN THE LIMITS OF THE PROTECTION CONFERRED BY THE BASIC PATENT...”

5. Article 4 of the SPC-Regulation begins by saying that the protection conferred by the SPC should be “*within the limits of the protection conferred by the basic patent...*”.

The phrase “*within the limits of the basic patent*” appears to cover the same load as Article 3(a) of the SPC-Regulation, i.e. the requirement, upon grant, that “*the product is protected by a basic patent in force*”.

In recent years discussion has arisen as to the precise meaning of the term “*protected by the basic patent*”. The case law which led to this discussion is discussed by András Kupecz in a contribution which is published simultaneously with this one on www.eplawpatentblog.com. Although this debate was triggered by a number of court decisions on the interpretation of Article 3(a) of the SPC-Regulation, it also appears relevant for the interpretation of Article 4 of the Regulation, where this term is not expressly, but at least implicitly used, in view of the explanation given to the phrase “*within the limits of the basic patent*” in § 39 of the Explanatory Memorandum to the SPC-Regulation.

6. There appear to be essentially (at least) two camps in this discussion.

The first camp says that for a product consisting of a combination of active ingredients to be “protected” by the basic patent within the meaning of Article 3(a) of the SPC-Regulation, it is required that the combination *as such* is expressly disclosed in the basic patent. This is the *identification or express disclosure* test. To this camp, belong in particular the English and the French courts.²

The second camp, to which mainly belong the German and (some) Dutch courts, do not follow this approach and have applied an *infringement* test pursuant to Article 69 EPC to determine whether the (combination) product, although not expressly disclosed, would be “protected” by the patent.³

² See the decisions of the London High Court in *Takeda Chemical Industries Ltd's SPC application* [2004] RPC 3; *Gilead's SPC application*, [2008] EWHC 1902; *Astellas Pharma's SPC application* ([2009] EWHC 1916. These decisions are consistently followed by the IPO (see most recently, http://www.ipo.gov.uk/pro-types/pro-patent/pro-os/p-challenge-decision-results-bl?BL_Number=O/052/09). See also the decision of the Paris Court of Appeal in *Daiichi Sankyo Company Limited v. INPI*, 6 November 2009, Case No. 09/06530, published on www.eplawpatentblog.com.

³ For Germany: see in particular the decision of the Federal Supreme Court of 8 July 2008, “*Anti-helicobacter preparation*”, FSC X ZB1. For The Netherlands: the decisions of the District Court of The Hague of 12 October 2005, *Merial/Sankyo*, B.I.E. 2007, p. 25; and of the OCNL of 13 November 2008, *Stallergenes SA's application*, unpublished, later confirmed by District Court of The Hague on 4 November 2009). Both the Dutch and the

This being said, neither camp appears to have reached a final consensus so far, because in both camps dissenting opinions can be heard. Thus, in the English *Gilead* and *Astellas Pharma* cases, both Kitchin J and Arnold J already suggested that the question of “*protection by the basic patent*” may perhaps be better determined on the basis of an infringement test. Conversely, the Court of Appeal of The Hague indicated that the question whether a product is “*protected by a basic patent*” within the meaning of Article 3(a) of the SPC-Regulation, is fundamentally different from the question whether a product infringes the basic patent.⁴

7. I find it difficult to see why this discussion is still ongoing, since the ECJ in *Farmitalia* has already held that the question whether a product is protected by a basic patent, i.e. to determine that patent’s scope of protection, can be determined only in the light of non-Community rules which govern patents.⁵ Those non-Community rules are Article 69 EPC and its Protocol, or their national equivalents. This is therefore *acte clair*. A medicinal product consisting of one or more active ingredients is thus protected by the basic patent and the subsequent SPC for one of those ingredients, unless expressly excluded from that protection.

“...THE PROTECTION CONFERRED BY A CERTIFICATE SHALL EXTEND ONLY TO THE PRODUCT COVERED BY THE AUTHORIZATION TO PLACE THE CORRESPONDING MEDICINAL PRODUCT ON THE MARKET ...”

8. The tenth recital of the preamble of the SPC-Regulation further explains this part of Article 4. It states, in its last sentence, 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*”. Under a strict interpretation of Article 4, this part of Article 4 of the SPC-Regulation could be (and is) used to argue that the scope of an SPC for one active ingredient cannot extend to a medicinal product containing that active ingredient in combination with one or more other active ingredients. The question is whether this approach is correct.

9. Also taking into account the last part of Article 4, which will be discussed below, this second part of Article 4 appears to mean nothing more than, in order to know what the subject matter of the protection of the SPC is, one should look at the marketing authorization (‘MA’) for the corresponding medicinal product. For example, if the MA for medicinal product X mentions product Y as its active ingredient, the protection of the SPC for product Y will only extend to that active ingredient Y, and not to any other active ingredient.

German courts seem to rule out, however, that the question whether a product is “protected” by the basic patent, can also be answered on the basis of an indirect infringement analysis (see the references in the contribution by András Kupecz to the decisions of the Dutch District Court of The Hague, 28 May 2008, *Aventis/OCNL*, B.I.E. 2009, p. 46; confirmed by decision of 27 May 2009 from the Dutch Council of State, available at www.rechtspraak.nl; and of the German Federal Supreme Court in the said “*Anti-helicobacter preparation*” case).

⁴ Court of Appeal of The Hague, 21 February 2008, *Ranbaxy*, available at http://www.iept.nl/files/2008/IEPT20080221_Hof_Den_Haag_Ranbaxy_v_Warner-Lambert_ABC_Atorvastatine.pdf. This decision, however, can be criticized. The Court held that, upon grant of an SPC, there can be no claim construction “*as this occurs when determining infringement by equivalence*” (decision, at §9). These findings are incorrect, *inter alia* because claim construction does not only arise in discussions on equivalence, but also on literal infringement, and because the court later on seems to admit that the granting authority should, if necessary *ex officio*, examine the prosecution file of the basic patent to determine whether the product is protected by the basic patent, which is inconsistent with the court’s earlier statement on claim construction.

⁵ ECJ, 16 September 1999, C-392/97, *Farmitalia*, § 27, www.curia.eu (“*Accordingly, in the absence of Community harmonisation of patent law, the extent of patent protection can be determined only in the light of the non-Community rules which govern patents*”).

In other words, this second part of Article 4 is the “title song” of Article 4 and determines *the subject matter of protection* (“in Dutch: “*voorwerp van de bescherming*”; in French “*objet de la protection*”; in German “*Schutzgegenstand*”; in Spanish “*objecto de la protección*”; etc.) of the SPC. This subject matter is determined by the MA for the corresponding medicinal product. Nothing more, nothing less.

The *scope of protection* of the SPC, however, is determined by the last part of Article 4. Interpreting the second part of Article 4 as limiting the *scope* of an SPC for a product consisting of one active ingredient to situations where a third party’s medicinal product also only contains product Y, therefore disregards that Article 4 does not stop after the second part.

“...AND FOR ANY USE OF THE PRODUCT AS A MEDICINAL PRODUCT THAT HAS BEEN AUTHORIZED BEFORE THE EXPIRY OF THE CERTIFICATE”

10. Pursuant to this last part of Article 4 of the SPC-Regulation, the scope of protection of an SPC extends to (a) the “product” (e.g. the one active ingredient) as covered by the initial MA for the corresponding medicinal product; *and* (b) *any* subsequently authorized *use* (i.e. therapeutic application) of the “product” as a medicinal product.

There is no indication in Article 4, or in any other provision of the SPC-Regulation, that this new use of the product should be limited to the new medical use of “the product” *as such* and that it could not occur in combination with another product (“*any use*”).

In the example given earlier, a medicinal product containing both product Y and another active ingredient Z, constitutes a new “use” of product Y, notably a use in combination with active ingredient Z and will thus fall under the scope of protection of the SPC for product Y, provided that the combined use is authorized after the initial MA for the medicinal product containing active ingredient Y (i.e. the one in Article 3(d) of the SPC-Regulation) and before the expiry of the SPC for product Y.

11. Any other interpretation of this third part of Article 4, e.g. in the sense that the SPC for a product consisting of one active ingredient only offers protection for any new use of the (i.e. the *same*) product, seems to disregard that there is no correlation between the terms “product” and “medicinal product” in the sentence “...*any use of the product as a medicinal product*”.

As explained earlier, these are two separately defined terms. There is no indication that if the term “product” in this sentence is given the meaning of “one active ingredient” (e.g. product Y), the term “medicinal product” should equally be given the meaning of “(one) substance” (e.g. a substance having *only* product Y as active ingredient), or *vice versa*. If the term “product” in this sentence is given the meaning of “active ingredient” (e.g. product Y), the term “medicinal product” can also be given the meaning of “combination of substances” (e.g. a combination of product Y *and* active ingredient Z).

This interpretation also finds support in a decision from the Brussels District Court⁶ which held that the term “*as a medicinal product*” in the sentence “...*for any use of the product as a*

⁶ Brussels District Court, 20 November 2008, *CNRS-Pierre Fabre Médicament / Ajinomoto Omnicem, ICIP 2009*, 33, reported in English in [2009] *E.I.P.R.* 41. In that case, the SPC-protected active ingredient had been encountered in Belgium, whereas the actual medicinal product containing that ingredient was subsequently manufactured in the US. The decision therefore focussed primarily on the question whether a foreign and future use as a medicinal product could be enjoined on the basis of Article 4 (and 5) of the SPC-Regulation. However, the decision is also useful in the present discussion since it confirms that the term “product” in the sentence “...*and for any use of the product as a medicinal product that has been authorized before the expiry of the certificate*” can be dissociated from the term “as a medicinal product” in the same sentence. In particular, the finding that the said sentence is only there to exclude from the scope of protection of the SPC uses outside the pharmaceutical field, is helpful because it indicates that the SPC allows its proprietor to prevent any use of the “product” in the manufacture of *any* medicinal product, regardless of whether it contains one or more active ingredients.

medicinal product” was exclusively added to emphasise that the “product” can only be used for medicinal purposes, and not for any other purpose, such as e.g. the use as a cosmetic. In other words, the sentence “*for any use of the product as a medicinal product*” is solely aimed at excluding from the scope of protection of the SPC uses outside the pharmaceutical field. This is also confirmed by the requirement that the new use of the product which is the subject matter of the SPC must have been authorized (i.e. as a pharmaceutical product) before the expiry of the certificate.

12. I believe that this is effectively the only limitation imposed on the proprietor of an SPC for a product consisting of one active ingredient, compared to the rights of the proprietor of a patent for that active ingredient. Whereas the proprietor of the patent has absolute protection allowing him to act against any third party use of the patented active ingredient, even where this use is not patented as such and even if it is outside the pharmaceutical field, the protection of the proprietor of the SPC is limited to authorized uses of the active ingredient in the pharmaceutical field. In that sense, the protection conferred by the SPC is not as “absolute”, as is confirmed by § 40 of the Explanatory Memorandum to the SPC-Regulation. This appears to be the only correct interpretation of the terms “*subject to the provisions of Article 4*”, in Article 5 of the SPC-Regulation.

This leaves us with two final issues that need to be resolved.

FIRST ISSUE: DOES THE FACT THAT A SEPARATE SPC FOR A PRODUCT CONSISTING OF TWO ACTIVE INGREDIENTS WAS GRANTED, LIMIT THE SCOPE OF PROTECTION OF THE EARLIER SPC FOR ONE OF THOSE INGREDIENTS?

13. Would, in the example given earlier, the scope of protection of the SPC for product Y be limited by a later SPC for the product consisting of active ingredients Y and Z?⁷

The question whether two separate SPCs were obtained for two separate “products” which are covered by two different MAs, does not seem relevant for the assessment of whether the medicinal product containing the two active ingredients Y and Z falls under the scope of protection of the SPC for product Y. This discussion could, if at all, perhaps be held in the context of the validity of the SPC (Articles 3(c) and (d) of the SPC-Regulation), but it is not an issue of infringement.

There is nothing in Article 4 or 5 of the SPC-Regulation to suggest that the scope of protection of an SPC for a product consisting of one active ingredient, would be limited by the mere existence of another SPC for a product consisting of that same active ingredient in combination with another active ingredient.

Deciding otherwise would lead to the rather bizarre situation that a medicinal product consisting of two active ingredients *could* infringe an SPC for a product consisting of one active ingredient if no separate SPC for the combined active ingredients was granted, but that it *could not* infringe the former SPC if the latter SPC was granted...

It would also have as an effect that there can be no overlapping protection between two SPCs, whereas such an overlap is possible between the two basic patents underlying those SPCs. Nobody will contest that a patent for active ingredient Y covers a medicinal product containing active ingredients Y and Z, regardless of whether that combination is protected by a separate patent. It cannot be seen why such an overlap would not be possible for SPCs.

⁷ See in that sense, Brussels Court of Appeal, 23 February 2010, *DuPont de Nemours et al. / Mylan*, case 2010/KR/53, published on www.eplawpatentblog.com, see <http://www.eplawpatentblog.com/eplaw/mylan/>.

SECOND ISSUE: DOES THE FACT THAT A PAEDIATRIC EXTENSION WAS GRANTED ONLY FOR THE SPC FOR THE PRODUCT CONSISTING OF ONE ACTIVE INGREDIENT, LIMIT THE SCOPE OF PROTECTION OF THIS SPC?

14. The European legislator has developed a whole set of measures to stimulate pharmaceutical companies to carry out additional research into the possibility of using existing or new medicinal products specifically for children. This set of measures was finally adopted in the aforementioned Regulation 1901/2006.

15. Regulation 1901/2006 primarily amends the legislation concerning the marketing of medicinal products (Directive 2001/83 and Regulation 726/2004), as well as the legislation on clinical trials (Directive 2001/20/EG), to introduce a number of obligations and rewards for those companies who do research on medicinal products for children (the "paediatric population", as the legislator calls them). The legislator has, however, also deemed it important to provide a specific incentive in terms of SPC-protection. This incentive is given under Article 36 of Regulation 1901/2006. It is in view of this incentive that the initial SPC-Regulation (nr. 1768/92) was consolidated into a text (the current Regulation 469/2009), which also implemented the relevant provisions of Regulation 1901/2006. As already said, this is how the present consolidated SPC-Regulation came to exist.

16. However, the European legislator has chosen only to amend certain provisions of the SPC-Regulation. This is presently the case for Article 1(e), Article 8(1)(d), Article 16(1) and Article 13(3). These provisions all relate to the grant, duration and revocation (of the extension) of the SPC. The European legislator has chosen not to change any other provisions of the SPC-Regulation. This is particularly important for Articles 4 and 5. Since these provisions dealing with the scope of protection and enforcement of the SPC (Articles 4 and 5) were not amended, it cannot be assumed that Regulation 1901/2006 has any influence on the interpretation of these provisions.

17. This means that, as soon as the "application for an extension of the duration" (Article 1(e) of the SPC-Regulation) is granted for a product protected by an SPC, the protection term of the SPC for this product is extended with six months, without any impact on the scope of protection under Article 4. Since it appears from Article 36(1), § 2 of Regulation 1901/2006 that the extension of the term of protection can be granted regardless of whether the paediatric investigation plan ("PIP") leads to the authorisation of the paediatric indication, this PIP can *a fortiori* not have any effect on the scope of protection of the SPC.

If, for example, a PIP is submitted for a medicinal product consisting of SPC-protected product Y in accordance with Regulation 1901/2006, the SPC for product Y will be extended by six months, so that the proprietor of this SPC can exercise his rights under Article 5 of the SPC-Regulation for six months longer than initially foreseen. The mere fact that no such PIP was submitted for a medicinal product consisting of the (possibly also SPC-protected) combination product Y+Z, does not limit those rights in the sense that the SPC for product Y could no longer be invoked against a third party's medicinal product containing both active ingredients Y and Z.⁸

This second issue should therefore also be answered negatively, because an affirmative answer would necessarily run counter to Article 5 of the SPC-Regulation, as interpreted above.

⁸ In this sense, see the decision of 12 February 2010 by the President of the Paris District Court (case nr. 10/51453 *DuPont de Nemours et. al. / Mylan*). In another sense, see the decision of the same day by the Brussels Commercial Court which took a different view (case R.K. 14/2010, *DuPont de Nemours et. al. / Mylan*). Both decisions are published on www.eplawpatentblog.com, see: <http://www.eplawpatentblog.com/eplaw/mylan/>

CONCLUSION

18. The scope of protection of SPCs is a topic with regard to which almost no case law exists. The first decisions dealing with this issue have been rendered only very recently and it will be interesting to see how case law develops in this respect. In any event, in view of the ongoing discussions regarding the interpretation of Article 4 of the SPC-Regulation, it is likely that this matter will one day end up on the plate of the ECJ.