SPC Flood in Luxembourg: CJEU's Eli Lilly, Actavis and Georgetown Judgments

Kluwer Patent Blog
December 12, 2013

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Please refer to this post as: Rik Lambers, 'SPC Flood in Luxembourg: CJEU's Eli Lilly, Actavis and Georgetown Judgments', Kluwer Patent Blog, December 12 2013, http://patentblog.kluweriplaw.com/2013/12/12/spc-flood-in-luxembourg-cjeus-eli-lilly-actavis-and-georgetown-judgments/

SPC judgments galore in Luxembourg this morning. The Court of Justice of the European Union (CJEU) provided its judgments in the Eli Lilly case (C-493/12), in the Actavis case (C-443/12), and in the Georgetown case (C-484/12). The CJEU's Medeva judgment (case C-322/10), and AG Trstenjak's opinion in that case, raised burning questions on the interpretation of Article 3 (a) SPC Regulation (what does "specified in the wording of the claims" mean?), and Article 3 (c) SPC Regulation (is more than one SPC per basic patent possible?). For your initial thoughts the CJEU's answers in quotes:

Eli Lilly

The CJEU reformulates the questions:

> *24 By its three questions, which it is appropriate to consider together, the referring court asks, in essence, whether Article 3(a) of Regulation No 469/2009 must be interpreted as meaning that, in order for an active ingredient to be regarded as 'protected by a basic patent in force' within the meaning of that provision, the active ingredient must be identified in the claims of the patent by a structural formula, or whether the active ingredient may also be considered to be protected where it is covered by a functional formula in the patent claims.*

The CJEU considers:

> *34 By finding that Article 3(a) of Regulation No 469/2009 precludes the grant of an SPC relating to active ingredients which are not specified in the claims of a basic patent (see Medeva, paragraph 25, and the orders in Case C-630/10 University of Queensland and CSL [2011] ECR I-12231, paragraph 31, and Case C-6/11 Daiichi Sankyo [2011] ECR I-12255, paragraph 30), the Court emphasised the key role played by the claims for the purpose of determining whether a product is protected by a basic patent within the meaning of that provision.*
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> *[…]*
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> *36 In the main proceedings, it is common ground that the active ingredient tabalumab, namely LY2127399, is not expressly named in the claims of HGS's patent. Moreover, it would appear that it is not otherwise specified in the descriptions or specifications of that patent and cannot, therefore, be identified as such.*
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> *37 With regard to the fact that the marketing of that active ingredient by Eli Lilly during the lifetime of HGS's patent would constitute an infringement of the patent, it is clear, in the light of what has been stated at paragraphs 32 and 33 above, that that is not a crucial factor, for the purpose of granting an SPC on the basis of Regulation No 469/2009, in particular Article 3(a) of that regulation, in the determination of whether that active ingredient is protected by that patent.*
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> *38 It should be recalled that, in accordance with the case-law cited at paragraph 34 above, an active ingredient which is not identified in the claims of a basic patent by means of a structural, or indeed a functional definition cannot, in any event, be considered to be protected within the meaning of Article 3(a) of Regulation No 469/2009.*
>
> *[…]*
>
> *42 In the light of the objective of Regulation No 469/2009, the refusal of an SPC application for an active ingredient which is not specifically referred to by a patent issued by the EPO relied on in support of such an application may be justified – in circumstances such as those in the main proceedings and as observed by Eli Lilly – where the holder of the patent in question has failed to take any steps to carry out more in-depth research and identify his invention specifically, making it possible to ascertain clearly the active ingredient which may be commercially exploited in a medicinal product corresponding to the needs of certain patients. In such a situation, if an SPC were granted to the patent holder, even though – since he was not the holder of the MA granted for the medicinal product developed from the specifications of the source patent – that patent holder had not made any investment in research relating to that aspect of his original invention, that would undermine the objective of Regulation No 469/2009, as referred to in recital 4 in the preamble thereto. 39*

The CJEU rules:

> *Article 3(a) 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 meaning that, in order for an active ingredient to be regarded as 'protected by a basic patent in force' within the meaning of that provision, it is not necessary for the active ingredient to be identified in the claims of the patent by a structural formula. Where the active ingredient is covered by a functional formula in the claims of a patent issued by the European Patents Office, Article 3(a) of that regulation does not, in principle, preclude the grant of a supplementary protection certificate for that active ingredient, on condition that it is possible to reach the conclusion on the basis of those claims, interpreted inter alia in the light of the description of the invention, as required by Article 69 of the Convention on the Grant of European Patents and the Protocol on the interpretation of that provision, that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question, which is a matter to be determined by the referring court.*

Actavis

The CJEU reformulates the second question (and will conclude there is no need to answer the first question):

> *26 By its second question, which it is appropriate to examine first of all, the referring court asks, in essence, whether, in circumstances such as those in the main proceedings, in which, on the basis of a patent protecting an innovative active ingredient and an MA for a medicinal product containing that ingredient as the single active ingredient, the holder of that patent has already obtained an SPC for that active ingredient, Article 3(c) of Regulation No 469/2009 must be interpreted as precluding the holder of that patent from obtaining, on the basis of that same patent but an MA for a different medicinal product containing that active ingredient in combination with another active ingredient which is not protected as such by the patent, a second SPC relating to that combination of active ingredients.*

The CJEU considers:

> *29 In that regard, it is possible, on the basis of a patent which protects several different 'products', to obtain several SPCs in relation to each of those different products, provided, inter alia, that each of those products is 'protected' as such by that 'basic patent' within the meaning of Article 3(a) of Regulation No 469/2009, in conjunction with Article 1(b) and (c) of that regulation (Case C-482/12 Georgetown University [2013] ECR I-0000, paragraph 30).*
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> *30 However, in circumstances such as those in the main proceedings, even if the condition laid down in Article 3(a) of Regulation No 469/2009 were satisfied, for the purpose of the application of Article 3(c) of that regulation, it cannot be accepted that the holder of a basic patent in force may obtain a new SPC, potentially for a longer period of protection, each time he places on the market in a Member State a medicinal product containing, on the one hand, the principle active ingredient, protected as such by the holder's basic patent and constituting, according to the statements of the referring court, the core inventive advance of that patent, and, on the other, another active ingredient which is not protected as such by that patent.*
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> *[…]*
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> *32 In the main proceedings, Sanofi's patent, which protects the active ingredient irbesartan as such within the meaning of Article 3(a) of Regulation No 469/2009, has already enabled its holder to obtain an SPC relating to that active ingredient. Moreover, it is common ground that hydrochlorothiazide, an active ingredient that is a member of a class of diuretics, is not protected as such by that patent or indeed by any other patent.*
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> *[…]*
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> *35 It follows that that first SPC permitted Sanofi to oppose the marketing of a medicinal product containing irbesartan in combination with hydrochlorothiazide for a similar therapeutic use to that of Aprovel, so that if one of that pharmaceutical laboratory's competitors had marketed a medicinal product similar to CoAprovel for similar therapeutic use, Sanofi would have been able to oppose the marketing of such a product by invoking its SPC for irbesartan […]*
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> *36 In such a situation, Article 13 of Regulation No 469/2009 dictates that, upon expiry of the initial SPC, the holder thereof may no longer, in connection with the basic patent used as the basis for the grant of the SPC, oppose the marketing by third parties of the active ingredient which was the subject of the protection conferred by that SPC. […]*
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> *37 Moreover, with regard to the second SPC granted in the main proceedings, the possibility cannot be ruled out that, under national law which provides a degree of protection against indirect infringement, an SPC relating to the irbesartan-hydrocholorothiazide combination may permit the holder to oppose the marketing of a medicinal product containing the active ingredient irbesartan, as a single active ingredient or in combination with another active ingredient. In such a situation, the second SPC may in fact confer upon its holder, albeit partially and indirectly, further protection for irbesartan, extending de facto the protection it enjoyed as a result of the grant of the first SPC relating to that active ingredient, under the conditions referred to at paragraph 35 above. Thus, in view of the consequences of it being granted, in terms of the extension of protection, the situation outlined above confirms that an SPC such as the second SPC at issue in the main proceedings cannot be issued.*
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> *38 Similarly, if, in circumstances such as those in the main proceedings, the medicinal product CoAprovel had obtained MA before Aprovel, which would have enabled its proprietor to obtain an SPC either, in the light of paragraph 34 of Medeva, for irbesartan alone, or for the irbesartan-hydrochlorothiazide combination, and MA had subsequently been obtained for Aprovel, that could not have secured a second SPC for irbesartan, in view of the condition laid down in Article 3(c) of Regulation No 469/2009.*

The CJEU rules:

> *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.

Georgetown

The CJEU reformulates the first question (and will conclude there is no need to answer questions 2-5):

> *26 By its first question, the referring court asks, in essence, whether, in circumstances such as those in the main proceedings, where, on the basis of a basic patent and an MA in respect of a medicinal product consisting of a combination of several active ingredients, the patent holder has already obtained an SPC for that combination of active ingredients, which is protected by the basic patent within the meaning of Article 3(a) of Regulation No 469/2009, Article 3(c) of that regulation must be interpreted as precluding that patent holder from also obtaining an SPC in respect of one of those active ingredients which is also protected as such, individually, by that patent.*

The CJEU considers:

> *29 However, the main proceedings concern a different situation, namely that in which the same basic patent may be regarded as protecting a number of products within the meaning of Article 3(a) of Regulation No 469/2009, thus raising a different question, namely whether such a patent may permit its holder to obtain several SPCs.*
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> *30 In that regard, it is possible, in principle, on the basis of a patent which protects several different 'products', to obtain several SPCs in relation to each of those different products, provided, inter alia, that each of those products is 'protected' as such by that 'basic patent' within the meaning of Article 3(a) of Regulation No 469/2009, in conjunction with Article 1(b) and (c) of that regulation (Case C-443/12 Actavis Group PTC and Actavis UK [2013] ECR I-0000, paragraph 29), and is contained in a medicinal product with an MA.*
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> *[…]*
>
> *32 In the main proceedings, it would appear to be common ground that the basic patent held by Georgetown University protects, at the very least, both the HPV-6, HPV-11, HPV-16 and HPV-18 and the HPV-16 and HPV-18 combinations, as contained in Gardasil and Cervarix, and HPV-16, as marketed in Gardasil.*
>
> *[…]*
>
> *34 It follows that the answer given by the Court to the second question referred in the case which gave rise to the judgment in Actavis Group PTC and Actavis UK cannot be applied to the question at issue in the present case.*
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> *35 In the main proceedings, in the light of paragraph 30 above, the combination of the four active ingredients in question (which includes HPV-16) as well as HPV-16 as an active ingredient individually, are protected by Georgetown University's basic patent within the meaning of Article 3(a) of Regulation No 469/2009. Therefore, Article 3(c) of that regulation does not, in principle, preclude Georgetown University being granted, on the basis of that patent and the same MA, namely the marketing authorisation for Gardasil, an SPC both for the combination of active ingredients (HPV-6, HPV-11, HPV-16 and HPV-18) and for the active ingredient HPV-16 individually. Even if the protection conferred by two such SPCs were to overlap, they would, in principle, expire on the same date.*
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> *36 Accordingly, the grant of such multiple SPCs relating to different 'products' makes it possible re-establish a sufficient period of effective and uniform protection for the two SPCs referred to above, by permitting the holder to enjoy an additional period of exclusivity on the expiry of his patent, which is intended to compensate, at least in part, for the delay to the commercial exploitation of his invention or inventions by reason of the time which has elapsed between the date on which the application for the patent was filed and the date on which the first MA in the European Union was granted (see Case C-229/09 Hogan Lovells International [2010] ECR I-11335, paragraph 50, and Actavis Group PTC and Actavis UK, paragraph 31).*
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> *37 However, it would appear from the information provided in the order for reference that the active ingredient protected by the basic patent in respect of which Georgetown University has applied, in the main proceedings, for an SPC on the basis of the MA for Gardasil, namely HPV-16, may also be found in another medicinal product, Cervarix, which was subsequently granted an MA.*
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> *38 It should be noted in that regard that, where the holder of a patent obtains an SPC relating to an active ingredient on the basis of the MA for the first medicinal product placed on the market comprising, among its active ingredients, the active ingredient protected by the basic patent (Medeva, paragraph 40), such as, in the main proceedings, an SPC relating to HPV-16 on the basis of the MA for Gardasil, the wording of Article 3(c) of Regulation No 469/2009 itself precludes that holder from obtaining, on the basis of that same patent, another SPC relating to the very same HPV-16 as a 'product' on the basis of a subsequent MA for another medicinal product which also contains HPV-16, unless, in that other medicinal product, the 'product' that is the subject of the SPC application relates in fact to a different HPV-16 falling within the limits of the protection conferred by the basic patent relied upon for the purposes of that application (see, to that effect, Neurim Pharmaceuticals (1991), paragraph 30).*

The CJEU rules:

> *In circumstances such as those in the main proceedings, where, on the basis of a basic patent and a marketing authorisation for a medicinal product consisting of a combination of several active ingredients, the patent holder has already obtained a supplementary protection certificate for that combination of active ingredients, protected by that patent within the meaning of Article 3(a) 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, Article 3(c) of that regulation must be interpreted as not precluding the proprietor from also obtaining a supplementary protection certificate for one of those active ingredients which, individually, is also protected as such by that patent.*

Let the SPC debates begin once more!