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CJEU allows multiple SPCs per patent under a qualified test, but uncertainties remain

On 12th December 2013, the CJEU handed down its rulings in three cases, Georgetown II (C-484/12), Actavis (C-443/12) and Eli Lilly (C-493/12), which have had SPC practitioners on tenterhooks for some time.

While the decisions clarify a number of contentious points, it is no surprise to see that the rulings also throw up further debatable issues. Whilst future referrals still seem likely, perhaps the UK judges will now try to implement the guidance they have been given, ambiguous as this still is, rather than referring further questions to the Court of Justice of the European Union (CJEU).

To summarise, the key messages from these judgments are:

- There is no blanket preclusion on basing more than one supplementary protection certificate (SPC) on a single patent (Georgetown II).
- There are, however, cases where it will not be possible to obtain more than one SPC on a single patent, despite the patent covering different products (Actavis).
- The precise circumstances in which the Actavis reasoning will preclude more than one SPC being based on a single patent are not clear.
- In order for the product which is the subject of an SPC to be “protected by a basic patent in force” as set forth in Article 3(a) of Regulation 469/2009, there is no need for a product to be “identified in a structural formula” (Eli Lilly). Instead, it is sufficient that the product is “covered by a functional formula”, provided that the claims relate “implicitly, but necessarily and specifically” to the product.
- The CJEU has arguably cast some doubt on the validity of the practice of applying for SPCs based on other parties’ marketing authorisations (MAs) (Eli Lilly).

Initial thoughts

Georgetown II comes as a relief to the pharma and biotech sectors in that it confirms that there is no blanket preclusion on basing more than one SPC on a single patent, when those SPCs are directed to different products. Comments made in a number of recent Advocate General opinions had suggested a serious prospect of such a restriction being levied,

which would of course have curtailed protection in the case of chemical patents that cover a range of products in a generic formula, and biotech patents that cover different antigens (e.g. as used in vaccines) and different antibody variants.

Accordingly, Georgetown will be permitted to obtain an SPC for its HPV-16 vaccine antigen, despite already having SPCs for combinations of HPV-16 with other HPV types that are based on the same patent and the same MA (because these combinations are counted as being different products from HPV-16 alone).

However, the Actavis ruling confirms that there are limits on the extent to which multiple SPCs can be based on a single patent. In the Actavis case, the patentee Sanofi had a patent where claim 1 is directed to the antihypertensive compound irbesartan and a dependent claim is directed to a combination of irbesartan with "a diuretic". Sanofi had obtained two SPCs based on this patent, the first to irbesartan (marketed as Aprovel) and the second to a combination of irbesartan with the diuretic hydrochlorothiazide (marketed as CoAprovel). The judgment indicates that this second SPC is invalid and distinguishes the facts of this case from those of Georgetown II. However, whilst there certainly are a number of factual distinctions between Actavis and Georgetown II, it is not clear precisely which factual differences led to the outcome being different from that in Georgetown II. Some of the factual differences between the two cases are identified and analysed below, in an attempt to rationalise the CJEU's message.

Eli Lilly concerns the requirement for the product which is the subject of an SPC to be "protected by a basic patent in force" as set forth in Article 3(a) of Regulation 469/2009. The precise criteria to determine whether a product is "protected" by a basic patent have been debated at length, prompting multiple previous references to the CJEU in Medeva (C-322/10), Georgetown I (C-422/10), Yeda (C-518/10), Queensland (C-630/10) and Daiichi (C-6/11), in addition to these latest decisions.

The CJEU has previously stated that a product is protected by a basic patent within the meaning of Article 3(a), when the product is "specified" or "identified" in the wording of the claims of the basic patent but that, of course, raised questions about the meaning of the terms "specified" and "identified". For example, need a product be named explicitly in the claims, or is it sufficient that the claims describe the product by its characteristics or encompass it within a generally defined class?

In Eli Lilly, the CJEU rejected a requirement for a product to be "identified in a structural formula". Instead, the CJEU held that it is sufficient that the product is "covered by a functional formula", provided that the claims relate "implicitly, but necessarily and specifically" to the product. In interpreting the claims, the CJEU confirmed that account must be taken of Article 69 EPC and its protocol, under which the claims must be interpreted in light of the description of the patent. The criterion for assessing what "protected" means is more liberal than some had feared, although the subjective nature of the criterion seems likely to result in disharmony in the implementation of this law by national courts and patent offices.

A point not in dispute

The Eli Lilly dispute concerned the possibility that HGS could apply for an SPC based on the HGS patent, using Lilly's intended MA for Lilly's antibody. If permitted, this could allow HGS to obtain an additional five years of protection. Although not a point that was referred to the CJEU, we note that the CJEU arguably casts some doubt on the validity of the practice of applying for SPCs based on other partys' MAs (paragraph 43):

"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."

Reconciling Georgetown II with Actavis

As mentioned above, the CJEU was at pains to point out that the facts of Georgetown II are different from those in Actavis, and that these factual differences are responsible for the different outcomes (Georgetown II, paragraphs 33 and 34). We have identified the following factual differences between these two cases in an attempt to work out which aspects were deemed to be crucial to the outcomes.

In Georgetown II, it was accepted that the combination products and the mono product (i.e. the single antigen) were all "protected" by the basic patent in the sense of Article 3(a). In contrast, in Actavis, the CJEU appears to be of the view that the combination product was "not protected as such by the basic patent but simply referred to in the wording of the claims of the patent in general terms" because the term "diuretic" did not sufficiently specify the hydrochlorothiazide component. However, this is not clear because another passage of Actavis (paragraph 28) suggests that the combination product was "protected" by the basic patent. Paragraphs 30 and 44 suggest that this "protected" issue was not decisive to the result, but it is hardly a model of clarity for us poor practitioners to implement and enforce (let alone the courts).

In Georgetown II, the combination SPC was granted first, and the dispute focused on the validity of the subsequent SPC filing directed to the single antigen. In Actavis, the order was reversed: the irbesartan SPC was granted first, and the dispute was about validity of the SPC on the combination product. However, paragraph 38 of Actavis suggests that these timing considerations were not decisive.

In Georgetown II, all products were based on the same MA – and hence the SPCs would expire on the same day, giving Georgetown no extra term advantage in having the additional SPC. In Actavis, however, the later combination product SPC application was based on a later authorisation than the monotherapy, meaning that the duration of Sanofi's combination SPC was greater than that of the monotherapy SPC. This factor certainly seems to have weighed on the CJEU's mind but we cannot be certain that it was decisive.

In Actavis, the CJEU voiced concerns that the SPC should be granted only in respect of the "core inventive advance" embodied in the patent, which, in that case, it regarded as being irbesartan, rather than the combination of irbesartan and hydrochlorothiazide. This follows a concept postulated by Arnold J. in his referral to the CJEU (Actavis v Sanofi [2012] EWHC 2545 (Pat)) that "if the product is protected by a basic patent within Article 3(a) because the active ingredient (or combination of active ingredients) embodies the inventive advance of the patent, then one SPC may be granted in respect of that product and that patent". In Georgetown II, however, no consideration was given as to what was the "core inventive advance".

It is likely that future references to the CJEU will be required to assess precisely which fact patterns may permit multiple SPCs based on a single patent, and which will be subject to the restrictive ruling of Actavis. Will that come to pass, or will the judges just make the best of it? Even if this were not clear before, surely now it must be apparent to everyone that complete clarity on how Article 3 of the SPC Regulation should function will not be forthcoming at any time soon.

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