Possibility to obtain SPCs broadened by three eagerly awaited CJ decisions

On 12 December 2013, the Court of Justice of the European Union ("CJ") handed down three important decisions regarding the interpretation of Regulation 469/2009 (the "SPC Regulation"). These three decisions are expected to impact your SPC strategies. In Actavis v Sanofi (C-443/12) and Georgetown II (C-484/12), the CJ clarified the circumstances in which Article 3(c) of the SPC Regulation may allow the granting of more than one supplementary protection certificate ("SPC") per basic patent. In Eli Lilly v HGS (C-493/12), the CJ sanctioned a broad interpretation of "protected by a basic patent in force" (3(a) SPC Regulation) which can also include functional claims.

Background: uncertainty after Medeva, Georgetown I and Queensland

Two years ago, the CJ handed down a series of decisions regarding the granting of SPCs for combination products (click here for our Legal Alert on Medeva and Georgetown(I) and here for the one on Yeda, Queensland and Daiichi). The interpretation of these decisions created considerable uncertainty and led to multiple referrals by national courts to the CJ, three of which have now been decided, clarifying the following two items from the earlier rulings that had sparked discussion:

(i) In the 2011 decisions the CJ ruled that, in relation to marketing authorisations ("MA") for combination products, a product is "protected by a basic patent in force" as required by Art 3(a) SPC Regulation if the product "is specified (or identified) in the wording of the claims of the basic patent" (the "Medeva-rule"; therewith dismissing the "infringement test" and embracing the "disclosure test", see our publication for more details). However, what remained unclear to industrial property offices ("IPOs") and national courts was the level of
specification in the claims required to obtain an SPC for active ingredients.

(ii) In **Queensland** the CJ considered "where a product is protected by a number of basic patents in force, each of those patents may be designated for the purpose of the procedure for the grant of a certificate but only one certificate may be granted for that basic patent (...).". This prompted several national IPOs to stop their practice of granting SPCs for different products based on the same patent whereas other IPOs continued to grant several SPCs based on one basic patent.

*Eli Lilly v HGS* concerns the first issue and *Georgetown II* and *Actavis v Sanofi* shed light on the second controversy as discussed below.

(i) When is an active ingredient considered "protected by a basic patent in force" (Art. 3(a) SPC Regulation)?

*Eli Lilly* was developing a specific antibody that would fall within the protection of HGS' patent. The patent contains a broad claim covering all (therapeutic) antibodies specifically binding to a certain new protein (neutrokine-α) which HGS discovered to be linked to autoimmune diseases. Antibodies that can bind to this protein could thus be beneficial and the patent claims such antibodies functionally, without specifying individual antibodies (including the one that *Eli Lilly* was developing) explicitly. In so far as relevant here, the parties are divided about whether HGS would be able to claim an SPC for *Eli Lilly*'s antibody. More specifically, the issue that kept parties divided was whether for HGS' patent individual antibodies are sufficiently "specified in the wording of the claims of the basic patent" to be considered protected by the basic patent (Art. 3(a) SPC regulation) as set out in the Medeva-rule. The referring court essentially asked the CJ to clarify whether to meet this rule the claims of a patent should contain a structural definition of the specific active ingredient (the antibody), or whether a functional definition suffices.

In *Eli Lilly v HGS* the CJ has now ruled that in order for an active ingredient to be regarded as 'protected by a basic patent in force' within the meaning of Article 3(a) SPC Regulation, it is not necessary for the active ingredient to be identified in the claims of the patent by a structural formula. A functional description can be sufficient for identification purposes (the CJ adds that this is for national courts to decide while also taking article 69 EPC into account), provided that it is possible to conclude on the basis of the claims of the basic patent "that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question". Dutch Courts already interpreted the Medeva-rule in a similar way (Court of Appeal of The Hague in *Lundbeck v Generieken*, 24 January 2012, and District Court of The Hague in *Sanofi v Pharmachemie and Teva*, 14 September 2012). The CJ clearly considers – in paragraph 38 - that an active ingredient which is not identified in the claims of a basic patent through either a structural or functional definition cannot be regarded as "protected by a basic patent" within the meaning of article 3(a).

This decision broadens the possibility of obtaining SPCs, as the Medeva-test can also be fulfilled by functional claims and not only by structural claims.
(ii) Does Article 3(c) preclude the patent owner from obtaining SPCs for multiple products under one basic patent?

For the granting of an SPC, Article 3(c) SPC Regulation requires that "the product has not already been the subject of a certificate". In both Actavis v Sanofi and Georgetown II the referring courts, from the UK and the Netherlands respectively, sought to clarify whether Article 3(c) SPC Regulation precludes the holder of the basic patent from being granted an SPC for each of the products protected in situations where a basic patent in force protects several products. The answer in Actavis v Sanofi is yes, and in Georgetown II no. The difference in outcome lies in the factual circumstances of the cases. The general rule seems to be that on the basis of a patent which protects several different 'products' it is possible to obtain several SPCs in relation to each of those products, provided that each active ingredient of a product is as such protected as an 'inventive advance' by the basic patent.

In Actavis v Sanofi, Sanofi had obtained one SPC for irbesartan and another one for irbesartan in combination with HCTZ (pre-Medeva), based on an MA for irbesartan and a second (later obtained) MA for irbesartan and HCTZ. The patent claimed both the product irbesartan separately and the combination product irbesartan with a diuretic (HCTZ is a diuretic). The referring court had established that only irbesartan constituted the "core inventive advance" of the patent. The CJ noted that Sanofi could already act against a combination product with irbesartan and HCTZ on the basis of its first SPC. The earlier SPC containing the (only) protected active ingredient in this case precludes the issue of a second SPC.

In Georgetown II, the patent claimed a vaccine for the prevention of (human) papillomavirus (HPV) infection comprising at least a protein or one or several claimed fragments of that protein. Georgetown had obtained two SPCs claiming combinations of HPV fragments. Its SPC application for one active ingredient, which was also part of the combination SPC, was refused based on Article 3(c). As both the combination and the single active ingredient are separately protected as 'products' as such by the patent, the CJ ruled that Article 3(c) did not preclude Georgetown from obtaining an SPC for one of the active ingredients individually. In other words, the earlier combination SPC did not concern the same (new) product in the sense of Article 3(c). This is advantageous for the patent holder in cases where the patent protects multiple products as such.

Questions remain

Yet, questions remain and new ones are raised by these decisions, including several questions related to filing strategies of (multiple) SPCs:

- The second to fifth questions in Georgetown II are unanswered. Therefore, it remains unclear whether holders of an SPC may decide to withdraw an SPC application or surrender an SPC already granted to allow another SPC to be granted.
- Interestingly, in Eli Lilly v HGS (par. 43), the CJ reflects on whether the holder of a basic patent can apply for an SPC on the basis of an MA by a third party in the
specific circumstances of these proceedings. The CJ seems to suggest that an IPO could refuse to grant an SPC to the patent holder, since this would be contrary to the rationale of the SPC Regulation, therewith apparently suggesting that this is a separate criterion for the granting of an SPC.

- In its ruling in Actavis v Sanofi, the CJ seems to make the fact that the first SPC (for one active ingredient) can also be used to oppose the use of the active ingredient in combination with other active ingredients conditional for the inadmissibility of a second combination SPC. Does this suggest that the outcome in Georgetown II might have been different had the first SPC been granted for one active ingredient only instead of for the combination? If this reasoning were to be followed, one should carefully review the order of obtaining an SPC in cases where the patent protects multiple products.

- Does the CJ's consideration (par. 35 in Georgetown II): "Even if the protection conferred by two such SPCs were to overlap, they would, in principle, expire on the same date" have implications for the calculation of the duration of an SPC (Art. 13(1) SPC Regulation)? In cases where a basic patent protects several products, it can also be argued that the MA referred to in Art. 13(1) should be interpreted as the first MA for the relevant product which could result in different expiry dates for SPCs based on the same patent.

**Practical significance**

All three decisions broaden the possibility of obtaining SPCs and they remove a considerable amount of the uncertainty created by earlier case law. However, they also raise new questions and leave some queries unanswered. In Eli Lilly v HGS the CJ sanctions a broad interpretation of the Medeva rule. Actavis v Sanofi and Georgetown II clarify that the rule 'one SPC per patent' should be interpreted as 'one SPC per product per patent', provided each product claimed is an active ingredient or a combination of active ingredients that is protected as an advance as such by the patent.

These decisions should be reviewed carefully in view of your drafting and SPC filing practices. Of course, we would be pleased to discuss the practical consequences these CJ decisions may have for your business.

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