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Medeva/Georgetown (C-322/10 & C-422/10)

The EU's highest court explains (albeit with some ambiguity) how to get an SPC for a combination drug, and confirms that an SPC for a single active ingredient can be used to stop sales of a combination drug containing the same active ingredient.

Background

The Court of Justice of the European Union (CJEU) handed down its decisions this morning in the widely followed *Medeva/Georgetown* referrals. These decisions deal with the substantive requirements for obtaining supplementary protection certificates (SPCs, patent term extensions) under EU law and have far-reaching implications for the pharmaceutical and plant protection industries.

The CJEU was faced with two difficult issues that have vexed the SPC system for years. The first issue (under Article 3(a) of the SPC regulations) is whether a patent with claims that describe only one active ingredient from a combination of active ingredients in an authorised drug can be used to obtain an SPC for that drug. This is a common scenario, particularly in the vaccine field where patents are generally filed for single classes of active ingredients (antigens) many years before combination uses are identified. Before the *Medeva/Georgetown* referrals, several national courts had decided that SPCs could not be granted in this situation, despite a perceived unfairness in this approach.

The second issue (under Article 3(b)) is whether the authorisation of a drug that contains a combination of active ingredients can be used to obtain an SPC for only one active ingredient from that combination. Some national courts had endorsed this approach, particularly to avoid the unfairness discussed above: if the patent had claims that described only one active ingredient from the combination, then an SPC could be granted for that single active ingredient.

Lurking behind both issues is a third issue of wide importance to industry. This is whether an SPC for a single active ingredient can be infringed by sales of a drug that contains this active ingredient in combination with other active ingredients. Although this issue (under Articles 4 and 5) was not raised in the referrals (and is indeed the subject of other pending CJEU referrals), it seemed difficult for the CJEU to reach a decision on the other issues without tackling this third issue head on.

Despite being heard together, the two referrals were dealt with in separate decisions. In summary, the CJEU addressed the first issue by deciding that an SPC could be granted for a combination of active ingredients only if those active ingredients were "specified in the wording of the claims". In rejecting a direct infringement test, this approach would seem consistent with the approach of the national courts, although we envisage future difficulties in deciding whether the active ingredients in a combination drug are adequately "specified in the wording of the claims" to obtain an SPC. While a narrow, specific disclosure of multiple active ingredients would seem acceptable, what about a broad, generic disclosure (c.f. the UK Gilead decision on this point)? C-322/10, ruling:

"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 precluding the competent industrial property office of a Member State from granting a supplementary protection certificate relating to active ingredients which are not specified in the wording of the claims of the basic patent relied on in support of the application for such a certificate."

The second issue was decided generously for SPC applicants, allowing SPCs to be granted for single active ingredients that are authorised for use with other active ingredients (C 422/10, ruling):

"Article 3(b) 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, provided the other requirements laid down in Article 3 are also met, that provision does not preclude the competent industrial property office of a Member State from granting a supplementary protection certificate for an active ingredient specified in the wording of the claims of the basic patent relied on, where the medicinal product for which the marketing authorisation is submitted in support of the supplementary protection certificate application contains not only that active ingredient but also other active ingredients."

This approach will be welcomed by many, and would seem to allow Georgetown et al. to obtain the SPCs that they sought in their referral. Crucially, however, an SPC for a single active ingredient (or combination of active ingredients) that is authorised for use with other active ingredients will only be allowable if the authorisation represents the first time it has been authorised. In contrast to Georgetown et al., this qualification would seem to prevent Medeva from obtaining the SPCs that it sought in its referral (C-322/10, 40):

"However, it should be added that, in a situation such as that in the main proceedings, first, only the authorisation in respect of the first medicinal product placed on the European Union market comprising, among its active ingredients, the combination of the two active ingredients identified in the wording of the claims of the patent, namely pertactin and filamentous haemagglutinin, may be regarded as the first MA for that 'product' as a medicinal product within the meaning of Article 3(d) of Regulation No 469/2009."

The third issue was again decided generously for SPC holders, suggesting that an SPC for a single active ingredient will be infringed by sales of a combination drug that contains the same active ingredient and other active ingredients (C-422/10, 32):

"In accordance with Article 5 of Regulation No 469/2009, a SPC thus granted in connection with such a product confers, upon the expiry of the patent, the same rights as were conferred by the basic patent in relation to the product, within the limits of the protection conferred by the basic patent, as provided for in Article 4 of the regulation. Accordingly, if, during the period in which the patent was valid, the patent holder could oppose, on the basis of his patent, all use or certain uses of his product in the form of a medicinal product consisting of such a product or containing it, the SPC granted in relation to that product would confer on the holder the same rights for all uses of the product, as a medicinal product, which were authorised before the expiry of the certificate."

However, SPC applicants will be more concerned by the possible endorsement of the "one SPC per patent" rule proposed in the Advocate General's earlier opinion in these referrals. Although national authorities have for many years allowed multiple SPCs to be granted on the basis of single patents provided that each SPC relates to a different active ingredient, the Advocate General suggested that this was not the correct approach. Many commentators felt that the Advocate General had misunderstood the CJEU's earlier Biogen decision in reaching this opinion, in particular by failing to consider whether more than one SPC could be granted for different active ingredients covered by a single patent. Worryingly, the CJEU does not seem to explicitly rule out the Advocate General's interpretation, so SPC applicants will have to rely on its reference to the Biogen decision to argue that the previous practice based on this decision remains correct (C 322/10, 41):

"Second, where a patent protects a product, in accordance with Article 3(c) of Regulation No 469/2009, only one certificate may be granted for that basic patent (see Biogen, paragraph 28)."

Although these decisions bring some much needed clarity to the application of the SPC regulations to combination drugs, we foresee several issues that remain unclear, particularly the meaning of "specified in the wording of the claims" in relation to Article 3(a). A brief review of the French, German and Spanish versions of the current decisions does not seem to remove the ambiguity, although they possibly lean towards a more restrictive approach than that implied by the English-language decisions. It is possible that these issues will be addressed by future CJEU decisions, for example in other pending referrals that deal with similar issues. Indeed, the Daiichi referral has set out possible tests related to the meaning of "specified in the wording of the claims", so perhaps the CJ will be forced to provide further detail on this issue in due course. Another referral (Queensland) queries whether it is permissible to consider what might be "specified in the wording of the claims" across a family of patents derived from the same application. A further referral (Yeda) deals with whether claims that specify two active ingredients can be used to obtain an SPC for only one of those active ingredients, but the Court seems to have pre-empted this referral and decided against this approach (C-322/10, 26):

"Similarly, if a patent claims that a product is composed of two active ingredients but does not make any claim in relation to one of those active ingredients individually, a SPC cannot be granted on the basis of such a patent for the one active ingredient considered in isolation."

Need advice?

We hope that this initial analysis has been of interest to you. We will now review the decisions in detail. If you have any questions about these decisions, or SPCs more generally, please let us know. Carpmaels & Ransford has been at the forefront of SPC law and practice for many years and last year filed more national SPC applications than any other UK firm. It is also leading the Queensland and Neurim SPC referrals at the CJEU, which raise further fundamental questions of SPC law. For more information, please contact:

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