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SPCs FOR COMBINATION PRODUCTS – OPINION OF THE ADVOCATE GENERAL

– ADDENDUM –

On November 24, 2011, the European Court of Justice handed down its judgment in the joined cases of Medeva (C-322/10) and Georgetown et al. (C-422/10). These cases relate to the interpretation of Article 3 of Regulation 469/2009/EC, more specifically to the requirements for grant of a supplementary protection certificate (SPC) for a partially patented combination product.

In brief, the questions to be dealt with by the Court are: (1) can a SPC for a combination product comprising the active ingredients A+B+C be granted based on a marketing authorization (MA) for the combination product A+B+C if the parent patent is only directed to a combination product A+B; and (2) can a SPC for a combination product A+B be granted if the basic patent is directed to a combination product A+B but a MA is for ta combination product A+B+C?

In addressing the first question, the Court noted that it is to be examined whether Article 3(a) of the Regulation must be interpreted as precluding the grant of a SPC where the active ingredients specified in the application include active ingredients not mentioned in the wording of the claims of the basic patent relied on in support of such an application.

The Court made reference to Article 5 of the Regulation, which provides that any SPC confers the same rights as conferred by the basic patent and is subject to the same limitations and the same obligations. From that, it would follows that Article

3(a) of the Regulation precludes the grant of a SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent. 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.[1]

Accordingly, the ECJ held that Article 3(a) of Regulation 469/2009/EC must be interpreted as precluding the competent industrial property office of a Member State from granting a SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent relied on in support of the SPC application.[2]

In addressing the second question, it is to be examined whether Article 3(b) of the Regulation may be interpreted as not precluding the grant of a SPC for a combination of active ingredients, corresponding to that specified in the claims of the basic patent relied on, where the medicinal product for which the MA is submitted in support of the SPC application contains not only that combination of the active ingredients but also other active ingredients.

The Court noted that it is apparent from the observations submitted, at present innovative medicinal products placed on the market, often consist of combinations of active ingredients for multiple therapeutic uses which can be administered to patients in a single preparation.

If the holder of a basic patent relating to such an innovative active ingredient or combination of active ingredients were to be refused a SPC on the ground that, in the commercial version of the medicinal product which places that active ingredient or that combination on the market for the first time, the active ingredient or the combination coexists in the medicinal product alongside other active ingredients or combinations which have other therapeutic purposes and may or may not be protected by another basic patent in force, the fundamental objective of Regulation

[1] Cf. C-322-10, points 25 and 26 of the reasoning.
[2] Cf. C-322-10, headnote 1.

469/2009/EC, which is to ensure sufficient protection to encourage pharmaceutical research and play a decisive role in the continuing improvement in public health, could be undermined.

The holder of such a patent would enjoy only the period of effective protection conferred by the patent, which is insufficient to cover the investment put into pharmaceutical research, which is why that legislature created a SPC for medicinal products designed to make up for that insufficiency. Further, such an approach would tend to favor the development of monovalent medicinal products, which may not be in the interests of patients or national public health authorities.

In such a situation, the holders of such patents would be forced to develop commercially and maintain on the market medicinal products containing only the active ingredients specified as such in the basic patent in order to obtain a MA for a medicinal product covering precisely those active ingredients which, as such, the holder could be certain would confer entitlement to a SPC. It is clear that such an outcome cannot be compatible with the fundamental objectives pursued by the SPC Regulation.

The requirement in the Regulation that the 'product' must be covered, as a medicinal product, by a MA confirms that approach in that that requirement does not in itself rule out the possibility that the MA may cover other active ingredients contained in such a medicinal product. Moreover, in accordance with Article 4 of the Regulation, a SPC is intended to protect the 'product' covered by the MA, not the medicinal product as such.[3]

Hence, the ECJ ruled that Article 3(b) of the Regulation 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 SPC for a combination of two active ingredients, corresponding to that specified in the wording of the claims of the basic patent relied on, where the medicinal product for which the MA is submitted in support of the application for a

[3] Cf. C-322-10, points 33 to 37 of the reasoning, and C-422/10, points 27 to 30 of the reasoning.

special SPC contains not only that combination of the two active ingredients but also other active ingredients.[4]

Interestingly, in various national decisions on the interpretation of Article 3 of the Regulation, the competent authorities have answered the above-referenced questions in different ways. For example, some German courts were of the opinion that the 'infringement test' should be used to determine whether the product of the SPC is covered by the basic patent. Other courts and a number of national patent offices (*inter alia* in the Netherlands) used the 'subject-matter' test for this analysis, which is a narrower interpretation of the requirement of Article 3. Still others (some British courts) used the 'disclosure' test. If an SPC were requested for a combination of compounds, this combination should at least be disclosed somewhere in the patent, but not necessarily in the claims. This disparity in interpretation of Article 3 was one of the reasons for the referrals to the ECJ in the subject cases.

However, the ECJ did not discuss the previously used tests, which leaves the phrase used in the present rulings – "specified in the wording of the claims" – open to different interpretations. Accordingly, some commentators have already speculated on another referral to the ECJ with regard to an interpretation of Article 3 of Regulation 469/2009/EC.

[4] Cf. C-322-10, headnote 2, and C-422/10, headnote.