

Client Alert

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Supplementary Protection Certificates – Follow-Up of *Medeva* Will We Go From Worse to Worst?

Yesterday, Advocate General Jääskinen gave his opinion on the questions referred by the Dutch court in the *Georgetown* case (C-484/12), one of the follow-up cases to the *Medeva* ruling in November 2011. The CJEU mainly has to decide whether, where a basic patent covers several products, national patent offices may grant an SPC for each product protected by the basic patent. If they may not, may the patent holder waive the SPC with retrospective effects and so seek a new SPC for another (supposedly better) product?

Advocate General Jääskinen's opinion is important because the CJEU typically – but not always - follows the opinion of its Advocate General. Unfortunately, the opinion is not favorable to patent holders. Advocate General Jääskinen seems to consider that only one SPC may be granted per basic patent, and he limits the effects of the waiver of an SPC to the future.

The Court's decision is expected by June 2014. If the CJEU were to follow Advocate General Jääskinen's opinion, many (more) SPCs would become invalid as, for more than 20 years, national patent offices have been granting an SPC per active ingredient or combination of active ingredients rather than per basic patent and many basic patents protect several active ingredients or combination of active ingredients. This would undoubtedly have several ripple effects, for example on patent litigation, life cycle management for medicinal products or paediatric research. Moreover, companies would have to start contemplating filing one patent per active ingredient or combination of active ingredients. In addition, patent holders would be deprived from the possibility to correct the (wrong) choice they made among the products protected by the same basic patent at the time they were still allowed to be granted an SPC per active ingredient or combination of active ingredients. The only hope would reside in the Court deciding that its ruling only applies for the future only. However, so far, the Court only rarely used that possibility.

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In Europe (European Union, Iceland, Liechtenstein, and Norway), national patent offices may grant supplementary protection certificates (SPCs) to patent holders, subject to certain conditions. An SPC extends for maximum five years the patent protection over the 'product', i.e. the active ingredient or the combination of active ingredients, contained in the medicinal product on the basis of which the SPC is applied for. The conditions include, for the country concerned, a valid (compound, process, or application) patent (so-called 'basic patent') for the product, a first marketing authorisation (MA) for a medicinal product which contains the product, and no previous SPC for the product. SPCs are currently governed by Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products. Since 1992, national courts have referred many interpretation questions to the Court of Justice of the European Union (CJEU), in particular as regard to Article 3 which sets out the substantive conditions for the granting of an SPC.

On 24 November 2011, the CJEU ruled in the *Medeva* and *Georgetown* cases (C-322/10 and C-422/10) that (i) Article 3(a) of Regulation 469/2009 precluded an SPC for active ingredients which are not specified in the wording of the claims of the basic patent, and (ii) Article 3(b) does not preclude an SPC for a combination of two active ingredients where the medicinal product for which the MA is submitted

contains not only that combination of the two active ingredients but also other active ingredients. To put it simply, an SPC can be granted for a combination of active ingredients A+B, even if the medicinal product contains a combination of active ingredients A+B+C, provided that the combination A+B is specified in the wording of the claims of the basic patent. The CJEU added that only the MA for the first medicinal product comprising, among its active ingredients, the combination of the two active ingredients identified in the wording of the claims of the patent, may be regarded as the first MA for that 'product', and that where a patent protects a product, only one SPC may be granted for that basic patent. The day after, the Court confirmed its ruling in three other cases (Yeda Research, C-518/10; Queensland, C-630/10; *Daiichi Sankyo*, C-6/11).

The *Medeva* ruling clarified that the test for granting an SPC is a semi-identity test rather than a full identity test or an infringement test. This answered a question which had been debated for years by national patent offices and thereby rendered invalid many SPCs as CJEU's rulings have retrospective effects. The vagueness of the ruling also raised two new key questions.

The first question is the level of specification required for a product to be considered as "specified in the wording of the claims". Typically, the active ingredient contained in the medicinal product is indicated by its INN, and the patent holder requests an SPC for that INN. However, patent claims rarely mention INNs, and the situation is even worse for biological substances. A UK court has already referred the question back to the CJEU (*Eli Lilly v. Human Genome Sciences*, C-493/12); meanwhile the validity of many SPCs remain uncertain.

The second question is whether, in case the basic patent covers several products, national patent offices may grant an SPC for each product protected by the basic patent. The question has also been referred back to the CJEU, by a Dutch court (*Georgetown*, C-484/12) and a UK court (*Actavis v. Sanofi*, C-443/12). The Dutch court asked four ancillary questions (Questions 2 to 5) in case the CJEU were to decide that only one SPC may be granted on the basis of a same basic patent.

Yesterday, Advocate General Jääskinen gave his opinion on the questions referred by the Dutch court in *Georgetown*.

The Advocate General only examined the ancillary questions as he considered that the main question could be answered in light of the CJEU's case law and the opinion of Advocate General Trstenjak in the *Medeva* and *Georgetown* cases. He did not answer that question clearly, but his summary of the case suggests that he considers that, where a basic patent protects several products, the patent holder may not be granted an SPC for each product.

Questions 2 and 3 concerns the situation where a patent holder filed several applications for SPC which are all pending. Assuming that only one SPC will be granted, is it for the patent holder or the national patent office to choose the application which has to be given priority? The Advocate General considered that the national patent office must formally ask the patent holder to choose among the applications for SPC, but, in the absence of choice, the patent office may draw the consequences under national law.

Questions 4 and 5 concern the SPC holder's right to waive the SPC with retrospective effect. Assuming that only one SPC is to be granted, can the SPC holder waive the existing SPC and, the waiver having retrospective effects, file a new application for SPC for another product covered by the basic patent? According to Advocate General Jääskinen, a waiver of the SPC is governed by Article 14 (b) of Regulation 469/2009 and such waiver is effective only for the future so that it may not be admitted that, as a result of the waiver, the product had never been granted an SPC.

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