# Breaking news from the CJEU: no SPCs for new therapeutic applications

Stibbe

On 9 July 2020, the Grand Chamber of the CJEU ruled on the interpretation of Article 3(d) of Regulation 469/2009 concerning the supplementary protection certificate (CCP) for medicinal products.

This provision, combined with item (b) of the same Article 3, provides that an SPC can only be granted if the product for which the SPC is requested has previously obtained a MA and that this MA is the first MA granted for this product. The decision of 9 July 2020 in the *Santen* case (C-673/18) follows on from other CJEU judgments on these conditions (*Pharmacia Italia*, 19 October 2004, C-31/03; *Massachusetts Institute of Technology*, 4 May 2006, C-431/04; *Yissum*, 17 April 2007, C-202/05), and puts aside the much debated *Neurim* judgment of 19 July 2012 (C-130/11).

The facts that led to the Santen judgement are the following. Santen is a pharmaceutical company that holds a patent filed on 10 October 2015 and which protects, inter alia, an ophthalmic emulsion with ciclosporin as the active ingredient. Based on this patent, Santen filed an application for an SPC on a medicinal product using ciclosporin for the treatment of keratitis. This application was rejected by the French Industrial Property Office (INPI) in view of the existence of a previous MA granted to Santen for a product with the same active ingredient, but used for other indications. Santen brought an action against this rejection decision before the Court of Appeal of Paris, which asked the Court of Justice to clarify its interpretation of Article 3(d) of Regulation 469/2009.

In the Neurim judgment of 19 July 2012, the CJEU had indeed stated that the existence of a prior MA does not preclude the grant of an SPC for a different application (a new indication) of the same active ingredient, provided that the new application falls within the scope of protection conferred by the basic patent relied upon for the purposes of the application for the SPC.

The questions referred to the CJEU in the present case required the CJEU to clarify two uncertain and controversial concepts set out in the Neurim judgment: the concepts of “different application of the same product” and of “application falling within the scope of protection conferred by the basic patent”.

In its judgement, the Court firstly sets out that the term “product” (defined in Article 1(b) of Regulation 469/2009 as “the active ingredient or combination of active ingredients of a medicinal product”) has to be strictly understood, in the sense that it is not dependent on the manner in which that product is used (§ 44-46). Therefore, a new application of an active ingredient (or a combination of active ingredients) does not confer on this active ingredient (or this combination)

the status of a distinct product (§ 47).

Secondly, the CJEU considers that the wording of Article 3(d) "does not refer to the scope of protection of the basic patent" (§ 50) and that the concept of first MA of Article 3(d) refers to the first MA for a medicinal product incorporating the active ingredient irrespective of the therapeutic application in respect of which that MA was obtained (§ 51).

The Court thus adopts a restrictive approach and explicitly invalidates its own previous interpretation in Neurim (§53) that allowed the granting of an SPC for a new therapeutic application of an active ingredient previously approved as a medicinal product for another application.

The Court among others justifies its decision by invoking the need to have a simple and predictable SPC system, stating that the introduction of a distinction between different therapeutic applications, without that concept being defined in Regulation 469/2009, could lead the national offices to adopt complex and divergent interpretations of the condition laid down in Article 3(d) of Regulation 469/2009 (§59).

While this simplification of the European SPC system is certainly a welcome development as such, the Santen judgement is at the same time bad news for innovators. Not only those who have obtained SPCs based the Neurim case law and could now see the validity of their SPCs called into question, but also those who were counting on the future grant of an SPC for ongoing R&D efforts. As the validation of new therapeutic indications can require substantial investments and, at the same time, lead to clear benefits for patients, there is no doubt that the Court's statement that the interpretation adopted in its judgment coincides with the policy objective to strike fair a balance between innovation and public health requirements (§57), will be questioned by some.

The consequences of this new CJEU judgment are thus important in practise, and will have to be taken into account in the R&D strategies of innovative pharma companies. It is questionable whether this is a good thing, especially in the current context, where a number of active ingredients already approved for others diseases, are being tested to determine their efficacy in treating COVID-19.

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