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BREAKING NEWS: CJEU reverses Neurim and completely abolishes SPCs for new therapeutic applications in Santen judgment (C-673/18)

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The question whether SPCs should be available for new therapeutic applications of previously approved active ingredients has been a matter of debate ever since the SPC Regulation for Medicinal Products came into force in the European Union more than a quarter-century ago. While a literal reading of the SPC Regulation would clearly seem to exclude any such possibility, as Article 3(d) requires that the marketing authorization relied upon for an SPC must be the "*first*" marketing authorization for the corresponding product and Article 1(b) defines the term "product" as simply the active ingredient or combination of active ingredients of a medicinal product, the interpretation of these provisions has been put under scrutiny in a number of referrals to the Court of Justice of the EU.

While the CJEU had initially endorsed a restrictive approach in *Pharmacia Italia* (C-31/03), *MIT* (C-431/04) and *Yissum* (C-202/05), it surprisingly made a complete U-turn in the *Neurim* judgment (C-130/11) rendered in 2012. In this decision, the Court found that, in the case at hand, the grant of an SPC was not precluded by the existence of an earlier marketing authorization for the same active ingredient.

Yet, the precise conditions and the scope of applicability of the *Neurim* approach have given rise to considerable controversy and divergent approaches in different EU member states. A referral to the CJEU aimed at clarifying these conditions was made by the Paris Court of Appeal in 2018 (as previously reported on this blog) and left practitioners in eager anticipation of the CJEU's forthcoming judgment. The fact that this judgment has now been rendered by the CJEU as a Grand Chamber of 13 judges testifies to the significance of the issues at stake.

We have clarity at last, as the CJEU has handed down its judgment in *Santen* (C-673/18) today.

As it turns out, the CJEU has heeded the advice of its Advocate General who called upon the Court to make a clear choice and either bluntly reject the *Neurim* approach, or else embrace it wholeheartedly and endorse a broad interpretation of the relevant legal provisions (as previously reported on this blog). Alas, the CJEU chose the first option and concluded in its judgment:

"*Article 3(d) of [the SPC Regulation] must be interpreted as meaning that a marketing authorisation cannot be considered to be the first marketing authorisation, for the purpose of that provision, where it covers a new therapeutic application of an active ingredient, or of a*

combination of active ingredients, and that active ingredient or combination has already been the subject of a marketing authorisation for a different therapeutic application."

In reaching this conclusion, the Court reasoned that Article 1(b) defines the "product" of an SPC independently from its use or its approved therapeutic application. Therefore, if an active ingredient is used for a new therapeutic application, this does not make it a different "product" where this same active ingredient has already been used for a different therapeutic application before. Interested readers will note that this is essentially the same conclusion that the CJEU already reached in *Yissum* (C-202/05) – i.e., prior to its *Neurim* judgment.

In *Santen*, the CJEU further addressed the relevance of the concept of "the first marketing authorization within the scope of protection of the basic patent" which was previously invoked in *Neurim*. In this regard, the Court quite correctly observes that the wording of Article 3(d) does not refer to the scope of protection of the basic patent. According to the CJEU, it follows from the aforementioned strict interpretation of the concept of the "product" that Article 3(d) must be understood as relating to the first marketing authorization for any medicinal product incorporating the active ingredient (or combination of active ingredients) under consideration, regardless of the therapeutic application for which it is approved.

This is furthermore held to be in line with the legislator's intention to establish a simple and predictable system for the grant of SPCs – whereas any other approach that distinguishes between different therapeutic applications, which as a concept are not even defined in the SPC Regulation, would risk leading national patent offices to adopt complex and divergent interpretations.

The scope of the basic patent therefore has no relevance for determining which is the first marketing authorization within the meaning of Article 3(d). Remarkably, the CJEU explicitly noted, in paragraph 53 of the *Santen* judgment, that this conclusion is "*contrary to what the Court held in paragraph 27 of the judgment in Neurim*".

While there is no further discussion of *Neurim* in the *Santen* judgment, it appears safe to assume that *Neurim* has been overturned in its entirety.

With today's judgment in *Santen*, the CJEU has certainly succeeded in reducing the infamous complexity of the European SPC system, albeit at the price of significantly curtailing the incentives for pharmaceutical research and development. This adds to the CJEU's recent and equally restrictive decisions in *Abraxis* (C-443/17) (discussed here) and *Boston Scientific* (C-527/17) (discussed here). One might take this opportunity to reflect upon Lord Justice Jacob's emphatic admonition in his judgment [2011] EWCA Civ 228 that led to the *Neurim* referral:

"*In short, if Neurim are wrong, then the [SPC] Regulation will not have achieved its key objects for large areas of pharmaceutical research: it will not be fit for purpose.*"

Lastly, after the CJEU's decision in *Santen*, it would appear that the pending referral in *Novartis (C-354/19)* has become obsolete, which was meant to address the question of whether the grant of a second SPC for a different therapeutic application is precluded if the second SPC is filed by the same rights holder who has already been granted a first SPC for the same active ingredient. For now, it seems, the long-lasting controversy over the availability of SPCs for second medical uses has finally been put to rest.

Dr. Alexa von Uexküll *and* ***Oswin Ridderbusch****, both partners at the IP-specialized law firm Vossius & Partner, are the editors of the handbook* ***European SPCs Unravelled: A Practitioner's Guide to Supplementary Protection Certificates in Europe*** *published by Wolters Kluwer in 2018. See here for a review by Judge Jürgen Schell (in German) and a review by Miquel Montañá (in English).*

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