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The CJEU reaches a decision in *Santen* (C-673/18)

Europe's highest court restricts availability of SPCs based on new medical uses

Today the CJEU issued its judgment in *Santen* (C-673/18), restricting the availability of SPCs based on new medical uses of previously approved active ingredients.

According to *Neurim (C-130/11),* SPCs for new applications of a previously authorised active ingredient are available, despite the literal wording of Article 3(d) indicating that the marketing authorisation has to be "the first authorisation to place the product [i.e. the active ingredient] on the market as a medicinal product". Patent offices throughout the EU have interpreted the test set out in *Neurim* in a range of different ways.

In *Santen* the Paris Court of Appeal referred two questions to the CJEU relating to how to apply Article 3(d) of the SPC Regulation in light of specific aspects of the CJEU's earlier *Neurim* decision, and the particular facts of the SPC application in suit, as we reported here.

In brief, the French Court's first question sought to clarify the type of new authorisation which qualifies as a "new application" and so benefits from a new SPC under *Neurim*. The second question sought to clarify what scope of basic patent is required to meet the test set out in *Neurim*.

In *Santen*, the CJEU answered the questions that had been referred as follows:

"Article 3(d) 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 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 its reasoning, the CJEU endorsed a previous line of case law (*MIT* (C-431/04) and *Forsgren* (C-631/13)) in which it had held that the term "active ingredient" had to be interpreted strictly, without any limitation to the therapeutic applications. It then considered the test that had been endorsed in *Neurim*, namely that earlier authorisations should give rise to objections under Article 3(d) only if they fall within the scope of the basic patent. The CJEU in *Santen* explicitly ruled "contrary to what the Court held in paragraph 27 of the judgment in Neurim" that "to define the concept of 'first [MA for the product] as a medicinal product' for the purpose of Article 3(d) of Regulation No 469/2009, there is no need to take into account the limits of the protection of the basic patent" (paragraph 53).

This referral stems from Santen's filing for an SPC application for the product "ciclosporin eye drop emulsion" based on its patent to oil-in-water ophthalmic emulsions (EP1809237) and an MA for the product Ikervis, which uses this emulsion. The French patent office refused the SPC application for failing to comply with Article 3(d) of the SPC Regulation, noting the existence of an earlier MA to the medicinal product Sandimmun, where the active ingredient, like in Ikervis, is ciclosporin. The decision was appealed to the Paris Court of Appeal.

Santen argued that the earlier authorisation for Sandimmun was not relevant in light of *Neurim* because it used an oral solution and not the emulsion of the basic patent. Therefore, Santen argued that Ikervis was the "first authorisation" in respect of the ciclosporin emulsion covered by the basic patent. According to Santen, this is consistent with the broad test suggested in *Neurim*, which limited the relevant authorisations under Article 3(d) to only those that fall within the scope of the basic patent.

Santen also argued that Ikervis is an eye drop emulsion for the treatment of a type of severe keratitis (a disease affecting the cornea of the eye). Sandimmun, on the other hand, is taken orally for a number of indications including endogenous uveitis (inflammation of the uvea, a part of the eye distinct from the cornea). Santen therefore argued that Ikervis is distinguished from Sandimmun by at least its different method of administration and indication.

Santen's appeal has reached the end of the road, and the judgment is likely to have adverse repercussions on a number of other SPC filings too. The CJEU's decision does however provide some clarity in this area, allowing innovators to plan ahead with a more certain view of the future. We would be happy to discuss if and how this ruling might affect any of your SPC filings based on new medical uses, and in particular whether it is likely to have retroactive effect.

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