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The CJEU's Judgment in Santen v INPI
Courts calls grant of Neurim-type SPCs based on second medical use patents in question

The Court of Justice of the European Union's (CJEU's) recently rendered Judgment in Santen v INPI (C-673/18) is expected to shape the landscape of patent extensions by Supplementary Protection Certificates ("SPCs") more than any other decision of this court over the last 10 years and not to the favor of the researching pharmaceutical industry. It is generally considered a complete reversal of case law which the same court had initiated in 2012.

On July 19, 2012, in a ground-breaking judgment (C-130/11; *Neurim Pharmaceuticals* (1991) Ltd v Comptroller), the CJEU decided to allow the grant of SPCs also in circumstances where the product of the SPC application, i.e. the active ingredient or combination of active ingredients, had already been the subject of an earlier human or veterinary Marketing Authorization ("MA"). This became possible by a teleological interpretation of Art. 3(d) of Regulation (EC) No 469/2009 construing the meaning of "*first authorization*" as being limited to the MA of the first medicinal product authorised for a therapeutic use corresponding to that protected by the basic patent (CJEU *Neurim*, para. 26).

In the framework of the circumstances of the *Neurim* case, this ruling was considered by most stakeholders as leading to a correct and fair result, *inter alia* since *Neurim's* SPC application for melatonin had relied upon a MA requiring a full application for marketing. Moreover, the two earlier MAs that had been cited by the UKIPO against *Neurim's* application concerned completely unrelated veterinary approvals of melatonin which had been issued to other companies. Therefore, *Neurim* did not benefit at all from the existence of these earlier veterinary MAs. Against this background, the CJEU also emphasized that one fundamental objective of the SPC Regulation is to ensure sufficient protection to encourage pharmaceutical research (CJEU *Neurim*, para. 22) implying thereby that also the research for and finding of new therapeutic application of existing products can be worthy of being rewarded by an SPC extension.

However, many patent offices and national courts struggled with the concept of a "*new therapeutic application of the same active ingredient*" introduced by the CJEU (*Neurim*, para. 25). How far removed does a therapeutic application need to be from an existing approved application of the same active ingredient in order to be "*new*"? Can the concept of a "*new therapeutic application*" also be applied to new dosage forms? The difficulty to correctly apply CJEU *Neurim* led to several diverging decisions of the national courts and finally two referrals to the Court of Justice, first in *Abraxis BioScience* (C-443/17), and then in *Santen* (C-673/18), for a preliminary ruling on the interpretation of Article 3(d) of the Regulation.

In *Abraxis*, the court already adopted earlier this year a strict interpretation of Article 3(d) of the Regulation when ruling that this article must be interpreted as meaning that an MA relied on, in support of an SPC application concerning a new formulation of an old active ingredient, cannot be regarded as being the first MA for the product concerned when that active ingredient has already been the subject of a marketing authorisation as an active ingredient.

In *Santen*, the CJEU follows this strict line of interpretation and held that an MA cannot be considered to be the first MA for the purpose of Article 3(d) of the Regulation when 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 an MA for a different therapeutic application.

On the face of it, CJEU *Santen* thus seems to repeal the *Neurim* judgement, although this is not expressly stated in *Santen*. The court rather remarks that, contrary to what the court held in paragraph 27 of the judgement in *Neurim*, to define the concept of "*first (MA for the product) as a medicinal product*" for the purpose of Article 3(d) of Regulation 469/2009, "*there is no need to take into account the limits of the protection of the basic patent*" (*Santen*, para. 53). Yet, other sections of the judgement seem to leave no doubt that *Neurim* can no longer be applied. This is primarily reasoned by a reading of Article 1(b) of the Regulation in conjunction with Article 4 thereof, according to which the fact that an active ingredient is used for the purposes of a new therapeutic application does not confer on it the status of a distinct product. The court also considered that any other interpretation of Article 3(d) might compromise the simplicity and the predictability which the EU legislator intended the system to have in order to guarantee the implementation of a uniform solution at EU level by the national patent offices (*Santen*, para. 59).

Where does all this leave SPC applicants and owners of SPCs that were granted in line with CJEU *Neurim*? In view of CJEU *Santen*, it has become very difficult for SPC applicants to obtain an SPC based on a marketing authorization for a new therapeutic application of a known product where an earlier MA for the same product exists. Interestingly, the court criticises and repeals the interpretation of Article 3(d) of the Regulation which underlined the *Neurim* judgement, but not necessarily the result thereof. Therefore, it remains to be seen whether other teleological interpretations of the SPC Regulation might justify the grant of second medical use SPCs in similar circumstances. As to SPCs standing in force, which were granted in accordance with CJEU *Neurim*, the question arises as to whether the *Santen* judgement can be applied retroactively to these, and if so, whether they can be successfully defended taking into consideration the protection of trust, i.e. the legitimate expectation that the highest European court does not repeal its own jurisprudence within a relatively short period of time.

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