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New SPC reference to the CJEU

The CJEU is asked to consider specific aspects of the Neurim test

The Paris Court of Appeal is referring 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 (C-130/11) and the particular facts of the SPC application in suit. According to *Neurim,* SPCs for new applications of a previously authorised product are available, but patent offices throughout the EU have interpreted the test set out in *Neurim* in a range of different ways. The French Court's first question seeks to clarify the type of new authorisation which qualifies as a new "application" and so benefits from a new SPC under *Neurim*. It also seeks to clarify what scope of basic patent is required to meet the test set out in *Neurim*.

Santen filed 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.

Seeking to apply the *Neurim* jurisprudence in a "measured way", the French patent office stated that Article 3(d) could be satisfied in this particular case if: (1) the later authorisation relates to an indication that falls within a "new therapeutic field" as compared to the previous

MA, or the active ingredient in the later authorised medicinal product has a different mechanism of action; and (2) the scope of the basic patent is "consistent" with the later authorisation (and is therefore "limited" to the new indication). It suggested that neither of these requirements were met for Ikervis, because both Ikervis and Sandimmun were authorised for treatment of inflammation of parts of the eye in humans and worked by the same mechanism of action. In addition, the French patent office suggested that the scope of the basic patent was inconsistent with the Ikervis MA because the claims are not limited to the new authorised indication.

In its decision, the Paris Court of Appeal held that in the context of this particular SPC application the *Neurim* decision does not provide sufficient detail to interpret what is meant by the phrase "different application" and that it is unclear whether the basic patent must be limited to the new indication of the invoked MA. It therefore referred two questions to the CJEU:

Question 1

- *Must the concept of a 'different application' within the meaning of the judgment of 19 July 2012, Neurim (C-130/11, EU:C:2012:489), be interpreted strictly, that is to say:*
- *as limited only to the situation where an application for human use follows a veterinary application;*
- *or as relating to an indication within a new therapeutic scope, in the sense of a new proprietary medical product, compared with the earlier marketing authorisation, or a medicinal product in which the active ingredient acts differently from how it acts in the medicinal product to which the first marketing authorisation related;*
- *or more generally, in the light of the objectives of Regulation (EC) No 469/2009 of establishing a balanced system taking into account all the interests at stake, including those of public health, must the concept of a "new therapeutic use" be assessed according to stricter criteria than those for assessing the patentability of the invention;*

or must it on the other hand be interpreted broadly, that is to say, as including not only different therapeutic indications and diseases, but also different formulations, posologies and/or means of administration?

Question 2

- *Does the expression "[application] within the limits of the protection conferred by the basic patent" within the meaning of the judgment [of the Court of Justice] of 19 July 2012, Neurim (C-130/11, [EU:C:2012:489]), mean that the scope of the basic patent must be the same as that of the marketing authorisation relied upon and, therefore, be limited to the new medical use corresponding to the therapeutic indication of that marketing authorisation?*

In attempting to clarify what is intended by "different application", question 1 asks what sort of a new application of an old active ingredient might be enough to allow a *Neurim*-style SPC, setting out four options for what might be required. Question 2 focuses on what scope the claims need to have in order to be eligible for an SPC when applying the test set out in *Neurim*. As a result, the answers to this new referral could provide additional clarity as to when SPCs can be filed for new applications of previously authorised products.

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