EIP

Neurim no more – Santen restricts SPCs to first marketing authorisation

On 9 July 2020 the CJEU issued its decision in Santen Case C□673/18. The judgment will have major repercussions as the earlier decision in Neurim Case C□130/11 has been overturned.

The facts

Santen were seeking an SPC for Ciclosporin for use in the treatment of keratitis (inflammation of the cornea) based on their marketing authorisation for their medicinal product Ikervis, which contains ciclosporin in the form of an ophthalmic emulsion.

However, a much earlier marketing authorisation already exists for ciclosporin albeit in a completely different formulation: Sandimmune, which is an oral solution indicated for preventing organ rejection. However, the therapeutic indications for Sandimmune also include the treatment of endogenous uveitis, an inflammation of all or part of the uvea, the middle part of the eyeball.

While the formulations of the two ciclosporin products are quite different - ophthalmic emulsion as opposed to oral solution, both are indicated for uses that might be considered ophthalmic.

The law

The main issue was whether Santen's SPC application complied with the requirements of Article 3(d) of the SPC Regulation No 469/2009, which stipulates that the marketing authorisation on which the SPC application is based must be "the first authorisation to place the product on the market as a medicinal product". If there is an earlier

authorisation in respect of that product (product being defined in the SPC Regulation as meaning active ingredient or combination of active ingredients), then ostensibly an SPC cannot be granted.

Santen relied on the earlier CJEU decision Neurim, in which it was held that an earlier authorisation for veterinary use of a product (melatonin) did not preclude the granting of an SPC based on a later marketing authorisation for human use and a later patent directed towards that use. However, the judgment in Neurim was cast in broader terms than was strictly required to dispose of that case, and it was stated "the mere existence of an earlier marketing authorisation obtained for a veterinary medicinal product does not preclude the grant of a supplementary protection certificate for a different application of the same product for which a marketing authorisation has been granted, provided that the application is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the supplementary protection certificate."

The scope of the applicability of the Neurim judgment to later cases (in particular where the earlier marketing authorisation is for a human pharmaceutical product rather than a veterinary product) has been unclear, but one interpretation of the Neurim decision would be that in any situation where there is a later patent directed towards a new use of an existing product, an SPC can be granted if there is later marketing authorisation directed towards that use.

The decision

In the Santen decision (read here), the CJEU disregarded the legal questions put forward by the referring Court (the Cour d'appel de Paris), and instead addressed the underlying premiss, namely that it may be possible in certain circumstances to obtain an SPC for a new therapeutic application of an active ingredient which has already been the subject of an marketing authorisation prior to the marketing authorisation on which the application for that SPC is based.

The CJEU explicitly departed from Neurim to hold that this premiss is not correct. While there is no explicit statement that the Neurim judgment is overruled or reversed, it is clear that the test set out in Neurim, of considering the "first" marketing authorisation to mean the first falling within the scope of protection of the basic patent, is disapproved and no longer applies.

The CJEU upheld the textual meaning of Article 3(d), holding in the operative part of the judgment that it is to be interpreted as "meaning that a marketing authorisation cannot be considered to be the first marketing authorisation, …, 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".

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The CJEU followed the recommendation of the Advocate General, whose Opinion stated that the CJEU should abandon the test of the "protection conferred by the basic patent" set out in Neurim and return to a literal interpretation of Article 3(d).

This reasoning implies that however different the formulation or therapeutic use, an earlier marketing authorisation for a particular active ingredient will be an absolute bar to obtaining an SPC based on a later marketing authorisation relating to the same active ingredient.

Outlook

While the Neurim decision offered hope of a more flexible interpretation of the SPC Regulation to allow under certain circumstances an SPC to be granted where Article 3(d) suggested it would not be possible, the price of that hope was a troubling lack of clarity as to what the limits might be. This judgment has removed that possibility of flexibility, but has instead provided clarity that Article 3(d) means what it says.