Court of Justice of European Union Overrules *Neurim* Case Law and Excludes Right to SPC for New Therapeutic Application of Previously Authorised Medicinal Product

On 9 July 2020, the Court of Justice of the European Union (***CJEU***), sitting in Grand Chamber, ruled that it is not possible to obtain a supplementary protection certificate (***SPC***) for a second medical use of a previously authorised medicinal product. The CJEU held that a marketing authorisation (***MA***) cannot be considered as the first MA within the meaning of Article 3(d) of Regulation (EC) No 469/2009 of 6 May 2009 concerning the supplementary protection certificate for medicinal products (the ***SPC Regulation***) when it concerns a new therapeutic application of a known active ingredient (or combination of active ingredients) which has already been the subject of an MA for a different therapeutic application.

The CJEU handed down its judgment at the request of the Paris Court of Appeal in a dispute between the ophthalmological pharmaceutical company Santen SAS and the French patent office (*Institut national de la propriété industrielle*) regarding the interpretation of Articles 1(b) and 3(d) of the SPC Regulation. Article 3(d) of the SPC Regulation contains a "*first authorisation*" requirement in the sense that no SPC can be granted if there has been an earlier MA for the same "product", which is defined in Article 1(b) as "*the active ingredient or combination of active ingredients of a medicinal product*".

Factual Background and Questions Referred for Preliminary Ruling

In 1983, Santen obtained an MA for the medicinal product SANDIMMUN®, which contains the active ingredient cyclosporin. In 2015, it applied for an SPC based on a European patent and a centralised MA for the medicinal product IKERVIS®, which contains the same active ingredient.

The French patent office rejected Santen's SPC application based on the earlier MA for SANDIMMUN®. Santen appealed to the Paris Court of Appeal, which decided to stay the proceedings and ask the CJEU to clarify its *Neurim*[1] judgment of 19 July 2012.

In *Neurim*, the CJEU held that "*the mere existence of an earlier MA* […] *does not preclude the grant of an SPC for a different application of the same product for which an MA 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 SPC*" (§27). The Paris Court of Appeal requested the CJEU to clarify the scope of the terms "*different application*" and "*application* […] *within the limits of the protection conferred by the basic patent*" as used in this paragraph.

CJEU Judgment

The CJEU first examined whether a new therapeutic application of a previously authorised active ingredient can be considered to be a distinct "product" under Article 1(b) of the SPC

[1] CJEU, 19 July 2012, Case C-130/11, *Neurim Pharmaceuticals*, EU:C:2012:489.

Regulation, so that a further MA covering that new therapeutic application would constitute a "*first authorisation to place the product on the market*" within the meaning of Article 3(d) of the SPC Regulation.

The CJEU noted that the term "product" refers to the active ingredient or combination of active ingredients of a medicinal product and is not limited to any particular therapeutic application. As the term "product" is to be interpreted strictly as the active ingredient, there can be no distinct product if an active ingredient or combination of active ingredients is used for a new therapeutic application.

The CJEU continued that Article 3(d) of the SPC Regulation does not refer to the scope of protection of the basic patent. Considering the scope of the basic patent would go against the definition of "product" in Article 1(b) as it would allow to grant an SPC for a new therapeutic application of a known active ingredient in situations where the same active ingredient is already covered by a previous MA for another therapeutic use.

The CJEU concluded that an MA cannot be considered to be the first MA for the purpose of Article 3(d) when it covers a new therapeutic application of an active ingredient, or combination of active ingredients, which has already been the subject of an MA for a different therapeutic application.

The CJEU's conclusion is diametrically opposed to its earlier conclusion in the *Neurim* judgment, which might explain why the new judgment was delivered in Grand Chamber. While it is unusual for the CJEU to expressly admit that it is overruling its earlier case law, it is interesting to note that the *Santen* judgment expressly acknowledges that "*the premise* [on which the *Neurim* judgment is based] *must be disregarded*" (§60).

Obviously, the judgment will come as a disappointment to pharmaceutical companies which were aiming for an SPC for new therapeutic uses of an authorised medicinal product. Yet, it has at least the merit of bringing clarity to the interpretation of Article 3(d) of the SPC Regulation.

(CJEU, 9 July 2020, Case C-673/18, *Santen,* EU:C:2020:531)

Brussels, 17 July 2020
Van Bael & Bellis