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CJEU, C-673/18: no supplementary protection certificate for a new therapeutic application of an active ingredient which has already been the subject of a previous marketing authorisation

Background to the case and parties to the dispute

On 9 July 2020, the Court of Justice of the European Union (CJEU) delivered a preliminary ruling in a case (C-673/18) on the interpretation of Article 1(b) and 3(d) of Regulation (EC) no. 469/2009 concerning the supplementary protection certificate for medicinal products ("SPC Regulation")[1].

The parties to the main proceedings are Santen SAS ("Santen") and the Director-General of the Institut National de la Propriété Industrielle ("INPI"), who rejected the application for a supplementary protection certificate ("SPC") lodged by Santen for a medical product, as specified hereafter.

Santen, a pharmaceutical laboratory specialising in ophthalmology, holds a European patent which protects, *inter alia*, an ophthalmic emulsion in which the active ingredient is "ciclosporin". In March 2015, Santen obtained a marketing authorization ("MA") from the European Medicines Agency ("EMA") for a medicinal product sold under the name of "Ikervis", containing "ciclosporin" as active ingredient and used to treat keratitis in adult patients with dry eye disease. Therefore, in June 2015 Santen filed an application for an SPC for the product in question.

However, a MA had already been granted for another medicinal product containing "ciclosporin" as its active ingredient, called "Sandimmun", presented in the form of an oral solution for the prevention of rejection of

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[1] **Article 1** of the **SPC Regulation** defines the following terms: *"(a) "medicinal product" means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals; (**b) "product" means the active ingredient or combination of active ingredients of a medicinal product**; (c) "basic patent" means a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate; **(d) "certificate means the supplementary protection certificate" (…)**".
Article 3 reads: "'***A certificate shall be granted if**, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application: (a) the product is protected by a basic patent in force; (b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83 or Directive 2001/82, as appropriate; (c) the product has not already been the subject of a certificate; **(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product***" (i.e., a "MA").
Article 4, provides that "*Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate*".

solid organ and bone marrow grafts and for other therapeutic indications, including the treatment of endogenous uveitis.

Taking the view that the MA granted to Santen was not the first MA for the purpose of Article 3(d) of SPC Regulation, the Director-General of the INPI rejected Santen's SPC application for "ciclosporin".

Santen, in turn, brought an action against that decision before the Court of Appeal of Paris, seeking the annulment of the decision at issue or, in the alternative, a referral to the Court of Justice of the European Union ("CJEU").

The Court of Appeal of Paris decided to stay the proceedings and to refer a question to the CJEU for a preliminary ruling concerning the interpretation of Article 3 and Article 4 of SPC Regulation, also taking into account the findings in *Neurim*[2].

Findings of the CJEU

Firstly, the CJEU deemed it necessary to examine whether Article 3(d) of SPC Regulation must be interpreted as meaning that a MA may be considered to be the first MA, for the purpose of that provision, where it covers a new therapeutic application of an active ingredient or combination of active ingredients and that active ingredient or combination has already been the subject of a MA for a different therapeutic application.

As the MA to which Article 3(d) of the SPC Regulation No 469/2009 refers must be granted for a specified product, as provided for in Article 1(b) SPC Regulation, the CJEU examined the concepts of "product" and "active ingredient". In this respect, as a result of a combined reading of Article 1(b) of the SPC Regulation in conjunction with Article 4 thereof, the term "product" must be understood to mean the active ingredient or combination of active ingredients of a medicinal product and it must not be limited to any particular therapeutic application to which such an active ingredient or combination of active ingredients may give rise. It follows that the term "product", pursuant to SPC Regulation, is not dependent on the manner in which that product is used and that the intended use of the medicinal product does not constitute a decisive criterion for the grant of a SPC.

In the light of the above, Article 1(b) of SPC Regulation must be interpreted as meaning that **the fact that an active ingredient** or a combination of active ingredients **is used for the purposes of a new therapeutic application does not make it a distinct product where the same active ingredient** or the same combination of active ingredients **has been used for the purposes of a different, already known, therapeutic application**.

Secondly, the CJEU deemed it appropriate to determine whether a MA granted for a new therapeutic application of an active ingredient or of a combination of active ingredients may be regarded as being the first MA granted for that product as a medicinal product, for the purpose of Article 3(d) of Regulation no. 469/2009, in the case where that MA is the first MA to fall within the limits of the protection of the basic patent relied on in support of the application for an SPC.

Following on from the abovementioned definition of "product", the analysis of the wording of Article 3(d) of the SPC Regulation implies that **the first MA for the medical product is the one in which the medical product incorporates the active ingredient or the combination of active ingredients at issue, regardless of the**

[2] Case C-130/11, decision of 19 July 2012. In this case, the CJEU concluded that Articles 3 and 4 of SPC Regulation must be interpreted as meaning that the mere existence of an earlier MA obtained for a veterinary medicinal product does not preclude the grant of an SPC for a different therapeutic application of the same product for which a 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.

therapeutic application of that active ingredient or combination of active ingredients, in respect of which that MA was obtained.

In the CJEU's view, that interpretation is confirmed by the purpose of **the SPC Regulation**, which **is aimed at rewarding only pharmaceutical research leading to the first placing on the market of an active ingredient** or a combination of active ingredients as a medicinal product as opposed to any research giving rise to the grant of a patent. In this perspective, contrary to what is stated in *Neurim*, to define the concept of "*first MA for the product as a medicinal product*" for the purpose of Article 3(d) of the SPC Regulation, the limit of the protection of the basic patent must not be considered.

The CJEU concluded that the answer to the questions referred by the Paris Court of Appeal is that **a MA cannot be considered to be the first MA**, for the purpose of Article 3 (d) SPC Regulation, **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 MA for a different therapeutic application**.