

## Newsalert

*IP, TMT and Data Protection Department*

**The CJEU rejects the possibility to be granted SPCs for new therapeutic applications of an existing active ingredient already covered by an MA**

On 9 July 2020 in case C-673/18, the Court of Justice of the European Union (“**CJEU**”) issued a decision on the interpretation of the term “product” within Article 3(d) of the Regulation 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate (“**SPC**”) for medicinal products (“**SPC Regulation**”). Said Article 3(d) provides that an SPC can only be granted if the product for which it is requested has previously obtained an MA, provided that it is the first MA granted for such product.

Such preliminary ruling has been requested in the context of the *Santen SAS vs. Directeur général de l’Institut national de la propriété industrielle* case (INPI) (C-673/18). Most notably, Santen - on the basis of the European patent No. 057959306, filed on 10 October 2005 which protects an ophthalmic emulsion containing ciclosporin as active ingredient, and of the marketing authorisation (“**MA**”) thereof granted by the European Medicines Agency - filed an application for an SPC for a medicinal product marketed under the name ‘Ikervis’, with ciclosporin as its active ingredient. The *Directeur general* of the INPI rejected the application on the grounds that a previous MA had already been granted for a product with the same active ingredient, but used for other indications.

Given the above, the Court of Appeal of Paris referred to the CJEU, requesting a clarification on the following two questions:

1. how should the concept of “*different application of the same product*” be interpreted?
2. does the expression “[application] *within the limits of the protection conferred by the basic patent*” mean that the scope of the basic patent must be the same as that of the MA relied upon and, therefore, be limited to the new medical use corresponding to the therapeutic indication of that MA”?

Otherwise said, the CJEU was called to clarify if an SPC can - or not - be granted for a new therapeutic application of a drug based on already existing active ingredients, which had already been granted with an MA.

In its judgement, the CJEU firstly stated that the term “product” - defined under Article 1(b) of the SPC Regulation as the active ingredient or combination of active ingredients of a medicinal product - is to be understood as that “*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 factor for the grant of an SPC*”. In this regard, the CJEU concluded that it is not possible to grant an SPC in case of a new application of an existing active ingredient (or a combination of active ingredients), as such new therapeutic application does not confer on it the status of a distinct product.

As to the second question, CJEU notes that in defining the term “first MA”, Article 3(d) does not mention the limits of protection of the basic patent, and further to that such term means the first MA obtained for a medicinal product containing an active ingredient (or the combination of active ingredients), regardless of the therapeutic application thereof.

In light of the above, it is clear that the CJEU adopted a strict and literal interpretation of the SPC Regulation, overturning the decision of the Neurim Pharmaceuticals Ltd vs. Controller General of Patents judgement, (C-130/11, so called “Neurim”) that, on the contrary and despite the wording of Article 3(d) of the SPC Regulation, allowed pharmaceutical companies to obtain an SPC for new applications of a previously authorised active ingredients. As such, for the time being, the Santen judgement could impact on the SPC filings.

*Here is the link to the CJEU website:*

*<http://curia.europa.eu/juris/document/document.jsf?jsessionid=C55A2810AC4C7BE6E76E1F38B352BCB1?text=&docid=228371&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=9849634>*

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