Neurim Reloaded: New CJEU referral to clarify the availability of SPCs for novel therapeutic applications

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Supplementary protection certificates (SPCs) used to be granted in the European Union only for novel active ingredients, but not for new therapeutic applications of previously authorized active ingredients. While this practice fundamentally changed as a result of the CJEU's landmark decision *Neurim* (C-130/11) of 19 July 2012, the scope of this ruling has given rise to considerable controversy ever since.
A new referral to the CJEU is expected to clarify the requirements established in *Neurim*. This referral was made by the Court of Appeal of Paris with decision of 9 October 2018 in *Santen v. INPI* (RG no. 17/19934) , which was first reported on the SPC Blog. It is not only noteworthy as being the first French referral relating to the SPC Regulation (EC) No. 469/2009; the prospective ruling of the CJEU can be safely assumed to have major significance for the availability of SPCs for new therapeutic applications of "old drugs", and possibly even beyond that.

In the case underlying this referral, an SPC application was filed by Santen SAS, the French subsidiary of Japanese company Santen Pharmaceutical, for "ciclosporin for use in the treatment of keratitis" (SPC no. 15C0040), relying on a marketing authorization for the medicinal product "Ikervis". This authorization was granted in 2015 for the treatment of severe keratitis, an inflammation of the cornea in patients with dry eye disease.

The SPC application was rejected by the French Patent Office (INPI) for lack of compliance with Article 3(d) of the SPC Regulation, which requires that the marketing authorization relied upon must be "the first authorization" to place the product of the SPC on the market in the respective member state. An earlier marketing authorization had already been granted for the medicinal product "Sandimmun" in 1983, containing the same active ingredient ciclosporin, for various therapeutic indications including the prevention of graft rejection and the treatment of endogenous uveitis (an inflammation of the uveal layer of the eye).

Santen lodged an appeal against the rejection of its SPC application with the Court of Appeal of Paris, arguing that the active ingredient ciclosporin in the earlier authorized medicinal product "Sandimmun" must be distinguished from that of the later authorized "Ikervis". This is because the earlier formulation does not fall within the claims of the basic patent underlying the SPC application, the approved therapeutic indications of "Sandimmun" and "Ikervis" are different, and the dosage and mode of administration of the respective formulations are different.

Santen thereby tried to rely on the principles established in *Neurim*, where the CJEU found that an earlier marketing authorization does not preclude the grant of an SPC "for a different application of the same product" on the basis of a corresponding new marketing authorization, provided that "the application is within the limits of the protection conferred by the basic patent relied upon".

The French Patent Office, in turn, argued that the basic patent relied upon by Santen did not only protect the newly approved therapeutic application of ciclosporin but also, and indeed primarily, a novel formulation of ciclosporin as such, as well as various therapeutic applications thereof, including the treatment of keratitis but also uveitis. In order to rely on *Neurim*, however, the scope of the basic patent would have to conform with that of the new marketing authorization, so that the claims of the patent would have to be limited to the newly approved therapeutic application. Moreover, the earlier approved indication of endogenous uveitis and the later approved indication of severe keratitis were both inflammations of the human eye, making use of the same anti-inflammatory property of ciclosporin, so that the earlier and the later therapeutic applications would not be truly "different" within the meaning of *Neurim*.

The Court of Appeal of Paris considered the correct interpretation of the concept of a "different application" invoked by the CJEU in *Neurim* to be crucial for deciding the case at hand, and also the relationship between the new application and the scope of the basic patent. It therefore decided to refer the following two questions to the CJEU (unofficial translation from French):

1.) Does the concept of "different application" within the meaning of the CJEU decision *Neurim* of 19 July 2012, C-130/11, have to be understood in a strict sense, that is:

- to be limited solely to the case of a human application, following an earlier veterinary application,
- or to concern an indication relating to a new therapeutic field, in the sense of a new medical specialty, compared to the earlier marketing authorization, or a medicament in which the active ingredient exerts an action different from that which it exerts in the medicament that was the subject of the first marketing authorization;
- or, more generally, with regard to the objectives of Regulation (EC) No. 469/2009 aimed at putting in place a balanced system that takes into account all the interests at stake, including those of public health, is it to be assessed under more demanding criteria than those applying to the assessment of patentability of inventions;

or should it, on the contrary, be understood in an extensive manner, i.e. including not only different therapeutic indications and diseases, but also different formulations, dosages and/or modes of administration?

2.) Does the notion of the "application falling within the scope of protection conferred by the basic patent" within the meaning of the CJEU decision *Neurim* of 19 July 2012, C-130/11, imply that the scope of the basic patent should conform with that of the marketing authorization relied upon and, consequently, be limited to the new medical use corresponding to the therapeutic indication of that marketing authorization?

The CJEU's answers to these questions are bound to fundamentally shape the future approach to SPCs for new therapeutic applications (and possibly new formulations) of previously authorized active ingredients. Hopefully, the CJEU will also provide practitioners with the long-awaited guidance as to how delimited from the prior approval the claims of a basic patent need to be drafted in order to secure an SPC for a new therapeutic application. In the meantime, we might already gain insight into the CJEU's position from its forthcoming ruling in another referral, *Abraxis Bioscience* (C-443/17), which relates to the applicability of the *Neurim* approach to novel formulations of previously approved active ingredients. Stay tuned.

Alexa von Uexküll *and* ***Oswin Ridderbusch*** *are the editors of the new handbook "European SPCs Unravelled: A Practitioner's Guide to Supplementary Protection Certificates in Europe" published by Wolters Kluwer.*