CJEU’s Advocate General in Abraxis (C-443/17) denies SPCs for new formulations of old drugs and questions Neurim approach

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A quarter-century after supplementary protection certificates (SPCs) were introduced in the European Union, there are still a number of unresolved questions as to which types of products are, in principle, eligible for SPC protection.
One further important piece in this puzzle will be provided by the CJEU’s forthcoming decision in the pending referral *Abraxis Bioscience* (C-443/17), which addresses the question whether SPCs can be granted for new formulations of previously approved active ingredients, where the marketing authorization relied upon is the first authorization within the scope of the basic patent. This CJEU decision could significantly enlarge the number of newly approved medicinal products that can benefit from SPC protection.

Pharmaceutical industry and SPC aficionados alike have therefore been waiting in suspense for the opinion of the CJEU’s Advocate General in this referral, which has been published just today.

In the case underlying this referral, the UK IPO had refused an SPC application filed by Abraxis Bioscience for the product “paclitaxel formulated as albumin-bound nanoparticles” (nab-paclitaxel; marketed as Abraxane®) for lack of compliance with Article 3(d) of the SPC Regulation (EC) 469/2009, given that the marketing authorization relied upon by Abraxis was not the first authorization of the active ingredient paclitaxel.

Abraxis had argued essentially that Article 3(d) of the SPC Regulation must be understood, in light of the CJEU’s judgment in *Neurim* (C-130/11), as requiring that the marketing authorization relied upon is the first *relevant* authorization, i.e. the first marketing authorization *falling within the scope of the basic patent*, and that the same policy considerations invoked by the CJEU in relation to a new therapeutic use of an old active ingredient in *Neurim* should likewise apply to a new formulation of an old active ingredient (even if the therapeutic use is the same).

In the referring decision, Mr. Justice Arnold of the UK Patents Court considered it unclear how far the reasoning of the CJEU in *Neurim* extends. While he referred the aforementioned question to the CJEU, he suggested that it should be answered in the negative, i.e. that SPCs should not be available for new formulations of previously approved active ingredients, which he justified with the need for clear-cut rules and legal certainty.

In his opinion, handed down today, the CJEU’s Advocate General Saugmandsgaard Øe conceded that the *Neurim* judgment requires clarification as it is difficult to reconcile the guidance provided here with the Court’s earlier case law, in particular *MIT* (C-431/04) and *Yissum* (C-202/05).

The Advocate General emphasized that the SPC regime was introduced as an incentive for the research and development of *new* active ingredients, as reflected by a literal interpretation of Article 3(d) of the SPC Regulation.

As such, in his opinion a restrictive reading of the concept of “product” within the meaning of Article 1(b) of the SPC Regulation is warranted. Therefore, the “scope of protection of the basic patent test” which has been advocated in light of *Neurim* should be rejected. As a consequence, in line with the principles as set out in the decisions *MIT* and *Yissum*, the grant of an SPC should be precluded under Article 3(d) where the marketing authorization relied upon is not the first authorization for the corresponding active ingredient(s) as a medicinal product. Remarkably, this would not only apply to the specific case group at hand, i.e. for a new formulation of a previously authorized product, but would effectively undo the liberal approach established in *Neurim*.

The Advocate General, in recognition that the guidance provided by the Court in *Neurim* remains at odds with its previous case law and the wording and objectives of the SPC Regulation, conceded that it is difficult to justify a distinction between inventions relating to a new second medical use of an already authorized active ingredient (which following *Neurim* may be subject matter of an SPC) and inventions relating to a new formulation of such an active ingredient for a known therapeutic use (which according to *MIT* are precluded from SPC protection).

As the marketing of a medicinal product for human use always requires the submission of a full regulatory dossier, even if the product has previously been approved for veterinary use, the Advocate General concluded that it would not seem unreasonable to assume that such an invention may be considered as a basic therapeutic advance.

Therefore, and in order to promote the coherence of the CJEU’s case law by allowing *Neurim* to coexist alongside the previous judgments of the Court relating to the interpretation of the concept of “product”, the Advocate General in the alternative has proposed that the Court should rule that the “scope of protection of the basic patent test” should only apply where a product previously authorized as a veterinary medicinal product is subsequently granted a marketing authorization for a new therapeutic indication in human medicine. In such a situation, Article 3(d) of the SPC Regulation should not preclude the grant of an SPC on the basis of that marketing authorization, provided it is the first to fall within the scope of the protection conferred by the basic patent relied upon in support of the SPC application.

While the restrictive interpretation of the Advocate General in relation to the concept of “product” may be a disappointment, it is of comfort to note that the Advocate General has not only recognized the lack of coherence of the CJEU judgments in this regard but has also placed his finger deep into this wound.

It remains to be seen how the CJEU will resolve the apparent contradictions between *Neurim* and its earlier case law, and whether it will endorse the restrictive approach suggested by the Advocate General. While the forthcoming decision in this referral is very likely to also affect the applicability and scope of the earlier *Neurim* judgment in relation to new therapeutic applications, the CJEU will have a further opportunity to elucidate these issues in the recent referral in *Santen* (C-673/18), which has been previously discussed on this blog.

Dr. Alexa von Uexküll *and* ***Oswin Ridderbusch****, both partners at the IP-specialized law firm Vossius & Partner, are the editors of the new handbook “European SPCs Unravelled: A Practitioner’s Guide to Supplementary Protection Certificates in Europe” published by Wolters Kluwer in November 2018.*