CJEU takes a restrictive approach to the grant of SPCs for new formulations of old active ingredients but uncertainty remains

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In a post yesterday our colleagues at Vossius commented on the CJEU's decision, which had just been handed down in *Abraxis**.

As Vossius have explained, although the decision appears to give clarity for new formulations of old products, it remains unclear as to how this can be reconciled with *Neurim*, which was not overturned. In its decision the CJEU merely states that *Neurim* cannot call the earlier case law into question and quotes the decision in Neurim 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 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 SPC application*" (emphasis added).

Given that in *Neurim* the patent claim was for a new formulation of an old active ingredient, the key differences between *Neuri*m and *Abraxis* seem to have been that in Neurim the earlier MAs were for a veterinary medicinal product and/or for a new therapeutic application. However the CJEU has failed to respond to the AG's request for a clarification as to how Neurim can be reconciled with the earlier case law, in particular:

a) can an SPC be granted for any new therapeutic application?;
b) can an SPC be granted only where the earlier MAs were for veterinary medicinal products?; or
c) can an SPC only be granted for a new therapeutic application where the earlier MAs were for veterinary medicinal products?

The CJEU cites a number of paragraphs of the AG's opinion with approval, including some of his comments on the situations in which derivatives, such as salts and esters, could be entitled to a separate SPC. However, interestingly, the CJEU does not cite the paragraph of the AG's opinion (paragraph 68) where the AG suggested that such SPCs should only be permitted for "new and distinct" active ingredients. In the footnote to this paragraph the AG noted that the conditions under which a derivative could be considered to be a distinct active ingredient had not been addressed by the CJEU and suggested that one approach would be to consider whether it was a new active ingredient within the meaning of the EU rules relating to placing on the market of medicinal products.

No doubt there will be further references both in relation to this and the situations in which *Neurim* can be applied. As Vossius have noted, there is already a pending reference (Santen C-673/18) from the Paris Court of Appeal as to the correct interpretation of Article 3(d) in the light of *Neurim*, which asks, *inter alia*, whether Neurim is limited to:

i. cases of human application after veterinary application;
ii. indications in a new therapeutic field; or
iii. cases where the active ingredient exerts a different action to that exerted by it in the drug that was subject to the earlier MA.

Overall, *Abraxis* may be added to the long line of missed opportunities to provide clarity to the interpretation of the SPC Regulation. If any point of principle can be extracted from this decision, it is perhaps that the direction of travel continues to be slightly more restrictive.