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CJEU bids farewell to SPCs for new formulations of old drugs

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The eagerly-awaited judgment of the Court of Justice of the European Union (CJEU) in the SPC referral *Abraxis Bioscience* (C-443/17) has been handed down 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 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*. Moreover, 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 its judgment rendered today, however, the CJEU found that SPCs can not be granted for new formulations of previously approved active ingredients under Article 3(d) of the SPC Regulation, even if the marketing authorization for the new formulation is the first one that falls within the scope of the basic patent relied upon for the SPC filing.

In reaching this conclusion, the CJEU endorsed a narrow interpretation of Article 3(d) of the SPC Regulation, which it found to be supported by the objective expressed in recital 10 of the Regulation that all interests at stake, including those of public health, should be taken into account. In the Court's view, this was further confirmed by the Explanatory Memorandum to the original SPC Regulation (COM(90) 101 final – SYN 255), which made clear that the legislator's intention in establishing the SPC regime was to protect not all pharmaceutical research giving rise to the grant of a patent and the marketing of a new medicinal product, but only to protect research leading to the first placing on the market of a new active ingredient or a new combination of active ingredients. Allowing SPCs for new formulations of previously approved drugs would jeopardize this objective, and would furthermore lead to legal uncertainty and inconsistencies.

The CJEU's refusal to allow SPCs for new formulations of previously approved drugs is a bitter disappointment to research-based pharmaceutical industry, but it does certainly not come as a surprise, given that both Justice Arnold in the referring decision of the UK Patents Court and the

CJEU's Advocate General in his opinion suggested this same response.

Nevertheless, there is a silver lining as the CJEU has at least not overturned its earlier liberal approach to the grant of SPCs for new therapeutic applications established in *Neurim* (C-130/11).

Scrapping the *Neurim* approach entirely had been the preferred course of action proposed by the Advocate General in his opinion, as previously reported on this blog, the second best being the limitation of *Neurim* to the very specific case that an active ingredient previously authorized as a veterinary medicinal product is subsequently granted a marketing authorization for a new therapeutic indication in human medicine. According to the Advocate General, only in such narrow circumstances should Article 3(d) of the SPC Regulation not preclude the grant of an SPC on the basis of the marketing authorization for the new therapeutic application, provided that it is the first authorization to fall within the scope of the basic patent relied upon for the SPC application.

Yet, in its judgment in *Abraxis Bioscience* the CJEU merely reiterated some of the conclusions of its earlier *Neurim* decision but completely avoided to undertake any reappraisal or qualification of that decision, which will be perceived with great relief by the pharmaceutical industry. All eyes are now on the CJEU's forthcoming decision in the pending referral in *Santen* (C-673/18), previously discussed on this blog, in which the precise scope of the *Neurim* approach and, quite possibly, its continued future application will be decided.

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

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