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Prodrug SPCs: invalidation action dismissed in Sweden

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The Swedish Patent and Market Court ("**PMC**") recently issued a judgment on an important aspect of SPC law, namely the correct interpretation of the term 'product' under Article 1(b) of the SPC Regulation (see **PMC 16666-23**, 21 January 2025, English translation). This action was commenced by STADA, who challenged the validity of an SPC for the prodrug, L-lysine-d-amphetamine (lisdexamfetamine), which is marketed by Takeda for the treatment of attention deficit/hyperactivity disorder *inter alia* under the brand name Elvanse®.

STADA challenged the validity of Takeda's SPC under various grounds, but all of them turned on whether the 'product' or 'active ingredient' according to Article 1(b) is lisdexamfetamine (the prodrug, as Takeda contended) or dexamfetamine (the active metabolite, as STADA contended). This distinction was an important one for SPC purposes as dexamfetamine had been authorized in the EU before the regulatory approval of Elvanse®.

The PMC started its legal assessment by considering the Explanatory Memorandum to the proposal for the creation of Supplementary Protection Certificates (the "**Explanatory Memorandum**"), noting that the concept of 'product' had been chosen by the Union legislator as a common denominator between the patent system and the pharmaceutical regulatory system. Similarly, the PMC went on to state that: "*The case law of the CJEU further shows that the concept of active ingredient within the meaning of the Supplementary Protection Regulation should be understood in the same way as the definition of "active substance" in Article 1(3)(a) of the Medicinal Products Directive*." The Court therefore shared Takeda's view that the starting point for determining whether a product constitutes an 'active ingredient' (for SPC purposes) must be based on how the substance in question has been defined according to the pharmaceutical regulatory system, i.e. the system governing the process of marketing authorizations for medicinal products according to the Medicinal Products Directive.

The PMC found it clear that it is the active substance contained in the medicinal product that is subject to the marketing authorization procedure. According to the PMC, this substance is listed in the Summary of Product Characteristics under Clause 2, "Qualitative and quantitative composition". Therefore, lisdexamfetamine is the active substance in the authorization process for the medicinal product, Elvanse®.

The Court went on to consider whether STADA's other submissions or the case law of the CJEU would affect their conclusions. STADA had pointed in particular to the CJEU judgments in Forsgren (C-631/13), Santen (C-673/18), MIT (C-431/04), GSK (C-210/13) and Abraxis

(C-443/17). However, the PMC concluded that the circumstances in all of these cases differ from those in the current case, acknowledging among other things that none of these CJEU rulings concern an active substance/ingredient in the form of a prodrug.

Consequently, the Court concluded that lisdexamfetamine is the active ingredient of Elvanse® and thus the 'product' under Article 1(b) of the SPC Regulation. In the Court's view, this conclusion is supported by the regulatory framework governing the process for the marketing authorization of medicinal products and by what the EU legislature expressed in the Explanatory Memorandum. Nor is this conclusion contradicted by the practice developed at the CJEU on the interpretation of the terms 'active ingredient' and 'product' in Article 1(b) of the SPC Regulation. Since STADA had failed to demonstrate that the active ingredient in Elvanse® is dexamfetamine, the invalidation action was dismissed by the Court.

This judgment of the PMC can therefore be contrasted with an earlier decision of the Federal Patent Court in Germany in case 3 Ni 22/22 (EP) (see **here**). This decision was raised by STADA in the Swedish proceedings but not cited in the judgment. In essence, the German court assessed that the active metabolite dexamfetamine, rather than the prodrug lisdexamfetamine, is the 'active ingredient' in the medicinal product and thus the 'product' according to Article 1(b) of the SPC Regulation. In light of this, the German court declared the corresponding German SPC invalid. Among other things, the German court did not apply the conclusions from the marketing authorization procedure where lisdexamfetamine was assessed as the active substance in the medicinal product. This decision is under appeal.

Takeda was represented in these SPC proceedings by Advokatfirman Vinge (Sweden) and supported by Carpmaels & Ransford LLP (European coordination counsel). This decision may be subject to a future appeal.

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