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SPC limitations: concept of "product"

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- Introduction
- Facts
- Decision
- Comment

Introduction

In this case,[(1)] the Patent and Market Court of Appeal (PMCA) addressed the fundamental issue of which documents are relevant for defining the "product" in the sense of article 1(b) of Regulation No. 469/2009 (SPC Regulation).

In summary, the issue concerned whether only the marketing authorisation (MA) and its annexes, including the summary of product characteristics (SmPC), should be of relevance, or whether other evidence such as the European Public Assessment Report (EPAR), expert opinions and publications may be considered. In essence, the PMCA held that consultation of the EPAR is acceptable to answer obscurities in the MA but dismissed the sought grant of a supplementary protection certificate (SPC). The PMCA's reasoning is well worth studying closely by litigators and patent attorneys.

Facts

A patent holder to an immunogenic composition, a vaccine comprising a truncated protein, applied for an SPC for various product definitions relating to the truncated protein.

The Swedish Intellectual Property Office (IPO), and the Patent and Market Court (PMC) both dismissed the application by finding that the MA held by the applicant only covered the full-length protein, not the truncated version covered by the basic patent. Moreover, the IPO and the PMC both held that reference could not be made to the EPAR document to establish a basis for the truncated version of the protein in the MA.

The case was appealed to the PMCA, including a request to refer the case to the Court of Justice of the European Union (CJEU) for a preliminary ruling.

Decision

The PMCA dismissed the request for a preliminary ruling in sweeping fashion, concluding that neither the circumstances nor the legal issues necessitated a clarification from the CJEU.

As regards the possibility to consider the EPAR for the purposes of defining the "product" in the sense of article 1(b), the PMCA took its starting point by accounting for the MA application procedure, and the function of the EPAR within that process. In short, MA grants are preceded by an examination by the Committee for Medicinal Products for Human Use (CHMP), which is the committee that processes all MA applications before the European Medicines Agency (EMA). As part of its examination, the CHMP includes its considerations in the EPAR which is to be enclosed to all recommendations to grant, which are sent to the European Commission. In turn, the Commission issues a recommendation based on the opinion of the CHMP, whereto the EPAR is not enclosed. Considering the function of the EPAR and case law on product definitions, the PMCA held that there is nothing preventing that consideration be paid to the EPAR when necessary to clarify potential unclarities on the granted product in the MA.

Turning to the facts of the case, the Court noted that, even though a truncated version of the protein was indeed mentioned in the EPAR, the Court's overall conclusion was that the product recommended for grant was the full-length protein. The PMCA thus dismissed the main SPC request but did allow for the case to be appealed to the Supreme Court. However, the SPC applicant surprisingly did not appeal to the Supreme Court.

Comment

The PMCA's decision in this case adds to its previous decision in PMÖD 2022:13, where the general prohibition against consideration of documents not encompassed by the MA application was laid down. While some readers may be ready to draw the hasty conclusion that the PMCA's conclusion marks a liberal, and applicant-friendly shift, the Court's assessment on the issue of the truncated versus the full-length protein in the EPAR illustrates and confirms the prevailing strict view on product definitions under article 1(b) of the SPC Regulation. It is also notable that the PMCA's ruling is contrasted by the grant of corresponding SPCs in over 20 EU member states as well as the United Kingdom, which is unfortunate from a harmonisation standpoint. Certain conclusions on the implications of this decision, if any, will have to wait but the legal uncertainty concerns expressed by the IPO on an opposite outcome where the SPC would have been granted, seem somewhat exaggerated at this stage, in particular considering that no such concerns appear to have prevailed in other jurisdictions where the SPC has been granted.

As to the PMCA's decision not to refer the case to the CJEU, this is somewhat surprising in light of last year's debated Supreme Court decision where the PMCA's dismissal of such request in an SPC case was considered to constitute a grave procedural error in that case. While this case will not be subject to new SPC case law from the Supreme Court, the seemingly evergreen source of new issues related to SPC's is unlikely to dry out any time soon.

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Endnotes

(1) PMCA, PMÖÄ 10788-22.