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Patent and Market Court of Appeal clarifies concept of "product" under EU SPC Regulation

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Introduction

In the case discussed in this article,[1] the Patent and Market Court of Appeal provided further guidance as to the application of article 3(b) of the EU Supplementary Protection Certificate (SPC) Regulation and the concept of "product".[2] In its assessment, the Court concluded that a product will not be eligible for an SPC if it is explicitly identified as an excipient in the summary of the product's characteristics. The Court also established that evidence which was not part of the application for a market authorisation cannot be considered in determining which products are included in such market authorisation.

Facts

The applicant had requested the grant of an SPC for the product Trastuzumab and recombinant human hyaluronidase. According to the invoked market authorisation for the pharmaceutical subcutaneous herceptin, Trastuzumab was identified as the active ingredient and recombinant human hyaluronidase as one of several excipients. The applicant further explained that recombinant human hyaluronidase was decisive for the therapeutic effect as it made it possible to administer Trastuzumab subcutaneously.

The Swedish Intellectual Property Office and the Patent and Market Court rejected the application since it could not be established that the applicant had fulfilled the requirement in article 3(b) of the EU SPC Regulation. The Court found that it had not been shown that recombinant human hyaluronidase on its own had a clinical effect that fell within the therapeutic indications that the market authorisation encompassed. The applicant appealed the decision.

Decision

The main question before the Patent and Market Court of Appeal was whether recombinant human hyaluronidase could be considered an active ingredient or a combination of active ingredients under the invoked market authorisation. With reference to established case law from the Court of Justice of the European Union, the Court clarified that a distinction should be made between an "active ingredient" and an "adjuvant", where an adjuvant cannot be considered an active ingredient.[3] Further, the Court concluded that an active ingredient whose effect does not fall within the therapeutic indications covered by the wording of the marketing authorisation cannot be granted an SPC.[4]

In its assessment, the Court found that neither the summary of the product's characteristics nor the market authorisation presented evidence that recombinant human hyaluronidase had an effect on breast cancer on its own – that is, an effect on the therapeutic indication covered by the market authorisation on its own. Instead, recombinant human hyaluronidase was throughout referred to as an excipient. Consequently, according to the Court, recombinant human hyaluronidase was not an active ingredient. With this conclusion, Trastuzumab and recombinant human hyaluronidase could not be considered a combination of active ingredients either.

The Court also had the opportunity to clarify that it is only the documentation on which the market authorisation is based that is relevant when identifying the product or active ingredient. The additional evidence regarding the effects of recombinant human hyaluronidase on cancer invoked by the applicant could therefore not be considered.

Comment

This decision is the first time that the Patent and Market Court of Appeal has applied article 3(b) of the EU SPC Regulation and has thus shed further light on the complex distinction of the concept of "product" in article 1(b) of the EU SPC Regulation. While this decision will not resolve all questions relating to SPCs, it is a useful reminder that the documentation on which the market authorisation is based will be decisive for the assessment of the concept of "product" under the EU SPC Regulation.

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Endnotes

(1) PMÖÄ 12516-21.

(2) Regulation No. 469/2009.

(3) *GlaxoSmithKline Biologicals*, C-210/13, paragraph 38.

(4) *Forsgren*, C-631/13, paragraph 55.