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# Swedish Supreme Court weighs in on SPCs – possible increase in Swedish referrals to CJEU

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## Introduction

Since the entry into force of the EU Supplementary Protection Certificate (SPC) Regulation,<sup>(1)</sup> the Court of Justice of the European Union (CJEU) has tried a plethora of cases relating to its interpretation. However, new questions are continuously raised by the pharmaceutical industry while challenging the decisions of the competent authorities and, as a consequence, the case law is still evolving.

In this case, the Supreme Court found that the Patent and Market Court of Appeal (PMCA), ex officio, should have requested a preliminary ruling from the CJEU since the interpretation of EU law was unclear and of relevance for the outcome.

## Facts

The applicant was granted an SPC for the product dapagliflozin in February 2014. The grant was based on a European patent regarding C-aryl glucoside SGLT2 inhibitors and the first market authorisation for the product Forxiga.

In July 2014 the applicant requested the grant of an SPC for a product that consisted of a combination of the substances dapagliflozin and metformin. The same European patent was invoked as a basis for the grant and a first market authorisation for the product Xigduo.

The Intellectual Property Office rejected the application as the applicant had already been granted an SPC based on the same European patent. One of the questions in the case was how to interpret article 3c of the EU SPC Regulation as to whether the product – the combination of dapagliflozin and metformin – had already been subject of a certificate. Upon appeal, the Patent and Market Court and the PMCA both rejected the application. In neither of the instances was the question of referral to the CJEU raised by the parties or the courts.

The applicant lodged a complaint for grave procedural error to the Supreme Court. In the complaint, the applicant claimed that the PMCA's omission to ex officio request a preliminary ruling from the CJEU regarding the interpretation of article 3c of the EU SPC Regulation constituted a grave procedural error that could have affected the outcome of the decision.

## Decision

In light of the complaint lodged, the Supreme Court had to determine whether the PMCA ex officio had had an obligation to request a preliminary ruling from the CJEU regarding the interpretation of article 3c of the EU SPC Regulation in view of the established case law from the CJEU and the specific circumstances in the case.

Following article 267 of the Treaty on the Functioning of the European Union (TFEU) and article 19(3)(b) of the Treaty of the European Union, the reference for a preliminary ruling is a fundamental mechanism of EU law. If a question relating to EU law is raised in a court in which decisions cannot be appealed according to national law, that court is in principle obliged to refer the question to the CJEU.<sup>(2)</sup> Therefore, as explained by the Supreme Court, an omission to request a preliminary ruling from the CJEU could be considered a procedural error.

However, such an omission may not always constitute a grave procedural error to which end the decision rendered will be quashed. The decisive factors for finding that an error was grave are if:

- the court in question was the last instance;
- the court in question rendered a decision with prejudicial effect; and
- the question of EU law would determine the outcome of the dispute.

As the first two requirements were already fulfilled, the question to be determined by the Supreme Court was the importance of the interpretation of article 3c of the EU SPC Regulation in the case.

The Supreme Court found that the CJEU in fact had interpreted article 3c of the EU SPC Regulation on several occasions, but that this was not an indication that further guidance was superfluous. Instead, the Supreme Court noted that the CJEU had provided its previous guidance in relation to the specific circumstances in the main proceedings. This favoured the conclusion that the details of the national proceedings should be given great importance in the assessment of whether the CJEU had provided an answer that could be applied in the case at hand.

The Supreme Court noted that this was even more relevant since the interpretation of article 3c of the EU SPC Regulation was more restrictive than its literal wording and, in principle, limited the rights holder's possibilities. As a consequence, the Supreme Court found

that, where the circumstances in the national proceedings are not identical to the circumstances already tried, previous case law from the CJEU should only be applied if it unequivocally answers the questions of relevance to the case at hand.

Since the circumstances in the case in fact differed from the CJEU's judgment in *Actavis Group PTC and Actavis UK*,<sup>(3)</sup> this was enough for the Supreme Court to find the interpretation of article 3c of the EU SPC Regulation unclear. The fact that other member states had found that article 3c did not prevent the grant of an SPC for a combination of the substances dapagliflozin and metformin added further support to this conclusion. Finally, the Supreme Court found that the multiple referrals to the CJEU, regarding the interpretation of article 3c of the Regulation, clearly indicated that further guidance was necessary and that an exception from the obligation to refer the case to the CJEU did not exist.

The Supreme Court therefore found that previous case law from the CJEU could not be considered to unequivocally answer the questions in the case. The interpretation of article 3c of the EU SPC Regulation was therefore not clear and did not lack relevance for the assessment. The omission by the PMCA to request a preliminary ruling from the CJEU regarding the interpretation of article 3c of the EU SPC Regulation was therefore considered to be a grave procedural error, which presumably could have affected the outcome of the case. The PMCA's decision was thereby revoked, and the case referred back to the PMCA.

#### Comment

The Supreme Court rarely renders decisions finding that a grave procedural error has occurred, and it is equally unusual that the Supreme Court provides guidance in cases handled within the PMCA's jurisdiction. Even though the Supreme Court did not assess whether the applicant in this case fulfilled article 3c of the Regulation, it is clear that the Supreme Court did not find the provision to be obvious. This may affect the Intellectual Property Office's decisions moving forwards. Further, this decision will most likely result in an increase in referrals to the CJEU from the PMCA, even without the question being raised by the parties.

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#### Endnotes

(1) Regulation (EC) No. 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products.

(2) See article 267(3) of the TFEU.

(3) C-443/12, EU:C:2013:833.