Kluwer Patent Blog

New CJEU referral on Article 3(c) of the SPC Regulation on the horizon – Sweden following in the footsteps of Finland and Ireland?

Oswin Ridderbusch, Alexa von Uexküll (Vossius & Partner) · Wednesday, December 28th, 2022

There are currently two referrals on SPC law pending before the Court of Justice of the European Union (CJEU), both of which concern the interpretation of Article 3(c) of the SPC Regulation (EC) 469/2009. This provision essentially ensures that the same person cannot obtain more than one SPC for the same product (active ingredient), which is often referred to as "one SPC per product per patent holder" rule. As European law allows the grant of SPCs not only for single active ingredients but also for combinations of active ingredients, and since a combination of two (or more) active ingredients is regarded as a different product than any of the individual active ingredients comprised in the combination, there should be nothing to prevent a patentee from obtaining a first SPC for a single active ingredient A and a second SPC for a combination of active ingredients A+B. Alas, as any European practitioner knows, it is not that simple.

The CJEU has addressed such situations in its decisions *Actavis v. Sanofi* **(C-443/12)**, *Georgetown University v. Octrooicentrum Nederland* **(C-484/12)** and *Actavis v. Boehringer Ingelheim Pharma* **(C-577/13)** almost 10 years ago. Simply put, the CJEU found that a first SPC granted for a single active ingredient A may preclude the subsequent grant of a second SPC for a combination of active ingredients A+B under Article 3(c) if the two SPCs are based on the same patent, if the scope of protection conferred by the first SPC already encompasses the combination of A+B, and if the combination of A+B is not an "independent invention", i.e., an invention in its own right that is distinct and independent from the invention embodied by the single active ingredient A. Such an "independent invention" may be acknowledged, e.g., if the patent discloses that the combination of A+B achieves an unexpected synergistic effect. Yet, attempting to define the precise conditions under which the grant of a second SPC should be precluded (or allowed) is prone to cause headaches. This has been further compounded by the CJEU's recent decision in *Royalty Pharma* **(C-650/17)**, in which the "core inventive advance" of the basic patent was effectively found to have no relevance in the context of Article 3(a) of the SPC Regulation (as previously reported on this blog), prompting the question whether this would necessitate a reassessment of the CJEU's prior case law on Article 3(c).

Further guidance on these intriguing questions (and also on the Article 3(a) requirement) can be expected from two currently pending CJEU referrals, i.e., *Teva v. Merck Sharp & Dohme* **(C-119/22)** made by the Finnish Market Court in February 2022 (see here for an English translation of the referring decision) and *Merck Sharp & Dohme v. Clonmel Healthcare* **(C-149/22)**

made by the Irish Supreme Court in March 2022 (see here for the referring decision). According to a reply from the CJEU's registry, these two referrals have not been joined and are both still pending (despite earlier rumors that the lawsuit before the Finnish Market Court might be settled, leading to a withdrawal of the corresponding CJEU referral).

Meanwhile, an additional CJEU referral relating to the Article 3(c) requirement can be expected from the Swedish Patent and Market Court of Appeal in the near future.

By way of background, an SPC application (SE 1490041-9) filed by AstraZeneca for the combination of dapagliflozin + metformin was rejected by the Swedish Patent Office for lack of compliance with Article 3(c) in view of an earlier SPC (SE 1390017-0) granted for dapagliflozin alone on the basis of the same patent. The rejection of this SPC application was appealed by AstraZeneca, but the appeal was dismissed by the Patent and Market Court and subsequently by the Patent and Market Court of Appeal with decision PMÖÄ 1213-20 of April 7, 2021 (PDF version; rough English machine translation). Since the Patent and Market Court of Appeal did not grant leave for appeal, its decision would normally have been final. Remarkably, however, the Swedish Supreme Court has accepted a further appeal, set the appealed decision aside on the grounds of a serious legal error (*domvilla*), and remitted the case to the Patent and Market Court of Appeal.

In the corresponding decision Ö 5978-21 issued on December 20, 2022 (PDF version; rough English machine translation), the Supreme Court found that the Patent and Market Court of Appeal, as the court of final instance, should have made a referral to the CJEU to obtain clarification about the interpretation of Article 3(c) of the SPC Regulation. In reaching this conclusion, the Supreme Court held that the interpretation of Article 3(c) adopted by the CJEU in *Actavis* **(C-443/12)**, *Georgetown* **(C-484/12)** and *Boehringer* **(C-577/13)** imposes farther-reaching conditions than the plain wording of Article 3(c) suggests, and that these conditions cannot easily be transposed to other case constellations than those underlying the respective decisions. Moreover, the Supreme Court could not exclude the possibility that the more recent CJEU decisions *Teva v. Gilead* **(C-121/17)** and *Royalty Pharma* **(C-650/17)** relating to Article 3(a) might indeed affect the interpretation of Article 3(c). The extensive number of prior CJEU referrals on Article 3(c) was seen not as a sign of settled case law but rather as reflecting persisting difficulties of interpretation, and the specific case at hand was regarded as showing significant similarities to the cases underlying the pending Finnish and Irish CJEU referrals.

Under these circumstances, the Swedish Supreme Court found that the Patent and Market Court of Appeal would have been obliged to obtain a preliminary ruling on the interpretation of Article 3(c) from the CJEU, regardless of whether such a referral had actually been requested by the parties. The failure to make such a referral was found to constitute a serious error and, in turn, a substantive procedural violation that requires setting aside the decision of the Patent and Market Court of Appeal.

As the Swedish courts dealing with patent and SPC matters usually work admirably fast, it appears safe to assume that we may see a decision from the Patent and Market Court of Appeal and presumably a new CJEU referral rather soon. In theory, it might still happen that the CJEU could hand down its decisions in the pending Finnish and Irish referrals quickly enough to potentially obviate the need for a new Swedish referral, but it currently seems unlikely that the CJEU would decide these cases before the last quarter of 2023.

Taking a broader perspective, the Supreme Court's decision Ö 5978-21 can also be expected to prompt the Swedish courts to make CJEU referrals much more frequently in the future (as also noted on the Delphi EU and Competition Blog), particularly in SPC matters where a uniform and consistent application of the pertinent EU regulations still remains elusive.

Oswin Ridderbusch *and* ***Alexa von Uexküll*** *are the editors of the handbook* ***European SPCs Unravelled: A Practitioner's Guide to Supplementary Protection Certificates in Europe (Second Edition)****, which was published by Wolters Kluwer in 2021.*

To make sure you do not miss out on regular updates from the Kluwer Patent Blog, please subscribe here.

This entry was posted on Wednesday, December 28th, 2022 at 1:33 am and is filed under CJEU,

European Union, Finland, Ireland, Pharma, SPC, Sweden

You can follow any responses to this entry through the Comments (RSS) feed. Both comments and pings are currently closed.