Kluwer Patent Blog

SPCs: the CJEU recognizes that A + B = C

Matthieu Dhenne (Dhenne Avocats) · Monday, January 6th, 2025

Although the equation A + B = C seems self-evident (even for a five years old boy: remember you), the fact remains that it needed clarification by the Court of Justice of the European Union ("CJEU"), in relation to SPCs for product combinations (in application of article 3 c) of the SPC Regulation), which has been done with the decision handed down on December 19, 2024 in joined cases C-119/22 and C-149/22 (see also precedent interesting comments here). This judgment allows the Court to return to and clarify the interpretation of articles 3 a) and 3 c) of the SPC Regulation independently.

FACTS

Both Cases C-119/22 and C-149/22 concerned SPC applications filed by Merck for combinations of active ingredients: respectively (i) sitagliptin and meformin, and (ii) ezetimibe and simvastatin. The basic patents were related to one active ingredient (sitagliptin and ezetimibe respectively) but included dependent claims in combination with another active ingredient (meformin and simvastatin respectively). Merck had also already obtained SPCs for sitagliptin and ezetimibe alone. The questions raised were: firstly, is such a combination protectable under Article 3 c) of the SPC Regulation? Secondly, could it be protected, where applicable, under article 3 a)?

PREVIOUS CASE LAW

The CJEU initially rejected product combination protection under Articles 3 a) and 3 c) combined in the Actavis cases (C-443/12 and C-577/13) when the combination was claimed in a basic patent in which only one of the two components of the combination constituted the **sole subject-matter** of the invention. This rejection was recently reiterated by the French Supreme Court in relation to the combination of ezetimibe and simvastatin.

To understand this rejection, we need to return to the heart of the matter: the interpretation of article 3 a). While there are few decisions relating to article 3 c), those relating to 3 a) are particularly numerous, and often confusing. As a reminder, article 3 of the SPC Regulation stipulates that an SPC may be granted, provided that "*the product is protected by a valid basic patent*" (a) and that "*the product has not already been the subject of an SPC*" (c). The position adopted in relation to article 3 a) thus necessarily and directly influences the interpretation of 3 c). Indeed, depending on how we define the product covered by a basic patent according to 3 a), we may or may not accept that a combination is admissible within the meaning of 3 c). For example, if the mere mention of the product in the claim is sufficient to consider that a product is covered by the basic patent, this implies that the said product cannot then be protected in combination with

another product within the meaning of 3 c).

However, three tests for compliance with Article 3 a) have been considered by the courts: (i) the so-called **"infringement test"**, according to which it is sufficient for the approved product to be covered by the claims of the basic patent; (ii) the **"*specifically identifiable*" (or "*specified*") test,** according to which the approved product must not only fall within the claims of the basic patent, but must also be sufficiently identifiable (preferably as a specific compound) in the claims and/or description of the basic patent; (iii) finally, **the "invention" (or "*inventive progress*") test**, according to which the approved product must also reflect the inventive contribution made by the patent.

The infringement test (i) was rejected by the CJEU in the Medeva case (C-322/10), in favor of the second test. The Court held that a product is only protected by a basic patent, in accordance with Article 3 a) of the Regulation, if it is "*specified in the wording of the claims*". However, from Actavis (C-433/12 and C-577/13) onwards, which introduced test (iii) of inventive progress in addition to test (ii), the European Court's position gradually moved away from Medeva, softening its approach to the notion of a product covered by the basic patent. Thus, in the Teva case (C-121/17), the CJEU introduced a two-step test to assess whether a combination product met the requirements of Article 3 a): (1) the combination of active ingredients necessarily falls, in the light of the description and drawings of that patent, within the invention covered by the patent, and; (2) each of those active ingredients must be "specifically identifiable", in the light of all the information disclosed by the patent, at the date of filing or priority of the application. Furthermore, in Royalty Pharma (C-650/17), the Court confirmed the "*specifically identifiable*" criterion, but also held that a mere functional definition of the product in the basic patent did not satisfy 3 a), if the approved product had been "*developed after the filing or priority date of the basic patent, as a result of an independent inventive step*".

CONTRIBUTION

To say that the CJEU's case law on the interpretation of Article 3 a) is confused would be an understatement. This confusion stems from the mixture of tests (ii) of "*specifically **identifiable***" and (iii) of "*inventive progress*" referred to above.

As such, since the Medeva case law, which focuses on the "*specifically **identifiable** *" test (ii), the Court has changed its interpretation of Article 3 a), enabling it, in the judgment under review, to consider that **it is not enough for a product to be expressly mentioned in the claims of the basic patent for it to be covered by that patent; that product must fall within the invention covered by the patent**. This interpretation of 3 a) authorizes the Court to consider that a SPC may relate to the combination of a product specifically covered with another product under 3 c). In other words, the reinterpretation of 3a) played an essential role in the reinterpretation of 3c).

Beyond the legitimate criticisms of the CJEU's case law, there can be little doubt that it is the European text itself whose sibylline nature raises difficulties. In the absence of further clarification, the notion of "product covered by the basic product", which lies at the heart of Article 3, is bound to give rise to debate.

The abundant and complex case law relating to article 3 of the SPC regulation is a reminder of the need for reform of this text. Of course, we could write a doctoral thesis on how bad European legislations are in general and how to improve them (even if mostly employing lawyers instead of

economists and technocrats to write laws would mostly resolve the problems). But that's not our topic today, even if it is the core of the problematic and if we will need to rethink about it while establishing the unitary SPC system. It is to be hoped that the current project of the unitary SPC will provide some answers, and above all that it will not exacerbate the confusion by excluding the jurisdiction of the UPC (which is nonetheless competent to rule on national SPCs).

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

This entry was posted on Monday, January 6th, 2025 at 12:35 pm and is filed under CJEU, Pharma, SPC
You can follow any responses to this entry through the Comments (RSS) feed. You can leave a response, or trackback from your own site.