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The time is ripe for the CJEU to explicitly apply its renewed doctrine on the meaning of "product" also to art. 3(c) of the SPC Regulation

Miquel Montañá (Clifford Chance) · Tuesday, April 27th, 2021

The long and winding road, as *The Beatles* would put it, that led to the judgments of the CJEU in *Teva et altri v. Gilead Sciences* (Case C-121/17) and *Royalty Pharma v. Deutsches Patent und Markenamt* (Case C-650/17), which renewed the Court's case law on the meaning of "*product*", started in the *Medeva* judgment (Case C-322/10), a relatively old decision from which the CJEU itself has struggled to distance itself during the last decade. Even the national Court (Justice Arnold) that had sent the preliminary questions to the CJEU in that case, complained that the answers of the CJEU (the infamous "*It follows*" of par. 25), in reality, did not "follow" from the legal grounds of the decision.

Although the answers of the CJEU in *Medeva* dealt with articles 3(a) and 3 (b) of the SPC Regulation only, down the road, that decision caused collateral damage to cases dealing with article 3(c) also. A good example may be found in *Actavis v. Sanofi* (Case C-443/12) and *Actavis v. Boehringer Ingelheim* (Case C-577/13). In both cases, the national Courts had referred cases dealing with both article 3(a) and 3(c) although, in the end, in the first case the CJEU answered the question dealing with article 3(c) only. The answer of the CJEU in *Actavis v. Sanofi* was predetermined by the so-called "*core inventive advance*" test (see par. 30 of the judgment), which has since been explicitly abandoned by the CJEU in cases dealing with article 3(a).

With regard to the *Actavis v. Boehringer Ingelheim* judgment, as highlighted by the CJEU at par. 32, the answers to question 2 (dealing with article 3 generally and, specifically, with paragraph c)) and question 3 (dealing with article 3(a) specifically), hinged on the interpretation of the concept of "*product as such*" in article 1(c) of the Regulation:

> "*32. For the purposes of providing a useful answer to Questions 2 and 3, it should be noted that the expression «as such», as used in Article 1(c) of Regulation No 469/2009, must be given an autonomous interpretation in the light of the objectives pursued by that regulation and the overall scheme of which that expression forms part.*"

Therefore, it is clear that, for the CJEU, the interpretation of the concept of "*product*" in article 1(c) predetermined the answers both to the question dealing with article 3(a) and the question dealing with article 3(c). From here on (par. 33-37), the CJEU reviewed its case law on the interpretation of article 1(c) in the context of cases (C-443/12 *Actavis v. Sanofi* and C-484/12 *Georgetown University*) dealing with the scope of article 3(c). And after citing, once again, in the

last sentence of par. 37, the judgment in case C-443/12 *Actavis v. Sanofi* (a case dealing with article 3(c) only), it immediately reached the following conclusion:

> *"38. It follows that, in order for a basic patent to protect «as such» an active ingredient within the meaning of articles 1(c) and 3(a) of Regulation No 469/2009, that active ingredient must constitute the subject-matter of the invention covered by that patent."*

And without adding anything else, not even a sentence, on article 3(c), the Court proposed the following answer to Questions 2 and 3:

> "*39. In the light of the foregoing considerations, the answer to Questions 2 and 3 is that articles 3(a) and (c) of Regulation No 469/2009 must be interpreted as meaning that, where a basic patent includes a claim to a product comprising an active ingredient which constitutes the sole subject-matter of the invention, for which the holder of that patent has already obtained an SPC, as well as a subsequent claim to a product comprising a combination of that active ingredient and another substance, that provision precludes the holder from obtaining a second SPC for that combination."*

From the reasoning of the judgment, it is clear that the Court: (a) considered that the answers to the questions dealing with both article 3(a) and article 3(c) hinged on the interpretation of the concept of "*product as such*" in article 1(c); (b) did not examine the requirements of article 3(a) and article 3(c) separately, as it assumed that the interpretation of the concept of "*product as such*" in article 1(c) predetermined the answers to both questions; (c) found an intimate connection between article 3(a) and article 3(c), as the scope of both articles depends on the interpretation of "*product as such*" in article 1(c).

This intimate connection between article 3(a) and article 3(c) – both hinging on the interpretation of "product" in article 1 – calls for an explicit fine-tuning of the CJEU's case law on article 3(c) to make it consistent with its latest case law on article 3(a): *Teva et altri v. Gilead Sciences* and *Royalty Pharma*.

The point under discussion in the first case was whether the combination (Tenofovir Disoproxil, "TD", and Emtricitabine, a compound not mentioned in claim 27 of the basic patent) could be considered to be "protected" by the basic patent. In response to the preliminary questions referred by that Court and to try to overcome the lack of clarity of the previous tests, in its judgment of 25 July 2018 (case C-121/17 *Teva et altri v. Gilead*), the CJEU tried to further clarify its previous test:

> *"[…] a product composed of several active ingredients with a combined effect is «protected by a basic patent in force» within the meaning of that provision where, even if the combination of active ingredients of which that product is composed is not expressly mentioned in the claims of the basic patent, those claims relate necessarily and specifically to that combination. For that purpose, from the point of view of a person skilled in the art and on the basis of the prior art at the filing date or priority date of the basic patent:*
>
> > *– the combination of those active ingredients must necessarily, in the light of the description and drawings of the patent, fall under the invention covered by that patent, and*
> >
> > *– each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent.*"

In the second case (*Royalty Pharma*), the case involved a patent that disclosed a method for lowering blood sugar levels in mammals through the administration of inhibitors of the enzyme dipeptidyl peptidase ("DP IV"), which contributes to the regulation of blood sugar levels. Royalty Pharma filed an application for an SPC for sitagliptin, a drug falling into the functional category of dipeptidyl peptidase inhibitors not specifically disclosed in the basic patent, which had been developed by a licensee of Royalty Pharma and protected in a different patent. In response to the questions referred by the national Court, the CJEU, after leaving aside the "core inventive advance" test (par. 30-31) reached the following conclusions:

> *"1. Article 3(a) of 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 must be interpreted as meaning that a product is protected by a basic patent in force, within the meaning of that provision, if it corresponds to a general functional definition used by one of the claims of the basic patent and necessarily comes within the scope of the invention covered by that patent, but is not otherwise indicated in individualised form as a specific embodiment of the method of that patent, provided that it is specifically identifiable, in the light of all the information disclosed by that patent, by a person skilled in the art, based on that person's general knowledge in the relevant field at the filing date or priority date of the basic patent and on the prior art at that date.*
>
> *2. Article 3(a) of Regulation No 469/2009 must be interpreted as meaning that a product is not protected by a basic patent in force, within the meaning of that provision, if, although it is covered by the functional definition given in the claims of that patent, it was developed after the filing date of the application for the basic patent, following an independent inventive step."*

The final sentence of the second question is of greatest interest, as it makes it clear that, when the CJEU states that an SPC may not be granted for work carried out after the priority date of the basic patent, it is referring to the invention of active ingredients that, although perhaps generally protected by the structural or functional characteristics of a claim of the basic patent, were not sufficiently identifiable in the basic patent. Certainly, the concerns of the CJEU could not relate to the clinical trials carried out to test the efficacy, safety and quality of compounds already disclosed in the basic patent (either alone and/or in combination with other active ingredients) because, as is well known, these clinical trials, as a general rule, are normally conducted after the priority date of the basic patent. Otherwise, the novelty of the inventions disclosed in the basic patent would be at risk.

Although the questions sent by the referring Court in *Royalty Pharma* dealt with article 3(a), the concept discussed in this paragraph was exactly the one mentioned in article 3(c): which is "*the subject of a certificate*." If, as implied by the CJEU, for a "*product*" to be considered "*the subject of a certificate*", that "*product*" must have been identifiable both in the SPC and in the basic patent, it is clear that, for example, a combination of "A+B" cannot be considered to be "*the subject of a certificate*" that only mentions "A", notwithstanding the fact that such SPC, under the "*infringement test*", may have allowed its holder to prevent third parties from marketing a combination product composed of "A+B."

This is further confirmed by the *Teva et altri v. Gilead* decision. In par. 46, the CJEU already advanced that:

> *"46. It follows from the above that the subject matter of the protection conferred by an SPC must be restricted to the technical specifications of the invention covered by the basic patent, such as claimed in that patent."*

Like in the *Royalty Pharma* case, although the questions sent by the referring Court in *Teva et altri v. Gilead* dealt with article 3(a), the concept discussed in this paragraph was exactly the one mentioned in article 3(c): which is "*the subject of a certificate*." From the CJEU's latest case law, it follows that, the fact that an SPC that protects "A", under the "*infringement test*", may allow its holder to prevent third parties from marketing a combination product composed of "A+B", is irrelevant for the purpose of examining the concept of "*product*" used in article 1 (b) and article 1(c) and, therefore, the scope of article 3(a) and article 3(c) of the Regulation, which depend on how the concept of "*product*" enshrined in article 1 is interpreted. The relevant test is whether the combination product was one of "the subjects" of the basic patent (article 3(a)) or of the first SCP (article 3(c)).

All in all, the time is ripe for the CJEU to explicitly apply its revised doctrine on the meaning of "product" also to art. 3(c) of the SPC Regulation. This is because interpreting that the EU Legislator intended the expression "*product as such*" of article 1(c) to mean one thing in the context of article 3(a) and a different thing in the context of article 3(c) does not pass muster for those driving down the legal certainty road.

This entry was posted on Tuesday, April 27th, 2021 at 10:53 am and is filed under CJEU, Patents, SPC
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