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# CJEU clarifies the conditions for SPC grant in Royalty Pharma (C-650/17): The “core inventive advance” of the basic patent has no relevance for Article 3(a) of the SPC Regulation

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With the rendering of the judgment in *Royalty Pharma* (C-650/17) by the Court of Justice of the European Union today on 30 April 2020, a series of referrals relating to the interpretation of Article 3(a) of the SPC Regulation, which requires that the product of an SPC must be “protected” by the basic patent, finally comes to a close.

The interpretation of Article 3(a) was only recently scrutinized in the CJEU’s decision in *Teva v. Gilead* (C-121/17) of 25 July 2018, which is the first SPC judgment rendered by the Grand Chamber of the CJEU and was presumably meant to set a definitive standard for the assessment of the highly contentious Article 3(a) requirement. While, unsurprisingly, the test endorsed by the CJEU in *Teva v. Gilead* has now been confirmed in *Royalty Pharma*, the CJEU has taken this opportunity to provide welcome clarification on important details.

It has long been a point of contention between the national courts of different EU member states whether or not the “technical contribution”, “inventive contribution” or “core inventive advance” of the basic patent should be taken into account when assessing, under Article 3(a) of the SPC Regulation, whether an active ingredient is “protected” by the basic patent. While this was roundly rejected by the Advocate General in the *Teva v. Gilead* referral, the CJEU did not explicitly address this point in its corresponding judgment. This omission, together with the somewhat peculiar terminology used by the CJEU (such as: “*it is necessary to ascertain whether a person skilled in the art can understand … that the product to which the claims of the basic patent relate is a specification required for the solution of the technical problem disclosed by that patent*”), led Mr. Arnold J of the UK Patents Court to conclude in [2018] EWHC 2416 (Pat) that one part of the two-pronged test established by the CJEU in *Teva v. Gilead* should be “*a test of whether the skilled person would readily understand from the patent and their common general knowledge that the product embodies the technical contribution made by the patent*”. This position stands in stark contrast to the interpretation of the CJEU’s *Teva v. Gilead* judgment adopted by the German Federal Patent Court, which in its judgment in *Truvada* (4 Ni 12/17) held that there is no room for any assessment of inventive step or inventive quality in the context of Article 3(a) of the SPC Regulation, and that this is in full accordance with the CJEU’s findings in *Teva v. Gilead* (as previously reported on this blog). Although the UK Court of Appeal in [2019] EWCA Civ 2272 subsequently overturned Arnold J’s interpretation and found that the CJEU had definitely set its face against the introduction of a test relying on the inventive advance or technical contribution of

the basic patent, the prospect that the CJEU's test established in *Teva v. Gilead* could still be open to fundamentally diverging interpretations caused consternation among practitioners. Indeed, the lack of unambiguous clarification of precisely this point was invoked by the German Federal Patent Court as justification for maintaining its referral in the *Royalty Pharma* case even after the issuance of the CJEU's judgment in *Teva v. Gilead*.

Against this backdrop, it comes as a relief that the CJEU in its *Royalty Pharma* judgment has now expressly clarified that its interpretation of Article 3(a) endorsed in *Teva v. Gilead* does not accord any relevance to the "core inventive advance" of the basic patent. Any remaining ambiguity in this respect should thus be resolved.

In addition, the CJEU in *Royalty Pharma* affirmed that the grant of an SPC for a product that falls within a general functional definition used in the claims of the patent but is not derivable from the patent as a specific embodiment in individualized form, is not in principle precluded. In such a case, the product is nevertheless "protected" by the basic patent within the meaning of Article 3(a) if it is specifically identifiable by a person skilled in the art, based on their general knowledge in the respective field at the filing date or priority date of the patent and in consideration of the prior art at this point in time and all information disclosed in the patent.

Conversely, the CJEU held that a product which was developed only after the filing date or priority date of the basic patent as the result of an independent inventive activity is not "protected" by the corresponding patent within the meaning of Article 3(a) of the SPC Regulation. This finding confirms the CJEU's corresponding reasoning in *Teva v. Gilead*.

Lastly, the CJEU's judgment in *Royalty Pharma* also confirms that the test established by the Court in *Teva v. Gilead* is applicable not only to combinations of active ingredients (as in the specific case underlying the *Teva v. Gilead* judgment) but likewise to single active ingredients. While this question has stirred very little controversy, any potentially remaining doubts in this respect have been dispelled by today's judgment in *Royalty Pharma*.

At present, there are no more pending CJEU referrals relating to the interpretation of Article 3(a) of the SPC Regulation. Yet, experience suggests that this provision might never stop prompting new questions and new CJEU referrals (although possibly in lesser frequency, following the UK's exit from the European Union). One such question relating to a generic chemical Markush formula was raised in the *Sandoz v. Searle* (C-114/18) referral, which was joined with the *Royalty Pharma* referral in May 2019 but was withdrawn after the issuance of the Advocate General's preliminary opinion (discussed here), so that the referred question was left unanswered in the CJEU's order in *Sandoz v. Searle* (C-114/18) of 17 January 2020. It remains to be seen whether Markush formulae will become the subject of a new CJEU referral in the future.

With today's publication of the *Royalty Pharma* judgment, it is reassuring to see that the CJEU continues to resolve SPC referrals under the current constraints of the coronavirus crisis. For now, the excitement regarding Article 3(a) may have passed, but there are still highly significant CJEU referrals dealing with other aspects of SPC law in the pipeline, notably *Santen* (C-673/18) and *Novartis* (C-354/19), both of which are concerned with second medical use SPCs. Following the conduction of an oral hearing in the *Santen* referral in November 2019 and the publication of the Advocate General's opinion in January 2020 (as previously reported on this blog), it would appear that the corresponding judgment will not be a long time coming. Stay tuned.

***Dr. Alexa von Uexküll*** *and* ***Oswin Ridderbusch****, both partners at the IP-specialized law firm Vossius & Partner, are the editors of the handbook* ***European SPCs Unravelled: A Practitioner's Guide to Supplementary Protection Certificates in Europe*** *published by Wolters Kluwer in 2018. See here for a review by Judge Jürgen Schell (in German) and a review by Miquel Montañá (in English).*

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