CJEU’s Advocate General expounds on the availability of SPCs where the basic patent claims a functionally defined active ingredient or a Markush formula in the joined cases Royalty Pharma (C-650/17) and Sandoz v. Searle (C-114/18)

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In the field of supplementary protection certificates (SPCs) in the European Union, the majority of all CJEU referrals resolved to date have dealt with the interpretation of the – presumably simple – condition that an SPC can only be granted for an active ingredient (or a combination of active ingredients) that is “protected” by the basic patent relied upon. Ever since the CJEU endorsed the “identification test” (rather than the “infringement test”) in its landmark decision *Medeva (C-322/10)*, concluding that an active ingredient must be “specified” or “identified” in the claims of the basic patent in order to be “protected” within the meaning of Article 3(a) of the SPC Regulation, an intense controversy has emerged in relation to the question just how specifically an active ingredient has to be identified in the basic patent in order to allow the grant of an SPC.

Further clarification of this question can be expected from two pending CJEU referrals, i.e. *Royalty Pharma (C-650/17)* and *Sandoz v. Searle (C-114/18)*, which have recently been joined by the CJEU with decision of 7 May 2019.

The first referral, *Royalty Pharma (C-650/17)*, was made by the German Federal Patent Court and concerns the SPC application DE 12 2014 000 122.7 filed by Royalty Pharma for the active ingredient sitagliptin, relying on their basic patent EP 1 084 705 B1 and a marketing authorization for the medicament Januvia containing this active ingredient. Sitagliptin is an inhibitor of the enzyme dipeptidyl peptidase IV (DP IV) and thus falls within the functional term “DP IV inhibitor” recited in the claims of the basic patent. The specific DP IV inhibitor sitagliptin as such, however, is not identified in Royalty Pharma’s basic patent as it was developed only after the filing date of the patent (and gave rise to a distinct patent filed by Merck & Co., Inc.). The Federal Patent Court on appeal sided with the German Patent Office which had rejected the SPC application on the grounds that sitagliptin is not actually made available by the basic patent and, therefore, does not form part of its subject-matter of protection (in German: *Schutzgegenstand*). Although the Court dismissed the argument that sitagliptin should nevertheless be regarded as being “protected” by the basic patent because it embodies the “core inventive advance” of that patent, it did acknowledge that a corresponding approach is followed in the United Kingdom (and other EU member states), resulting in a divergent practice across the European Union. The German Federal Patent Court in its decision therefore referred three questions to the CJEU, asking in essence whether an active ingredient must be provided in individualized form, i.e. as a specific embodiment of a class of active ingredients that are functionally defined in the claims of the basic patent, in order to allow the grant of an SPC under Article 3(a) of the SPC Regulation.

The second referral, *Sandoz v. Searle (C-114/18)*, was made by the UK Court of Appeal and concerns the validity of Searle’s SPC for the active ingredient darunavir (SPC/GB07/038), which had been maintained in a first-instance judgment rendered by the UK Patents Court. The basic patent (EP 0 810 209 B1) underlying Searle’s SPC claims a generic group of compounds defined by a Markush formula. The specific active ingredient darunavir is encompassed by this general formula but is not individually disclosed in the basic patent. The UK Court of Appeal in its decision would have acknowledged that darunavir is “protected” by the basic patent and that the SPC is thus valid, but found it necessary to refer a question to the CJEU. In essence, the Court asked whether it is sufficient under Article 3(a) of the SPC Regulation that the active ingredient at issue can, upon examination of its structure, immediately be recognized as a compound falling within a Markush formula recited in the claims of the basic patent, in a case where all the compounds defined by the Markush formula embody the core inventive advance of the patent, or whether the specific groups/substituents required to form this active ingredient from the claimed Markush formula must be derivable by a skilled person on the basis of the patent and their common general knowledge.

In view of the fundamental importance of the questions raised in the two referrals *Royalty Pharma* (C-650/17) and *Sandoz v. Searle* (C-114/18), SPC practitioners have been eagerly awaiting the opinion of the CJEU’s Advocate General which has just been released today on 11 September 2019.

In his opinion, Advocate General Gerard W. Hogan suggests that the questions raised in these two referrals have been largely superseded by the CJEU’s latest decision on Article 3(a) issued in *Teva v. Gilead (C-121/17)* on 25 July 2018. In this decision, the CJEU found that a combination of active ingredients which is not expressly mentioned in the claims of the basic patent is nevertheless “protected” by the patent within the meaning of Article 3(a) if, from the perspective of a person skilled in the art, (i) the combination of active ingredients necessarily falls under the invention covered by the patent and (ii) each of these active ingredients is specifically identifiable on the basis of the patent and the prior art at the filing date or the priority date of the patent. The Advocate General considers this to be a definitive test for establishing whether a product is “protected” by the basic patent, and makes suggestions how this test could be applied to the cases at issue.

Specifically, the Advocate General explains that the two-part test established in *Teva v. Gilead*, as outlined above, should be applicable not only to combinations of active ingredients, as in the specific case underlying that decision, but likewise to single active ingredients. This is because the CJEU in its reasoning developed the corresponding test and only then held that it *also* applies to products composed of several active ingredients, and further because any distinction between single active ingredients and combinations of active ingredients would be immaterial for the purpose of this test.

Notably, the Advocate General furthermore takes the position that the two-part test of *Teva v. Gilead* is entirely different from, and unrelated to, the concept of the “core inventive advance” of the basic patent, which the UK Patents Court had proposed as the relevant test in the referring decision leading to the CJEU’s judgment in *Teva v. Gilead*. The concept of the “core inventive advance” should therefore not apply and have no relevance in the context of Article 3(a). With this proposition, Advocate General Hogan endorses the same suggestion that was already made by Advocate General Wathelet in his opinion in *Teva v. Gilead* but was not explicitly addressed in the corresponding judgment rendered by the CJEU.

With respect to the consideration of Markush formulae, the Advocate General proposes a balanced approach, as in his view the question whether or not a Markush formula may be regarded as an express mentioning of the corresponding active ingredient(s) cannot be decided in a general manner for each and every Markush formula but, rather, can only be addressed in consideration of the individual facts of the case at hand, which must be assessed by the competent national courts. What he considers to be ultimately decisive is that the two-part test established in *Teva v. Gilead* is satisfied, regardless of whether the claims of the basic patent use a functional definition or a Markush formula to define an active ingredient.

The Advocate General further attempts to shed light on the requirement that the two-part test of *Teva v. Gilead* must be applied from the perspective 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. In this regard, he suggests that the questions of who is “a person skilled in the art” and what is “the prior art” should be regarded as matters of national law as these concepts are not harmonized by the EU, so that they would have to be assessed by the national courts. Yet, the Advocate General nevertheless expresses the opinion that an interpretation of the CJEU’s reference to “the prior art” in *Teva v. Gilead* as meaning “the common general knowledge” would be in direct conflict with the unambiguous wording of that decision and should therefore be rejected. This notion may come as a surprise to patent practitioners but, if adopted by the CJEU, could result in a more liberal application of the two-part test, as resorting to the entire prior art available at the effective date of the patent – rather than merely the skilled person’s common general knowledge – could mean that considerably more specific embodiments will be derivable from a functional definition used in a basic patent.

In relation to the first criterion of the aforementioned two-part test, according to which the active ingredient(s) at issue must “necessarily” fall under the invention covered by the basic patent, the Advocate General expounds that this criterion should be satisfied if the corresponding product referred to in the claims of the patent is *required* for the solution of the technical problem disclosed in the patent, or else the product would not fall under the invention covered by that patent. This interpretation, if adopted by the CJEU, could pose problems for the filing of SPCs for combinations of active ingredients in cases where the claims of the basic patent refer to one of these active ingredients merely as an optional component.

In respect of the second criterion of the two-part test, which requires that the active ingredient(s) must be “specifically identifiable”, the Advocate General suggests that this should require that a person skilled in the art must be able to derive the product in question on the basis of all the information contained in the patent and the prior art at the filing date or priority date of the patent. Conversely, if under these circumstances the product (or a constituent element of the product, corresponding to a specific meaning of a variable group in a Markush formula) remains unknown to the skilled person, then the second criterion of the two-part test should not be fulfilled.

As always, it remains to be seen whether and to what extent the CJEU will follow the suggestions made by the Advocate General. One can only hope that the forthcoming decision of the CJEU will provide useful clarification on the correct application of the two-part test established in *Teva v. Gilead* (C-121/17) without giving rise to new points of contention.

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).*