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German Federal Patent Court in Truvada (4 Ni 12/17) expounds on the requirements for SPCs based on patents claiming functionally defined active ingredients

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Practitioners dealing with supplementary protection certificates (SPCs) have been holding their breath at the unfolding of the "Truvada saga" around Gilead's SPCs for the HIV medicament Truvada, which contains the active ingredients tenofovir disoproxil and emtricitabine. The lawsuits involving the Truvada SPCs in various European countries have already given rise to such noteworthy decisions as the CJEU's judgment in *Teva UK v. Gilead Sciences* (C-121/17) of 25 July 2018, which set the current standard as to how the requirement under Article 3(a) of the SPC Regulation (EC) 469/2009 that the product must be "protected" by the basic patent is to be applied in the context of functional definitions of active ingredients, as well as the Swiss Federal Supreme Court's judgment 4A_576/2017 of 11 June 2018, which effectively put an end to the "infringement test" in Switzerland.

The German chapter of the "Truvada saga" began in 2011 with the grant of SPC no. DE 12 2005 000 041 to Gilead Sciences for the product "tenofovir disoproxil and salts, particularly the fumarate salt, hydrates, tautomers and solvates thereof in combination with emtricitabine", following a ruling of the German Federal Patent Court (15 W (pat) 24/07) of 12 May 2011. In this decision, which predates the CJEU's seminal *Medeva* judgment (C-322/10), the Federal Patent Court still applied an "infringement test" and found that the combination of tenofovir disoproxil with emtricitabine fell within the scope of protection of the basic patent and was therefore "protected" by the patent within the meaning of Article 3(a) of the SPC Regulation.

Once the Truvada SPC entered into force, Gilead sued various generics manufacturers before the Munich District Court, claiming injunctive relief for infringement of its SPC, while the generics manufacturers filed revocation actions against this SPC with the German Federal Patent Court. After the Munich District Court rejected Gilead's claim for injunctive relief with judgment 7 O 11152/17 of 17 August 2017, relying on a negative preliminary opinion of the Federal Patent Court regarding the validity of the SPC, the Federal Patent Court followed suit and pronounced the revocation of the Truvada SPC in oral proceedings on 15 May 2018.

Yet, before the Federal Patent Court could issue its corresponding reasoned decision in writing, the CJEU handed down its judgment in *Teva UK v. Gilead Sciences* (C-121/17) on 25 July 2018, relating to the parallel Truvada SPC in the United Kingdom and addressing essentially the same substantive issues. Practitioners have since been waiting in suspense to see how exactly the Federal Patent Court, in knowledge of this later-issued CJEU ruling, would justify the revocation of

Gilead's German Truvada SPC.

The German Federal Patent Court's written judgment in *Truvada* (4 Ni 12/17) of 15 May 2018 has now finally been published.

In this judgment, the Federal Patent Court found that the combination of tenofovir disoproxil with emtricitabine was not "protected" by the basic patent within the meaning of Article 3(a) of the SPC Regulation because the active ingredient emtricitabine was not "sufficiently concretized" as part of the subject-matter of the invention claimed in the basic patent.

In effect, a generic functional term recited in the claims of the basic patent can, by itself, sufficiently concretize a specific active ingredient only if the latter's specific medicinal effects are already reflected by the functional term. Conversely, if the generic functional term also encompasses other types of active ingredients having different modes of action, it cannot relate "implicitly but necessarily and specifically" to the specific active ingredient at issue. The Court did not consider these criteria to be met in the case at hand, given that the basic patent underlying Gilead's SPC merely referred to "other therapeutic ingredients" and failed to provide any more specific disclosure pointing to emtricitabine.

It is also noteworthy that the Federal Patent Court expressly rejected the necessity to assess any other criteria in the context of Article 3(a), particularly any assessment whether the combination of active ingredients in question has "inventive quality". According to the Court, the requirement of Article 3(a) of the SPC Regulation does not leave any room for an assessment of inventive step (or the "core inventive advance") of the basic patent. The Federal Patent Court thereby reaffirmed the position already taken in its earlier decisions *Hexavalenter Impfstoff* (14 W (pat) 10/16) of 23 January 2018 and

Sitagliptin III (14 W (pat) 12/17) of 17 October 2017 in this regard.

The Federal Patent Court in *Truvada* (4 Ni 12/17) further considered these conclusions to be fully in line with the CJEU's findings in *Teva UK v. Gilead Sciences* (C-121/17).

The judgment of the Federal Patent Court is open to appeal before the Federal Supreme Court. In view of the CJEU's rather discouraging evaluation of Gilead's basic patent, it remains to be seen whether Gilead will appeal this judgment and will give the German Federal Supreme Court an opportunity to further elucidate what is required for a product to be "protected" by a basic patent reciting a functional definition of an active ingredient.

***Dr. Alexa von Uexküll** and **Oswin Ridderbusch**, both partners at the IP-specialized law firm Vossius & Partner, are the editors of the new handbook "European SPCs Unravelled: A Practitioner's Guide to Supplementary Protection Certificates in Europe" published by Wolters Kluwer.*

This entry was posted on Monday, November 5th, 2018 at 9:24 am and is filed under Case Law, CJEU, Germany, SPC
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