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Was there really no reason for (any) SPC-referrals after Medeva? Some thoughts about Judge Meier-Beck's interpretation of the CJEU's case law

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In light of the *Teva/Gilead*-judgment handed down on 25 July 2018 by the CJEU (C-121/17) as well as the latest referral from the German Federal Patent Court dated 17 October 2017 in re *Sitagliptin III* (14 W (pat) 12/17), which is pending as C-650/17, Prof. Meier-Beck, the presiding Judge of the German Federal Supreme Court, summarized in a presentation given on 3 December 2018 for GRUR which issues regarding SPCs have actually been clarified and what questions still remain unanswered. Regarding the latter, according to Prof. Meier-Beck, one of the major unresolved issues is whether equivalents could be protected by SPCs.

The (translated) title of his presentation *"Teva/Gilead or: The product protected by a basic patent according to the SPC-regulation – any news from the CJEU?"* already gave a strong indication to the audience about his interpretation of the CJEU-judgments. To cut a long story short, he has not seen the need for the numerous referrals to the CJEU since *Medeva* (C-322/10) was handed down. Hence, unsurprisingly to him at least, there is not any news in sight. In fact, his view seems to be that the CJEU has already back then given a clear guidance on how to interpret Art 3 (a) of the SPC-regulation.

Before actually dealing with *Teva*, he walked the audience through *Medeva*, *Actavis v Sanofi* (C-443/12) as well as *Eli Lilly v HGS* (C-493/12) (both judgments issued on 12 December 2013). As set out by the title of his presentation, *Teva* (which was decided by the Grand Chamber of the CJEU) does not deviate from the previous case-law. Especially, the fact that *Teva* was handed down by the Grand Chamber makes him think that the court would like to make a final point on this issue. In this regard, his opinion is that the CJEU has given unambiguous guidance on the interpretation of Art 3 of the SPC-regulation. According to his understanding, the CJEU has always made it clear that the national patent law is decisive when it comes to assessing which product is protected by the basic patent in force. Nevertheless, he also concludes that the assessment by the CJEU is *not* of "patent law-nature" but rather "SPC-nature".

At first glance, one wonders how Prof. Meier-Beck arrives at this conception. For this, he refers to Art 1 (b) of the SPC-regulation defining the term "product" within the regulation. Accordingly, a "product" is "*the active ingredient or combination of active ingredients of a medicinal product*". In combination with the aim of the SPC-regulation as outlined by the CJEU in *Actavis v Sanofi*, namely *"to compensate for the delay to the marketing of what constitutes the core inventive advance that is the subject matter of the basic patent"*, the actual technical teaching of the patent is

decisive.

Having arrived at this understanding, he seems to propose a third view on how to interpret the CJEU-decisions. He disregards the so-called *"disclosure"*-test due to the fact that the basis for this interpretation (i.e. the court's reference to *"specified in the wording of the claims"*) is actually nothing more than a reference to the subject-matter of the patent claim. The so-called *"infringement"*-test which asks whether the active ingredient (or the combination thereof) is an infringement of the basic patent in force, is not sufficient in his view. Rather, he favours an interpretation asking whether the active ingredient or combination is protected by the basic patent. The difference between his view and the *"infringement"*-test is that it is not decisive whether there would be an infringement but actually, whether the active ingredient or combination falls under the (whole) *scope of protection.* Unlike the *"infringement"*-test, Prof. Meier-Beck's *"scope of protection"*-test would in fact include equivalents.

It remains to be seen whether his opinion on the inclusion of equivalents will be picked up by national courts and especially the CJEU. The referral in re *Sitagliptin III* would arguably be a good occasion for the CJEU to decide on this issue. Nevertheless, given the wording of the questions referred by the Federal Patent Court, it seems to be just as likely that we do have to wait for a further referral after all.

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