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SPCs for Combination Products – First Court Decision in Germany on the Interpretation of "Medeva"

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The German Federal Patent Court (FPC) has recently published its first decision (3 Ni 28/11 of 2 May 2012 “Ranibizumab”, GRUR 2013, 58) dealing with the interpretation of related CJEU Judgments “Medeva” (C-322/10) of 24 November 2011 and “University of Queensland” (C-630/10) of 25 November 2011.

The FPC decision was rendered in nullity proceedings concerning Supplementary Protection Certificate (SPC) DE 12 2010 000 026 for ranibizumab based on European patent EP 2 055 777 B1.

Specifically, the FPC had to determine whether the conditions of Art. 3(a) of Regulation (EC) No. 469/2009 for the creation of an SPC were met, since the product (ranibizumab), for which the SPC had been granted, was described neither in the claims nor in the description of the basic patent. Hence, Plaintiff had argued that Art. 3(a) of the Regulation is not satisfied because, contrary to the requirements set forth by the CJEU in Medeva and Queensland, the active ingredient is not specified or identified in the wording of the claims of the basic patent.

The FPC discusses in this decision possible German meanings of the terms “identified” and “specified” used by the CJEU in these judgements. These meanings range from “described” (beschrieben) to “concretely described” (genau beschrieben) and “singly named” (einzeln genannt). Despite the evident differences in the possible meanings of “identified” or “specified”, the court, in view of the factual circumstances of the nullity case, found it unnecessary to set forth in more detail how the rather vague terms “identified” or “specified”, which are moreover alien to patent law, could be interpreted and applied in the future SPC practice.

However, the FPC did not doubt that the current SPC practice in Germany needs to be changed in light of Medeva and Queensland. It clearly expressed that in view of these judgments of the CJEU, it is no longer appropriate to (solely) examine whether the product identified in the SPC application falls within the protective scope of the basic patents. In the view of the FPC, the infringement test, which had been utilized by the German Federal Court of Justice in examining the condition of Art. 3(a) of the Regulation, can thus no longer be relied upon.

Further, the FPC ruled that the requirement that an SPC can only be granted for active ingredients which are specified or identified in the wording of the claims of the basic patent, applies likewise to products of single active ingredients and combinations of active ingredients. In the decision, the FPC sets forth in more detail why it fails in light of Medeva and Queensland to see any reason to distinguish between SPCs for single and multiple active ingredients, respectively.

The FPC granted Plaintiff’s motion to invalidate the SPC for ranibizumab. Interestingly, as pointed out by the FPC, the outcome of the proceedings would have been the same under the old practice

because the basic patent did not confer protection to ranibizumab. The FPC took the stand that the production of ranibizumab was not concluded with the final process step of the method protected in the basic patent, i.e.

…producing in a recombinant system separate from filamentous bacteriophage particles a molecule with binding specifity for the target,…

but required an additional site-specific mutagenesis. Due to this additional process step, the FPC did not acknowledge that ranibizumab represents the product directly obtained by the protected process in the sense of Art. 64(2) EPC.

Although the FPC did not present any final conclusions as to the interpretation of “specified” or “identified”, the decision and several remarks made therein raise the concern that it could become difficult to obtain an SPC in Germany for a new active ingredient if the same is not singly named in the claims. This might for instance be the case for a generic chemical formula covering the same or claims using functional language as is frequently the case with inventions in the biotechnology area. Should the German case law further develop in this direction, it is more than questionable whether SPCs still fulfill their function of compensating the investment for innovative research.

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This entry was posted on Friday, February 1st, 2013 at 12:25 pm and is filed under Biologics, Scope of protection, SPC, Validity
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