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Medeva and the Limitation of Composition Claims

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In Medeva (C-322/10 of 24 November 2011) the Court of Justice of the European Union (CJEU) had ruled that a Supplementary Protection Certificate relating to a combination of active ingredients can only be granted in view of Art. 3(a) of the Regulation (EC) No. 469/2009, if the active ingredients are “specified” in the wording of the claims of the basic patent relied on. Otherwise, in the view of the CJEU, the necessary protection in the sense of Art. 3(a) of the Regulation does not exist. Since it remains fully unclear what the CJEU means with “specified”, a term alien to patent law, this question meanwhile has become the subject matter of two new referrals to the CJEU, i.e. C-443/12 and C-493/12.

The Medeva judgement has caused among the owners of SPCs for combination products the concern that the validity of their SPC could be endangered. This applies in particular to cases in which the claims of the basic patent include a composition claim of the type reading “composition comprising active X”, while the combination of X and Y, being the subject of the SPC, is only disclosed in the description. In order to make the granted claims fit for a very narrow interpretation of Medeva requiring the explicit naming of the two combination partners in the claims, some SPC owners have initiated limitation proceedings pursuant to Art. 105a EPC before the EPO, or national limitation proceedings.

The EPO has already published decisions on such limitation requests in which the competent Examining Division found the incorporation of the combination partner into the openly defined composition claim as satisfying the requirements of the EPC, including Art. 123(3) EPC, i.e. the prohibition to extend the protective scope after grant (see e.g. EP 1 761 529 B3 in the name of Novartis AG). This practice is in full accordance with earlier decisions of the EPO Boards of Appeal (e.g. T 502/98) rendered in opposition cases in respect of a similar factual scenario.

The German and the French patent offices have however rejected similar limitation requests for composition claims with the reasoning that the incorporation of a combination partner would lead to an extension of the protective scope, contrary to the national provision corresponding to Art. 123(3) EPC. In France, Syngenta Ltd., the owner of European patent EP 382 375 B1, had requested a limitation of the French part thereof in order to incorporate a list of further actives into fungicidal composition claim 8. INPI rejected this request as it considered the combination to be a different invention, thereby extending the protective scope. The Paris Appeal Court affirmed this decision while recently, on 19 March 2013, the French Supreme Court (Court de Cassation) decided to set aside the decision of the Paris Appeal Court and stated that the claim at issue should have been construed in light of the description in order to determine whether the subject matter of

the limited claim is disclosed therein.

Also, the German Patent and Trademark Office (GPTO) had rejected a limitation request aiming at the incorporation of a list of further active ingredients into an openly defined pharmaceutical composition claim. This request concerned DE 59 209 330 in the name of Dr. Karl Thomae GmbH serving as basic patent for an SPC protecting the combination of telmisartan and hydrochlorothiazide (HCTZ). The GPTO justified the rejection of the request with the lack of admissibility to the effect that the requested amendment would lead to a different subject matter, i.e. an "aliud". The GPTO considered that pharmaceutical compositions containing the combination of the single active already defined in the granted composition claim with a further active ingredient could not be inferred from the plain wording of the granted claim. Moreover, the GPTO was of the opinion that, owning to the Medeva decision of the CJEU, stricter examination criteria for national German limitation procedures are henceforth to be applied.

Upon the Applicant's appeal, the German Federal Patent Court has now reversed the decision of the GPTO in decision 15W (Pat) 25/12 of 31 July 2013. The Federal Patent Court acknowledged that the requested amendments correspond to the established official and decision-taking practice of the GPTO and Federal Patent Court in opposition, opposition appeal and nullity proceedings and concur as well with the practice of the EPO. Relying on a series of decisions rendered by the German Federal Court of Justice, among others, "Bodenwalze" (X ZB 18/88 of 30 October 1990), it held that a patent proprietor can limit its patent as long as the invention as defined in the granted claims is not replaced with another one ("aliud"). The incorporation of a feature from the description into a granted patent claim is admissible if the originally broader teaching is thereby limited to a narrower teaching and if it was evident that the incorporated feature is disclosed in the description as part of the claimed invention. All of these conditions as prerequisites for an admissible limitation were considered by the Federal Patent Court to be met by the amendment requested by Dr. Karl Thomae GmbH.

Specifically, the Court acknowledged that a teaching regarding the dosing of the combination partners, such as hydrochlorothiazide (HCTZ), in a combined formulation with the newly developed active ingredient (e.g. telmisartan) sufficiently supports the limitation, despite missing concrete formulation examples for this combination. The Federal Patent Court was also satisfied that the subject matter of the limited claim was comprised by the granted patent claim 8 owning to the expression "containing", which imparts an open character to this pharmaceutical composition claim. Contrary to the position taken by the GPTO, the Court also set forth why Medeva concerned a different legal question, namely the criteria for applying Art. 3(a) of the Regulation (EC) No. 469/2009 and can be ignored when assessing the admissibility of limitation requests.

The decision of the Federal Patent Court is to be welcomed, since it establishes harmony with a long-standing decision-taking practice of the EPO and clearly states that the conditions for granting SPCs in light of the CJEU's Medeva ruling and the limitation of pharmaceutical or agrochemical composition claims are completely different legal issues which do not influence each other.

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