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German Federal Patent Court – Sitagliptin: Another referral to the CJEU on Art. 3(a) SPC Regulation

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Adding to the long series of referrals concerning the interpretation of Art. 3(a) Reg. (EC) No. 469/2009 (“SPC Regulation”) (“the product is protected by a basic patent in force”) the UK Court of Appeal (*Sandoz/Searle*, Case No. A3 2017 1483) on 25 January 2018 referred further questions to the CJEU. This latest referral from the UK follows an earlier referral of the German Federal Patent Court of 17 October 2017, 14 W (pat) 12/17 – *Sitagliptin.*

Background to this earlier referral by the Federal Patent Court is that the German Patent Office had refused to grant an SPC for the dipeptidyl peptidase IV (“DP IV”)-inhibitor Sitagliptin. The referred basic patent concerned the use of “effectors” of DP IV activity for lowering the blood sugar level below the glucose concentration characteristic of hyperglycaemia in mammals. It defined the claimed substances functionally, wherein claim 2 claimed the group of active compounds of DP IV-inhibitors. Sitagliptin was not individualized as specific compound in the patent. The German Patent Office refused to grant an SPC based on this patent, because the product was not protected by the patent within the meaning of Art. 3(a) SPC Regulation. The applicant appealed this decision. The seized Federal Patent Court stayed the proceedings and referred the case to the CJEU seeking further clarification on the interpretation of the Art. 3(a) requirement.

To recall, the CJEU had ruled in C-322/10 – *Medeva* that Art. 3(a) SPC Regulation must be interpreted as precluding the granting of an SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent. Further, the CJEU had explained that in the absence of European Union harmonisation of patent law, the extent of patent protection can only be determined by the non-European Union rules governing patents, namely Art. 69 EPC and the corresponding national rules. In C-493/12 – *Eli Lilly and Company* the CJEU had stressed that the “infringement test” was not to be applied for determining whether a product is “protected by a basic patent in force”. Beyond this, the CJEU concretised that in principle a functional definition of an active ingredient in the patent claims can be sufficient for Art. 3(a) SPC Regulation on the condition however that it is possible to conclude on the basis of the claims, interpreted inter alia in the light of the description of the invention “that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question”.

These judgments gave little clear guidance about the relevant criteria for Art. 3(a) SPC Regulation. Diverging decisions across Europe were the consequence: the German Federal Patent Court for example had decided in German Federal Patent Court, Judgment of 2 May 2012 ? 3 Ni 28/11 –

Ranibizumab that it was pivotal for the Art. 3(a) SPC Regulation requirement "if the active substance for which the SPC was requested was named respectively identified in the patent claims". In the decision reported here, the Federal Patent Court required that the concerned active compound needed to be specified in the patent claims in such a way that "it is identifiable as such and accordingly factually provided to the skilled person". The British High Court of Justice [2017] EWHC 987 (Pat) – *Sandoz/Searle*, to give the other example leading to the latest referral from the UK Court of Appeal of 25 January 2018, understood from C-493/12 – *Eli Lilly and Company* that it was sufficient for the claim to specify the product by means of a Markush formula. But the better test would be to require that the product fell within the patent claims and that it embodied the inventive advance (or technical contribution) of the patent claims. After Arnold J had declined a referral to the CJEU, the Court of Appeal (*Sandoz/Searle*, Case No. A3 2017 1483) now stayed the proceedings and sought further clarification on the interpretation of Art. 3(a) SPC Regulation.

The applicant of the *Sitagliptin* case reported here referred to the "inventive advance test" practiced by the English High Court and reasoned that the refusal to grant an SPC for Sitagliptin was unlawful, because the German Patent Office had not considered sufficiently that the contribution and the core of the invention of the basic patent was the use of DP IV-inhibitors for the treatment of diabetes mellitus in general and not the use of a specific compound. Thus, Sitaglipin was an embodiment of the inventive concept of the basic patent. Thus, the functionally defined generic term of "DP IV-inhibitors" had to be considered sufficiently specific to relate "implicitly but necessarily and specifically" to Sitagliptin.

In order to avoid a further divergence of the practice in the member states the Federal Patent Court referred following questions to the CJEU:

1. Is a product only protected by a basic patent in force within the meaning of Art. 3(a) Reg. (EC) No. 469/2009 if it belongs to the subject-matter of protection defined by the patent claims and thus is provided to the skilled person as concrete embodiment?
2. Is it accordingly insufficient for the requirement of Art. 3(a) Reg. (EC) No. 469/2009 if the concerned product – though falling within the general functional definition of a class of active compounds contained in the patent claims – is, beyond this, not individualised as concrete embodiment of the teaching protected by the patent?
3. Is a product not protected by a basic patent in force within the meaning of Art. 3(a) Reg. (EC) No. 469/2009 if it falls within the functional definition contained in the patent claims, but has only been developed after the application date of the basic patent due to self-reliant inventive activity?

The efforts of the Federal Patent Court to clarify the interpretation of Art. 3(a) SPC Regulation by referring further questions to the CJEU must be welcomed due to the diverging practices across Europe and the uncertainties associated with this. However, the referred questions show how far the discussion has moved away from the actual text of the SPC Regulation. Art. 3(a) SPC-Regulation "the product is protected by a basic patent in force" does neither contain any indication that the product must be part of the subject-matter of the invention of the basic patent nor that it must make use of the core of the invention. Maybe the "infringement test" would still be the better suited solution to interpret Art. 3(a) SPC Regulation?

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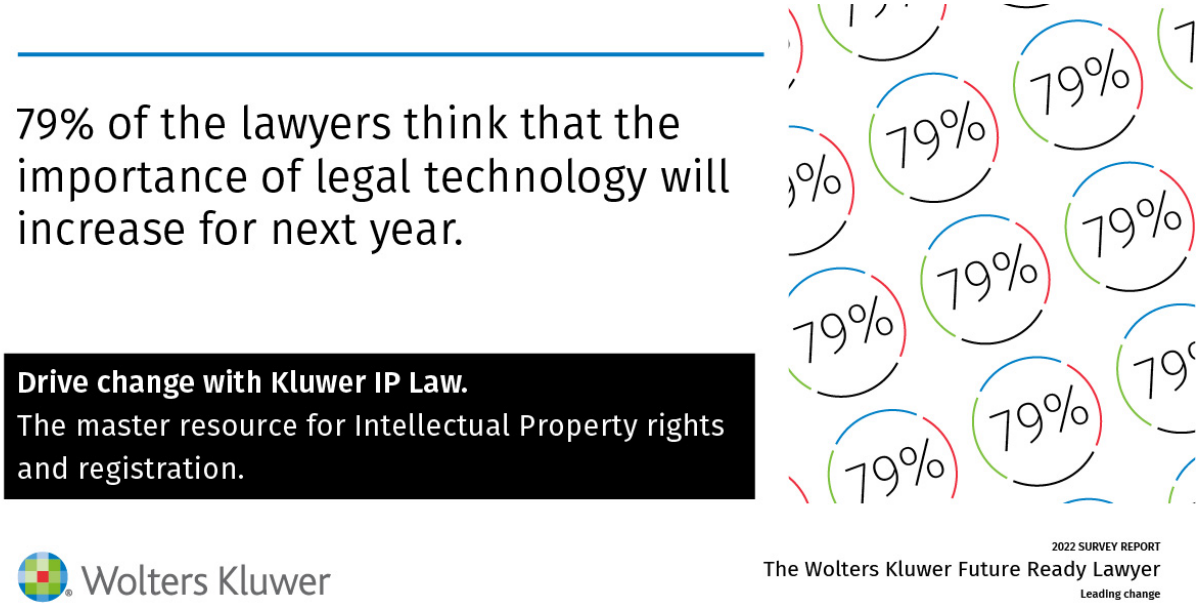

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