CARPMAELS & RANSFORD

The final chapter in C-650/17 *Royalty Pharma Collection Trust*

German court applies the CJEU's new guidance to refuse the sitagliptin SPC

The CJEU arguably left little doubt as to the likely final verdict on Royalty Pharma's SPC application for sitagliptin when it delivered its preliminary ruling of 30th April 2020 in Case C-650/17 *Royalty Pharma Collection Trust*, reported in our earlier note here. That final verdict was recently delivered by the German Federal Patent Court (Bundespatentgericht), the referring court in this case, which rejected Royalty Pharma's appeal.

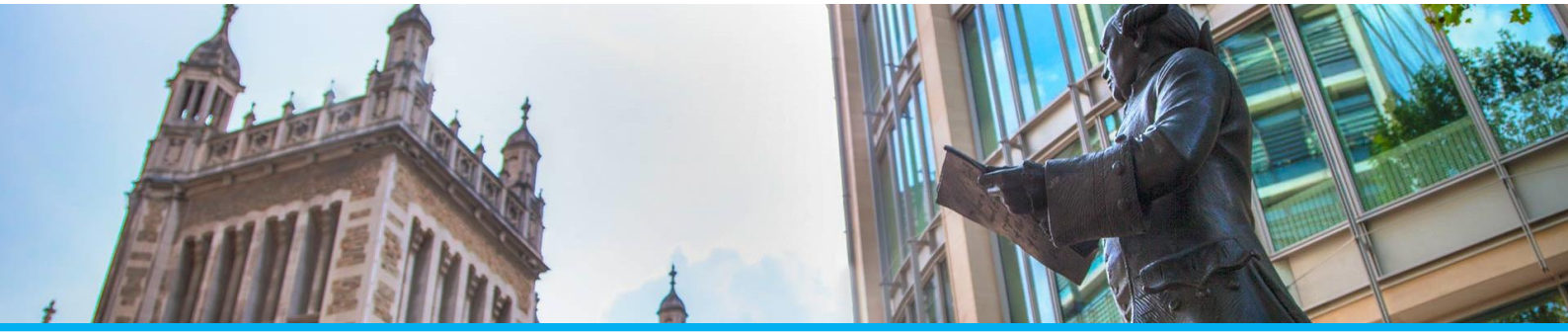
Two aspects of the Federal Patent Court's decision are discussed below: first, the Court's interpretation of the requirement for a product to be "specifically identifiable" as stated in point 1 of *Royalty Pharma*; and second, the Court's view on the significance and meaning of point 2 of *Royalty Pharma*, where the CJEU referred to an "independent inventive step". The Federal Patent Court's reasoning might offer a glimpse of how other patent offices and courts could interpret and apply the CJEU's decision in *Royalty Pharma*.

Background

SPCs are a European mechanism for patentees to regain patent term lost due to delays in authorising pharmaceuticals.

The recent Case C-650/17 *Royalty Pharma* aimed to provide more clarity regarding the rules under Article 3(a), which concern what level of disclosure for the active(s) is required in order for a patent to be eligible for an SPC. To recap, at paragraph 40 of *Royalty Pharma* the CJEU said that in order to determine whether sitagliptin is "specifically identifiable" in the basic patent (i.e. whether sitagliptin fulfils the second condition of the Article 3(a) test as developed in Case C-121/17 *Teva*, paragraph 52), it is "for the referring court to ascertain whether the subject matter of the SPC concerned is within the limits of what a person skilled in the art is objectively able, at the filing date or priority date of the basic patent, to infer directly and unequivocally from the specification of that patent as filed, based on that person's general knowledge in the relevant field at the filing date or priority date, and in the light of the prior art at the filing date or priority date". So far so good, perhaps.

However, things certainly took a turn for the worse for Royalty Pharma when the CJEU stated in paragraph 49 that "a product which was developed after the filing date or priority date of the basic patent, following an independent inventive step" cannot be "specifically identifiable" in the basic patent and therefore must fail Article 3(a).



This statement was significant given that it had apparently been conceded by Royalty Pharma that sitagliptin indeed "was developed by a licensee of the basic patent at issue in the main proceedings after the date on which the application for that patent was filed. That licensee obtained a new patent covering sitagliptin, which served as the basic patent for the grant of an SPC" (see paragraph 12 of C-650/17)[1]. The CJEU did not elaborate what it meant by "independent inventive step", or exactly when a product is deemed "developed". Nevertheless, the facts of that case suggested that it would be difficult for Royalty Pharma to subsequently convince the referring court that sitagliptin had not been "developed after the filing date or priority date of the basic patent, following an independent inventive step".

Following the CJEU's preliminary ruling, the case returned to the Federal Patent Court. It was now that court's task to apply the CJEU's guidance to the facts of the case and issue a decision in the matter. . In a decision dated 2nd September 2020 (BPatG 14 W (pat) 12/17), the Federal Patent Court rejected Royalty Pharma's appeal against the refusal of its SPC application, thereby denying Royalty Pharma any SPC protection for sitagliptin. Two interesting aspects of the court's reasoning are discussed below.

(1) The Court suggested that the skilled person has to be able to "specifically identify" the product without any fictitious knowledge of the product's identity

Royalty Pharma argued that the skilled person would have been able to ascertain that sitagliptin is a compound in accordance with the functional definition in the claims of the basic patent, had they been provided with sitagliptin at the priority date of the basic patent. The methods necessary for such a determination were known to the skilled person from the patent and the prior art at the priority date.

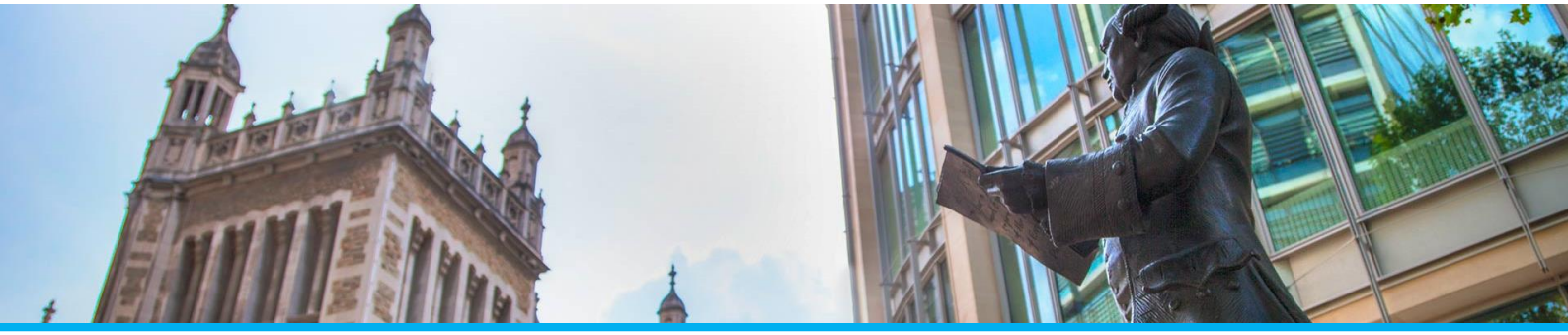
Sitagliptin was therefore "specifically identifiable" by the skilled person, thereby fulfilling the CJEU's test as summarised in point 1 of the operative part of *Royalty Pharma*. It therefore seems that, according to Royalty Pharma, the question to be answered was not whether the skilled person was able to provide sitagliptin at the priority date in light of the teaching in the patent and the prior art, but whether the skilled person was able to identify the compound as a member of the functional class of compounds defined in the patent's claims.

In this context, Royalty Pharma also referred to an earlier decision by the German Federal Court of Justice (Bundesgerichtshof, Germany's highest court of civil and criminal jurisdiction), BGH X ZB 8/12[2]. That decision related to the priority application of the basic patent that supported Royalty Pharma's SPC application, and concerned the requirement of sufficiency under German patent law. The Federal Court of Justice stated in that decision that the requirement of sufficiency can still be fulfilled if a functional definition encompasses not only compounds that were already known or are disclosed in the patent specification, but also compounds that will be made available in the future, even if that required inventive activity. Royalty Pharma's position seems to have been that a finding that sitagliptin was not specifically identifiable in the patent by the skilled person at the priority date would be inconsistent with the Federal Court of Justice's findings and principles of interpretation developed in its earlier decision[3].

[1] The licensee's SPC, which was based on a patent filed five years after Royalty Pharma's basic patent, was itself the subject of a referral to the CJEU, concerning the interpretation of Article 13 of the SPC Regulation, see Case C-125/10 *Merck Sharp & Dohme Corp.*

[2] An English translation is available here: http://patentblog.kluweriplaw.com/wp-content/uploads/sites/52/2013/12/Translation-of-BGH-X-ZB-8-12.pdf

[3] Based on our review, the Federal Court of Justice's decision did not discuss whether sitagliptin specifically was enabled by the disclosure in the priority application. We are also aware that the Federal Court of Justice's views were not shared by the EPO in T 544/12, which at point 4.9.3 expressly disagreed with the reasoning in BGH X ZB 8/12 and instead stated that "in order for a functional definition of a group of substances in a claim to meet the requirements of Article 83 EPC, the substances falling under this functional definition must all be available to the skilled person. ...This legal principle means that the patent monopoly is not extended to subject-matter which, after reading the patent specification, would not be at the disposal of the skilled person, eg since an inventive step would still be required."



In response, the Federal Patent Court acknowledged that the use of sitagliptin fell within the scope of the claims of the basic patent. Nonetheless sitagliptin was not individualised in the basic patent. Thus for the assessment of Article 3(a) it was still necessary to consider whether the skilled person was able to "specifically identify" sitagliptin in light of the teaching of the basic patent, the common general knowledge and the prior art at the priority or filing date of the basic patent. That criterion could not be fulfilled by fictitiously providing the product to the skilled person and asking whether the skilled person is able to ascertain whether the product meets the functional definition of the claims. Such an approach was said to merely consider whether the product falls within the scope of the claims, but not whether the product is specifically identifiable. Thus the Federal Patent Court concluded that sitagliptin was not "specifically identifiable" in the basic patent, and so the SPC application failed to meet Article 3(a).

(2) The meaning of "independent" in "independent inventive step"

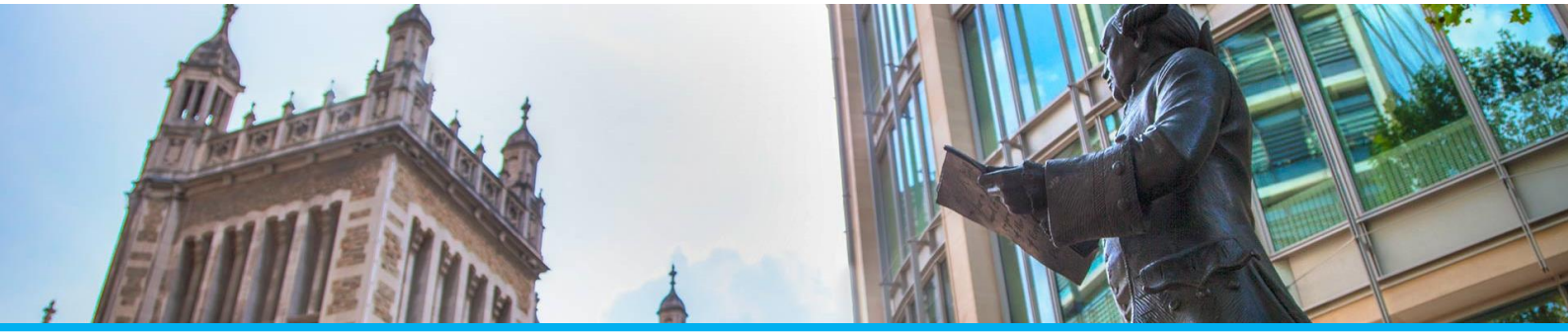
Despite this finding, the Federal Patent Court continued to consider the applicability of the CJEU's second point of the operative part of *Royalty Pharma*. Royalty Pharma contended that its SPC application did not fall within the exclusion from SPC protection as formulated by the CJEU in the second point of *Royalty Pharma*, i.e. sitagliptin had not been "developed after the filing date or priority date of the basic patent, following an independent inventive step". In particular, Royalty Pharma attempted to make that distinction on the basis that sitagliptin had not been developed following an "independent" inventive step.

According to Royalty Pharma, its licensee had developed sitagliptin with knowledge of the invention disclosed in Royalty Pharma's basic patent. The licensee had consciously, and not merely accidentally, made use of Royalty Pharma's invention in the development of sitagliptin.

The licensee's own later-filed patent relating to sitagliptin might well have involved an inventive step over Royalty Pharma's basic patent, said Royalty Pharma, but that was not an "independent" inventive step – as the licensee's invention of sitagliptin had not been made independently of the teaching in Royalty Pharma's basic patent.

Royalty Pharma asserted therefore that its SPC application to sitagliptin fulfilled the CJEU's criterion that the product must not have been "developed after the filing date or priority date of the basic patent, following an independent inventive step". Sitagliptin had been developed following a dependent inventive step – it was dependent on the general teaching in Royalty Pharma's basic patent of the functional class of compounds of which sitagliptin was an example. According to Royalty Pharma, the CJEU merely wanted to preclude the issuance of SPCs based on patents which had not contributed at all or had contributed only accidentally to the subsequent development of the authorised product.

This did not convince the Federal Patent Court. The Court took the view that all pharmaceutical research was to some degree based on previous research, suggesting that there are no such scenarios as described by Royalty Pharma, where a patent covers a product but the teaching in the patent did not at all or only accidentally contribute to the development of the product. The aim of the SPC Regulation however was to reward not all research but only that research which resulted in the first placing on the market of a product as medicinal product. In point 2 of *Royalty Pharma*, the CJEU illustrated in an exemplary scenario the application of the test under Article 3(a): if the product was developed after the priority or filing date of the basic patent following an inventive step by a party other than the SPC applicant (i.e. "independent"), then the skilled person could not specifically identify the product in the basic patent. Furthermore, in the present case, the licensee had obtained a composition of matter patent for the later development of sitagliptin. According to the Federal Patent Court, this would not have been possible if sitagliptin had already been identifiably disclosed in Royalty Pharma's basic patent.



The Federal Patent Court therefore rejected Royalty Pharma's submission that sitagliptin had not been developed after the filing date or priority date of the basic patent following an independent inventive step. The court furthermore considered that outcome consistent with the aims of the SPC Regulation, emphasising that it would be contrary to the aims of the SPC Regulation to take into account the results of research obtained after the priority or filing date of a basic patent.

Comment

We understand that no appeal against the judgment from the Federal Patent Court is pending, thus the rejection of Royalty Pharma's SPC application to sitagliptin has become final.

While the outcome itself is arguably unsurprising following the CJEU's comments in *Royalty Pharma*, it is interesting to see the Federal Patent Court's reasoning, in particular its interpretation of point 2 of *Royalty Pharma*. For example, one might speculate what the Federal Patent Court's answer would have been had the licensee's later patent to sitagliptin instead belonged to Royalty Pharma – would Article 3(a) be fulfilled because no "independent" inventive step was involved? The Federal Patent Court's reasoning suggests that its view on Article 3(a) would not have changed. For instance, the Federal Patent Court emphasised that the results of research obtained after the priority or filing date of the basic patent must not be taken into account in the assessment of Article 3(a), or else there is a risk that the aims of the SPC Regulation are contravened. The Federal Patent Court did not expressly limit that statement to the results of research provided by a third party. Furthermore, the Federal Patent Court took the view that point 2 of *Royalty Pharma* did not constitute a further "test" under Article 3(a), but merely described one exemplary scenario in which a product is not "specifically identified". Thus one might say that if the facts of a case are outside of that one exemplary scenario, then it does not necessarily follow that the requirements of Article 3(a) are met.

It remains to be seen how other patent offices and courts will apply the CJEU's guidance in *Royalty Pharma*, in particular to cases involving facts that significantly differ from those in *Royalty Pharma*.

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