

CJEU REFUSES UK HC'S REQUEST FOR PRELIMINARY RULING ON SPC APPLICATIONS BASED ON THIRD-PARTY MAS, ON ACCOUNT OF REFERRED QUESTION BEING "HYPOTHETICAL" (C-239/19 ELI LILLY V GENENTECH)

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Legal Briefings - By **Sebastian Moore, Martina Maffei and Priyanka Madan**

On 5 September 2019, the Ninth Chamber of the CJEU refused a request for referral in relation to the interpretation of Article 3(b) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products ('**SPC Regulation**').

BUSINESS IMPACT

In its order, the CJEU held that this request for a preliminary ruling was manifestly inadmissible under Article 52(3) of the Rules of Procedure of the Court of Justice, as the question referred was hypothetical for the purposes of the dispute in the main proceedings.

The referral request was made by High Court of Justice (England and Wales) in proceedings [2019] EWHC 388 (Pat) between Eli Lilly and Genentech. The referral was concerned with whether the SPC regulation should preclude SPC applications based on third-party marketing authorisations ('**MAs**'), which is where a patent holder seeks to obtain an SPC for a product without the consent of the unrelated third party that has developed that product and obtained the necessary a MA for it.

This issue is not a new one, and was previously referred to in *Eli Lilly v HGS* (C-493/12). Although it was not being pursued as a standalone ground, the CJEU decision observed in this case that if an SPC were granted to the patent holder, even though he was not the holder of the MA granted for the medicinal product developed from the specifications of the patent, and had therefore not made any investment in research relating to that aspect of his original invention, that would undermine the objective of the SPC Regulation. In a similar vein, in *Gilead v Teva* (C-121/17; a case that did not concern grant of SPCs based on third-party MAs) the CJEU held in paragraph 50 of its decision that when applying Article 3(a) of the SPC Regulation no account should be taken of research which took place after the filing date or priority date of the basic patent, as this would enable the SPC holder to unduly to enjoy protection for those unknown results.

The refusal of the reference means that disappointingly, the rather important question of SPC applications based on third-party MAs remains unanswered. Nevertheless, it is likely that there will be a further reference on this issue in the future, perhaps from one of the other national courts where the dispute between Eli Lilly and Genentech remains live, or from the Court of Appeal in the UK (should this happen before Brexit).

BACKGROUND

The referral request was made by the UK High Court in proceedings which related to Genentech's patent EP (UK) 1 641 822, entitled '*IL 17A/F heterologous peptides and therapeutic uses thereof*' (the '**Basic Patent**') and Eli Lilly's MA for their product 'ixekizumab' marketed under the brand name 'Taltz'.

Genentech contended that the formulation for ixekizumab fell within the scope of the Basic Patent, and applied for an SPC on the basis of the Basic Patent and Eli Lilly's MA for ixekizumab.

Eli Lilly in turn contended that two grounds precluded the grant of the SPC: 1) the SPC application at issue did not comply with Article 3(a) of the SPC regulation, since the formulation for ixekizumab was not protected by the Basic Patent; and 2) the application did not comply with either Article 2 or Article 3(b) and (d) of the SPC Regulation, because the MA for ixekizumab is not a relevant MA, since it is owned by a third party and was relied upon without that party's consent.

By the time the referring decision was handed down, the Basic Patent had already been held to be invalid in parallel proceedings. Nevertheless, Mr Justice Arnold considered it necessary to make a referral to the CJEU on whether the SPC Regulation should preclude SPC applications based on third-party MAs. Various factors played a role in making the referral:

1. Even though the Basic Patent had been held to be invalid in parallel proceedings, it may be maintained on appeal;

2. Because of Brexit, it is highly probable that the Court of Appeal will cease to have jurisdiction to refer a question for a preliminary ruling to the Court of Justice, so it was considered necessary that the High Court refer such a question now;
3. As of the date of the reference decision, Eli Lilly and Genentech were in dispute on this issue not only in the United Kingdom but also in other Member States;
4. This issue had arisen in other previous cases.

Keeping the above in mind, Mr Justice Arnold referred the following question to the CJEU:

Does [the SPC Regulation] preclude the grant of an SPC to the proprietor of a basic patent in respect of a product which is the subject of a marketing authorisation held by a third party without that party's consent?

ANALYSIS

The CJEU's order clarifies that the role of the CJEU is to aid with interpretation of such EU law as is necessary for national courts to give judgment in cases upon which they are called to adjudicate. A reference for a preliminary ruling made by a national court is to be rejected where it is obvious that the interpretation of EU law that is sought is unrelated to the actual facts of the main action or its object, or where the problem is hypothetical.

In considering whether the clarification or interpretation of EU law sought in the referral is necessary, the CJEU held that it is not sufficient to say that there may be an appeal down the line which may render the hypothetical scenario true. Neither is it of relevance that the same issue exists in proceedings in other jurisdictions, or may have been raised in previous proceedings - the existence of disputes in other Member States of the European Union or of previous disputes does not support the conclusion that the interpretation of EU law that is sought is necessary for the resolution of the dispute which the referring court is called upon to resolve.

The CJEU also clarified that the referring court could not pre-emptively request a reference pending Brexit, on the basis that the appeal court might subsequently lose its jurisdiction to refer the same question because of withdrawal from the European Union pursuant to Article 50 of the TFEU, and while EU law continues in full force in the UK.

CONCLUSION

Although the refusal of the CJEU to decide on the referral is disappointing, it is hoped that the question of SPC applications based on third-party MAs will not remain unanswered much longer, and that there will be a decision that clarifies this issue in the foreseeable future. Meanwhile, the CJEU's order sheds light on some important issues like the CJEU's approach to references in light of Brexit, which will no doubt inform litigation strategy in the coming months.

KEY CONTACTS

If you have any questions, or would like to know how this might affect your business, phone, or email these key contacts.



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