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CJEU declines to assess unfriendly SPCs based on third-party MAs in Eli Lilly v. Genentech (C-239/19)

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One of the features that render the European Union's Supplementary Protection Certificate (SPC) unique in comparison to similar legal instruments in other jurisdictions, including the United States and Japan, is that there is no legal provision expressly calling for any specific relationship or agreement between the patent proprietor (and SPC applicant) on the one hand, and the holder of the marketing authorization relied upon for the SPC filing on the other hand. In line with this, and following the CJEU's judgment in *Biogen* (C-181/95), it has become common practice that SPCs are granted to patent proprietors who rely on a marketing authorization held by a third party, including even a competitor, without the consent of that third party. Yet, the validity of this practice has stirred controversy for more than 20 years, which has never been fully resolved.

It was therefore welcomed by many practitioners that the CJEU was called upon by the UK Patents Court under Mr. Justice Arnold to answer precisely this question, i.e. whether the SPC Regulation precludes the grant of an SPC to the proprietor of a basic patent on the basis of a marketing authorization held by a third party without that party's consent.

In the referring decision [2019] EWHC 388 (Pat), which was previously discussed on this blog by Brian Cordery and Laura Reynolds, Arnold J held that an SPC could not validly issue in the case at hand because the basic patent was found to be invalid in a parallel first-instance decision. Quite unusually, he nevertheless considered it appropriate to refer the above question to the CJEU, as the basic patent could still be maintained on appeal and the looming Brexit could subsequently prevent the UK Court of Appeal from making a corresponding referral.

The referral, but unfortunately not the referred question, has now been answered by the CJEU with its order in *Eli Lilly v. Genentech* (C-239/19) of 5 September 2019.

In this decision, the CJEU found that the referral made by the UK Patents Court was manifestly inadmissible, as the referred question was purely hypothetical for the purposes of the underlying dispute. Specifically, the CJEU held that the justification provided by Arnold J for the referral was based on the hypothetical premises that an appeal will be filed against the decision of the UK Patents Court declaring the basic patent to be invalid, that the UK Court of Appeal will overturn that decision, that the latter will find it necessary to refer a question to the CJEU for a preliminary ruling, and that the Court of Appeal will at that time have lost its jurisdiction to make a corresponding referral due to Brexit. This would not justify the preemptive referral of a question which might eventually become relevant for the UK Court of Appeal, i.e. a court different from the

referring court.

While this result is not entirely unexpected, it is deeply disappointing that the fundamental question whether or not the consent of the holder of a marketing authorization is required for the filing of an SPC remains unresolved. Yet, chances are that this same question could be referred to the CJEU again in the near future, possibly in contentious proceedings between the same parties in another EU member state or in the context of a different case with similar factual circumstances, of which there are more than a few.

Dr. Alexa von Uexküll and **Oswin Ridderbusch**, both partners at the IP-specialized law firm Vossius & Partner, are the editors of the handbook **European SPCs Unravelled: A Practitioner's Guide to Supplementary Protection Certificates in Europe** published by Wolters Kluwer in 2018. See here for a review by Judge Jürgen Schell (in German) and a review by Miquel Montañá (in English).

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