Appeal court confirms revocation of Spanish SPC for Truvada

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Introduction

During the current state of alarm, on 23 April 2020 the Barcelona Court of Appeal issued a judgment confirming the invalidity of Gilead's supplementary protection certificate (SPC) for the combination of tenofovir disoproxil + emtricitabine, thus upholding a first-instance decision favourable to generic competitors Teva and Mylan.

The matter has been broadly followed in Europe, where the UK Patents Court referred a question to the Court of Justice of the European Union (CJEU), which issued a judgment on the interpretation of the requirement under Article 3(a) of the EU SPC Regulation (469/2009).

Background

Gilead was the proprietor of European Patent EP0915894 (EP'894), entitled "Nucleoside analogues", and held a Spanish SPC based on the same over the combination drug product tenofovir disoproxil + emtricitabine, which it commercialises under the brand Truvada for the treatment of HIV.

The SPC was granted on the basis of Claim 27 of EP'894, despite the fact that emtricitabine was not mentioned in the same nor anywhere throughout the patent specification. Claim 27 read as follows: "A pharmaceutical composition comprising a compound according to any one of claims 1-25 together with a pharmaceutically acceptable carrier and optionally other therapeutic ingredients."

Gilead has been litigating over the infringement and validity of its SPCs derived from patent EP'894 in several countries. As mentioned above, following a referral from the UK Patents Court, the CJEU issued a judgment on 25 July 2018 (C-121/17) establishing a double-step test for national courts to determine whether a product is protected by the basic patent as required by Article 3(a) of the EU SPC Regulation in situations where such product is not expressly mentioned in the patent claims.

At present, the Truvada SPCs have already been revoked in many jurisdictions, including Belgium, Finland, France, Germany, Ireland, Italy, Portugal and the United Kingdom. Gilead's appeals are still pending in some cases.

Dispute

In May and June 2017, Gilead filed actions against Teva and Mylan, together with preliminary injunction requests, for alleged imminent infringement of its Spanish SPC.

The preliminary injunctions were initially granted *ex parte*, but subsequently revoked on the grounds that the SPC seemed *prima facie* invalid for being contrary to Article 3(a) of the EU SPC Regulation and the applicable CJEU case law. The Barcelona Court of Appeal further confirmed such decision on 18 December 2018, following the July 2018 CJEU judgment on the matter.

In the main proceedings on the merits, the defendants Teva and Mylan argued that the basic patent would protect tenofovir disoproxil, but not its combination with emtricitabine, considering Claim 27 would have exactly the same scope with or without the wording "and optionally other therapeutic ingredients". On the other hand, Gilead argued that the combination was an independent product comprised within Claim 27. Further, Gilead claimed that the skilled addressee would understand that the invention was mainly focused on the treatment of HIV, and this would lead to identify emtricitabine as one of only a few "other therapeutic ingredients".

After the trial, which took place in January 2019, Barcelona Commercial Court No 4 concluded that the SPC was invalid. While applying the CJEU's double-step test, the judge stated that the basic patent was not directed exclusively or mainly to the treatment of HIV, but to viral infections in a broader sense. Hence the expression "other therapeutic ingredients" would not necessarily encompass emtricitabine. As regards to the second step, it was noted that emtricitabine was subject to preliminary stages of development at the time of the priority date of the patent (July 1996). Therefore, such active ingredient could not be specifically identified by a skilled person in view of the information disclosed by the patent.

Gilead appealed the decision. A second-instance hearing before the Barcelona Court of Appeal took place in February 2020.

Decision

By means of its judgment of 23 April 2020, the Barcelona Court of Appeal has confirmed that Gilead's SPC does not meet the requirement of Article 3(a) of EU SPC Regulation since the combination of tenofovir disoproxil + emtricitabine is not protected by the basic patent in the sense of said provision.

The judgment first clarified that the technical problem addressed by EP'894 was in fact to provide prodrugs of compounds from the prior art (eg, tenofovir) in order to enhance their poor oral bioavailability. It also reiterated that the patent is directed to the treatment of viral infections in general, and not exclusively or mainly to the treatment of HIV in particular. Thus, it set out that the expression "optionally" in Claim 27 would never lead a skilled person to understand that it necessarily entails the combination of two active ingredients. Further, the judgment recalled that the efficacy of emtricitabine for the treatment of HIV had not yet been tested in humans at the priority date of the patent, as emtricitabine was only in its early stages of development at that time.

All in all, the court confirmed that the first step of the CJEU's test had not been met, which

rendered Gilead's SPC null and void under Article 15.1(a), in relation to Article 3(a), of the EU SPC Regulation, without it being necessary to further analyse the second step of the CJEU's test.

Gilead could still try to file a further extraordinary appeal to the Spanish Supreme Court.

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