ES- GILEAD v. MYLAN & TEVA

Gilead Biopharmaceutics Ireland UC, Gilead Sciences, S.L.U., Gilead Sciences Ireland UC & Gilead Sciences, INC. v. Mylan S.A.S., Mylan Pharmaceuticals S.L. & Teva Pharma, S.L.U., Appeals Court of Barcelona, Section 15, 12 December 2018, Docket 121/2018.

The Court of Appeals of Barcelona ruled in a preliminary injunction case on the requirements for an SPC, in relation to the basic patent, to be considered valid in light of Article 3 of Regulation (EC) No. 469/2009, as well as the decision of the Court of Justice of the European Union on case C-121/17. In addition, the main point of this decision concerned the competence of the civil jurisdiction to assess the validity of an SPC that had been previously evaluated by the contentious-administrative jurisdiction courts.

This decision was issued by the Court of Appeals of Barcelona within the framework of a preliminary injunction case based on the infringement of SPC No. C200500034 (SPC'034), with base patent ES 2.198.003 (ES'003), the Spanish validation of patent EP 0.915.894 (EP'894). SPC'034 protects a medicine comprising emtricitabine + tenofovir disoproxil (TD). The patent expired on 25 July 2017, thus SPC'034 entered into force on 26 July 2017. SPC'034 was based on claim 27 of patent ES'003 which reads 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 Biopharmaceutics Ireland UC, Gilead Sciences, S.L.U., Gilead Sciences Ireland UC & Gilead Sciences, INC. (hereinafter and jointly, "GILEAD") filed an *ex parte* preliminary injunction request against Mylan S.A.S. & Mylan Pharmaceuticals S.L. (hereinafter and jointly, "MYLAN") and Teva Pharma, S.L.U. (hereinafter, "TEVA") for the infringement of SPC'034. The preliminary injunction request sought to obtain an order prohibiting the defendants from marketing the drugs TD Teva and Emtricitabine/TD Teva and Emtricitabine/TD Mylan. Initially, the First Instance Court granted the *ex parte* preliminary injunction.

The defendants opposed the measures alleging that SPC'034 infringed Art. 3.a) of Regulation No. 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, since the basic patent did not protect a combination of emtricitabine + tenofovir disoproxil, but only tenofovir. Secondly, they considered that SPC'034 infringed Art. 3.c) of the aforementioned

Regulation. The First Instance Court issued a decision upholding the opposition[1]. The Order lifting the preliminary injunction provisionally considered that SPC'034 was null based on Art. 3.a) of the Regulation. GILEAD filed an appeal giving rise to the decision analyzed in this article.

The most relevant aspect of this decision is the argument raised by the appellant GILEAD in relation to the competence of the civil courts to hear and examine the validity of an SPC, when it had previously been subjected to review by the contentious-administrative courts.

SPC'034 was initially denied by the Spanish Patent and Trademark Office (hereinafter, "SPTO"). This decision was appealed by the patentee before the contentious-administrative section of the Superior Court of Justice of Madrid, which finally revoked the SPTO's decision and granted SPC'034. GILEAD considered that the validity of SPC'034 should not be reviewed by the Court of Appeals based on the incompatibility between contentious-administrative and civil jurisdictions to determine the validity of SPCs.

The appellant GILEAD considered that the decision rendered in the previous contentious-administrative proceedings had already examined the same question discussed in this proceeding regarding the validity of SPC'034 and that the subject matter of both proceedings was the same. Therefore, GILEAD considered applicable Art. 103.5 of the Spanish Patents Act (hereinafter, "SPA"), which reads as follows: "*The invalidation of a patent may not be sought before the civil jurisdiction on the same nullity grounds as those that have already been the subject of a judgment on the merits rendered in contentious-administrative proceedings, on the same facts invoked as a ground of invalidity*". Based on Art. 103.5, GILEAD considered that the civil courts were not entitled to decide on the validity of SPC'034.

The Court of Appeals considered that even though Art. 103 SPA refers to patents, it is applicable to SPCs, but it also established that in order to consider that the decision of the Superior Court of Justice had *res judicata* effects, it would have been necessary for the current defendants to have been a party to the proceeding before the contentious-administrative jurisdiction, which was not the case. Thus, said decision did not stop the civil jurisdiction from hearing the case at stake.

Additionally, the Court of Appeals considered that it was not bound by the contentious-administrative court's decision but, under Article 4 of the Spanish Law of the Judicial Branch, the ECJ's decision was binding for the Appeals Court. Therefore, the Appeals Court

[1] First Instance decision previously commented here: http://eplaw.org/es-gilead-v-teva-mylan-tenofovir-emtricitabine-interim-injunction-opposition/

proceeded to analyze whether or not SPC'034 met the requirements set out in Article 3 a) of the Regulation.

The Court of Appeals proceeded to refer to the well-known decision issued by the Grand Chamber of the European Court of Justice (hereinafter, "ECJ") dated 25 July 2018, Case-121/17, in relation to the request for a preliminary ruling from the High Court of Justice of England & Wales, where the question posed was: '*What are the criteria for deciding whether "the product is protected by a basic patent in force" in Article 3(a) of Regulation No. 469/2009?*'[2].

Based on the conclusions established by the ECJ, the Court of Appeals assessed whether the combination of the active ingredients, emtricitabine + tenofovir disoproxil, must necessarily be included in the invention in light of the description and drawings of that patent. The Court of Appeals concluded that neither the claims nor the description mentioned emtricitabine and even if an expert were to pose such a combination as a hypothesis on the priority date, that mere probability would not be enough. Following the ECJ's decision, said combination could only be the subject of an SPC if the expert considered the combination as necessarily included in claim 27, a difficult conclusion considering that on the priority date (1996), emtricitabine was simply being tested and its results evaluated. It was in 2003, seven years later, when it was finally authorized by the health authorities.

Therefore, the Court of Appeals upheld the first-instance decision and maintained the dismissal of the preliminary injunction requested by GILEAD, in view of the high probability that the SPC would be declared invalid in the proceedings on the merits.

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[2] http://curia.europa.eu/juris/document/document.jsf?text=&docid=204388&pageIndex=0&doclang=en&mode=lst&dir=&occ=first&part=1&cid=2648642