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Ezetimibe and simvastatin combination SPC revoked by Barcelona Patent Court

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On 21 April 2021 Barcelona Commercial Court Number 5 declared the Spanish supplementary protection certificate (SPC) covering the combination of ezetimibe and simvastatin to be invalid.

Background

Merck Sharp & Dohme (MSD) holds SPC C200500011 (SPC'011) for the combination of ezetimibe and simvastatin, based on the basic patent EP0720599, entitled 'Hydroxy-substituted azetidinone compounds useful as hypocholesterolemic agents'. The SPC expired on 2 April 2019.

MSD also held SPC C200300018 (CCP'018) for ezetimibe, based on the same patent, which expired on 17 April 2018.

The basic patent was related to a family of compounds of Formula I, including ezetimibe, which was specifically protected under Claim 8. The patent also referred generally to the combination of the Formula I compounds with cholesterol biosynthesis inhibitor drugs, including simvastatin.

MSD commercialises Ezetrol (ezetimibe) and Inegy (ezetimibe and simvastatin) for the treatment of atherosclerosis and the reduction of cholesterol.

Facts

In March 2018 MSD filed actions against several generic companies, together with *ex parte* preliminary injunction requests, for alleged imminent infringement of its SPC'011 for the combination of ezetimibe and simvastatin.

The court refused to grant any preliminary injunction *ex parte* due to lack of extreme urgency that would justify its grant without hearing the defendants. A hearing was scheduled and, finally, by means of a decision issued on 12 September 2018, the court dismissed the preliminary injunction requests considering the *prima facie* invalidity of MSD's SPC based on Article 15.1(a) of the SPC Regulation, in relation to Articles 3(c) and 3(a) of the regulation and the applicable Court of Justice of the European Union (CJEU) case law.

In the main proceedings on the merits, MSD unsuccessfully attempted to challenge the jurisdiction of the commercial courts to judge the validity of an SPC on the grounds of Articles 15.1(a) and 3.

Regarding invalidity, the defendants argued that SPC'011 did not comply with the requirements of Article 3 and the applicable CJEU case law, for the following reasons:

- ezetimibe had already been protected by a previous SPC (SPC'018), based on the same patent and on a previous marketing authorisation, and therefore the grant of SPC'011 would be contrary to Article 3(c);
- the basic patent does not protect the combination of ezetimibe and simvastatin in the sense of Article 3(a); and
- one of the defendants also argued that the marketing authorisation for Ezetrol (ezetimibe), and not for Inegy (ezetimibe and simvastatin), was in fact the first relevant marketing authorisation, and therefore the SPC would also be contrary to Article 3(d).

MSD alleged that the defendants would be misinterpreting the CJEU case law concerning Article 3(c). In this regard, MSD tried to rely on the CJEU judgments in *Teva* (C-121/17) and *Royalty Pharma* (C-650/17), which in fact relate to the interpretation of Article 3(a). MSD also maintained that the combination of ezetimibe and simvastatin was expressly mentioned in the claims of the basic patent in the sense of Article 3(a), considering simvastatin was cited among a group of cholesterol biosynthesis inhibitors in Claim 17. Ultimately, MSD argued that the marketing authorisation for Inegy would be the first for the combination product in the sense of Article 3(d).

The trial took place on 12 and 13 April 2021.

Decision

In its decision of 21 April 2021, which was deliberated by the three Barcelona patent judges, the court upheld the defendants' arguments and declared SPC'011 for ezetimibe and simvastatin invalid, dismissing MSD's infringement action.

After reviewing all the relevant CJEU case law from *Medeva* (C-322/10) to *Royalty Pharma* (C-650/17), the judge concluded that SPC'011 is invalid for being contrary to Article 3(c) of the SPC Regulation, taking into account that MSD already benefited from a previous SPC for ezetimibe based on the same patent and a previous marketing authorisation.

The judge emphasised that the controversy and the facts of the case at stake are analogous to those in cases *Actavis I* (C-443/12, irbesartan and hydrochlorothiazide) and *Actavis II* (C-577/13, telmisartan and hydrochlorothiazide) previously examined by the CJEU, and so the doctrine of its decisions in those matters is binding and directly applicable.

Having found SPC'011 invalid under Article 3(c), the judge did not deem it necessary to analyse the rest of the invalidity grounds raised by the defendants.

MSD has appealed the judgment.

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