INTELLECTUAL PROPERTY - SPAIN

Preliminary injunction request dismissed due to *prima facie* invalidity of asserted SPC

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On 12 September 2018 Barcelona Commercial Court Number 5 dismissed a preliminary injunction request filed by Merck Sharp & Dohme (MSD) regarding the commercialisation of generic medicinal products comprising ezetimibe and simvastatin.

Background

MSD holds Supplementary Protection Certificate C200500011 (SPC'011) for the combination of ezetimibe and simvastatin. The basic patent for SPC'011 is European Patent 0720599 (EP'599), which is entitled "Hydroxy-substituted azetidinone compounds useful as hypocholesterolemic agents". The expiry date for SPC'011 is 2 April 2019.

In addition, MSD previously held SPC C200300018 (SPC'018), which was based on the same patent and protected ezetimibe as a single active ingredient. SPC'018 expired on 17 April 2018.

EP'599 concerns a family of compounds of Formula I, including ezetimibe, which is specifically protected under Claim 8. The patent also refers 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

On 27 February 2018 Barcelona Commercial Court Number 5 admitted a protective brief filed by several pharmaceutical companies. On 26 March 2018 MSD filed an infringement action, together with an *ex parte* preliminary injunction request, against those companies.

The court, by means of a 17 April 2018 decision, ordered the scheduling of a hearing, as it concluded that there were no proven circumstances of urgency that would justify the granting of preliminary injunctions without hearing the defendants.

In the hearing, which took place on 4 and 5 July 2018, the defendants opposed the preliminary injunction request, alleging the invalidity of SPC'011. They argued that SPC'011 was invalid according to Article 15.1(a) of the EU SPC for Medicinal Products Regulation (469/2009) – in relation to Article 3 and the applicable European Court of Justice (ECJ) case law – for the following reasons:

- Ezetimibe had already been protected by the previous SPC'018, which was based on the same patent and a previous marketing authorisation. Therefore, the granting of SPC'011 had contravened Article 3(c).
- The basic patent (EP'599) does not protect the combination of ezetimibe and simvastatin in the sense of Article 3(a).

MSD tried to refute these allegations, but also argued that in any event the validity of SPC'011 could not be questioned and that the court was therefore incompetent to judge its possible invalidity. In this regard, MSD argued that the granting of an SPC is a final administrative act which cannot be challenged before the civil or commercial courts.

Decision

The court upheld the defendants' arguments and rejected the preliminary injunction request in an order of 12 September 2018, which was deliberated by the three Barcelona patent judges.

In its decision, the court first clarified that the commercial courts are competent to judge the validity of SPCs, including whether they fulfil the requirements of Article 3 of the EU SPC Regulation in relation to Article 15.1(a).

Subsequently, after reviewing all of the relevant ECJ case law (from *Medeva* (C-322/10) to *Gilead* (C-121/17)), the court concluded that SPC'011 was *prima facie* invalid, taking into account the following matters:

- MSD had already benefited from a previous SPC for ezetimibe based on the same basic patent and a previous marketing authorisation. Therefore, SPC'011, which covers the combination of ezetimibe and simvastatin, contravenes Article 3(c) of the EU SPC Regulation.
- The core of the invention of EP'599 is the family of Formula I compounds, including ezetimibe, but not the specific combination of ezetimibe and simvastatin. In this regard, the court emphasised that the patent refers to no effect or advantage of such combination, which were actually investigated and discovered years after the priority date. Thus, the court concluded that the combination is not protected by EP'599 in the sense of Article 3(a) of the EU SPC Regulation.

MSD is likely to appeal this decision.

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