

The CNMC fines pharmaceutical company Merck Sharp and Dohme 39 million euros for abuse of a dominant position in the market for vaginal contraceptive rings

- In 2017, the company took unjustified legal action against its competitor Insud Pharma under the pretext of protecting its patent.
- With this strategy, it sought to delay the market entry of its competitor's • product.

Madrid, 25 October 2022.- The CNMC has fined the pharmaceutical company Merck Sharp and Dohme (MSD) 38,934,000 euros for abuse of a dominant position in the market for contraceptive vaginal rings (S/0026/19).

Background

The pharmaceutical company MSD enjoyed a monopoly from 2002 until 2018 as it held the patent protecting the contraceptive Nuvaring, the first vaginal ring in Spain¹.

A competing company Insud Pharma had developed an alternative vaginal ring to the one protected by MSD's patent, which was launched in June 2017 under the name Ornibel.

Unjustified legal actions

Among other actions, by invoking its patent rights and alleging reasons of urgency, MSD requested the Commercial Court No. 5 of Barcelona to carry out fact-finding proceedings and, subsequently, an ex parte interim injunction, i.e. without hearing Insud Pharma, to stop the manufacture and sale of the Ornibel ring in Spain.

The CNMC considers it proven that, both when requesting the fact-finding proceeding and the subsequent interim measures, MSD deployed a strategy of deception, by withholding relevant factual and technical information from the court.



¹Patent Law, Article 58 "Duration and calculation of effects". A patent shall last for a non-extendable period of twenty years from the filing date of the application and shall take effect from the day on which the notice of grant is published.



The lack of transparency in the information provided during this process was a determining factor in obtaining the injunction requested, which halted the marketing and sale of Ornibel between September and December 2017.

It is therefore considered to be established that the purpose of MSD's legal actions was not to enforce its patent rights, but was part of a plan to suppress competition from the new market entrant for as long as possible.

Insud Pharma was unable to resume production of Ornibel until December 2017, when the interim injunction was lifted by a court order following Insud Pharma's opposition.

As the only factory producing its rings was located in Spain, the halt in production affected distribution and sales in all the countries where the rings had started to be marketed. Consequently, MSD's conduct also affected competition in several EU countries.

This production stoppage led to the extension of MSD's dominant position, thereby disrupting the evolution of the market for vaginal rings which would have occurred had the normal competitive dynamics been maintained.

The CNMC considers that the lack of transparency of MSD's conduct is contrary to merit-based competition, as every dominant undertaking has a "special responsibility not to impede, through its conduct, the development of effective and undistorted competition in the common market".

Sanctions imposed

As a result, the CNMC has sanctioned MSD with 38,934,000 euros for a very serious infringement which constitutes an abuse of a dominant position and is punishable under Article 2 of the Spanish Competition Act (LDC) and Article 102 of the Treaty on the Functioning of the European Union (TFEU).

In addition to considering MSD's Spanish subsidiary as the perpetrator of the practices concerned, the CNMC has declared its parent company MSD Human Health Holding jointly and severally liable for the payment of the fine.

Report of the European Commission

This kind of practices have long been in the sights of the European authorities: in July 2009, the European Commission published its Pharmaceutical Sector Inquiry Report in which it analysed the reasons for delays in bringing generic drugs to the market.

The European Commission found that certain legal actions apparently aimed at protecting patents were part of strategies to expand the extent and duration of





the protection conferred by their patents, in order to block or hinder the entry of generic drugs into the market. At the time of this decision, the European Commission is pursuing proceedings for misuse of the patent system to circumvent competition.

The CNMC would like to point out that an administrative appeal may be lodged directly with the National High Court against these decisions within two months from the day following their notification.

