

# Barcelona patent court revokes preliminary injunction granted *ex parte* in NuvaRing case

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### Introduction

On December 12 2017 Barcelona Commercial Court Number 5 revoked a preliminary injunction which had been granted *ex parte* at the request of Merck Sharp & Dohme BV (MSD) against Laboratorios León Farma and Exeltis Healthcare for alleged patent infringement.

This case is notable, as the defendants' product – which is the first competitor of MSD's contraceptive vaginal ring, NuvaRing – is manufactured in Spain and sold in several European countries where other patent infringement proceedings are being prosecuted in parallel.

### Background

MSD is the holder of European Patent 0876815 (EP'815), entitled "Drug delivery system for two or more active substances". The patent expires on April 9 2018.

EP'815 covers a thermoplastic polymer vaginal ring comprising two active substances, etonogestrel and ethinylestradiol, in which the etonogestrel is dissolved above the saturation level in the ring's polymer core.

León Farma developed the first commercial contraceptive vaginal ring with a thermoplastic polyurethane core, which contains etonogestrel and ethinylestradiol as the active substances (the LF ring). Etonogestrel is dissolved in the LF ring's polyurethane core below the saturation level. The LF ring is manufactured by León Farma and marketed by Exeltis under the trademark ORNIBEL.

### Facts

On June 27 2017 MSD requested *ex parte* inspection proceedings in order to obtain evidence that the LF ring fell within the scope of EP'815. Specifically, MSD requested that the Spanish Drug Agency (AEMPS) be required to provide detailed technical information about the LF ring.

The court granted the inspection and appointed and instructed an expert to prepare a report on the possible infringement of EP'815 based on the documentation provided by the AEMPS.

The court-appointed expert held that she could not establish whether etonogestrel was dissolved in the LF ring's core above or below the saturation level due to insufficient information. However, she concluded that it was possible that the patent had been infringed.

On September 11 2017, before hearing the results of the inspection, MSD requested an *ex parte* preliminary injunction against León Farma and Exeltis for alleged infringement of EP'815 for the manufacture and marketing of the LF ring (ORNIBEL).

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MSD argued that the LF ring fell within the scope of protection of EP'815. To support its allegations, MSD filed an expert report which concluded that there was a "high probability" that etonogestrel was dissolved above the saturation level in the LF ring's core.

MSD's experts performed no tests or analysis on samples of the LF ring or the polyurethane of its core. Instead, they relied on a series of alleged indicia to infer patent infringement in terms of probability.

On September 18 2017 the court granted the preliminary injunction *ex parte*.

León Farma and Exeltis opposed the preliminary injunction, alleging non-infringement of EP'815 on the basis that etonogestrel in the LF ring is dissolved in the core significantly below the saturation level, which differs from EP'815's claims. In this regard, the defendants filed an expert report based on experimental tests concerning the saturation concentration of etonogestrel in the polyurethane used in the manufacture of the LF ring, thus confirming that etonogestrel is dissolved below the saturation level in the LF ring's core.

## Decision

The court upheld the opposition of León Farma and Exeltis and revoked the preliminary injunction through an order deliberated by the Barcelona patent judges.

The court reproached the performance of the court-appointed expert, concluding that she had acted in a partial manner and as MSD's expert, rather than a court-appointed expert. The court also reviewed MSD's expert evidence and criticised the fact that:

- it had not been based on tests or analysis of any kind; and
- MSD's experts had concluded the patent infringement in terms of probability.

In addition, the court criticised MSD's conduct in seeking an *ex parte* preliminary injunction without waiting for the outcome of the inspection proceedings that it had requested. The court concluded that MSD had had the burden of proving patent infringement and that it had failed to do so, despite having the greatest probative facility.

Further, the court made a positive assessment of the expert evidence provided by León Farma and Exeltis based on specific experimental tests and held that this had contributed to its conclusion of non-infringement.

MSD has appealed this decision.

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