

Barcelona Court of Appeal confirms revocation of *ex parte* preliminary injunction in NuvaRing case

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Facts

Ex parte inspection and *ex parte* injunction

Commercial court decision

Barcelona Court of Appeal decision

On 13 November 2018 the Barcelona Court of Appeal confirmed the revocation of the preliminary injunction granted *ex parte* at the request of Merck Sharp & Dohme (MSD) against Laboratorios León Farma and Exeltis Healthcare for the alleged infringement of MSD's NuvaRing patent.

Facts

MSD held European Patent 0876815 (EP'815), which protected a contraceptive vaginal ring comprising two active substances (ie, etonogestrel and ethinylestradiol) in which the etonogestrel was dissolved in the ring's core above the saturation level. The patent expired on 9 April 2018.

León Farma developed a contraceptive vaginal ring containing etonogestrel and ethinylestradiol in which the etonogestrel was dissolved in the ring's core below the saturation level. Exeltis began selling this vaginal ring in September 2017 under the trademark ORNIBEL.

Ex parte inspection and *ex parte* injunction

In June 2017 – before the commencement of the preliminary injunction proceedings – the court ordered the *ex parte* inspection that MSD had requested in order to obtain evidence that the ORNIBEL ring fell within the scope of EP'815. The court appointed an expert to prepare a report on the possible infringement of EP'815 based on technical documentation provided by the Spanish Drug Agency.

The court-appointed expert explained in her report that she could not establish whether the etonogestrel was dissolved in the core of the ORNIBEL ring above or below the saturation level due to a lack of sufficient information in this regard.

In September 2017, before learning the result of the inspection proceedings, MSD requested an *ex parte* preliminary injunction against León Farma and Exeltis for alleged infringement of EP'815 for the manufacture and marketing of ORNIBEL. On 18 September 2017 the court granted the preliminary injunction *ex parte*.

In order to prove the infringement of its patent, MSD filed an expert report which concluded that there was "a high probability" that the etonogestrel was dissolved above the saturation level in the core of the ORNIBEL ring. However, MSD's experts did not rely on tests or analysis of any kind, but rather on a series of alleged indicia to infer the patent infringement.

In their opposition and at the hearing, León Farma and Exeltis alleged the non-infringement of EP'815 based on the fact that, in contrast to the patent's claims, the etonogestrel in the ORNIBEL ring was dissolved in the core far below the saturation level. They filed an expert report based on experimental tests confirming this claim.



Commercial court decision

On 12 December 2017 Barcelona Commercial Court Number 5 upheld the defendants' opposition and revoked the preliminary injunction. In its decision, the court analysed the expert evidence of both parties and the court-appointed expert's evidence and concluded that despite having had the burden of proof and all procedural means at hand, MSD had failed to prove patent infringement.

The judge criticised the fact that the expert evidence filed by MSD was not based on tests or analysis of any kind. Further, he made a positive assessment of the expert evidence provided by León Farma and Exeltis, which contributed to his conclusion that there had been no infringement of EP'815.

MSD appealed this first-instance decision.

Barcelona Court of Appeal decision

On 13 November 2018 the Barcelona Court of Appeal dismissed MSD's appeal, thus confirming the first-instance decision.

First, the Barcelona Court of Appeal, by way of an *obiter dicta*, expressed its doubts as to whether the danger in delay requirement would actually be fulfilled given that EP'815 was already close to expiring when the *ex parte* preliminary injunction was first granted.

The court proceeded to explain that in preliminary injunction proceedings, the judgment as to whether a patent has been infringed must be made in a preliminary manner (ie, based on a provisional assessment of the available indicia). Thus, the Barcelona Court of Appeal confirmed that an assessment of disputed facts in this context does not require certainty, but rather probability. Therefore, MSD's appeal was deemed to be groundless as it alleged an infringement of the rules of the burden of proof, which – in reality – did not apply.

In this regard, the court explained that the defendants' expert evidence undermined MSD's *prima facie* case because, in addition to being supported by the expert's reputation, it was confirmed by objective data, including the experimental tests on which it was based.

The Barcelona Court of Appeal also criticised the court-appointed expert's performance (as the first-instance judge had done) for failing to:

- contact León Farma and Exeltis (despite having been ordered to do so); and
- do everything possible to resolve the alleged patent infringement.

The Barcelona Court of Appeal's decision is final.

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