INTELLECTUAL PROPERTY - SPAIN

Appeal court confirms revocation of *ex parte* preliminary injunctions against oxycodone/naloxone generics

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On 13 April 2018 the Barcelona Court of Appeal issued two decisions confirming the Barcelona Commercial Court Numbers 1 and 4 rulings revoking the preliminary injunctions that they had granted *ex parte* at Mundipharma's request against the first generics in Spain of its oxycodone/naloxone medicinal product for the treatment of pain (Targin) (for further details please see "Barcelona courts lift preliminary injunctions previously granted *ex parte* in oxycodone/naloxone case").

Facts

Mundipharma is the holder of European Patent 2425825 (EP'825), entitled 'Pharmaceutical preparation containing oxycodone and naloxone'. Claim 1 of the patent relates to an oral sustained release pharmaceutical formulation comprising one to 150 mg of oxycodone hydrochloride and one to 50 mg of naloxone hydrochloride in a weight ratio of 2:1.

At first instance, the commercial courts revoked and lifted the preliminary injunctions that they had initially granted *ex parte*, as they concluded the *prima facie* invalidity of EP'825 due to added subject matter, as argued by the defendants. Thus, in their decisions, dated 18 and 19 July 2017 respectively, the judges considered that the original application of EP'825 comprised no pointer to the combination of features ultimately claimed in the patent. Hence, multiple selections would need to be made to reach such a combination of features.

Appeals

The main grounds of Mundipharma's subsequent appeals were as follows:

- As the patent had been granted by the European Patent Office, the defendants in the preliminary injunction proceedings had to submit clear and obvious *indicia* of the patent's invalidity. According to Mundipharma, such burden had not been met in this case.
- The defendants' added subject matter arguments should fail, as the invention claimed in EP'825 derived directly and unambiguously from the original application as filed. In particular, all of the claimed features were preferred features within the original application as filed, which – according to Mundipharma – pointed to their combination.

The defendants opposed Mundipharma's appeals, reaffirming the invalidity of the patent due not only to added subject matter, but also to insufficiency of disclosure, lack of novelty and lack of inventive step, as they had argued in the first instance.

Decisions

The Barcelona Court of Appeal dismissed Mundipharma's appeals and confirmed the revocation of the preliminary injunctions. In its decisions, the Barcelona Court of Appeal concluded that EP'825 was *prima facie* invalid due to added subject matter, as argued by the defendants.

The Barcelona Court of Appeal considered that the claims of EP'825 amounted to an inadmissible generalisation with respect to the original patent application. This was because the claims of EP'825, as granted, omitted essential elements of the invention as disclosed in the filed application, which at all times required that the formulation provide not only a sustained release, but also an invariable and independent release. However, the claims of the patent, as granted, did not require such invariable and independent release.

Having reached this conclusion, the Barcelona Court of Appeal found it unnecessary to further consider:

- the grounds for the first-instance decisions (ie, added subject matter due to selection and combination of features); or
- the defendants' other invalidity arguments (ie, insufficiency, lack of novelty and lack of inventive step).

The Barcelona Court of Appeal's decisions are final, as Mundipharma cannot file any further appeal. Main proceedings on the merits are pending before the Barcelona Commercial Court Number 4. Opposition proceedings are also pending before the European Patent Office.

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