

Kluwer Patent Blog

Court of Appeal of Barcelona seeks to shed some light on second medical use claims

Miquel Montaña (Clifford Chance) · Sunday, July 24th, 2016

As readers know well, over the last few years courts around Europe have handed down several ground-breaking decisions on the scope of “second medical use” claims and, in particular, the activities required of third parties to guarantee the fair protection of such claims. Most of these decisions have revolved around the Lyrica® (pregabalin) patent, which sparked the first case where the enforceability of this type of claims has been considered in depth. The Court of Appeal of Barcelona has recently added its grain of salt to this debate in a decision of 5 July 2016, which partially reversed a decision of 23 June 2015 which had found that the defendants were not required to do anything to avoid the infringement of this type of claims.

The facts of the case may be summarised as follows:

In March 2015, Warner-Lambert filed an application for provisional measures against several companies that had obtained authorizations to market generics of pregabalin. Although they had “carved-out” the patented indication (pain) from the leaflet, Warner-Lambert alleged that the dynamics of the prescription system, coupled with the defendants’ failure to adopt any type of precautionary and information measures, would result in the prescription and dispensation of the defendants’ product for the treatment of pain. Against this background, Warner-Lambert requested the Court to order the defendants to inform the persons and bodies to whom they have offered their generic medicinal products and, in particular, to those acquiring the said medicinal products, that, while the patent is in force, such medicinal products must not be prescribed or dispensed for treating pain, and to refrain from supplying the aforementioned medicinal products unless the acquirers guarantee that they would not be prescribed and / or dispensed for the treatment of pain.

Commercial Court number 4 of Barcelona refused to adopt the provisional measures requested on the grounds that no acts of infringement had been proved. However, in its decision of 5 July 2016 the Court of Appeal of Barcelona considered that “carving out” the patented indication (i.e. pain) from the leaflet was insufficient to exclude the risk of infringement, as there was a “real probability” that the defendants’ product would be prescribed and dispensed for the treatment of pain. The Court added that the informative measures adopted by the patent owner were useful but insufficient to exclude such risk.

Moving on to the type of infringement involved (“direct” or “indirect” infringement), the Court ruled out “direct” infringement on the grounds that it had not been established that the defendants were manufacturing pregabalin for the purpose of having it used for the treatment of pain. On the

contrary, the Court considered that the acts of the defendants could constitute contributory infringement (i.e. “indirect” infringement) because they are aware or must be aware of the probable use of their product for the treatment of pain. Therefore, the defendants are supplying essential elements (pregabalin) that are finally prescribed for the treatment of pain, thus putting the invention into practice. The Court added that “if the defendants wish to market pregabalin they must contribute fairly to avoid the prohibited outcome [...]” and that “the defendants should have adopted reasonable measures to modify this situation [...]”

In conclusion, the Court partially reversed the first instance decision and ordered the defendants “to inform the persons and bodies to whom they have offered their generic medicinal products and, in particular, to those acquiring the said medicinal products, that, while the patent is in force, such medicinal products must not be prescribed or dispensed for treating pain, and to refrain from supplying the aforementioned medicinal products if there is reasonable evidence that their pregabalin medicinal products will be directly used for treating pain.”

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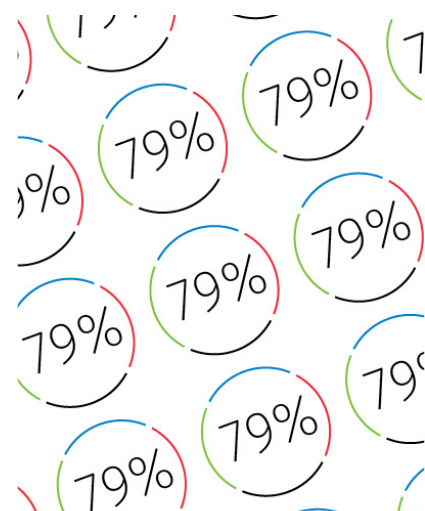
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