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Pregabalin continues to generate debate about indirect patent infringements and the conduct of regulatory agencies

Judgement of the Court of Justice of the European Union (CJEU) of 14 February 2019, Staat der Nederlanden v Warner-Lambert Company LLC, Case C-423/17

How to avoid indirect infringements

In 2016, the judgment of the Court of Appeal of Barcelona about pregabalin was a major milestone in the doctrine of indirect patent infringement and its connection with the regulatory environment.

Both Pfizer and the Court of Appeal understood that generic medicinal products that did not include pain treatment as an authorized indication did not directly infringe the still in force patent that protected the use of pregabalin for that indication. However, the Court of Appeal imposed certain information obligations on generic manufacturers, considering that the risk of generic products being prescribed and dispensed for the treatment of pain was real. According to the Court, such risk existed regardless of the fact that, to avoid incurring in a direct patent infringement, the data sheet of pregabalin generic products did not include the treatment of pain as an authorized indication.

According to the Court of Appeal, companies interested in marketing pregabalin generic products had to actively contribute to prevent such products from being used for the treatment of pain. Not including the treatment of pain as an authorized indication in the data sheet and refraining from undertaking campaigns that could associate their products with such indication were measures that the Court considered insufficient. The Court obliged generic manufacturers to inform healthcare professionals about the limitations of the use of pregabalin generic products The request consisting of converting the AEMPS in an active informative player regarding this matter was not accepted by the Court.

Conduct of the Regulatory Agencies

In this case, Pfizer sued the Dutch medicinal products agency (MEB) for not accepting the generic manufacturers' request to exclude the treatment of pain as an authorized indication for pregabalin products. The MEB, instead of accepting the exclusion of such indication from the datasheet of the generics, included a publication on its website warning about the existence of patents that could affect how the product should be prescribed or used.

The CJEU rules that an applicant for a marketing authorization (MA) for a generic medicinal product has the right to request the MEB to exclude certain indications from the technical data sheet of its product if this is made with the objective to prevent the infringement of a patent. Moreover, the CJEU states that the MEB must consider this request and must refrain from including such indications in the MA.

This clarification is important as it reinforces the idea that the contents of the MA is decisive for assessing the existence of a patent infringement. However, it does not alter the essence of the doctrine initiated by the Court of Appeal of Barcelona. The fact that the indication covered by the patent is not part of the MA triggers serious limitations regarding the way the product can be promoted; but such limitations did not prevent the Court of Appeal from imposing on the manufacturers of generic products an active information obligation as mentioned above.