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CLIENT ALERT

Generic drug product label did not induce infringement by indication that could but did not necessarily meet claim limitation

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Grunenthal GmbH v. Alkem Laboratories Limited, No. 2017-1153 (Fed. Cir. Mar. 28, 2019)
The patentee sued several companies that had filed Abbreviated New Drug Applications (ANDAs) to make generic versions of the patentee's drug. The patentee's drug was indicated to treat multiple types of pain – moderate to severe chronic pain and neuropathic pain. The asserted patents were only directed to treat neuropathic pain. Some ANDA filers excluded treatment for neuropathic pain covered from their generic products' proposed labels. The district court found that these ANDA filers neither induced nor contributed to the infringement of the patent for treating the condition excluded. Another ANDA filer argued that the crystal form claims were obvious and thus invalid. The district court found that the crystal form claims were not obvious and were valid. The Federal Circuit affirmed.

On the issue of induced infringement, the question was, "What direction did the label provide?" The only direction in the label was to treat chronic pain. Nothing in the label mentioned or provided direction regarding neuropathic pain. Although some types of chronic pain are neuropathic pain, chronic pain includes pain that is not neuropathic pain. Thus, the label was not specifically encouraging treatment of neuropathic pain. For contributory infringement, the question was whether there were substantial non-infringing uses. The parties presented competing expert testimony, and the district court considered this testimony and made factual conclusions that there were substantial non-infringing uses.

The court also affirmed the district court's decision that claims to a specific crystal form were not obvious because there was not a reasonable expectation of success in producing the claimed crystal form. The generic company argued that the claimed form would have been produced as part of a routine crystal screening because it was the most stable. On the record, the Federal Circuit found that there was not a reasonable expectation of success. Specifically, the record established that the drug was not known to have multiple crystal forms, the known synthesis of the drug did not produce the claimed form, and there was no guidance as to the particular crystallization steps which might produce the claimed form.
A copy of the opinion can be found here ►

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