

Axinn Leads Alvogen to Victory in Hatch-Waxman Case for Generic Zohydro[®]

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August 27, 2018

Axinn is pleased to announce that the United States District Court for the District of Delaware granted judgment to Alvogen Malta Operations, Ltd. (“Alvogen”) over patents related to Pernix Ireland Pain DAC and Pernix Therapeutics, LLC’s (“Pernix”) hydrocodone extended-release capsules, Zohydro[®]. Axinn was the lead trial counsel for Alvogen in the Hatch-Waxman Act case.

Pernix sued Alvogen for patent infringement over U.S. Patent Nos. 9,265,760 and 9,339,499, both of which are entitled, “Treating Pain in Patients with Hepatic Impairment,” under 35 U.S.C. § 271(e)(2). The case involved numerous, intricate legal issues that were presented in a three-day bench trial presided over by Judge William Bryson from the Federal Circuit Court of Appeals, who sat on the case by designation.

The Court found that the patent claims asserted by Pernix were invalid as obvious under 35 U.S.C. § 103, and for failure to satisfy the written description requirement of 35 U.S.C. § 112(a). The decision removes Pernix’s patents as a barrier to Alvogen bringing its lower-cost generic product to market more than a decade before the patents are set to expire.

The Axinn team was led by partners Matt Becker and Ted Mathias, with Thomas Hedemann.

The final judgment was filed August 24, 2018.

Press coverage:

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