

Axinn Achieves Trial Success for Norwich Pharmaceuticals as it Seeks to Market a Generic of Xifaxan®

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PRACTICE AREAS

Intellectual Property
Patents

On behalf of its client Norwich Pharmaceuticals, an affiliate of Alvogen, Axinn succeeded in proving at trial that two sets of patents directed to a method of treatment (IBS-D) and composition of matter (polymorph) were invalid as obvious. Norwich is seeking approval to market a rifaximin 550 mg tablet, a generic version of Salix's Xifaxan®, which is indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D).

Salix Pharmaceuticals, Ltd. and other subsidiaries of Bausch Health (NYSE: BHC) filed a patent infringement action against in the District of Delaware. Salix's complaint, filed in March 2020, involved 26 patents and more than 460 asserted patent claims, including composition of matter (polymorph), methods of using rifaximin to treat IBS-D, and methods of administering rifaximin for hepatic encephalopathy ("HE").

After a four-day bench trial in March 2022, which included testimony from ten medical and scientific experts, the District of Delaware issued its full opinion on August 10, 2022, holding that the asserted claims covering the composition of matter (polymorph) and methods of using rifaximin to treat IBS-D are invalid as obvious. Two weeks earlier, after District Judge Andrews released an order giving advanced notice of his findings, Bausch Health's stock plummeted, and trading was halted. The win was highlighted in the American Lawyer's "Litigator of the Week" column.

Axinn is lead defense counsel and handled all pre-trial proceedings, trial, and post-trial briefing. The team includes Chad Landmon, Matt Murphy, Matt Becker, Aziz Burgy, Stacie Ropka, Rebecca Clegg, Ricky Camposanto, and Chantelle Ankerman.