

NEWS RELEASES

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Husch Blackwell Scores Victory for Sigmapharm in Hatch-Waxman Litigation

DECISION OPENS DOOR FOR GENERIC DRUG MANUFACTURER IN MAJOR PRODUCT CLASS.

A Husch Blackwell trial team successfully defended Sigmapharm Laboratories, LLC in connection with its development and marketing of a generic version of the antidepressant vortioxetine. A selective serotonin reuptake inhibitor (SSRI), vortioxetine—marketed and sold in the U.S. as Trintellix® by Takeda Pharmaceuticals under license from H. Lundbeck—is used to treat major depressive disorder. In 2020 alone, Trintellix® generated 3.1 billion DKK (roughly \$482 million) in licensing revenue for patentholder Lundbeck, an impressive share of the multi-billion-dollar market for antidepressant pharmaceuticals, which includes SSRIs.

After Sigmapharm and other pharmaceutical companies filed abbreviated new drug applications (ANDA) with the U.S. Food and Drug Administration (FDA) seeking approval for generic versions of vortioxetine tablets, H. Lundbeck and business units of Takeda Pharmaceuticals filed complaints for patent infringement against 16 sets of defendants, alleging that the defendants' ANDA submissions constituted patent infringement. In sum, the plaintiffs asserted ten patents-in-suit; however, not all patents were asserted against each defendant. The lawsuits were consolidated in the United States District Court for the District of Delaware before Judge Leonard Stark.

In his 235-page opinion, Judge Stark found that Sigmapharm's proposed generic product would not infringe any of the patents-in-suit directed to any crystalline form of vortioxetine or any of the patents-in-suit directed to certain

methods of use. Overall, the opinion did not find in favor of the plaintiffs on any of their contested asserted claims of patent infringement against Sigmapharm. The opinion is subject to potential appeal.

The case was tried by Husch Blackwell partners Tom Heneghan, Don Mizerk and Philip Segrest with assistance from Marc Wezowski, Matt Kamps, Steve Howe, Femi Masha, Syed Rizvi, Ari Rodriguez and Anne Arundel.