NEWS RELEASES

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# Husch Blackwell Secures Federal Circuit Victory for TWi Pharmaceuticals in Hatch-Waxman Litigation

A Husch Blackwell trial team successfully defended TWi Pharmaceuticals in connection with its development and marketing of a generic version of cladribine when the Federal Circuit declined to reconsider decisions that invalidated Merck KGaA patents on multiple sclerosis drug Mavenclad®.

Merck sought rehearing of the opinion from October 2025 that affirmed a Patent Trial and Appeal Board (PTAB) decision that TWi Pharmaceuticals had shown several claims in Merck's patents—which cover dosing regimens for treating multiple sclerosis by orally administering cladribine—were invalid as obvious based on prior work that Merck argued was by some of the same inventors as the patents. In September 2024, Husch Blackwell prevailed on all challenged claims across two inter partes review (IPR) petitions.

Cladribine is a chemotherapy drug—marketed and sold in the U.S. as Mavenclad® by Merck KGaA—that is primarily used for hairy cell leukemia and relapsing forms of multiple sclerosis by interfering with and destroying abnormal B and T lymphocytes, thereby reducing inflammation and cancer cell growth. In 2024, Mavenclad® generated worldwide sales of €1.1 billion (approximately $1.3 billion).

The case was tried by Husch Blackwell partners Philip Segrest, Don Mizerk, and Steve Howe.

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