

PRESS RELEASE

Wiley Wins High-Profile Drug Patent Case on Behalf of Generic Manufacturer

FEDERAL DISTRICT COURT INVALIDATES PATENT ON ENTRESTO, A WIDELY USED HEART DRUG

July 13, 2023

Washington, DC – On behalf of generic drug manufacturer Macleods Pharmaceuticals Ltd., Wiley Rein LLP helped persuade a federal court in Delaware to invalidate a patent for a widely used cardiovascular medication.

The U.S. District Court for the District of Delaware ruled that a patent held by Novartis for Entresto (U.S. Pat. No. 8,101,659), a heart-failure drug that earned billions of dollars worldwide in 2022, was invalid for lacking an adequate written description.

The ruling was a victory for Macleods Pharma and two other manufacturers that are seeking to sell generic versions of Entresto and were named as defendants in the patent infringement litigation filed by Novartis. (*In re: Entresto (Sacubitril/Valsartan) Patent Litigation*, No. 20-2390 (D.Del.))

Under U.S. patent law, the written description requirement mandates that a patent applicant objectively demonstrate that the applicant actually invented the claimed subject matter. Specifically, the patent application's description must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed.

The Entresto patent is directed to a combination of two drugs to treat hypertension or heart failure. In particular, the patent claims a combination of valsartan, which is an angiotensin receptor blocker, and sacubitril, which is a neutral endopeptidase inhibitor.

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Intellectual Property

Patent

During a three-day trial in September 2022, Wiley successfully argued that Novartis' patent did not include any teachings on Entresto's unique chemical combination of valsartan and sacubitril, thus making the patent invalid.

Wiley Intellectual Property Practice chair Neal Seth and IP Practice attorney Corey Weinstein represent Macleods Pharma in this matter, along with co-counsel April M. Ferraro and John M. Seaman of Abrams & Bayliss LLP in Wilmington, DE.