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Polsinelli Secures Litigation Victory For MSN Pharmaceuticals in Lawsuit Against FDA Involving a Generic Version of Entresto

(Oct. 18, 2024) A team of Polsinelli attorneys recently secured summary judgment on behalf of intervenor-defendant MSN Pharmaceuticals Inc. in the highly publicized suit by Novartis Pharmaceuticals Corporation against the Food and Drug Administration (FDA) relating to FDA's approval of a generic version of the multibillion-dollar Entresto product. Novartis had filed the lawsuit under the Administrative Procedure Act (APA) against the FDA in late July, claiming that the U.S. regulator's approval of MSN's generic version of heart failure medication Entresto is unlawful.

The Honorable Judge Dabney L. Friedrich of the U.S. District Court for the District of Columbia issued the order in *Novartis Pharmaceuticals Corporation v. Becerra*, et al. (1:24-cv-02234) on October 13, 2024, finding that FDA did act lawfully in approving MSN's generic product with a label that carved out an indication and certain dosing information. In addition, the Court upheld FDA's decision that MSN's generic product has the same active ingredient as Entresto. The case is significant because it was one of the first legal challenges brought against FDA following the U.S. Supreme Court's decision this past year to overturn *Chevron* deference to decisions made by federal agencies in the *Loper Bright* decision.

Hatch-Waxman & Biologics Chair Chad A. Landmon led the team in this matter, which also included Shareholders Corey M. Casey and Associates Kendall K. Gurule, Suzanne E. Bassett, Dominique E. Smith and Melenie Van.

About Polsinelli

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