

Katten Secures Federal Circuit Victory for Mylan Pharmaceuticals

Katten represented Mylan Pharmaceuticals Inc. in winning a judgment against Actelion Pharmaceuticals Ltd. in significant patent litigation over its epoprostenol formulation patents.

In a precedential decision issued on May 13, the US Court of Appeals for the Federal Circuit affirmed the Northern District of West Virginia's ruling that Mylan's proposed generic epoprostenol product doesn't infringe Actelion's asserted patents relating to formulations of epoprostenol, the active ingredient in Actelion's Veletri® product. The decision, *Actelion Pharmaceuticals Ltd v. Mylan Pharmaceuticals Inc.*, No. 2024-1641, caps a second successful win at the Federal Circuit for Mylan, following the court's 2023 decision vacating an earlier judgment and remanding for further consideration of extrinsic evidence.

The Federal Circuit agreed with the district court that the asserted patent claims required pH measurements to be taken at standard temperature conditions and that Mylan's product didn't meet the claimed "pH of 13 or higher" limitation under that construction. The court also held that Actelion was barred from asserting infringement under the doctrine of equivalents based on prosecution history estoppel and the disclosure-dedication rule.

The ruling has attracted industry attention for its analysis of contextual claim interpretation and pharmaceutical industry standards governing pH measurements.

The Katten team was led by Partners Deepro Mukerjee, Lance Soderstrom, Jitendra Malik, Eric Werlinger and Timothy Gray, and Associate Jillian Schurr-Hendrix. Eric Werlinger argued the case before the Federal Circuit. Katten's Intellectual Property practice represents leading pharmaceutical and life sciences companies in high-stakes Hatch-Waxman and appellate litigation nationwide.