
WilmerHale Earns Win at Federal Circuit on Behalf of Takeda in Hatch-Waxman Litigation

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On July 17, 2017, WilmerHale achieved a significant victory for Takeda's wholly owned subsidiary, Millennium Pharmaceuticals, Inc., at the Federal Circuit when the appeals court reversed a district court finding of patent invalidity based on obviousness and remanded the case with instructions to enter judgment in favor of Takeda.

This Hatch-Waxman matter involved a patent owned by the United States government and exclusively licensed to Takeda covering the latter's blockbuster oncology drug Velcade®. In 2016, sales of Velcade in the United States were in excess of \$1 billion. Generic drug manufacturers including Sandoz filed ANDAs seeking to market generic versions of Velcade and Takeda filed suit for patent infringement in the US District Court for the District of Delaware. In reversing the lower court's ruling, the appeals court found that the asserted claims were directed to the mannitol ester of bortezomib—"a new compound with distinct chemical properties"—and that these claims were not obvious because "the prior art contains no teaching or suggestion of this new compound" or that "such a new compound would have the long-sought properties of stability and solubility, and sufficiently dissociate to release bortezomib at an effective rate in the bloodstream, all critical to effective use for treating multiple myeloma."

The WilmerHale team representing [Takeda](#) included Partners [Bill Lee](#), [Rob Galvin](#), [Lisa Pirozzolo](#), [Mark Fleming](#), [Emily Whelan](#) and [Vinita Ferrera](#), Counsel [Jason Liss](#), [Anna Lumelsky](#), [Tasha Bahal](#) and [Jon Roses](#), and Senior Associate [Samantak Ghosh](#).