

Katten Intellectual Property Team Secures Significant Victory for Apotex in Hatch-Waxman Litigation

November 1, 2022

Deepro Mukerjee, chair of Katten's global Intellectual Property practice, Lance Soderstrom, co-chair of the firm's Patent Litigation practice, and Intellectual Property partner Christopher Ferenc led a team of attorneys in scoring a significant win on behalf of Katten client Apotex in a Hatch-Waxman dispute before the US District Court for the District of Delaware. *Law360* and *Bloomberg Law* both featured the court's ruling, which granted Apotex a judgment of non-infringement in connection with its generic version of a cancer treatment.

In an October 25 opinion, Chief Judge Colm F. Connolly outlined his reasoning for rejecting Eagle Pharmaceuticals, Inc.s' effort to block new drug applications (NDAs) separately submitted by Apotex and another defendant related to a bendamustine product, Belrapzo, which is used to treat chronic lymphocytic leukemia as well as certain cases of indolent B-cell non-Hodgkin lymphoma.

Eagle Pharmaceuticals maintained that the NDA products infringed US Patent No. 11,103,483 – specifically claiming infringement of two claims that both cover a "ready to use liquid bendamustine-containing composition." Apotex and the other defendant countered that the patent was invalid. Apotex further requested declaratory relief, partly seeking a judgment that the sales and marketing of its NDA product would not infringe the patent.

At the conclusion of the first day of a scheduled two-day trial in September, Judge Connolly ruled from the bench against Eagle Pharmaceuticals' infringement claims and rendered a non-infringement judgment in favor of Apotex. The sole infringement issue in dispute was whether the NDA products "meet the 'ready to use' limitation of the asserted claims of the #483 patent," according to the opinion, which explained that the parties had stipulated to a specific meaning of the phrase "ready to use." Judge Connolly ultimately found that Eagle Pharmaceuticals failed to establish that the NDA products fall within the scope of "ready to use."

Expert testimony was the decisive factor in the outcome of the case, and the court noted that the defendants' expert was "one of the most credible witnesses I've had testify" in over a dozen trials during the past year.

The Katten team representing Apotex also included Intellectual Property partners Jitty Malik and Joseph Janusz; counsel Rachel Schweers; and associate Rachel Schaub.

Read Chief Judge Colm F. Connolly's opinion.

"Apotex, Slayback Beat Lymphoma Drug Patent Suit In Del.," *Law360*, October 26, 2022

"Eagle Loses Patent Ruling on Branded Rivals of Belrapzo Drug," *Bloomberg Law*, October 26, 2022

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