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Mylan Calls Apotex's Suit A Bid To Destroy Exclusivity Rights

By **Kelly Knaub**

Law360, New York (August 26, 2015, 8:54 PM EDT) -- Mylan Pharmaceuticals Inc. sought to intervene in Apotex Inc.'s suit for a declaration of noninfringement of Daiichi Sankyo Inc.'s Benicar HCT patent, saying Wednesday that Apotex is merely trying to "destroy" Mylan's 180-day exclusivity period for a generic of the blood pressure drug.

The generic-drug maker told an Illinois federal court that the company earned a statutory right to 180 days of marketing exclusivity for a generic version of Benicar HCT since filing the first abbreviated new drug application and Paragraph IV certification challenging Daiichi's U.S. Patent No. 6,878,703.

Mylan said it appeared Apotex filed the suit to ascertain whether Apotex infringed a patent that cannot legally be infringed, but is actually trying to abuse the ANDA statutory scheme by using a noninfringement judgment to force Mylan to forfeit its exclusivity right.

"But it was Mylan — not Apotex — who first filed a Benicar HCT ANDA, resulting in the disclaimer on which Apotex now depends," Mylan said. "And Mylan's effort entitles it to 180 days of generic exclusivity under the law. Yet, as it stands, because Mylan is not a party to this suit, it will be forced to sit on the sidelines while its hard-earned exclusivity rights hang in the balance."

The generic-drug maker noted that the Federal Circuit permitted it to intervene in a "virtually identical case" in which Apotex challenged the same patent at issue, and urged the district court to follow in the circuit's footsteps.

Apotex sued in April, asking the court to declare that the '703 patent is not infringed by Apotex's ANDA filing or manufacture and sale of a Benicar HCT generic. Apotex also asked the court to declare that the U.S. Food and Drug Administration can approve the company's application.

Attorneys for the parties did not immediately return a request for comment Wednesday.

The patent-in-suit is U.S. Patent Number 6,878,703.

Apotex is represented by Leonard Friedman, Daniel R. Cherry, Steven E. Feldman and Sherry L. Rollo of Hahn Loeser & Parks LLP.

Daiichi is represented by David C. Van Dyke and Emily E. Bennett of Howard & Howard Attorneys PLLC and Dominick A. Conde of Fitzpatrick Cella Harper & Scinto.

Mylan is represented by James B. Coughlan of Perkins Coie LLP.

The case is Apotex Inc. v. Daiichi Sankyo Inc. et al., case number 1:15-cv-03695, in the U.S. District Court for the Northern District of Illinois.

--Editing by Edrienne Su.

