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Apotex Pushes To Have Late Sandoz Subpoena Tossed

By **Dani Kass**

Law360, New York (November 17, 2016, 4:48 PM EST) -- Apotex Inc. on Wednesday asked a New Jersey federal judge to kill a subpoena Sandoz Inc. sent to one of Apotex's business partners during the damages stage of a patent infringement suit both drugmakers won against AstraZeneca, arguing the subpoena was filed a year too late and is irrelevant to the case.

In a letter to U.S. Magistrate Judge Ann Marie Donio, Apotex said the subpoena was served a year after the court's deadline passed and that Sandoz circumvented proper notification procedures. Apotex also accused Sandoz of using the litigation focused on past damages to get a peek at its future competition, specifically Nephron Pharmaceuticals' pediatric asthma medication — a one-milligram budesonide inhalation suspension, or BIS, product.

"Apotex has never even had approval for a 1 mg product, and whether Nephron is seeking approval for that product has absolutely nothing to do with Apotex's claim for the past damages it suffered during the injunctions," the letter states. "Sandoz, on the other hand, does have a 1 mg product, and is obviously interested in whether other parties may market that product, when, their capacity, etc. Sandoz is clearly using this request to try to obtain intelligence on future competition for that product."

Apotex had received U.S. Food and Drug Administration approval for a generic BIS product in 2009, but then AstraZeneca PLC sued, blocking the product from going to market. Apotex then teamed up with Nephron, which remained a third party during the litigation.

U.S. District Judge Renee Marie Bumb in February 2015 said AstraZeneca's patent was **invalid as obvious**, clearing the generics to go forward. The generic-drug makers must now prove past damages caused by injunctions during the infringement suit. Apotex said the deadline for discovery requests was Oct. 28, 2015, but Sandoz sent its subpoena on Oct. 18, 2016.

Sandoz had requested separate information about Nephron from Apotex before the deadline, so it can't claim to not have known about the partnership before, the letter states.

"Apotex also provided significant detail about the business relationship between Apotex and Nephron regarding BIS products when the parties served their responses to written discovery requests over a half year ago, both in interrogatory responses and by producing responsive Nephron documents (though, again, Sandoz already knew of Nephron long before this)," the letter states. "It is only now — after encountering unwanted competition from Nephron since mid-June — that Sandoz has suddenly decided this third party subpoena is warranted."

Additionally, Sandoz didn't tell Apotex about the subpoena before it was sent, as required under Rule 45, the letter states. Apotex said it should have been given notice so it would have had time to object. Going around the rules is proof that Sandoz knows it's in the wrong, according to the letter.

Sandoz didn't immediately respond to request for comment Thursday.

Apotex is represented by James E. Tonrey Jr. of Wilentz, Goldman & Spitzer and Richard J. Basile,

David W. Aldrich and Alyson J. DiLena of St. Onge Steward Johnston & Reens LLC.

Sandoz is represented by Taras A. Gracey, Brandon C. Helms, Thomas A. Rammer II and Gretchen P. Miller of Steptoe & Johnson LLP and Sheila Raftery Wiggins of Duane Morris LLP.

The case is AstraZeneca LP et al. v. Breath Ltd. et al., case number 1:08-cv-01512, in the U.S. District Court for the District of New Jersey.

--Editing by Kelly Duncan.

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