

Teva, AstraZeneca Say Court Rulings Kill Nexium Delay Suit

By **Aaron Vehling**

Law360, New York (August 26, 2014, 1:27 PM ET) -- Drugmakers Teva Pharmaceutical Industries Ltd. and AstraZeneca PLC on Monday asked a Massachusetts federal judge to toss claims that Teva purposely delayed marketing a generic version of Nexium by two years, saying the judge's recent rulings blow a hole in a class of drug buyers' antitrust suit against the companies.

Teva and AstraZeneca said that Judge William G. Young's rulings — that the plaintiffs failed to support an argument that first-filer Ranbaxy Inc. could have entered the market with a generic form of the heartburn drug prior to May 2014 — severely incapacitates the drug purchasers' allegation that Teva agreed to delay marketing its own generic Nexium as part of a patent settlement with AstraZeneca.

Ranbaxy, which as first-filer for approval of a generic Nexium will have 180 days of exclusivity to market that version, still hasn't marketed its own generic because it has encountered difficulty getting approval from the U.S. Food and Drug Administration, Teva and AstraZeneca said. Given that, it is legally impossible for Teva to have entered the market before May, and therefore it is not delaying as part of a collusive scheme, they said.

"This indisputable fact blows a gaping hole in plaintiffs' case regarding the Teva Nexium settlement," the drug companies said.

Judge Young in February granted summary judgment to Ranbaxy, ruling that the direct-purchaser plaintiffs hadn't shown that the company could have launched a generic version of the drug before 2014 due to "continuing and well-documented difficulties with obtaining FDA approval."

He also had granted AstraZeneca summary judgment on all claims arising from AstraZeneca's settlements with Teva, ruling that the plaintiffs had failed to demonstrate that Teva's settlement with AstraZeneca constituted a large, unjustified reverse payment that would trigger antitrust concerns.

Judge Young in April granted the buyers' motion for reconsideration of AstraZeneca-Teva settlement portions of the pay-for-delay suit, setting an October trial date for the revived case.

In their Aug. 25 motion for judgment on the pleadings, Teva and AstraZeneca argued that Judge Young's Ranbaxy causation rulings foreclose any remaining scenarios under which Teva could have entered the market before May 27, the licensed-entry date for Ranbaxy under its settlement agreement with AstraZeneca.

The three scenarios under which Teva could have entered before May — it launches 180 days after Ranbaxy, after Ranbaxy waives exclusivity or after Ranbaxy involuntarily forfeits exclusivity — are all precluded as a matter of law, the drug companies said.

Ranbaxy's problems with FDA approval mean none of the scenarios works, the drug companies said.

Without final approval, Teva couldn't just wait 180 days until exclusivity expired. Ranbaxy couldn't selectively waive its exclusivity because that is also pegged to approval. Involuntary forfeiture, which would pave way for Teva's entry, fails because the court already has rejected that Ranbaxy could have negotiated earlier milestone dates with the FDA it would then "miss," the drug companies said.

The suit is part of a larger MDL claiming that AstraZeneca, Ranbaxy, Teva and Dr. Reddy's Laboratories Ltd. wielded their market power to harm competition by entering into pay-for-delay settlements aimed at deferring the introduction of generic Nexium.

The direct purchasers' claims against Ranbaxy harken back to a 2008 deal that AstraZeneca allegedly struck with the company. According to the plaintiffs, the generic-drug maker agreed to delay its launch of the heartburn medicine until this May in exchange for a "large, unexplained payment."

Ranbaxy had derided the accusation that the patent settlement had caused a Nexium generic delay, saying in its December motion for summary judgment that the plaintiff's argument on how Ranbaxy could have obtained FDA approval for a generic Nexium was "sheer speculation."

Representatives for the parties were not available Tuesday for comment.

Teva is represented by Laurence A. Schoen and Adam L. Sisitsky of Mintz Levin Cohn Ferris Glovsky & Popeo PC and Karen N. Walker, Rebecca A. Koch and Jay P. Lefkowitz of Kirkland & Ellis LLP.

AstraZeneca is represented by Dane H. Butswinkas and John Schmidlein of Williams & Connolly LLP and William A. Zucker and Michael P. Kelly of McCarter & English LLP.

The plaintiffs are represented by Hagens Berman Sobol Shapiro LLP, Berger & Montague PC and Garwin Gerstein & Fisher LLP.

The case is In re: Nexium (Esomeprazole Magnesium) Antitrust Litigation, case number 1:12-md-02409, in the U.S. District Court for the District of Massachusetts.

--Additional reporting by Scott Flaherty and Allissa Wickham. Editing by Richard McVay.