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Actos Buyers Fight Takeda Appeal Bid In Drug Delay Case

By **Christopher Cole**

Law360 (December 16, 2019, 6:03 PM EST) -- End payors and direct buyers of the diabetes drug Actos have urged a New York federal judge to nix Takeda's bid to immediately appeal her decision preserving some class action claims against the drugmaker, which they have accused of using patent suits to hold off generic competitors.

The Japanese pharmaceutical firm has pushed for Second Circuit review of U.S. District Judge Ronnie Abrams' November ruling that kept intact the end-payor claims while also preserving some of the litigation by direct buyers. The suits from a range of Actos purchasers accuse Takeda of filing multiple patent claims to force challenges from generic makers and ultimately keep competing versions of the drug out of stores.

The legal teams for the two sets of Actos buyers argued in a filing Friday that Judge Abrams got it right and that Takeda's move for interlocutory review was not warranted, given established law on new drug applications. They said the law does not require disclosure of different, unapproved products to the Food and Drug Administration as part of a new drug application, or NDA, as Takeda argued in trying to kill the generic-delay claims.

"Takeda's failure to show any grounds for its statutory interpretation militates against the extraordinary and disfavored measure of interlocutory appeal," they said. "This court correctly held, in accord with decades of hornbook law, that NDA applicants may describe as drug-product patents only those that claim the approved drug product. That is the controlling issue of law for which Takeda must identify substantial grounds for difference of opinion. And it has not done so."

Takeda moved for immediate appeal to the circuit level Nov. 22, saying Judge Abrams mistakenly pegged her ruling largely on an interpretation of federal law known as Section 355(b)(1), which requires companies seeking to market new drugs to disclose patents to the FDA that describe the drug itself or as a "method-of-use" for the therapy if that use by a third party could trigger "a reasonable claim of patent infringement."

Takeda argued, however, that Judge Abrams' reasoning in her Oct. 8 ruling "cannot be squared with the plain language of the statute" and conflicts both with the interpretations of industry and the FDA.

The **judge held** Oct. 8 that Section 355(b)(1) requires companies seeking to market new drugs to disclose patents to the FDA that describe the drug itself or as a "method-of-use" for the therapy if that use by a third party could trigger "a reasonable claim of patent infringement."

On that basis, the judge agreed with purchasers that Takeda made "inaccurate" statements to the FDA on patent claims, leading the FDA to require generic drug companies seeking to market their own versions of the therapy to challenge Takeda's patents head-on instead of trying to market for different uses. As a result, Takeda allegedly could strike anticompetitive deals delaying generic entry.

But at the time, the judge tossed the rest of the direct buyers' lawsuit alleging that Takeda, Teva Pharmaceuticals, Sun Pharmaceutical Industries Ltd., Actavis PLC and Mylan Inc. illegally conspired to restrict trade of Actos, saying the buyers were not able to show that settlements between the generic-drug companies and Takeda violated antitrust laws.

In Friday's filing to oppose Takeda's appeal bid, the Actos purchaser groups said that "after six years of litigation, multiple rounds of briefing, and the hiring of a second global law firm, Takeda still cannot identify any grounds supporting its belief that the law required it to tell the FDA that patents claiming different, unapproved drug products claimed Actos."

"Knowing its patents did not claim Actos, Takeda tries to twist the law to have purportedly required Takeda to describe as drug-product patents those that claim products different from the product approved under the NDA (indeed, Takeda's interpretation of the law would require it to describe as drug-product patents those that claim hypothetical future products not even approved by the FDA)," they said.

Counsel for Takeda and the plaintiffs did not immediately respond to press inquiries Monday.

Takeda is represented by Steven A. Reed, R. Brendan Fee, Melina R. DiMattio, Scott A. Stempel and Alexander J. Scolnik of Morgan Lewis & Bockius LLP.

The direct purchasers are represented by Thomas M. Sobol, David S. Nalven and Gregory T. Arnold of Hagens Berman Sobol Shapiro LLP; Linda P. Nussbaum of Nussbaum Law Group PC; Juan R. Rivera Font of Juan R. Rivera Font LLC; and Joseph M. Vanek, Paul E. Slater, David P. Germaine and John P. Bjork of Sperling & Slater PC.

The end payors are represented by Hilliard & Shadowen LLP, Shepherd Finkelman Miller & Shah LLP, Wexler Wallace LLP, Motley Rice LLC, Robbins Geller Rudman & Dowd LLP, Miller Law LLC, Cohen Milstein Sellers & Toll PLLC, Glancy Prongay & Murray LLP, Cohen Placitella & Roth PC, Shepherd Finkelman Miller & Shah LLP, Gustafson Gluek PLLC, Morgan & Morgan, Girard Gibbs LLP, Robbins Geller Rudman & Dowd LLP, Cavanagh & O'Hara, Heins Mills & Olson PLC, Freed Kanner London & Millen, LLC, Hanly Conroy Bierstein Sheridan Fisher & Hayes LLP, James Hoyer Newcomer & Smiljanich P A, Simmons Browder Gianaris Angelides & Barnerd LLC, Robbins Arroyo LLP, Jacobs Burns Orlove & Hernandez, Cohen Milstein Sellers & Toll, PLLC, Hach Rose Schirripa & Cheverie LLP, Donovan Axler, Markowitz & Richman, Klausner Kaufman Jensen & Levinson, Zwerling Schachter & Zwerling Llp and Hausfeld LLP

The cases are In re: Actos Direct Purchaser Antitrust Litigation, case number 1:15-cv-03278, and In Re: Actos End Payor Antitrust Litigation, case number 1:13-cv-09244, in the U.S. District Court for the Southern District of New York.

--Additional reporting by Bryan Koenig, Matt Bernardini and Eric Kroh. Editing by Peter Rozovsky.
