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Antitrust

Lipitor Direct Purchaser ‘Pay for Delay’ Claim Implausible, Dismissed With Prejudice

Direct purchasers of Pfizer Inc.’s blockbuster cholesterol medication Lipitor failed to allege that a patent litigation settlement between drugmakers Pfizer and Ranbaxy Laboratories Ltd. involved an impermissible reverse payment, a federal court held Sept. 12 (*In re Lipitor Antitrust Litigation*, 2014 BL 254208, D.N.J., No. 3:12-cv-02389-PGS-DEA, 9/12/14).

Dismissing the direct purchasers’ complaint with prejudice, Judge Peter G. Sheridan of the U.S. District Court for the District of New Jersey said because the plaintiffs failed to plausibly estimate the monetary value of the complex settlement between Pfizer and Ranbaxy, the claim fell short of alleging an actionable reverse payment settlement agreement under the Sherman Act.

The decision “adds to the mixed bag of rulings from the lower courts concerning what types of ‘reverse payments’ are potentially actionable,” antitrust expert James M. Burns, of Dickinson Wright’s Washington office, told Bloomberg BNA Sept. 15. “It’s unlikely that we will see any consensus on the issue for some time to come.”

The direct purchasers—Stephen L. LaFrance Holdings Inc., Burlington Drug Co., Value Drug Co., Professional Drug Co., Rochester Drug Co-Operative Inc. and American Sales Co.—alleged that Pfizer Inc., Pfizer Manufacturing Ireland and Warner-Lambert Co. (Pfizer) entered into an illegal reverse payment settlement to keep Ranbaxy Inc. (and Ranbaxy Pharmaceuticals Inc. and Ranbaxy Laboratories Ltd.) out of the Lipitor market. Since Lipitor was grossing \$1 billion a month for Pfizer at the time of the agreement with Ranbaxy, the plaintiffs alleged that the value of Ranbaxy’s agreement to delay making a generic Lipitor was substantial.

The settlement agreement resolved multiple litigations pending worldwide including suits on brand drugs pending in the U.S. in addition to Lipitor.

The payments alleged by the plaintiffs included taking a “token payment” to settle patent damages claims against Ranbaxy on Accupril (forgoing what the plaintiffs allege were “hundreds of millions of dollars” worth of damages), in return for which Ranbaxy agreed to stay out of the generic Lipitor market and to keep its filings in place with the Food and Drug Administration to block anyone else from getting approval for a generic competitor for the drug.

Sheridan applied the standard enunciated by the U.S. Supreme Court in *FTC v. Actavis, Inc.*, 2013 BL 158126, 133 S. Ct. 2223 (2013) (11 PLIR 771, 6/21/13) to conclude that the settlement didn’t trigger antitrust scrutiny.

In *Actavis*, the Supreme Court held that the rule of reason approach should be used in analyzing reverse payments between drug companies. It advised courts to look to whether the consideration paid by the branded drugmaker to the generic competitor was, in fact, a reverse payment. As the payment in that case involved a large cash payment and little else, the court focused its discussion on cash.

“In this case, where Plaintiffs rely on a non-monetary reverse payment of an inchoate claim, they must plead plausible facts including an estimate [of] the monetary value of same so the *Actavis* rationale can be applied,” the court ruled.

Sheridan, noting that some courts require a cash payment to scrutinize a patent settlement under *Actavis*, adopted the more flexible approach that a payment need not be in cash to trigger the Sherman Act. Nonetheless, he said “the non-monetary payment must be converted to a reliable estimate of its monetary value so that it may be analyzed against the *Actavis* factors such as whether it is ‘large’ once the subtraction of legal fees and other services provided by generics occurs.”

The court said the payment still must be large and unexplained to be potentially anticompetitive and, in this case, the plaintiffs didn’t plead enough facts for the court to plausibly infer that was the case.

In this case, the court determined that the plaintiffs failed to give the court a factual basis for assessing the size of the nonmonetary benefit conveyed in the complex agreement between Pfizer and Ranbaxy. Accordingly, the court concluded that the plaintiffs failed to allege a “reverse payment” upon which to base their Sherman Act § 2 claim. Because the plaintiffs already had an opportunity to amend their complaint, the court dismissed the direct purchasers’ complaint with prejudice.

The court’s decision only involves the direct purchaser actions pending before the multidistrict litigation. However, as the court noted, the analysis “may pertain to other groups of plaintiffs as they rely on the same allegations.” Pending before the court are claims by direct purchasers who opted out of the putative class, a class of end-payer plaintiffs alleging state law claims, and a group of pharmacist plaintiffs asserting claims under California law.

Courts Struggling With *Actavis*. Burns said the decision shows that courts “continue to struggle with how *Actavis* should be interpreted.”

That lack of consensus, he said, could prompt the Federal Trade Commission to seek a legislative answer to the question of what type of reverse payment should be actionable, rather than await further clarification from the Supreme Court.

In a Sept. 12 statement, Pfizer said it is “pleased with the Court’s decision to dismiss this case. Pfizer has always believed that the procurement and enforcement of its Lipitor patents and the settlement of litigation relating thereto was at all times proper and lawful. The Company will continue to vigorously protect and defend its intellectual property, which is vital to developing new medicines like Lipitor that save and enhance patient lives.”

The firms of Schnader Harrison, Segal & Lewis LLP, Motley Rice LLC, Cohen Milstein Sellers & Toll PLLC and Wexler Wallace LLP represented end-payer plaintiffs.

Cohn, Lifland, Pearlman, Herrmann & Knopf LLP represented direct purchaser plaintiffs.

Hagens Berman Sobol Shapiro LLP represented the direct class plaintiffs.

Carella Byrne Cecchi Olstein Brody & Agnello PC represented the indirect end-payer class.

The Messina Law Firm PC firm represented the RP Healthcare plaintiffs.

Marcus & Shapira LLP represented plaintiff Giant Eagle Inc.

The firms of White & Case LLP and Connell Foley LLP represented defendant Pfizer.

The firms of Kirkland & Ellis LLP and Lite DePalma Greenberg LLC represented defendant Ranbaxy.

The court’s decision is at http://www.bloomberglaw.com/public/document/In_re_LIPITOR_ANTITRUST_LITIGATION_This_Document_Relates_To_Direc.