

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FEDERAL TRADE COMMISSION	:	CIVIL ACTION
	:	
v.	:	
	:	
ABBVIE INC., et al.	:	NO. 14-5151

MEMORANDUM

Bartle, J.

August 25, 2015

Before the court is the motion of the Federal Trade Commission ("FTC") for reconsideration of the court's order granting the defendants' partial motion to dismiss. See Fed. Trade Comm'n v. AbbVie Inc., Civil Action No. 14-5151, --- F. Supp. 3d ---, 2015 WL 2114380 (E.D. Pa. May 6, 2015). The FTC bases its motion on the recent decision of the Court of Appeals in King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp., 791 F.3d 388 (3d Cir. 2015).

The FTC brings this action for injunctive and other equitable relief under § 5(a) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 45(a), against defendants AbbVie, Inc. ("AbbVie"), Abbott Laboratories ("Abbott"), Unimed Pharmaceuticals, LLC ("Unimed" and, together with AbbVie and Abbott, the "AbbVie Defendants")¹, Besins Healthcare, Inc. ("Besins"), and Teva Pharmaceuticals USA, Inc. ("Teva"). The AbbVie Defendants and

¹ Unimed was sold to Solvay Pharmaceuticals in 1999. Abbott acquired Solvay in February 2010. On January 1, 2013, Abbott separated into two companies: Abbott and AbbVie, Inc.

Besins together hold U.S. Patent No. 6,503,894 (the "'894 Patent") for a popular brand-name testosterone drug, AndroGel. Teva was developing a generic version of the drug that, according to the complaint, falls outside the scope of the patent.

The FTC alleges that Abbott, Unimed, and Besins initiated sham patent infringement litigation against Teva in the District of Delaware for the sole purpose of delaying the entry of its generic drug into the AndroGel market. The lawsuit settled thereafter. In the FTC's view, the settlement involved a large, unjustified reverse payment by the patentees to the claimed infringer, Teva, in violation of the FTC Act and the dictates of the Supreme Court's decision in Federal Trade Commission v. Actavis, 133 S. Ct. 2223, --- U.S. --- (2013).

The FTC asserts that what occurred here amounts to unfair methods of competition under the FTC Act. In Count I of the complaint it claims monopolization against the AbbVie Defendants and Besins for initiating the alleged sham litigations against Teva. Count II, which was the principal subject of the defendants' motion to dismiss, presented a claim for restraint of trade against the AbbVie Defendants and Teva arising out of the settlement of their lawsuit. In an order dated May 6, 2015 we granted the motion of the AbbVie Defendants and Teva to dismiss Count II of the complaint and of the AbbVie Defendants and Besins to dismiss Count I to the extent it was based on the settlement of the patent litigation. The

court's reasons are set forth in a Memorandum accompanying the order. As noted above, the FTC now seeks reconsideration of this order in light of the recent decision of our Court of Appeals in King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp., 791 F.3d 388 (3d Cir. 2015).

A motion for reconsideration may be granted only where the moving party can establish one of the following: (1) there has been an intervening change in controlling law; (2) new evidence has become available; or (3) there is need to correct a clear error of law or prevent manifest injustice. Max's Seafood Cafe by Lou-Ann, Inc. v. Quinteros, 176 F.3d 669, 677 (3d Cir. 1999). The scope of a motion for reconsideration is quite limited. See Blystone v. Horn, 664 F.3d 397, 415 (3d Cir. 2011). The FTC urges that the decision in King Drug sets forth a new framework with which to analyze Actavis reverse payment claims and is thus a change in controlling law mandating reconsideration of our order. The defendants respond that King Drug is merely a straightforward application of the rule in Actavis to factually distinguishable circumstances.

The plaintiffs in King Drug were a putative class of direct purchasers of a brand-name drug called Lamictal, which is used in the treatment of epilepsy and bipolar disorder. The producer of the drug, GlaxoSmithKline ("GSK"), obtained a patent covering Lamictal's active ingredient. Yearly Lamictal sales

exceeded \$2 billion. The patent was scheduled to expire in July 2008.

Teva, also a defendant in King Drug, filed an application with the FDA to market a generic alternative to Lamictal. It certified that its generic would not infringe GSK's patent or that the patent was unenforceable. GSK responded by filing patent infringement litigation. The district court ruled that the patent's main claim was invalid. This decision made the remainder of GSK's case unlikely to succeed.

Before any ruling could be made on the merits of the remaining patent claims, GSK and Teva settled the dispute. In the first part of the agreement, GSK allowed Teva to market its generic Lamictal product at least 37 months before the expiration of its patent. Significantly, GSK also agreed that it would not market its own authorized generic in the 180 days following FDA approval of Teva's product. Since the first producer to obtain FDA approval for or otherwise begin marketing a generic drug would ordinarily enjoy a statutory 180-day period in which only it and the brand-name manufacturer may sell the generic version, this "no-AG agreement" meant that Teva would stand to reap six months of monopoly profits in the generic Lamictal market. The plaintiffs alleged that the no-AG agreement was a large, unjustified reverse payment intended to short circuit Teva's patent challenge and delay generic competition

for Lamictal. The district court disagreed and granted the defendants' motion to dismiss for failure to state a claim.

The Court of Appeals reversed. King Drug, 791 F.3d at 394. After a lengthy review of the Supreme Court's decision in Actavis, the court concluded that Actavis's prohibition on large, unjustified reverse payments is not limited to payments in cash. Id. at 403. The court explained that "a no-AG agreement, when it represents an unexplained large transfer of value from the patent holder to the alleged infringer, may be subject to antitrust scrutiny under the rule of reason." Id. (emphasis added). In the court's reading, Actavis turned on whether a reverse payment is motivated by the desire to foreclose competition rather than on the specific form of payment involved. Id. at 409. The court reasoned that no-AG agreements carry the same anticompetitive concern as reverse payments in cash. They can still carry great monetary value for the generic company and represent the forfeiture by the patentee of a valuable right to compete in the generic marketplace. The anti-competitive consequences are high in that the generic company can enjoy monopoly generic pricing at the expense of consumers. Id. at 404-05. Since no-AG agreements can "prevent the risk of competition" in the same manner as a cash payment, our Court of Appeals concluded that the Supreme Court's holding in Actavis applied equally to the circumstances before it. Id. at 405-06.

In this lawsuit, all parties agree that non-cash settlements can run afoul of Actavis as the Court of Appeals clarified in King Drug. However, the circumstances in King Drug and those before the court here are materially different. In King Drug the early entry date and no-AG agreement each dealt with the same product, Lamictal. In this action in contrast, the FTC has alleged that Teva gave up its patent challenge by offering an early entry date for AndroGel, the subject of the patent litigation, and by entering into a supply agreement with the patentee for a wholly-unrelated cholesterol drug, TriCor. Crucially, Teva's right to sell AndroGel at an early date accelerated competition in the synthetic testosterone gel market without any payment from the patentees. Indeed, the FTC has no problem with this agreement in and of itself. As to the TriCor supply agreement, there is nothing in the complaint to demonstrate that it did anything other than to facilitate competition in the market for that drug. The anticompetitive effects that the court dealt with in King Drug are simply absent here.

We further note that in King Drug, GSK does not appear to have received any freestanding consideration for its agreement not to market an authorized generic version of Lamictal. In contrast, in the TriCor supply agreement in this action, Teva would pay Abbott the cost of producing that drug plus a royalty and an additional percentage. The patentee made no agreement to stay out of the

TriCor market. The TriCor supply agreement and the AndroGel settlement simply do not raise the antitrust concerns that the court had before it in King Drug. See Pac. Bell Tel. Co. v. Linkline Commc'ns, Inc., 555 U.S. 438, 457 (2009).

Finally, we do not agree that King Drug handed down a new framework in which to evaluate Actavis reverse payment claims. As the defendants note, our Court of Appeals began their analysis with a detailed explication of Actavis. It carefully limited its holding to no-AG agreements at the outset. It stated that “[f]or the following reasons, we think that a no-AG agreement, when it represents an unexplained large transfer of value from the patent holder to the alleged infringer, may be subject to antitrust scrutiny....” Id. at 403. The conclusion of the Court of Appeals in King Drug that Actavis is not limited to reverse payments made in cash is not surprising. However, it does not affect our decision here where no reverse payments in any form as defined by the Supreme Court or our Court of Appeals are set forth in the complaint.

Having reviewed in detail the decision of our Court of Appeals and the arguments of the parties, we see nothing in King Drug which calls our analysis into question. King Drug is distinguishable from the circumstances alleged here and is not a change in controlling law. As a result, the motion of the FTC for reconsideration of our order granting the defendants’ partial motion to dismiss will be denied.