

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

FEDERAL TRADE COMMISSION,

Plaintiff,

vs.

ABBVIE INC., et al.,

Defendants.

Case Number: 2:14-CV-5151-HB

**Memorandum in Support of Plaintiff Federal Trade Commission's
Motion for Reconsideration**

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Introduction

The Third Circuit's recent decision in *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, No. 14-1243, --F.3d--, 2015 WL 3967112 (3d Cir. June 26, 2015) ("*King Drug*"), resolves in this Circuit a question that has been the subject of debate in numerous district courts: What is a cognizable reverse payment under *FTC v Actavis*, 133 S. Ct. 2223 (2013)? *King Drug* did more than simply reject the district court's holding that *Actavis* only applies to reverse payments that take the form of cash. It set out a framework for analyzing when allegations of a reverse payment involving non-cash consideration state a claim under *Actavis*.

King Drug teaches that, regardless of the form of payment, the critical question under *Actavis* is whether the plaintiff's allegations create a reasonable inference that the consideration at issue may have been used to eliminate the risk of competition. Analyzing a "no-authorized-generic" ("no-AG") agreement, the Third Circuit found that it was "likely to present the same types of problems as reverse payments of cash"—eliminating the risk of competition by inducing the generic patent challenger to drop its patent challenge and accept a later entry date. *King Drug*, 2015 WL 3967112, at *11. The Court thus found that the no-AG agreement was plausibly a reverse payment under *Actavis*.

This Court's May 6 decision conflicts with *King Drug* in two ways. First, it does not conduct the central inquiry that *King Drug* requires. Although the decision acknowledges that the TriCor deal was a transfer of "large value" from Abbott to Teva, it does not consider whether this transfer of value plausibly could have induced Teva to abandon its patent claims and accept an entry date later than it otherwise would have. Instead, the Court simply concludes that *Actavis* did not apply to "the opportunity afforded Teva to buy TriCor in the supply contract . . . and then sell it to the public." (Doc. No. 81 at 15-16.)

Second, *King Drug* makes clear that, when evaluating an alleged reverse payment agreement, the presence of some consumer benefits from the arrangement is not dispositive. As the Third Circuit explained, a court cannot dismiss a complaint that plausibly alleges that the anticompetitive harm of an alleged reverse payment agreement outweighs any procompetitive benefits. *King Drug*, 2015 WL 3967112, at *14, *17 n. 38. The May 6 decision, however, deems it critical that “the benefit flowing to Teva is also a benefit flowing to consumers who will now be able to purchase the generic form of TriCor at a reduced price.” (Doc. No. 81 at 16.) This Court’s determination at the motion to dismiss stage that the TriCor deal and the AndroGel settlement were “clearly in the best interests of the consumer”—notwithstanding allegations that the TriCor side deal bought years of protection for Abbott’s AndroGel monopoly while accelerating generic TriCor entry by just seven weeks—conflicts with *King Drug*.

Background

On May 6, 2015, this Court dismissed the FTC’s claim that the AbbVie Defendants and Teva settled their AndroGel patent litigation with an unlawful reverse payment agreement. The FTC Complaint alleges that (1) the payment took the form of a license and supply agreement relating to Abbott’s cholesterol drug TriCor that was worth hundreds of millions of dollars to Teva; (2) that, by giving Teva the ability to sell an authorized generic version of TriCor seven weeks before generic competition to TriCor would otherwise have occurred, Abbott gave up \$100 million in TriCor profits; and (3) that Abbott had no reason to facilitate generic competition to TriCor, apart from inducing Teva to agree to drop its patent challenge and forgo competing with AndroGel for three years. (Doc. No. 1 ¶¶ 119, 120, 131, 132.) The Court nonetheless ruled the TriCor deal does not constitute a reverse payment under *Actavis*.

The Court first found there were no direct monetary payments from the patentee to the alleged infringer, as was the case in *Actavis*. (Doc. No. 81 at 14-15 (“the AbbVie Defendants are not making any payments to Teva” but rather “Teva [] is paying Abbott for the supply of TriCor”).) The Court then acknowledged that “something of large value passed from Abbott to Teva” under the TriCor deal, but stated that *Actavis* does not encompass “the opportunity afforded Teva . . . to sell [TriCor] to the public in competition with Abbott.” *Id.* at 15-16. It went on to observe that “the benefit flowing to Teva is also a benefit flowing to consumers [of Tricor],” and said “[w]e see no basis in *Actavis*” for subjecting the Defendants’ agreement to antitrust scrutiny. *Id.* at 16. The Court concluded that the TriCor supply agreement—taken on its own—is procompetitive and that both the TriCor agreement and the AndroGel settlement were “clearly in the best interests of the consumer.” *Id.* at 16-17.

On June 26, the Third Circuit issued its decision in *King Drug*. This new Third Circuit authority is the first appellate decision to interpret *Actavis*. *King Drug* considered a challenge to a settlement between Teva and GlaxoSmithKline (“GSK”) concerning two forms of the prescription drug Lamictal, in which GSK promised not to launch an “authorized generic” Lamictal tablet (*i.e.*, the branded drug, but marketed as a generic). The Third Circuit reversed the district court’s dismissal of the complaint, concluding that “no-AG agreements are likely to present the same types of problems as reverse payments of cash.” *King Drug*, 2015 WL 3967112, at *11.

Standard for Reconsideration of Non-Final Orders

Under Rule 54(b), a decision “that adjudicates fewer than all the claims or the rights and liabilities of fewer than all the parties does not end the action as to any of the claims or parties and may be revised at any time before the entry of a judgment adjudicating all the claims and all

the parties' rights and liabilities.”¹ The district court “possesses inherent power over interlocutory orders, and can reconsider them when it is consonant with justice to do so.”²

In deciding whether to reconsider an interlocutory order, courts often consider Rules 59 and 60, which govern reconsideration and alteration of a final judgment. Under these rules, “a judgment may be altered or amended if the party seeking reconsideration shows at least one of the following grounds: (1) an intervening change in the controlling law; (2) the availability of new evidence that was not available when the court granted the motion for summary judgment; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice.”³ Because Rule 54(b) governs non-final orders, however, the standard is “less rigid” than the rules governing reconsideration of final judgments.⁴

Thus, an intervening court decision may warrant reconsideration of an interlocutory order under Rule 54(b), even if the strict standards applicable to final judgments are not met. For example, courts in the Third Circuit have granted motions for reconsideration where: (1) an intervening non-dispositive Supreme Court decision alters the applicable “analytical framework” to be applied,⁵ (2) a non-controlling decision by another district court “may have led [the court]

¹ Fed. R. Civ. P. 54(b).

² *Philadelphia Reserve Supply Co. v. Nowalk & Assocs., Inc.*, 864 F.Supp. 1456, 1460-61 (E.D. Pa. 1994) (quoting *United States v. Jerry*, 487 F.2d 600, 605 (3d Cir.1973)).

³ *Max's Seafood Cafe ex rel. Lou Ann, Inc. v. Quinteros*, 176 F.3d 669, 677 (3d Cir.1999).

⁴ *Gallant v. Telebrands Corp.*, 35 F. Supp. 2d 378, 394 n.16 (D.N.J. 1998) (parties “need not meet the strictures of” rules governing final judgments). See also *Garrett v. Firestone Tire & Rubber Co.*, 88-CV-0708, 1989 WL 21778 at *2 (D.N.J. Mar. 7, 1989) (“[C]ourts have routinely entertained motions to reconsider partial summary judgments based on supplemental evidence or new legal theories.”).

⁵ *Jones v. Pennsylvania*, 164 F. Supp. 2d 490, 493 (E.D. Pa. 2001) (Bartle, J.).

to a different result had it been considered,”⁶ or (3) an intervening non-controlling intermediate state appellate court decision provides “a datum for ascertaining state law.”⁷

The recent *King Drug* decision establishes the analytical framework that courts in this Circuit must apply when assessing reverse payment allegations involving non-cash consideration. Reconsideration under this new framework is appropriate under Rule 54(b).

Argument

I. *King Drug* Establishes the Framework for Assessing Reverse Payment Allegations Under *Actavis*

In *King Drug*, the Third Circuit held that the no-AG agreement at issue “falls under *Actavis*’s rule” because “it may represent an unusual, unexplained reverse transfer of considerable value from the patentee to the alleged infringer and may therefore give rise to the inference that it is a payment to eliminate the risk of competition.” *King Drug*, 2015 WL 3967112, at *2. As the court of appeals explained, “it is the prevention of that risk of competition—eliminating ‘the risk of patent invalidation or a finding of noninfringement’ by ‘paying the challenger to stay out’ of the market (for longer than the patent’s strength would otherwise allow)—that ‘constitutes the relevant anticompetitive harm.’” *Id.* at *10, quoting *Actavis*, 133 S. Ct. at 2236-37. “If the brand uses a no-AG agreement to induce the generic to abandon the patent fight, the chances of dissolving a questionable patent vanishes (and along with it, the prospects of a more competitive market).” *Id.* at *11.

King Drug does not turn on the Third Circuit’s recognition that a no-AG agreement is also “a separate restraint on competition,” as Defendants suggest. (Doc. No. 105 at 3.) Instead, *King Drug* focuses on the economic substance of the transaction and concludes that no-AG

⁶ *Bostic v. AT&T of the Virgin Islands*, 312 F. Supp. 2d 731, 734-35 (D.V.I. 2004).

⁷ *Philadelphia Reserve Supply*, 864 F.Supp. at 1461.

agreements fall within *Actavis* because they are likely to raise the *same* anticompetitive concerns as the cash payments to the generics under the separate co-promotion agreements in *Actavis*. *King Drug*, 2015 WL 3967112, at *11. As with a cash payment, in a no-AG agreement the patentee may be transferring large value to the generic patent challenger to “induce the generic to abandon the patent fight.” *Id.* And, as with a cash payment, when the generic receives monetary value from a no-AG agreement in addition to an “early-entry” license, it “presumably agrees to an early entry date that is later than it would have otherwise accepted.” *Id.*⁸

II. The FTC’s Complaint States a Claim Under the *King Drug* Framework

This Court’s May 6 decision never addressed what the Third Circuit deemed the key question under *Actavis*: whether Abbott used the TriCor deal to induce Teva to abandon its patent challenge and thereby avoid the risk of competition. Instead, it simply (1) determined that Abbott made no direct monetary payments to Teva; (2) decided that the large value Abbott transferred to Teva through the TriCor deal did not fall within *Actavis*; and (3) held the TriCor deal was procompetitive because it conferred a benefit on TriCor consumers. The Court deemed the presence of benefits to TriCor consumers to preclude any antitrust scrutiny under *Actavis*, even though the co-promotion agreements in *Actavis*, if they had been entirely independent and unrelated to the settlement, would also likely have some consumer benefit.

King Drug calls for a different approach. Rather than short-circuiting the antitrust analysis, the Court should undertake the inquiry mandated by *King Drug*. Under that framework, the FTC’s complaint amply states a claim under *Actavis*. Moreover, *King Drug* shows that the presence of some benefits to consumers cannot immunize a reverse payment claim from scrutiny.

⁸ See also *King Drug*, 2015 WL 3967112, at *13 (“the antitrust problem [in *Actavis*] was that, as the Court inferred, entry might have been earlier, and/or the risk of competition not eliminated, had the reverse payment not been tendered”).

A. As in *King Drug*, the alleged reverse payment here raises the same antitrust concern that the Supreme Court identified in *Actavis*

In concluding that the Lamictal no-AG agreement was a cognizable reverse payment, the Third Circuit focused on the capacity of no-AG agreements to cause the same type of harm as reverse payments in cash, that is, whether such an agreement may be “a payment to eliminate the risk of competition.” *King Drug*, 2015 WL 3967112, at *2. Regardless of its form, *King Drug* states, a payment “to induce the generic to abandon the patent fight” eliminates “the chance of dissolving a questionable patent,” and the generic challenger “presumably agrees to an early entry date that is later than it would have otherwise accepted.” *Id.* at *11. The Third Circuit set out various considerations that create an inference of such harm. Under this analytical framework, the FTC’s allegations likewise present the prospect of such harm in the AndroGel market.

First, *King Drug* observed that the alleged payment—the no-AG agreement—“may be of great monetary value” to the generic. *Id.* at *11. Here, the FTC’s complaint alleges that at the time of the agreement, Teva expected the TriCor deal to provide \$175 million in profits over four years (and it proved to be worth far more). (Doc. No. 1. ¶¶ 120-21.)

Second, the Third Circuit explained that “the source of the benefit to the claimed infringer is something costly to the patentee.” *King Drug*, 2015 WL 3967112, at *11 (internal quotations omitted). Though there was no direct monetary payment alleged, *King Drug* noted that the no-AG agreement, in substance, “transfers the profits the patentee would have made from its authorized generic to the settling generic.” *Id.*⁹ A similar costly transfer from the patentee to the settling generic is alleged here. (See Doc. No. 1 ¶¶ 9-10, 114-117, 125-128, 131-

⁹ *King Drug* thus rejected the contention that arrangements in which the value transferred to the generic takes the form of profits obtained by selling a generic product in competition with the brand-name drug manufacturer cannot constitute reverse payments as a matter of law.

132 (alleging that the TriCor deal effectively transferred to Teva branded TriCor revenues that Abbott would have otherwise earned had it not enabled Teva to launch generic TriCor in November 2012).) As alleged, Abbott calculated that under the TriCor deal it would likely sacrifice \$100 million in branded TriCor revenues. (Doc. No. 1 ¶ 132.)

Third, *King Drug* observed that a settlement is “something more than just an agreed-upon early entry” when the patentee acts against its economic interests by “giv[ing] up the valuable right to capture profits.” *Id.* at *11. *King Drug* reasoned that because “marketing an authorized generic was allegedly in GSK’s economic interest,” GSK’s agreement to sacrifice this economic interest via a no-AG agreement “was an inducement . . . to ensure a longer period of supracompetitive monopoly profits based on a patent at risk of being found invalid or not infringed.” *Id.* at *14. *See also id.* at *11 (same). Here, the Complaint similarly alleges that the TriCor deal—by giving Teva the ability to launch an authorized generic version of TriCor before independent generic was imminent—was contrary to Abbott’s economic interests (apart from its use as a payment to avoid the risk of competition). (Doc. No. 1 ¶¶ 125-127.)

Thus, under the *King Drug* framework, the FTC’s Complaint sufficiently alleges that the TriCor deal “represent[s] an unusual, unexplained reverse transfer of considerable value from the patentee to the alleged infringer,” which gives rise to the inference that the TriCor deal was “a payment to eliminate the risk of competition.” *King Drug*, 2015 WL 3967112, at *2.

B. *King Drug* establishes that the presence of some consumer benefit in another market is not dispositive

The Court’s May 6 opinion does not address whether the FTC’s allegations make it plausible that Abbott used the transfer of “something of large value” under the TriCor deal to induce Teva to accept the AndroGel settlement. Instead, it dismisses these allegations as merely the FTC’s belief that “Abbott signed a bad deal for itself.” (Doc. No. 81 at 16.) It deems the

transfer of value through the TriCor deal to be outside *Actavis*'s concept of a reverse payment and the deal procompetitive because "the benefit flowing to Teva is also a benefit flowing to consumers." *Id. King Drug*, however, makes clear that the presence of such a consumer benefit cannot justify granting a motion to dismiss unless there is "no dispute" that "the procompetitive benefits of the alleged reverse payment outweigh the payment's anticompetitive harm." *King Drug*, 2015 WL 3967112, at *17 n.38.

In *King Drug*, the plaintiffs alleged that Teva agreed to drop its challenge to GSK's patent and forgo launching its generic Lamictal tablet product for several years in exchange for two things: a "no-AG" agreement for Lamictal tablets and a license and supply agreement enabling Teva to sell an authorized generic version of GSK's chewable Lamictal product 37 months before the patent expired. *Id.* at *1, *4. The Third Circuit rejected arguments that the consumer benefits of the chewables agreement justified the district court's dismissal of the complaint. It noted, without deciding, that procompetitive benefits in one market might not be a permissible justification for anticompetitive harm in a different market. *Id.* at *14 n. 34. It concluded that, in any event, the plaintiffs' allegations made it plausible that "any procompetitive aspects of the chewables arrangement were outweighed by the anticompetitive harm from the no-AG agreement." *Id.* at *14.

A determination that an agreement between competitors is procompetitive is a factual issue. *Id.* at *16-17. Unless there is "no dispute" that procompetitive effects predominate, the weighing of procompetitive aspects of an allegedly anticompetitive agreement is to be resolved in a rule of reason balancing analysis, not as a matter of law on a motion to dismiss. *Id.* at *16-17 & n. 38. Where factual allegations taken as true make it plausible that the alleged harm of the alleged reverse payment agreement exceeds any procompetitive benefits, the plaintiff should be

afforded the opportunity to prove its case under the traditional rule of reason framework. *Id.* at *14. As noted above, such allegations are present here. (Doc. No. 1 ¶¶ 10, 116, 117, 127, 128 (the protection of the Abbott's AndroGel monopoly extended over a period of years and the benefit to consumers of TriCor was simply the seven-week period by which generic TriCor entry was advanced).) As *King Drug* makes clear, it was improper for the Court to foreclose antitrust scrutiny based on the presence of some benefits to TriCor consumers and resolve the net competitive effects of the challenged agreement on the pleadings.

Conclusion

Because the Complaint states a cognizable reverse payment claim under *King Drug*, the FTC respectfully requests that the Court reconsider and vacate its May 6 dismissal of the reverse payment claim, deny Defendants' motion to dismiss, and reinstate the reverse payment claim to allow the FTC the opportunity to prove its case.

Dated: July 20, 2015

Respectfully submitted,

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