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# 1st Circ. Charts Conservative Post-Actavis Course In Loestrin

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In its Feb. 22, 2016 unanimous panel decision in the Loestrin 24 Fe Antitrust Litigation,[1] the U.S. Court of Appeals for the First Circuit became the second federal appellate court since the U.S. Supreme Court's seminal decision in Federal Trade Commission v. Actavis[2] to wrestle with the knotty problem of "reverse payment" settlements of Hatch-Waxman Act-related[3] pharmaceutical patent infringement claims.[4] Although the court of appeals sought to limit its decision to a narrow legal question, the reader familiar with this growing body of litigation might take five points away from the decision.

1. In re Loestrin is most notable for overruling the district court's outlier holding that only cash payments can constitute "large and unjustified" settlement payments under Actavis and trigger antitrust scrutiny.[5] But the ruling is limited. Because the court of appeals decided this specific and narrow question of law, it did not reach the further question (also left undecided by the district court) whether the specific noncash compensation alleged in the complaint, including "no-AG agreements" and "acceleration clauses," could be unlawful "reverse payments" under Actavis.[6]

2. The argument that side deals made on commercially reasonable terms between the settling parties cannot give rise to "large and unjustified" payments has been made stronger. A simmering but little-discussed issue in the "reverse payment" settlement cases is whether side deals that are profitable for the generic manufacturer and reflect commercially reasonable, arm's- length terms may be freely entered into by settling parties. Typically, plaintiffs claim that side deals are merely pretexts for paying the generic to settle a Hatch-Waxman claim and are substantively equivalent to cash. Language in a number of opinions, building on language in Actavis itself, supports a reading that only payments in excess of fair market value for services rendered should trigger antitrust scrutiny, although the issue has not been definitively resolved.[7] The First Circuit's decision in Loestrin adds to the weight of authority supporting the view that only excessive compensation truly matters under Actavis. Indeed, the court's discussion arguably is part of its holding that noncash compensation is within the scope of Actavis:[8]

The district court reasoned that the reverse payments alleged in Actavis involved only cash payments, but that is not so: in Actavis, it was alleged that the reverse payments involved side deals in which the generic manufacturers agreed to promote the brand name drug at issue in exchange for multi-million dollar payments from the brand manufacturer. ... This fact alone demonstrates that the Supreme Court recognized that a disguised above-market deal, in which a brand manufacturer effectively overpays a

generic manufacturer for services rendered, may qualify as a reverse payment subject to antitrust scrutiny and militates against limiting the Supreme Court's decision to pure cash payments.

Further clarification of the question whether a market-rate side deal can be a "reverse payment" must await litigation in which such facts are squarely presented.[9]

3. The five-factor Actavis test is not a restatement of the rule of reason. In Actavis, the Supreme Court articulated five "sets of considerations" that the court said "lead to the conclusion that ... the FTC should have been given the opportunity to prove its antitrust claim."[10] These considerations were, in summary: (1) reverse payments have the "potential for genuine adverse effects on competition," (2) such anti-competitive effects "will at least sometimes prove unjustified," (3) where anti-competitive effects may occur, the patentee-brand manufacturer "likely possesses the power to bring about that harm about in practice," (4) litigation of the likely effects of a "large and unjustified payment" is feasible and litigating patent validity is "normally not necessary ... to answer the antitrust question," and (5) settlements of pharmaceutical patent litigation can occur in ways that do not implicate antitrust concerns.[11]

The district court, echoing an approach taken by some other courts, looked to the five considerations as a guide to application of the rule of reason. The First Circuit disagreed, characterizing the factors merely as reflecting the Supreme Court's reasons for deciding that "reverse payments" might under certain circumstances violate the antitrust laws.[12] In so ruling, the court of appeals nonetheless noted that certain of the five factors echoed elements of a traditional rule-of-reason analysis.[13] But the court's passing discussion of the rule of reason gives no indication of the extent to which that issue and the related issue of burdens of proof remain unsettled. The decision of the California Supreme Court in In re Cipro Cases I & II,[14] which established for "reverse payment" cases a "structured rule of reason," is an example of opportunities that remain to flesh out the determination of lawfulness, once a "large and unjustified" payment has been found.

4. Plaintiffs must plead some facts showing that a payment was "large and unjustified," but need not quantify their allegations with precision. The district court in Loestrin ruled that Actavis requires that complaints quantify and evaluate allegedly "large and unjustified" payments as a threshold pleading matter.[15] The lower court's decision that noncash payments did not suffice to make out a claim rested in part on its conclusion that the value of noncash payments is "almost impossible" to determine, and that the pleading standard therefore could not be met.[16] The court of appeals again disagreed, allowing that valuation might be "much more difficult to compute" than cash but that such tasks were often undertaken in antitrust cases.[17] The First Circuit then restated what it understood Bell Atlantic Co. v. Twombly[18] and Ashcroft v. Iqbal[19] to require in the context of reverse payment cases:[20]

We agree with those courts that, rather than rejecting wholesale Actavis's applicability to non-cash payments, have required that the plaintiffs plead information sufficient "to estimate the value of the term, at least to the extent of determining whether it is 'large' and 'unjustified.'" Consistent with Twombly, which declined to "require heightened fact pleading of specifics," we do not require that the plaintiffs provide precise figures and calculations at the pleading stage[.] Requiring such a high burden would impose a nearly insurmountable bar for plaintiffs at the pleading stage because "very precise and particularized estimates of fair value and anticipated litigation costs may require evidence in the exclusive possession of the defendants, as well as expert analysis." Nevertheless, the plaintiffs must allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under Actavis.

This guidance will probably have some clarifying effect at the margins, but at the same time it seems destined to spawn new grounds for both upholding and rejecting complaints.

5. Don't rush us! This stuff is hard! The First Circuit began its discussion by limiting its holding to the single legal issue of whether a noncash payment could trigger antitrust scrutiny and ended its discussion on the same note, stating that it would not even decide whether the complaints stated a claim: "At this juncture, we feel that the most prudent course is to proceed one step at a time, and we therefore leave for another day the question whether [the plaintiffs] adequately alleged that the individual provisions of the settlement agreements warranted antitrust scrutiny as unlawful reverse payments."[21] The Supreme Court demonstrated similar reticence when it expressly invited the lower courts to apply the Delphic language of Actavis to the many fact situations presented by the market.[22] No better evidence could be mustered that the issues raised by "reverse payment" settlements are difficult and occasionally confounding. Future courts may well take the lead of the First Circuit in focusing on the narrow issues that are squarely presented, boding an era of litigation that only slowly will yield consensus rulings on the many contentious issues that remain.

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[1] In re Loestrin 24 Fe Antitrust Litig., No. 14-2071, 2016 WL 698077 (1st Cir. Feb. 22, 2016).

[2] Federal Trade Commission v. Actavis, 570 U.S. ___, 133 S. Ct. 2223 (2013).

[3] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271, 282 (1984).

[4] A "reverse payment" settlement agreement typically occurs when a brand-name drug manufacturer, after initiating a Hatch-Waxman patent infringement action against a generic drug manufacturer, settles the action by making "payments" in some form to the generic manufacturer in exchange for a delay in the marketing of the generic product. The Actavis Court held that while not per se unlawful, certain of these agreements can be subject to rule of reason antitrust scrutiny under Section 1 of the Sherman Act.

[5] In re Loestrin, 2016 WL 698077, at *8-*9, rev'g, In re Loestrin 24 Fe Antitrust Litig., 45 F. Supp. 3d 180, 189, 193-93 (D.R.I. 2014).

[6] In re Loestrin, 2016 WL 698077, at *8, *12. A "no-AG" agreement is one in which the brand manufacturer agrees not to market an authorized generic during the 180-day generic exclusivity period enjoyed by the generic manufacturer, thereby giving the generic some measure of protection from

competition during the period. An "acceleration clause" allows generic entry by the settling generic earlier than the agreed-upon date if a different generic enters the market. Both forms of agreement have been the subject of much discussion in post-Actavis cases. See, e.g., King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp. (Lamictal), 791 F.3d 388, 403 (3d Cir. Jun. 26, 2015) (No-AG agreement may be anticompetitive "when it represents an unexplained large transfer of value from the patent holder to the alleged infringer"); In re Wellbutrin XL Antitrust Litig., CV 08-2431, 2015 WL 5582289, at *16-17 (E.D. Pa. Sept. 23, 2015) (No-AG agreement not tied to the cessation of litigation may not implicate Actavis); In re Actos End Payor Antitrust Litig., 13-CV-9244 RA, 2015 WL 5610752, at *15 (S.D.N.Y. Sept. 22, 2015) (plaintiff failed to prove the challenged acceleration clauses were anticompetitive reverse payments).

[7] See, e.g., Actavis, 133 S. Ct. at 2236 ("[w]here a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement"), 2237 ("the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification."); In re Opana ER Antitrust Litig., 14 C 10150, 2016 WL 521005, at *6-7 (N.D. Ill. Feb. 10, 2016) (noting that Actavis held reverse settlement payments may fail a rule of reason analysis if they are unjustified and large, i.e., "anything more than the value of the avoided litigation costs plus any other services provided from the generic to the brand manufacturer."). The Federal Trade Commission may take a contrary position. In a consent order entered in Fed. Trade Comm'n. v. Cephalon, Inc., 2:08-CV-2141, 2015 WL 4931442, at *2 (E.D. Pa. June 17, 2015), the definition of "reverse payments" included in certain circumstances sums provided to the generic in exchange for services rendered, "regardless of whether the [generic challenger] purportedly transfers value in return."

[8] In re Loestrin, 2016 WL 698077, at *8 (italics added).

[9] Brand manufacturers in various cases have contended that side deals reflected commercially reasonable terms, although published opinions do not always address the issue so as to present it for decision. See, e.g., In re K-Dur Antitrust Litig., 686 F.3d 197, 203 (3d Cir. 2012), cert. granted, judgment vacated sub nom., Merck & Co. v. La. Wholesale Drug Co., 133 S. Ct. 2849 (2013), and cert. granted, judgment vacated sub nom., Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co., 133 S. Ct. 2849 (2013), and reinstatement granted, No. 10-2077, 2013 WL 5180857 (3d Cir. Sept. 9, 2013); F.T.C. v. AbbVie Inc., 107 F. Supp. 3d 428, 436 (E.D. Pa. 2015), reconsideration denied sub nom., Fed. Trade Commn. v. AbbVie Inc., No. CV 14-5151, 2015 WL 5025438 (E.D. Pa. Aug. 25, 2015).

[10] Actavis, 133 S. Ct. at 2234.

[11] Id. at 2234-37.

[12] In re Loestrin, 2016 WL 698077, at *12 n.12.

[13] Id.

[14] See In re Cipro Cases I & II, 348 P.3d 845, 865-871 (Cal. 2015), reh'g denied (July 8, 2015).

[15] 45 F. Supp. 3d at 193. A number of other district courts have taken a similar approach. See, e.g., In re Effexor XR Antitrust Litig., CIV.A. 11-5479 PGS, 2014 WL 4988410, at *23 (D.N.J. Oct. 6, 2014) (granting in part the defendants' motion to dismiss, the court held it was impossible to establish the

value of the non-monetary reverse payment); In re Lipitor Antitrust Litig., 46 F. Supp. 3d 523, 547 (D.N.J. 2014) (granting a motion the dismiss, the court, when assessing whether the complaint satisfactorily plead a "large" payment, held that "this Court looking at the Complaint is unable to perform the analysis, as the Plaintiffs failed to plausibly allege an estimate of the monetary value of the non-monetary payment, and the amount of legal fees of Ranbaxy should have been subtracted from same").

[16] 45 F. Supp. 3d at 191-93.

[17] In re Loestrin, 2016 WL 698077, at *11.

[18] 550 U.S. 544 (2007).

[19] 556 U.S. 662 (2009).

[20] In re Loestrin, 2016 WL 698077, at *11 (citations omitted).

[21] Id. at *12.

[22] Actavis, 133 S. Ct. at 2238.