

# Post-Actavis Rulings Focus on What Constitutes a Payment in Reverse-Payment Settlements

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Nearly a year and a half after the Supreme Court's landmark decision in *Federal Trade Commission v. Actavis, Inc.*, 133 S.Ct. 2223 (2013), the hotly contested issue of the legality of reverse-payment settlements remains as fraught as ever. With *Actavis*, in which pharmaceutical patent holders allegedly made a payment to potential generic competitors to delay their entry into the market, the Supreme Court resolved the core question of what legal standard should apply to reverse-payment settlements in favor of the rule of reason. Under this standard, the Supreme Court held that pharmaceutical patent settlements can potentially be anti-competitive when a brand manufacturer makes a "large" and "unjustified" payment to a potential generic competitor. While the Supreme Court's lack of specific guidance led observers to expect that the lower courts would grapple with the question of what constitutes a "large" and "unjustified" payment, they have instead struggled with an altogether more basic question: What is a payment? Following the decision in *Actavis*, courts have largely split over whether the payment contemplated by *Actavis* requires a transfer of cash from the brand manufacturer to the generic competitor or if a noncash value transfer is sufficient to trigger antitrust scrutiny.

At least two district courts have concluded that arrangements between branded and generic pharmaceutical companies that do not involve cash cannot as a matter of law constitute unlawful payments under *Actavis*. However, most courts have reached the opposite conclusion, broadly reading *Actavis* to encompass other forms of payment, such as distribution, back-up manufacturing, copromotion or licensing agreements, or a commitment by the brand not to launch an "authorized" generic for a certain period of time. The most recent decisions take this analysis a step further — several courts have ruled that *Actavis* may apply to nonmonetary exchanges only if plaintiffs can "plausibly" and "reliably" value these alleged payments.

## Cash Controls

The clearest ruling holding that *Actavis* requires an actual cash payment may be found in *In re Lamictal Direct Purchaser Antitrust Litigation*. In January 2014, Judge William H. Walls of the District of New Jersey dismissed plaintiffs' claims that an agreement by the brand not to launch an authorized generic was an illegal reverse payment. Judge Walls reasoned that because the challenged settlement involved no cash payment, it was not subject to antitrust scrutiny under *Actavis*. The court noted that, while *Actavis* contains "scattered indications" that its holding could apply to nonmonetary settlements, those references could not counter the "overwhelming evidence that when the Supreme Court said 'payment' it meant a payment of money."<sup>1</sup> Nine months later, Judge William E. Smith of the District of Rhode Island followed suit, dismissing plaintiffs' claims relating to defendants' alleged scheme to delay generic entry of the birth control pill Loestrin 24 FE. Judge Smith emphasized the policy reasons supporting his decision not to extend *Actavis* beyond cash payments, which "militate in favor of a cautious approach by the district courts, and against a cavalier extension of the *Actavis* holding to virtually any non-cash settlement package that has presumably substantial value."<sup>2</sup>

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## Actavis Not Limited to Cash Payments

Most district courts have declined to read *Actavis* so narrowly, instead holding that *Actavis* is not limited to cash payments. In the District of Massachusetts, Judge William G. Young ruled that unlawful agreements could include nonmonetary payments because “[a]dopting a broader interpretation of the word ‘payment,’ ... serves the purpose of aligning the law with modern-day realities.”<sup>3</sup> In *In re Niaspan*, a reverse-payment case in the Eastern District of Pennsylvania, the court agreed with Judge Young that *Actavis* is not limited to cash payments. The court cited the dictionary definition of the word payment — “delivery of money or some other valuable thing” — and noted that “[c]onsistent with this broad definition, courts have refused to limit the term ‘payment’ to an exchange of cash in numerous areas of the law.”<sup>4</sup>

In *Lipitor* and *Effexor* (both authored by Judge Peter G. Sheridan of the District of New Jersey), the court agreed that noncash payments may trigger antitrust review but held that *Actavis* requires plaintiffs to plausibly allege a reliable estimate of any nonmonetary settlement in order to survive a motion to dismiss. The court dismissed the complaint in *Lipitor* with prejudice, not because the settlement did not involve a cash payment, but because plaintiffs failed to “determine an estimate of the monetary value of the settlement at that time.”<sup>5</sup> Similarly, in *Effexor*, Judge Sheridan dismissed reverse-payment allegations stemming from the brand manufacturer’s alleged agreement not to launch an authorized generic version of the drug during the period of the first-filing generic firm’s marketing exclusivity, thereby purportedly reducing competition because “[s]imply alleging some sort of value of a no-authorized generic agreement, absent a reliable foundation supporting that value, does not establish the plausibility required by Rule 12(b)(6).”<sup>6</sup>

More recently, Judge William H. Orrick of the Northern District of California agreed that *Actavis* is not limited to cash payments and denied defendants’ motion to dismiss plaintiffs’ claims, which were based in part on the same type of “no authorized generic” agreement at issue in *Lipitor*. Judge Orrick acknowledged that “in order to determine if a term is a large and unjustified payment, as *Actavis* requires, courts must be able to calculate its value,” but he was skeptical that a “cash-only” rule was warranted, emphasizing that “not all non-monetary-payments are impossible to value.”<sup>7</sup> Indeed, almost every judge that has considered whether *Actavis* applies to noncash payments acknowledged the potential difficulty in evaluating nonmonetary settlements. Nevertheless, the majority appear to be of the view that a cash-only rule may not adequately reflect the realities of pharmaceutical settlements today.

## Looking Ahead

Although *Actavis* imposed the rule of reason in evaluating the legality of reverse-payment settlements, the Supreme Court’s decision created many more questions than it answered and offered little guidance to the lower courts on the proper application of the rule of reason. Whether *Actavis* is limited to cash settlements is one such question, and the coming year promises to be an important one for further developments in reverse-payment cases as several new district court decisions are expected on this issue. In addition, the Third Circuit may

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become the first appellate court to weigh in on the debate following oral arguments held in late November in the *Lamictal* appeal. Given the number of pending reverse-payment cases around the country, and the willingness of district courts to dispose of such cases on motions to dismiss, 2015 likely will bring further development of post-*Actavis* case law at the Circuit Court of Appeals level.

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<sup>1</sup> *In re Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560, 568 (D. N.J. 2014). The *Lamictal* decision is currently on appeal in the Third Circuit. The court heard oral arguments in late November.

<sup>2</sup> *In re Loestrin 24 FE Antitrust Litig.*, MDL No. 13-2472-S-PAZ, 2014 WL 4368924, at \*10 (D.R.I. Sept. 4, 2014). The *Loestrin* plaintiffs filed a Notice of Appeal to the First Circuit on October 14, 2014.

<sup>3</sup> *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013).

<sup>4</sup> *In re Niaspan Antitrust Litig.*, MDL No. 2460, 2014 WL 4403848, at \*11 (E.D. Pa. Sept. 5, 2014) (citing Black's Law Dictionary 1309 10th ed. 2014).

<sup>5</sup> *In re Lipitor Antitrust Litig.*, Civil Action No. 3:12-cv-02389 (PGS), 2014 WL 4543502, at \*25 (D.N.J. Sept. 12, 2014).

<sup>6</sup> *In re Effexor XR Antitrust Litig.*, Civil Action No. 11:5479 (PGS(LHG)), 2014 WL 4988410, at \*21 (D. N.J. Oct. 6, 2014).

<sup>7</sup> Order Granting in Part and Denying in Part Motion to Dismiss, *In re Lidoderm Antitrust Litig.*, 3:14-md-02521-WHO, at \*18 (N.D. Cal. Nov. 17, 2014), ECF No. 117.