

Where We Stand On Pharmaceutical Patent Settlements

Law360, New York (October 23, 2015, 10:50 AM ET) -- Two and a half years after the pivotal U.S. Supreme Court opinion in *Federal Trade Commission v. Actavis Inc.*,^[1] lower courts continue to grapple with the broad contours of that decision. After more than 10 substantive rulings from the district courts during this time, the prescience of Justice John Roberts' statement in his dissent in *Actavis* — “good luck to the district courts”^[2] — is clear. This article starts by detailing the recent district court decisions in *In re Actos* and *In re Wellbutrin XL* to highlight issues the district courts are wrangling over today.

Beyond the district courts, appellate courts have begun to weigh in, first with *In re Lamictal*, where the Third Circuit ruled earlier this year that a “no-authorized generic” or “no-AG” provision (an agreement by a brand manufacturer to refrain from introducing its own generic version of a branded product) can constitute a payment under *Actavis*. In 2016, we are likely to see additional appeals rulings, as described below, out of the Third Circuit and with the First Circuit addressing the complexities of the *Nexium* case.

Finally, proposed legislative reform is also under consideration again. While the courts are actively putting gloss on *Actavis*, as the Supreme Court anticipated — reflected in the majority's statement that it would “leave to the lower courts the structuring of the present rule-of-reason antitrust litigation”^[3] — we see Congress stepping back in with a renewed proposal to legislate the standards of review for settlements.

Pay-for-Delay in the District Courts

Over a dozen pay-for-delay actions are currently percolating in the district courts, four of which were filed before *Actavis* and at least 10 of which were brought in the wake of the June 2013 decision. While early pay-for-delay cases (including *Actavis* itself) often relied upon the presence of an alleged cash payment by the brand manufacturer to the generic manufacturer, many cases have also focused on whether a no-AG provision can constitute a payment from brand to generic. Later-filed actions have further tested and expanded the theories behind pay-for-delay claims, with plaintiffs alleging that provisions such as “acceleration clauses” (allowing entry by a settling generic firm if any other generic is launched before the agreed-upon entry date), early entry licenses on products not at issue in the instant litigation, and forgiveness of debt in unrelated matters should also be considered anti-competitive payments from brands to generic firms.



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The year 2015 has seen eight substantive pay-for-delay decisions at the motion to dismiss, summary judgment, trial or post-trial phase. In the last month, two decisions of interest address what district courts will and won't consider to be anti-competitive payments in this context: In re Actos End-Payor Antitrust Litigation, No. 13-cv-9244 (S.D.N.Y. Sept. 22, 2015) and In re Wellbutrin XL Antitrust Litigation, No. 2:08-cv-2433 (E.D. Pa. Sept. 23, 2015)

In re Actos Antitrust Litigation

The In re Actos litigation (S.D.N.Y.) constitutes one of the first pay-for-delay cases that did not rely upon a no-AG provision, cash payment, or side-business arrangement as evidence of "pay-for-delay." Rather, indirect purchasers challenged settlement agreements concerning the drugs Actos and ACTOplus between Takeda Pharmaceutical Co. and four generic manufacturers containing: (1) early-entry licenses; (2) acceleration clauses; and (3) an authorized generic license to Teva Pharmaceutical Industries. The defendants moved to dismiss the complaint, arguing that these provisions, rather than reflecting a payment from brand to generic, provided for earlier and increased competition and thus could not be viewed as anti-competitive payments to keep the settling companies off the market. In particular, the plaintiffs' novel assertion that an acceleration clause could constitute "pay-for-delay" was rebutted by the defendants' argument that the provision bore no resemblance to the types of payments contemplated by Actavis, and in fact was a pro-competitive term.

Judge Ronnie Abrams agreed with the defendants, granting their motions to dismiss the complaint on Sept. 22, 2015. Although she noted that she shared the view that Actavis "is not limited to" cash payments,[4] she found that the terms at issue here were not anticompetitive because the generic defendants "received no compensation from Takeda, but rather were compensated only through the market when they began selling their generic product" — competition that would be "to the consumer's benefit." [5] Judge Abrams further explained that "at their core, the settlements at issue simply granted the [generic defendants] a compromise date of generic entry — the very type of settlement sanctioned by" Actavis.[6] In particular, regarding the acceleration clauses at issue, she found that their "practical effect" was to "increase competition" under certain circumstances, which made it "difficult to view the provisions as 'payments' from Takeda to the generics to retain monopoly pricing power." [7] The court agreed with the defendants that Actavis does not require the parties to "maximize competition" through their settlement agreements, only that they not "unlawfully restrict competition." [8]

In re Wellbutrin XL Antitrust Litigation

In re Wellbutrin XL (E.D. Pa.) presented another interesting twist in the developing "pay-for-delay" case law: The patent litigation settlement agreements at issue permitted the underlying patent litigation to continue, a circumstance not arising in any previous "pay-for-delay" cases. Here, direct and indirect purchasers challenged the Wellbutrin XL settlement agreements between GlaxoSmithKline PLC, Biovail Laboratories Inc. and multiple generic manufacturers, which — in addition to letting the patent litigation continue — also: (1) allowed generic entry upon a finding of non-infringement or patent invalidity, and in any case no later than May 30, 2008 (10 years before patent expiry); (2) granted sublicenses to patents at issue pending in a separate patent lawsuit; (3) provided a guaranteed supply of generic Wellbutrin XL; and (4) contained a no-AG provision for the generic manufacturers' period of exclusivity.

Judge Mary A. McLaughlin granted GSK's motion for summary judgment on Sept. 23, 2015, finding the settlement agreements permissible despite the inclusion of a no-AG provision. Although the court found dispositive the fact that these settlements did not terminate the underlying litigation, Judge McLaughlin went out of her way to assert that she was not creating a bright-line test that all patent settlements that allow the underlying litigation to continue are immune from antitrust scrutiny, because that would "create an easily exploited loophole." [9] Nonetheless, the court called it a "factor" and stated that the "plaintiffs cannot establish the anti-competitive harm contemplated by Actavis" and that they failed to establish the necessary groundwork to argue that the agreement led to a delayed introduction of generic Wellbutrin by showing "that an alternate settlement would have been reached absent a no authorized generic agreement." [10]

The Wellbutrin court also noted some unique facts presented by this case regarding the no-AG provision. Judge McLaughlin found compelling the fact that the settlement, on balance, was procompetitive, and would not have been agreed to by Teva without a no-AG provision. [11] She further noted that Teva, in negotiating at the time of the settlement (in 2005), was under the false impression that as the first-filer, the Hatch-Waxman Act provided it with the right to be the only generic on the market for 180 days, so by negotiating for a no-AG clause, it was merely trying to retain its rights. Ultimately, while this decision finds a no-AG permissible, it is under very limited facts.

Two other factors were of significance to the court. The court found that the settlements provided for benefits to the generics such as broader patent rights and product supply, and that the FTC had an opportunity to object to the settlement, but did not object.

Pay-for-Delay in the Appellate Courts

The experience of the district courts to date adjudicating "pay-for-delay" allegations highlights the challenges of navigating the post-Actavis waters. The appellate courts have begun to try to untangle some of the district court opinions, starting with the Third Circuit's decision issued earlier this year with regard to no-AG provisions and an upcoming Third Circuit decision broadly addressing the standards plaintiffs must satisfy to survive a motion to dismiss. Meanwhile, the First Circuit will hear later in 2016 the appeal of the Nexium case, which presents a highly complicated post-jury verdict factual record.

In re Lamictal

The sole appeals court to issue an opinion to date in the "pay-for-delay" arena is the Third Circuit. It ruled on June 26, 2015, in *Lamictal* that a no-AG provision can constitute a payment under Actavis "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." [12]

However, the Third Circuit's opinion appears to go beyond no-AG provisions, implying that other types of non-cash payments could constitute payments under Actavis. The court explained that it does "not believe Actavis's holding can be limited to reverse payments of cash" and noted that Actavis is primarily concerned with payments that "negatively impact consumer welfare by preventing the risk of competition." [13] The opinion adopted a substance-over-form approach to the defendants' contention that they were merely exercising their rights to grant exclusive licenses, reasoning instead that the defendants were attempting to "use valuable licensing in such a way as to induce a patent challenger's delay," an argument expressly rejected by Actavis. [14]

Subsequently, plaintiffs have argued in the numerous cases pending in the district courts that Lamictal is persuasive authority in support of the complaints they have brought challenging settlements. Meanwhile, after having their petitions for rehearing en banc denied, the Lamictal defendants have indicated their intention to file a writ for certiorari to the U.S. Supreme Court. However, it seems unlikely that the court would want to dive back in on these issues so soon after Actavis, especially since only one appeals court has weighed in to date in this area.

In re Effexor and In re Lipitor

Following its Lamictal decision, the Third Circuit has agreed to hear two additional pending “pay-for-delay” decisions together. The court granted the defendants’ request to consolidate the Effexor and Lipitor cases for disposition by a single panel, citing “the similarity of the reverse payment claims raised by Appellants in both the Effexor and Lipitor litigation.”[15]

At issue in both of these cases is whether a non-monetary payment may constitute “pay-for-delay” under Actavis and, if so, what pleading standard plaintiffs must satisfy in asserting that a non-monetary payment is a “large and unjustified” payment. In Lipitor, Judge Peter G. Sheridan (D. N.J.) dismissed a complaint alleging: (1) a “sweetheart” agreement to dismiss damages claims alleged to be worth hundreds of millions of dollars; and (2) the right to market generic Lipitor in at least 11 foreign markets outside the United States. He found that the plaintiffs failed to “demonstrate [a] reliable foundation showing a reliable cash value of the non-monetary payment.”

In Effexor, Judge Sheridan — the very same judge as in Lipitor — dismissed a complaint alleging “pay-for-delay” in the form of a no-AG provision. Judge Sheridan reasoned that although Actavis does not require a payment to be in cash, a “non-monetary payment must be converted to a reliable estimate of its monetary value so that it may be analyzed against the Actavis factors.”[16] He found that the plaintiffs had failed to sufficiently allege such an estimate.

The Third Circuit must now assess not only the application of Actavis to three distinct types of alleged payments, but (assuming Actavis applies) must also craft an opinion that provides guidance as to what plaintiffs must allege in all situations. The briefing schedule for Lipitor/Effexor runs through February 2016, with oral arguments yet to be scheduled.

In re Nexium

The First Circuit’s task in reviewing Judge William G. Young’s (D. Mass.) opinion in *In re Nexium* exemplifies the challenge resulting from increased complexity in settlement agreements, as well as a complex factual record. Most importantly, this is the only “pay-for-delay” case to go through trial and produce a jury verdict, so it presents important issues that may provide direction for cases proceeding towards trial in the First Circuit and other circuits.

The plaintiffs filed suit in August 2012 against brand AstraZeneca and generic companies Ranbaxy, Teva, and Dr. Reddy’s, alleging: (1) a no-AG provision; (2) contingent launch/acceleration clauses; (3) “sweetheart” side deals for other products; and (4) forgiveness for liabilities resulting from at-risk launches of other products. On top of this, the court needed to grapple with antitrust causation—i.e., the court was asked to evaluate whether and to what extent any or all of the generic defendants, or even an unknown generic manufacturer, would have entered the market but for the settlement agreements.

The district court's proceeding has created an incredibly complex factual record for the First Circuit; indeed, Judge Young admitted in February 2015, "I did not try this case very well." [17] Several key opinions preceding trial went back and forth in favor of the litigants. First, in September 2013, while ruling on the defendants' motions to dismiss, the court held that no-AG commitments and forgiveness of liabilities can constitute payments under Actavis. [18] However, in February 2014, the court granted several motions for summary judgment by the defendants, including: (1) Ranbaxy's argument for lack of causation because there is no evidence Ranbaxy would have launched at-risk; (2) Dr. Reddy's and Teva's argument for lack of a "large and unjustified payment" because the plaintiffs failed to introduce "economic evaluation of the so-called payment" and an "insufficient amount of evidence indicating Dr. Reddy's readiness to engage in an earlier generic launch"; and (3) AstraZeneca's motion for summary judgment on all claims with Dr. Reddy's and Teva and on causation with Ranbaxy. [19] Judge Young then reversed himself in part in September 2014, allowing the plaintiffs to proceed at trial against Teva and on the overarching conspiracy theory, reasoning "if any one of the Defendants is subject to antitrust liability, all the Defendants may be liable as co-conspirators." [20]

On the eve of trial, Dr. Reddy's settled and, separately, the court reversed course again, dismissing the overarching conspiracy claim. Teva later settled as well after the fifth week of trial, with both settling generic companies agreeing to participate as witnesses on behalf of the plaintiffs. After six weeks of trial, a unanimous jury found that AstraZeneca exercised market power in a relevant market, made a "large and unjustified" payment to Teva, and that this settlement was unreasonably anti-competitive. However, the jury then found that the plaintiffs failed to prove that Ranbaxy would have entered the market absent the payment, thereby finding for AstraZeneca on causation, resulting in a trial victory for the remaining defendants.

The plaintiffs filed a motion for a new trial on the grounds that the framing and timing of the jury instructions were improper; that the court improperly blended causation issues with the defendants' subjective beliefs; that the court excluded economic evidence that jurors required in order to assess the but-for world; and that the court's instructions regarding the role of the patent were inconsistent and confusing for jurors. Judge Young denied this motion.

The First Circuit is now left to untangle this complicated set of rulings and factual record, and determine precisely what the district court should have done, what evidence should have been allowed, and what standards should have been applied throughout the course of litigation. The plaintiffs have appealed the orders and rulings pertaining to several motions for summary judgment in 2014, the jury verdict, orders and rulings related to the jury slip, and the denial of the plaintiffs' motion for a new trial. Briefing and oral argument schedules have not yet been determined, but both are likely to occur in 2016.

Pay-for-Delay Legislation

On Sept. 9, 2015, U.S. Sens. Amy Klobuchar, D-Minn., and Chuck Grassley, R-Iowa, reintroduced the "Preserve Access to Affordable Generic Act" (S. 2019) legislation in the Senate. This legislation is intended to "prohibit brand name drug companies from compensating generic drug companies to delay the entry of a generic drug into the market" [21] and is the latest in a string of very similar proposals that have been offered over the last decade. However, this is the first proposal offered post-Actavis, and it surprised many in the pharmaceutical industry who had thought that legislative efforts would cease in light of the Supreme Court providing its Actavis "rule-of-reason" framework for antitrust analysis of patent settlements.

As with prior versions, the proposed legislation would modify the standard of review for FTC enforcement actions against pharmaceutical patent settlements by presuming anti-competitive effects and placing the burden of proof on defendants where the generic has received “anything of value” from the brand. This “presumption” in the legislation is contrary to the Supreme Court’s direct rejection of such a presumption as argued by the FTC before the court in *Actavis*. Defendants also would need to carry their burden subject to a heightened “clear and convincing” evidence standard, in contrast to the “preponderance” standard generally applied in “rule-of-reason” antitrust analysis.

The recent Klobuchar-Grassley proposal does differ from prior proposals in two notable respects. First, no-AG provisions are automatically subject to the presumption and burden shifting described above. Second, the legislation would apply retroactively to any settlements entered into since the *Actavis* decision.

The bill is presently pending in the Senate Judiciary Committee. No further action or hearings have been scheduled, and thus its future remains unclear.

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DISCLOSURE: Wilson Sonsini Goodrich & Rosati represents Mylan Pharmaceuticals Inc. in In re Actos Antitrust Litigation.

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[1] 133 S. Ct. 2223 (2013).

[2] *Id.* at 2245.

[3] *Id.* at 2238.

[4] *In re Actos End-Payor Antitrust Litigation*, No. 13-cv-9244, at 22 (S.D.N.Y. Sept. 22, 2015).

[5] *Id.* at 24-25 (citing *Actavis*, 133 S. Ct. at 2234).

[6] *Id.* at 24.

[7] *Id.* at 25.

[8] *Id.* at 26.

[9] *In re Wellbutrin XL Antitrust Litigation*, No. 2:08-cv-2433, at 43 (E.D. Pa. Sept. 23, 2015).

[10] *Id.* at 4-5.

[11] *Id.* at 27.

[12] *In re Lamictal*, No. 14-1243 (3d. Cir. June 26, 2015).

[13] Id. at 31.

[14] Id. at 38.

[15] In re Lipitor Antitrust Litigation, No. 14-4202, at 2 (3d. Cir. July 8, 2015).

[16] In re Effexor XR Antitrust Litigation, No. 3:11-cv-05479, at 35 (D.N.J. Oct. 6, 2014).

[17] In re Nexium (Esomeprazole) Antitrust Litigation, No. 1:12-md-02409, at 1 (D. Mass. July 30, 2015).

[18] In re Nexium (Esomeprazole) Antitrust Litigation, No. 1:12-md-02409, at 42 (D. Mass. Sept. 11, 2013) (memorandum and order granting in part and denying in part defendant's motion to dismiss).

[19] In re Nexium (Esomeprazole) Antitrust Litigation, No. 1:12-md-02409, at 4 (D. Mass. Feb. 12, 2014) (order granting and denying motions for summary judgment).

[20] In re Nexium (Esomeprazole) Antitrust Litigation, No. 1:12-md-02409, at 51-2 (D. Mass. Sept. 4, 2014) (order granting Dr. Reddy's motion for consideration).

[21] S. 2019, 114th Cong. (2015), available at <https://www.congress.gov/bill/114th-congress/senate-bill/2019/all-info>.