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Is Any Consideration a ''Payment''? The Continuing Struggle over How to Interpret FTC v. Actavis

By Laura Shores and Karin Garvey

Background

A little more than a year ago, the Supreme Court addressed, for the first time, the application of the antitrust laws to brand-generic patent litigation settlements. The Court rejected the enforcement agencies' position that settlements providing for a ''reverse payment'' from the branded patent holder to the generic infringer are per se illegal. Instead, the Court held, reverse payment settlements must be judged under the rule of reason. *See FTC v. Actavis Inc.*, 133 S. Ct. 2223 , 2237 (2013). Not every settlement qualifies for rule of reason treatment under *Actavis*, though; only those providing for a ''large'' and ''unjustified'' ''payment'' are subject to scrutiny. Unfortunately, the decision provides little guidance as to what qualifies as a payment, much less a large and unjustified one. The lower courts are grappling with this threshold question, and, predictably, have reached different conclusions.

Laura Shores is a partner in the Antitrust Practice of the Complex Commercial Litigation Department in Kaye Scholer's Washington, DC office. Laura is a trial lawyer with more than 20 years of experience in complex civil litigation, including antitrust and securities fraud matters. She can be reached at laura.shores@kayescholer.com .

Karin Garvey, Counsel, practices complex commercial litigation and has considerable experience in antitrust disputes. She has practiced before both state and federal courts and has also participated in alternative dispute resolution such as arbitration and mediation. She can be reached at karin.garvey@kayescholer.com .

Must a "Payment" Involve Money?

Actavis indisputably requires the presence of a payment from the brand company to the generic challenger to subject a settlement to rule-of-reason analysis. For example, the Court stated that while inclusion of a large, unjustified reverse payment in a settlement risks antitrust liability, parties to litigation may ''settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point.'' *Id.* at 2237. The question is what qualifies as a ''payment.'' While *Actavis* does not give a definitive answer, the opinion strongly suggests that the Court had something tangible and quantifiable in mind. Indeed, the opening paragraph of the majority opinion defines a reverse payment settlement as one in which ''A, the plaintiff, pays money to defendant B purely so B will give up the patent fight.'' *Id.* at 2227.

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Based on this language, as well as repeated references to money elsewhere in the opinion, two district courts have held that the alleged payment must be in cash to trigger a rule of reason analysis. In *In re Lamictal Direct Purchaser Antitrust Litigation*, the District of New Jersey, observing that the majority and dissenting opinions in *Actavis* ''reek with discussion of payment of money,'' concluded that ''the Supreme Court considered a reverse payment to involve an exchange of money.'' *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-cv-995, 2014 BL 19279, at *8 (D.N.J. Jan. 24, 2014). The court accordingly dismissed the complaint, which alleged only that the branded company had conferred ''substantial financial benefit'' to the generic firm by agreeing to refrain from launching a competing ''authorized'' generic (often referred to a ''no-AG agreement''). *Id.* In September, the District of Rhode Island agreed with the *Lamictal* court that the ''payment'' must consist of cash to trigger scrutiny under *Actavis*. Noting that while its decision was ''not an easy one,'' the court declined to endorse ''a cavalier extension of the *Actavis* holding to virtually any noncash settlement package.'' *In re Loestrin 24 FE Litig.*, MDL No. 13-2472-S, 2014 BL 245503 (D.R.I. Sept. 4, 2014) (granting motions to dismiss).

Other courts have declined to construe the term ''payment'' this narrowly. In *In re Nexium (Esomeprazole) Antitrust Litigation*, the District of Massachusetts denied defendants' motion to dismiss on this ground, finding that ''nowhere in *Actavis* did the Supreme Court explicitly require some sort of monetary transaction.'' *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. Sept. 11, 2013). In three cases from the Eastern District of Pennsylvania, courts also declined to limit *Actavis* to cash. In January 2014, in *In re Wellbutrin XL Antitrust Litigation*, the Eastern District of Pennsylvania called it a ''close question'' but deferred ruling on the issue. Despite finding defendants' argument to be ''powerful,'' the court said that it was not yet prepared to accept defendants' argument that *Actavis* applies only to cash payments. *See In re Wellbutrin XL Antitrust Litig.*, No. 08-cv-2431, DKT No. 534 (E.D. Pa. Jan. 17, 2014) (provisional opinion). In another case from the Eastern District of Pennsylvania, the court ruled without hesitation that ''the term 'reverse payment' is not limited to a cash payment.'' *In re Niaspan Antitrust Litig.*, No. 13-MD-2460, 2014 BL 248117, at *11 (E.D. Pa. 2014) (denying motion to dismiss reverse payment claims). And, in a separate case involving the *Nexium* settlement, the court held that ''reverse payments deemed anti-competitive pursuant to *Actavis* may take forms other than cash payments.'' *Time Ins. Co. v. AstraZeneca AB*, No. 14-4149, 2014 BL 281416, at *3 (E.D. Pa. Oct. 1, 2014) (granting end payor plaintiffs' motion to remand in case alleging state law claims).

In two cases, the court took a less categorical view. In a case involving the settlement of litigation regarding Lipitor, Judge Sheridan in the District of New Jersey held that *Actavis* applies to non-monetary payments but only if the alleged payment can be reliably converted to a monetary value—something the plaintiffs in that case were unable to allege plausibly in their complaint. *See In re Lipitor Antitrust Litig.*, No. 3:12-cv-02389, 2014 BL 254208, at *19 (D.N.J. Sept. 12, 2014) (granting motion to dismiss). The court appeared to be seeking a middle ground between the holdings of *Nexium* and *Lamictal*. *Id.* at *18 (''This Court somewhat agrees with the analysis of both cases. That is, it is true that *Actavis* never indicated that a reverse payment had to be a cash payment; but it is also true that *Actavis* emphasized cash payments.''). In another case involving a different drug, Effexor, Judge Sheridan, as he had in *Lipitor*, held that ''[i]n applying *Actavis* here, the non-monetary payment must be converted to a reliable estimate of its monetary value so that it may be analyzed against the *Actavis* factors.'' *In re Effexor Antitrust Litig.*, No. 11-5479, 2014 BL 282512, at *21 (D.N.J. Oct. 6, 2014). The court dismissed the complaint for failure to allege any reliable basis, used within the industry, on which such an estimate could be made. *See id.* at *24.

The Third Circuit, in an appeal from the dismissal of the *Lamictal* complaint, is presently considering the question whether a cash payment must be alleged. Both the appellant and the FTC (appearing as *amicus curiae*) suggested that the presence of consideration ''beyond what was at stake in the litigation'' would subject a settlement to rule of reason scrutiny. This point is designed to bring within the definition of ''payment'' a so-called ''no-AG agreement.'' This typically comes in the form of a wholly exclusive license, which gives the generic firm the sole right to market a generic product during a certain period following the FDA's approval of a generic application. Such a license prohibits even the brand firm from marketing its own ''authorized'' generic product, and thus ensures that the generic challenger's product will be free from competition during the term of the license. The generic firm could not have obtained this result even if it had won the patent case; while the Hatch-Waxman Act guarantees that FDA will not approve another generic during that period, nothing prevents the brand firm from competing with its own generic version of the branded drug. Thus, if a condemned ''payment'' is defined to include consideration that is beyond what is at stake in the litigation, the appellant and FTC argue, a so-called no-AG promise is a payment because it gives the generic firm more marketing exclusivity to which it would have been entitled had it not settled and won the patent case.

There are a number of problems with construing a so-called no-AG promise as an unlawful payment, though. One is that such a promise is not materially different from the grant of a wholly exclusive license, which prohibits the licensor from licensing others and from practicing the invention itself. Such a term is generally recognized as a legitimate exercise of the patent holder's rights. The ''payment'' at issue in *Lamictal* consisted only of an exclusive license that effectively prevented the brand company both from granting licenses to other generic firms and from marketing an authorized generic. At oral argument, defendants pointed out that exclusive licenses have long been upheld when challenged under the antitrust laws, even those containing restrictions on fields of use, territories, and even price.

How the Third Circuit will come out on the no-AG/exclusive license issue specifically, or the cash/noncash distinction generally, is anyone's guess. At oral argument, at least one member of the panel seemed hesitant to embrace the absolute position that cash is required, noting that Black's Law Dictionary defines payment as money or other value. Another commented that perhaps some other term should be used instead of ''payment.'' However, nothing suggested that the court

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would endorse an unlimited definition that would extend to any form of consideration.

When is a Noncash Payment ''Large''?

Applying *Actavis* to settlements in which the alleged payment is in non-monetary form presents another problem. How will the court determine whether an alleged noncash payment is sufficiently ''large'' to trigger antitrust scrutiny? What must be alleged to support such a claim has been addressed in the *Lipitor* and *Effexor XR* cases, both presided over by Judge Sheridan of the District of New Jersey. In each case, Judge Sheridan held that while a payment need not be in monetary form to trigger scrutiny under *Actavis*, it must be measurable; otherwise, there is no way to tell if it is ''large.'' As noted above, in *Lipitor* and *Effexor XR*, the court dismissed the complaints because they failed to allege sufficient facts from which a calculation of the value of the nonmonetary consideration could be made.

In *Lipitor*, the settlement agreement provided that the brand name company, Pfizer (Pfizer Inc., and Pfizer Manufacturing Ireland), would dismiss claims against the generic firm, Ranbaxy (Ranbaxy Inc., Ranbaxy Pharmaceuticals, Inc., and Ranbaxy Laboratories, Ltd.), in unrelated United States patent litigation involving a different product. According to plaintiffs, the released claims were worth hundreds of millions of dollars to Pfizer, yet Pfizer agreed to dismiss them in exchange for a so-called ''token'' payment from Ranbaxy of $1 million. Pfizer also agreed to settle pending patent litigation involving Lipitor and other products in numerous jurisdictions around the world, in each case granting licenses for Ranbaxy to enter prior to patent expiry.

Judge Sheridan rejected plaintiffs' allegations as to both settlement components for lack of plausibility. With respect to the first component—the release of the unrelated claims—the court emphasized the absence of specific allegations about Pfizer's likelihood of success in that other litigation. Plaintiffs' sweeping claims that the other case was a ''slam dunk'' for Pfizer and that Pfizer had Ranbaxy ''over the barrel'' were not enough.

The court also held that dismissal was warranted because the complaint failed to allege ''a measure of damages accepted within the industry and a discussion of the settlement factors relating to the claim.'' *In re Lipitor Antitrust Litig.*, 2014 BL 254208, at *22. Absent such an assessment, the court concluded, it would not be possible to assess the relative ''value'' of its agreement to settle for $1 million. The allegations with respect to the foreign licenses and settlements were equally deficient. The complaint made no effort to estimate the monetary value of the licenses, or to quantify the value of those settlements. Judge Sheridan found that without such allegations, plaintiffs' claims lacked the plausibility required by *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). *Id.* at *25.

The challenge to the settlement in *Effexor XR* suffered a similar fate, even though plaintiffs in that case attempted to assign a monetary value to the claimed ''payment.'' The plaintiffs alleged that Wyeth (Wyeth LLC, Wyeth Pharmaceuticals, Inc., Wyeth-Whitehall Pharmaceuticals LLC, Wyeth Pharmaceuticals Company), in exchange for the generic challenger Teva's (Teva Pharmaceutical Industries Ltd.), agreement to ''delay'' entry of its generic product, granted Teva an exclusive license—the effect of which was to prevent Wyeth from launching a competing authorized generic. Plaintiffs claimed that the license constituted a ''substantial financial inducement amounting to more than $500 million in value in exchange for Teva's agreement to delay selling its generic version of Effexor XR for two years.'' *In re Effexor Antitrust Litig.*, 2014 BL 282512, at *12. Plaintiffs had derived that figure from an estimate of loss made by another generic company in the context of an unrelated drug. The court found this ''vague and amorphous'' comparison to be insufficiently specific. ''While this comparison is useful for purposes of showing that a no-authorized generic agreement has value, it does not specifically value the monetary amount of the no-authorized generic agreement in the instant case.'' *Id.* at *22. The court declared that absent ''specific facts showing how the alleged non-monetary payment was calculated,'' a complaint lacks sufficient specificity to ''state a claim for relief that is plausible on its face'' under *Twombly* and *Iqbal*. *Id.* at *15, *23.[1]

Judge Sheridan also touched on how one might determine whether a payment, whatever its alleged monetary value, is ''large''—i.e., large as compared to what? In *Effexor*, he suggested that the value of an exclusive license ''could be based upon the difference in market expectations with and without an authorized generic.'' *In re Effexor Antitrust Litig.*, 2014 BL 282512, at *23. More specifically, he said, an acceptable complaint might ''include assumptions such as the share of the market that converts from the brand to the generic, the retail price of the generic during the 180-day exclusivity period, with and without an authorized generic, and the share of the generic market that would have been retained by the authorized generic if there had been one.'' *Id.*

The practical difficulty in applying *Actavis* to nonmonetary consideration is illustrated by the recently-decided *Nexium* case, which concerns settlements entered into by the brand name firm, AstraZeneca (AstraZeneca AB, Aktiebolaget Hassle, and Astrazeneca LP), with multiple generic challengers. *See In re Nexium (Esomeprazole) Antitrust Litig.*, No. 12-md-02409 (D. Mass.). In each case, AstraZeneca agreed to a generic Nexium (esomeprazole) entry date prior to patent expiration. Plaintiffs alleged that, but for the alleged payment, the agreed entry date in each instance would have been earlier.

A component of one settlement, between Teva and AstraZeneca, consisted of an agreement to settle a separate patent litigation involving a different drug, Prilosec, with a $9 million payment from Teva to AstraZeneca in exchange for a license to Prilosec. *See In re*

[1] Another reason for the court's dismissal in *Effexor XR* is that the FTC played a nontrivial role in the settlement process. After the parties to the patent litigation submitted their proposed settlement to the court and requested that they be included in a consent order, the court ordered the parties to submit the proposed agreement to the FTC, and ordered the FTC to file objections if it had any. *Id.* at *26. In response, the FTC submitted a letter stating that it would not file an objection, but stressed that its decision should not be construed as a determination that the settlement does not violate the antitrust laws. The court then approved the settlement. *Id.* at *13. Despite the FTC's disclaimer, Judge Sheridan gave considerable weight to the FTC's lack of objection under the rubric of analyzing whether the payment was ''unexplained'' or ''unjustified'' under *Actavis*. *Id.* at *26.

Nexium (Esomeprazole) Antitrust Litig., 2014 BL 245682, at *7, *46, *47 (D. Mass. Sept. 4, 2014). As in *Lipitor*, plaintiffs claimed that the Prilosec settlement was a sweetheart deal, offered to induce Teva to agree to a later entry date for generic esomeprazole. In support of that claim, the *Nexium* plaintiffs put forward a licensing expert, who said that AstraZeneca should have demanded royalty payments of $33 million, not $9 million, to settle the case. *Id.* at *47. The difference, say plaintiffs, amounted to a $24 million reverse payment. *Id.*

In a settlement with Ranbaxy, the alleged payments consisted of an agreement not to launch an authorized generic (through the grant of an exclusive license), as well as other commercial agreements involving manufacturing and distribution.

The parties went to trial in October. Teva settled midtrial, and the viability of its expert's theory thus was not tested. But Ranbaxy pressed on, and on December 5, 2014, a jury returned a verdict in favor of Ranbaxy and AstraZeneca. Although the jury agreed with plaintiffs that the consideration amounted to a ''large and unjustified payment,'' it nonetheless returned a verdict in favor of Ranbaxy, finding that plaintiffs had failed to establish causation.

The *Nexium* case raises an important point with respect to evidence of valuation. To prove that the exclusive license was ''large,'' plaintiffs relied on internal documents allegedly showing that Ranbaxy valued the license at more than $690 million. Thus, assuming plaintiffs are able to allege facts sufficient to survive a motion to dismiss regarding the value of a payment, they may well ultimately find evidence in the parties' own files to substantiate their claim that the payment was ''large.''

Conclusion

The fate of reverse payment settlements remains undetermined. *Actavis* can be read to apply only to settlements with a monetary payment, but several district courts have extended its reach to certain noncash consideration. Two cases have held that when an alleged payment is in something other than cash, it must be quantifiable to determine whether it is ''large'' enough to trigger rule-of-reason treatment. A clear resolution is unlikely until the Supreme Court revisits the issue. Until then, parties settling pharmaceutical patent litigation should be prepared for challenges to any settlement that involves more than an agreement on a generic entry date before patent expiration. Those contesting the legality of a settlement must be prepared to do more than make general allegations that it provides ''valuable consideration'' to the generic firm. As for the district courts, as Chief Justice Roberts famously said in his dissent in *Actavis*, ''Good luck.'' *Actavis*, 133 S.Ct. at 2245.

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