Cash or No Cash – That is No Longer the Question!

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Introduction

The U.S. Supreme Court's decision in *Federal Trade Commission v. Actavis, Inc*. finally answered the question, in the affirmative, that reverse payment settlement agreements are subject to antitrust scrutiny under a rule of reason analysis.[1] *Actavis* held that payments from a brand drug manufacturer to a generic drug manufacturer that are "large and unjustified" are subject to antitrust scrutiny.[2]

Following the Supreme Court's decision in *Actavis*, a new debate emerged: whether non-cash payments, like no-authorized-generic ("No-AG") agreements, co-promotion agreements, or other side agreements, for example, can be unlawful reverse payments under *Actavis*. District courts in the First and the Third Circuits—the circuits that have the majority of the pay-for-delay cases—were, for a time, not in agreement on the answer.[3] However, with the First Circuit's recent ruling in *Loestrin*, the First and Third Circuits, as well as many other district courts, are now in agreement that non-cash payments are subject to antitrust scrutiny under *Actavis*.[4]

Without any current circuit splits, the issue is unlikely to reach the Supreme Court any time soon, and, while another circuit might not agree, the issue has effectively been put to rest. But new questions are emerging. District courts and class plaintiffs are now grappling with how to value non-cash reverse payments and how to determine whether they are "large and unjustified" under *Actavis*.

Part I of this article will provide a brief overview of the Supreme Court's ruling in

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

[2] *Id.* at 2337.

[3] *See*, Lipman, *Law360's Pay-For-Delay Cheat Sheet For 2016*, LAW360 (Jan. 5, 2016), http://www.law360.com/articles/742815/law360-s-pay-for-delay-cheat-sheet-for-2016 (listing all pending pay-for-delay cases, majority of which are in either the First or Third Circuits).

[4] *See, e.g.*, *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013); *In re Actos End Payor Antitrust Litig.*, No. 13-cv-9244, 2015 WL 5610752, at *13 (S.D.N.Y. Sept. 22, 2015); *In re Aggrenox Antitrust Litig*., 94 F. Supp. 3d 224, 243 (D. Conn. 2015); *In re Effexor XR Antitrust Litig.*, No. 11-5479, 2014 WL 4988410, at *19 (D.N.J. Oct. 6, 2014); *Time Ins. Co. v. Astrazeneca AB*, 52 F. Supp. 3d 705, 710 (E.D. Pa. 2014); *In re Lipitor Antitrust Litig*., 46 F. Supp. 3d 523, 543 (D.N.J. 2014); *In re Niaspan Antitrust Litig*., 42 F. Supp. 3d 735, 751 (E.D. Pa. 2014); *United Food & Commercial Workers v. Teikoku Pharma USA*, 74 F. Supp. 3d 1052, 1069-70 (N.D. Cal. 2014) (rejecting the theory that *Actavis* only applies to cash reverse payments as "[t]here are many plausible methods by which plaintiffs may calculate the value of non-monetary terms").

Actavis. Part II will give a brief summary of the most common types of non-cash agreements. Part III will discuss in detail the *Loestrin* and *King Drug* decisions from the First and Third Circuits, respectively. Part IV will provide a brief overview of several district court cases that addressed the non-cash question. Finally, in Part V, the article will discuss the critical issue of how to quantify the value of non-cash payments.

Part I: The Supreme Court's *Actavis* Decision

The first major conflict over reverse payment agreements was whether such agreements should avoid antitrust review as long as the effects of the settlement fell within the scope of the exclusionary potential of the patent, known as the "scope of the patent" test.[5] Before *Actavis* was decided, the circuits were split between the "scope of the patent test,"[6] and the "quick look" test, under which reverse payments were considered "prima facie evidence of an unreasonable restraint in trade."[7]

In its 2013 decision in *Actavis*, the Supreme Court resolved that long-standing question, rejecting the "scope of the patent" test.[8] Instead, the Court held that settlement agreements between brand and generic drugmakers are subject to antitrust scrutiny and should be analyzed under the traditional rule-of-reason analysis.[9] Specifically, the Court found that "there is reason for concern that [reverse payment] settlements . . . tend to have significant adverse effects on competition," and as a result will lead to higher prices for pharmaceuticals by deterring generic entry and increased health care costs for consumers, employers, and the government.[10]

The Court looked to five considerations that led it to the conclusion that reverse payments should be subject to antitrust scrutiny: (1) reverse payment settlements have the "potential for "genuine adverse effects on competition"; (2) reverse payments may be unjustified; (3) where a reverse payment threatens anticompetitive harm, the patent holder likely possesses power to bring that harm about in practice; (4) preventing risk of competition is the relevant anticompetitive harm and assessing anticompetitive effects and potential justifications can be done without litigating the validity of the patent; and (5) reverse payments are not necessary for settlement.[11]

The Court ultimately held that a "large and unjustified [reverse payment] can bring with it the risk of significant anticompetitive effects."[12] The Court did not provide much guidance on how to analyze whether a payment was "large and unjustified," and tasked district courts with evaluating whether such a payment violates the antitrust laws.[13] However, the Court did note that: "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

[5] *Actavis*, 133 S. Ct. at 2230.

[6] *See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1332-36 (Fed. Cir. 2008).

[7] *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 218 (3d Cir. 2012).

[8] *Actavis*, 133 S. Ct. at 2231.

[9] *Id.* at 2237.

[10] *Id.* at 2231.

[11] *Id.* at 2237.

[12] *Id.* at 2337.

[13] *Id.* at 2238.

other convincing justification."[14] The Court further explained that a disproportionately large settlement payment unexplained by other factors "would normally suggest that the patentee has serious doubts about the patent's survival" and "that fact, in turn, suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market."[15]

Of course, *Actavis* involved, for the most part, payments of millions of dollars of cash from the brand manufacturer, Solvay Pharmaceuticals to generic companies Actavis Inc., Paddock Laboratories, and Par Pharmaceuticals to stay out of the market for generic versions of Solvay's Androgel.[16] It is relatively easy to measure the value of the cash payment and determine whether it is "large and unjustified."[17] But, one key question that has arisen since *Actavis* is whether a reverse payment must be in the form of cash in order to be subject to antitrust scrutiny, or whether non-cash forms of payment can also be unlawful.

Part II: Common Forms of Non-Cash Payments

Before discussing additional cases, it is helpful to discuss briefly the most common forms of non-cash payments.

No-AG agreements: An authorized generic is chemically identical to its counterpart brand drug, but sold by the brand company or its representatives as a generic product under the same regulatory approval as the brand-name drug. Under a no-authorized generic agreement, the brand manufacturer agrees not to launch its own authorized generic alternative when the first generic company begins to compete in exchange for the generic company delaying its entry. While the first filing generic company is entitled to the absence of generic competition by other challengers during its 180-day exclusivity period, without a No-AG agreement, the brand manufacturer may market its own generic product during that 180-day period.

An FTC empirical study of the competitive effects of authorized generics found that when a brand company does not launch an authorized generic during the exclusivity period reserved for the first-filing generic under the Hatch-Waxman Act, it substantially increases the first generic company's revenues, and consumers pay higher prices for the generic product.[18]

Part III: Decisions in *King Drug* and *Loestrin*

Third Circuit's Opinion in *King Drug*

The Third Circuit was the first federal court of appeals to weigh in on the issue of whether non-cash settlements can be reverse payments under *Actavis*. In *King Drug Company of Florence, Inc., et al., v. Smithkline Beecham Corp.*,[19] the Third Circuit overturned the lower court and

[14] *Id.* at 2237.

[15] *Id.* at 2236.

[16] *Id.* at 2229.

[17] In *Actavis*, the Supreme Court, in discussing the value of a reverse payment, explained that "the likelihood of a reverse payment bringing about anticompetitive effects depends on 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." *Id.* at 2237.

[18] Authorized Generic Drugs: Short-Term Effects and Long-Term Impact: A Report of the Federal Trade Commission, *available at* https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf.

[19] 791 F.3d 388 (3d. Cir. 2015) ("*King Drug*").

agreed with the majority of other district courts in holding that *Actavis* does apply to non-cash payments.[20]

Factual Background

The plaintiffs in *King Drug* were direct purchasers of Lamictal, a brand-name drug used to treat epilepsy and bipolar disorder, from defendant GlaxoSmithKline (GSK). In 2002, Teva sought FDA approval to market generic lamotrigine, Lamictal's active ingredient.[21] Teva challenged the validity of GSK's patents covering lamotrigine by filing a Paragraph IV Abbreviated New Drug Application, or ANDA. As required by the FDA, Teva's ANDA application alleged that GSK's patent on Lamictal was invalid or not infringed. This triggered patent infringement litigation with GSK.[22]

In January 2005, the New Jersey district court ruled in Teva's favor, finding that the primary claim in GSK's patent for the invention of Lamotrigine was invalid.[23] Before the court could rule on the validity of the patent's remaining claims, GSK and Teva entered into a settlement agreement where GSK would allow Teva to market generic lamotrigine tablets (GSK's $2 billion product at the time) six months before GSK's exclusivity would expire and would allow Teva to market generic lamotrigine chewable tablets (a $50 million product at the time) thirty-seven months before patent expiration. Pursuant to the settlement, GSK further agreed not to market an authorized generic of Lamictal during Teva's 180-day exclusivity period (No-AG agreement).[24]

The District of New Jersey's Ruling

In February 2012, a putative class of direct Lamictal purchasers sued GSK and Teva in the District of New Jersey, claiming GSK and Teva's settlement agreement fell within the Supreme Court's *Actavis* standard for "pay-for-delay" and constituted an illegal reverse payment in violation of Sections 1 and 2 of the Sherman Act.[25] Plaintiffs alleged that, absent the non-cash considerations from its settlement with GSK, Teva would have launched its generic lamotrigine tablet "at risk" after receiving FDA approval (which occurred later, in August 2006), even if the court had not yet

[20] The following cases held that *Actavis* applied to non-cash payments at the time the Third Circuit decided *King Drug*: *In re Aggrenox Antitrust Litig.*, No. 3:14-md-2516, 2015 WL 1311352, at *14 (D. Conn. Mar. 23, 2015) motion to certify appeal on other issues granted, No. 14-md-2516, 2015 WL 4459607, at *11 (D. Conn. July 21, 2015) (finding that even if an agreement to not market an authorized generic is tantamount to an exclusive license, such licenses still fall within Actavis); *In re Effexor XR Antitrust Litig.*, 2014 WL 4988410 (D.N.J. Oct. 6, 2014) (concluding non-cash payments are actionable if plaintiffs plead a reliable estimate of their monetary value); *In re Niapsan Antitrust Litig.*, 42 F. Supp. 3d 735 (E.D. Pa. 2014) (monetary terms not required); *United Food & Com. Workers Local 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1069 (N.D. Cal. 2014) (applying Actavis to non-cash consideration); *In re Wellbutrin XL Antitrust Litig.*, No. 08-2431, slip. Op. at 4 (E.D. Pa. Jan. 17, 2014) (rejecting defendants' argument that "only a large cash payment from the patentee to the generic is subject to antitrust scrutiny under *Actavis*"); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013) (*Actavis* not limited to cash payments); *In re Lipitor Antitrust Litig.*, MDL No. 2332, 2013 WL 4780496, at *26 (D.N.J. Sept. 5, 2013) (finding "nothing in Actavis strictly requires that the payment be in the form of money").

[21] *King Drug*, 791 F.3d 388 at 397.

[22] *See id.* (citing Complaint, *Smithkline Beecham Corp. v. Teva Pharm. USA, Inc.*, No. 02–3779 (D.N.J. Aug. 5, 2002) (ECF No. 1).

[23] *King Drug* at 397.

[24] *Id.*

[25] *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 2:12-cv-995, 2012 WL 6725580 (D.N.J. Dec. 6, 2012)

ruled the patent invalid.[26] Essentially, plaintiffs asserted that the No-AG agreement, which was effectively a "reverse payment," induced Teva to delay its generic entry into the lamotrigine market, thereby guaranteeing Teva a monopoly during its 180-day exclusivity period.[27]

GSK and Teva moved to dismiss, claiming that under the Third Circuit's decision in *In re K-Dur Antitrust Litigation*, only cash payments constituted actionable "reverse payments."[28] The district court granted the motion for finding "no allegation that [the settlement] involved cash payment for Teva to stay off the market."[29]

Following the Supreme Court's decision in *Actavis*, the Third Circuit remanded the case to the district court, which reconsidered the motion to dismiss in light of *Actavis*'s authority.[30] On reconsideration, the court found that *Actavis* did not change the outcome of Defendants' earlier motion to dismiss as the Supreme Court's ruling in *Actavis* only required antitrust review of pure cash reverse payments and *not* in cases that involved other types of consideration, such as No-AG agreements.[31] The district court stated that "[b]oth the majority and the dissenting opinions [in *Actavis*] reek with discussion of payment of money."[32]

[26] *King Drug*, at 397.

[27] *See Lamictal*, 2012 WL 6725580, at *6.

[28] *See id.* at *1.

[29] *See id.* at *7.

[30] *In re Lamictal Direct Purchaser Antitrust Litigation*, 18 F. Supp. 3d 560 (D.N.J. 2014).

[31] *See id.* at 567-69.

[32] *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-cv-995, 2014 WL 282775, at *7 (D.N.J. Jan. 24, 2014) (citing and quoting *Actavis*, 133 S. Ct. at 2227, 31, 33, 34).

The Third Circuit's Decision

On appeal, the Third Circuit reversed the district court, holding that No-AG agreements should be subject to antitrust scrutiny under a rule of reason analysis to determine whether a reverse payment settlement "could have an anticompetitive effect or, alternatively, whether it was reasonable compensation for litigation costs or the value of services."[33] The Third Circuit found that *Actavis's* holding should not be limited to reverse payments of cash where a "No-AG agreement . . . represents an unexplained large transfer of value from the patent holder to the alleged infringer."[34]

The Third Circuit recognized that an agreement not to offer an authorized generic "may be of great monetary value to . . . the first-filing generic."[35] Therefore, the No-AG agreement may pose the same types of problems as reverse cash payments: reduced competition in the market and increased prices for consumers. Essentially, the No-AG agreement allows the patentee to transfer the profits it would have made from its authorized generic to the settling generic, plus potentially more, in the form of higher prices. In forfeiting this "valuable right to capture profits in the new-two tiered market" and eliminating itself as the only other competitor during the 180-day exclusivity period, the brand creates a generic monopoly for the new entrant instead of a generic duopoly.[36] The patentee also avoids the risk of patent challenges and resulting litigation by inducing the generic challenger to abandon its claims in exchange for a share of its monopoly profits

[33] *King Drug*, 791 F.3d at 404.

[34] *Id.* at 403.

[35] *Id.* at 404.

[36] *Id.* at 405.

"that would otherwise be lost in the competitive market."[37]

The court also rejected defendants' argument that No-AG agreements are distinguishable from reverse payments because they are merely a form of exclusive license expressly permitted under patent law.[38] The court emphasized that defendants were not seeking the right to license their patents, but rather the "right to use valuable licensing in such a way as to induce a patent challenger's delay."[39]

Appeal to the Supreme Court

In July 2015, GSK and Teva petitioned the Third Circuit for a rehearing of the case, arguing that the Third Circuit incorrectly applied patent and licensing law in reaching its conclusion that the settlement did not qualify as an exclusive license.[40] GSK argued that there was sufficient precedent showing that patent holders could grant limited exclusive licenses.[41] The Washington Legal Foundation also filed an amicus brief arguing that this ruling disturbed the balance the Supreme Court established between antitrust and patent law in its *Actavis* decision.[42]

In September 2015, the Third Circuit denied the petitions for rehearing.[43] Shortly thereafter, on February 19, 2016, GSK and Teva filed a petition for certiorari asking the Supreme Court to review the Third Circuit's decision.[44] The petition asked the court to take the opportunity to dispel uncertainty about what kinds of settlements can trigger pay-for-delay suits under *Actavis*.[45] Although the drug purchasers initially waived their right to respond to GSK's and Teva's petitions for certiorari, on March 2, 2016, the Supreme Court requested King Drug and other Lamictal purchasers respond by April 1, 2016. While a request for a response to a cert petition does not guarantee that the Supreme Court will take the appeal, the Supreme Court has expressed interest in the case and may hear the appeal.

First Circuit's Opinion in *Loestrin*

On February 22, 2015, the First Circuit issued its opinion on the appeal of the district court's dismissal of the *Loestrin* case after the lower court held that *Actavis* did not apply to non-cash reverse payments.[46]

Factual Background

The dispute in *Loestrin* arose from two reverse payments made by the brand manufacturer, Warner Chilcott, to resolve litigation concerning its patent covering the oral contraceptive Loestrin 24 Fe. The first litigation arose when generic manufacturer Watson Pharmaceuticals, Inc. notified Warner that it would seek to introduce a generic version of Loestrin 24.[47] Warner filed suit against Watson for patent

[37] *Id.* at 405.

[38] *Id.* at 406-408.

[39] *Id.* at 406.

[40] *See King Drug*, 791 F.3d 388 (3d. Cir. 2015), *appeal docketed*, No. 14-1243 (3d. Cir. July 27, 2015).

[41] *Id.*

[42] Brief for the Washington Legal Foundation as Amicus Curiae Supporting Appellees, *King Drug*, 791 F.3d 388, No. 12-416 at 33-34.

[43] *See King Drug*, No. 14-1243 (3d. Cir. July 27, 2015), *reh'g denied*.

[44] Petition for Writ of Certiorari, *SmithKline Beecham Corp. d/b/a GlaxoSmithKline et a. v. King Drug Co. of Florence Inc. et al.*, No. 15-1055 (U.S. Feb. 19, 2016).

[45] *Id.*

[46] *In re Loestrin 24 Fe Antitrust Litigation*, Nos. 1402071, 15-1250, 2016 WL 698077 (1st Cir. Feb. 22, 2016).

[47] *Id.* at *5.

infringement.[48] The parties settled on the condition that Watson delay entry of its generic version of Loestrin 24, and, in exchange, Warner made the following agreements:

- Warner agreed in a No-AG agreement not to market, supply, or license its own authorized generic version of Loestrin 24 during Watson's first 180 days of marketing.[49]
- Warner granted Watson a "non-exclusive, fully paid, worldwide, royalty-free irrevocable license" to market Loestrin 24.
- Warner agreed to pay Watson annual fees and a percentage of net sales in connection with Watson's co-promotion of Femring, a Warner hormone therapy product, beginning in 2009.
- Warner gave Watson the exclusive right to earn brand sales of a Warner oral contraceptive (now known as Generess Fe) in late-stage development at the time of the agreement.
- Warner would not grant a license to any other manufacturer to produce a generic version of Loestrin 24 until at least 180 days after Watson entered the market.
- Warner agreed to permit Watson to enter the market before January 22, 2014, should another manufacturer enter the market with a generic Loestrin 24 before Watson.[50]

The second litigation arose when another generic manufacturer, Lupin Pharmaceuticals, Inc., similarly announced its plans to introduce a generic version of Loestrin 24. Warner brought a patent infringement suit against Lupin.[51] Again, Lupin agreed to wait to introduce its generic Loestrin 24 in exchange for the following from Warner:

- Warner granted Lupin a non-exclusive license as to Femcon Fe, another Warner branded oral contraceptive, which allowed Lupin to market an authorized generic of Femcon Fe in the United States.
- Warner gave Lupin the right to purchase and sell in the United States a generic version of Asacol 400mg, a branded medication for inflammatory bowel disease, to be supplied by Warner, if a generic Asacol 400mg was launched by another manufacturer in the United States.
- Warner paid Lupin an undisclosed amount toward attorney's fees.[52]

Two putative classes of plaintiffs subsequently brought antitrust claims alleging that the two settlement agreements were violations of Section 1 of the Sherman Act.[53] The first group, Direct Purchaser Plaintiffs (DPPs), included corporate entities that purchased Loestrin 24 directly from Warner. The second group, the End Payor Plaintiffs (EPPs), included health and welfare benefit plans that indirectly purchased, paid for, and provided reimbursement for their members' purchase of Loestrin 24. Both groups argued that Warner induced Watson to keep its generic Loestrin 24 off of the market until January 22, 2014, in exchange for payments that Warner made to Watson when, absent the agreement, Watson could have introduced a generic Loestrin 24 as early as 2009.[54] The DPPs argued that this anticompetitive conduct insulated Loestrin 24

[48] *Id.*

[49] *Id.*

[50] *Id.*

[51] *Id.*

[52] *Id.* at *6.

[53] *Id.*

[54] *Id.*

from generic competition, which would typically be priced far below the brand and eventually lead to reduced brand prices, and[55] therefore, Warner and Watson's agreement caused antitrust harm by subjecting the DPPs to artificially inflated prices.[56] The EPPs made similar allegations as to both the Warner-Watson and Warner-Lupin agreements.[57]

District of Rhode Island Ruling

Defendants filed motions to dismiss both the DPP and EPP complaints.[58] They argued that *Actavis* was limited to reverse payments in cash, not the types of non-cash agreements that were made in this case. The district court agreed with the defendants and granted their motions to dismiss.[59] The district court noted that the Supreme Court's discussion of patent settlements in *Actavis* "fixates on one form of consideration that was at issue in that case: cash."[60] The district court also took into account the five considerations listed above that the Supreme Court contemplated in determining that reverse payments are subject to antitrust scrutiny.[61] In the district court's view, those considerations require the plaintiff to assess or calculate the true value of the payment made by the brand company, and "a non-cash settlement, particularly one that is multifaceted and complex . . . is almost impossible to measure against these five factors."[62]

The district court did note that it had concerns about its holding, noting that if antitrust scrutiny is limited to reverse payments in cash, "non-cash pay for delay arrangements are likely to evade Sherman Act scrutiny so long as pharmaceutical companies take the obvious cue to structure their settlements in ways that avoid cash payments."[63] Nevertheless, the district court declined to extend *Actavis* to non-cash reverse payment settlements and entered final judgment, setting the decision up for immediate appeal.[64]

First Circuit's Decision

The specific question addressed by the First Circuit was whether reverse payment settlement agreements that do not involve pure cash are subject to antitrust scrutiny.[65] They answered this question in the affirmative.

To begin its discussion, the First Circuit was quick to point out that the district court was mistaken in believing that *Actavis* involved only cash payments.[66] The reverse payments in *Actavis* also involved side deals where the generic manufacturers agreed to promote the brand name drug at issue in exchange for multi-million dollar payments from the brand.[67] From the First Circuit's view, this fact alone proved that the Supreme Court recognized that a reverse payment that was not a pure cash deal, but rather a "disguised above-market deal, in which a brand manufacturer effectively overpays a generic manufacturer for services

[55] *Id.*

[56] *Id.*

[57] *Id.*

[58] *Id.*

[59] *Id.*

[60] *Id.* at 7.

[61] *Id.*

[62] *Id.*

[63] *Id.*

[64] *Id.*

[65] *Id.* at *8.

[66] *Id.*

[67] *Id.*

rendered," and "may qualify as a reverse payment subject to antitrust scrutiny."[68]

The First Circuit also refuted the notion that the Supreme Court was "fixated" on cash.[69] To emphasize its point, the First Circuit cited the following language from the Supreme Court's opinion: "*in substance*, the plaintiff agreed to pay the defendants many millions of dollars to stay out of its market."[70] The First Circuit found that "[t]his language acknowledges that antitrust scrutiny attaches not only to pure cash reverse payments, but to other forms of reverse payment that induce the generic to abandon a patent challenge, which unreasonably eliminates competition at the expense of consumers."[71] This approach, according to the First Circuit, elevates substance over form, as is the practice in applying antitrust law.[72] And while it is true that *Actavis* does reference cash money, the First Circuit stated the "key word throughout the opinion is 'payment,' which connotes a much broader category of consideration than cash alone."[73]

The First Circuit also dismissed the district court's determination that the near impossibility of measuring non-cash settlements was another reason not to apply *Actavis*,[74] concluding that "[a]lthough the value of non-cash reverse payments may be much more difficult to compute than that of their cash counterparts . . . antitrust litigation already requires courts to make intricate and complex judgments about market practices."[75] Complexity is not a justification for avoiding antitrust scrutiny.

Finally, the First Circuit recognized that plaintiffs are required, under *Actavis*, to plead information sufficient to estimate the value of the non-cash agreements, at least to the extent of determining whether the terms are "large and unjustified."[76]

Part IV: District Court Opinions

In addition to the First and Third Circuits, a majority of district courts that have considered the question of whether non-cash reverse payments are subject to antitrust scrutiny under *Actavis* have agreed that, regardless of the form of payment, reverse payments should be reviewed under the antitrust laws. Here are brief summaries of those holdings:

First Circuit

- *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013) ("This Court does not see fit to read into the opinion a strict limitation of its principles to monetary-based arrangements alone.").

Second Circuit

- *In re Actos End Payor Antitrust Litig.*, No. 13-cv-9244, 2015 WL 5610752, at

[68] *Id.*

[69] *Id.* at *9.

[70] *Id.* (emphasis in original) (quoting *Actavis*, 133 S. Ct. at 2231).

[71] *Id.*

[72] *Id.* (citing *Am. Needle, Inc. v. Nat'l Football League*, 560 U.S. 183, 191-92 (2010) ("We seek the central substance of the situation and therefore we are moved by the identity of the persons who act, rather than the label of their hats."); *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 760 (1984) ("The Sherman Act is aimed at substance rather than form."); *Podiatrist Ass'n v. La Cruz Azul de P.R., Inc.*, 332 F.3d 6, 14 (1st Cir. 2003) (describing the antitrust inquiry as "a functional one").

[73] *Id.*

[74] *Id.* at *11.

[75] *Id.*

[76] *Id.*

*13 (S.D.N.Y. Sept. 22, 2015) ("This Court shares the majority view that *Actavis's* holding is not limited to payments made in cash.")

- *In re Aggrenox Antitrust Litig*., 94 F. Supp. 3d 224, 243 (D. Conn. 2015) ("A settlement agreement may be very simple or tremendously complex, and it may involve all manner of consideration; and if, when viewed holistically, it effects a large and unexplained net transfer of value from the patent-holder to the alleged patent infringer, it may fairly be called a reverse-payment settlement.")

Third Circuit

- *In re Effexor XR Antitrust Litig.*, No. 11-5479, 2014 WL 4988410, at *19 (D.N.J. Oct. 6, 2014) ("The common use of the term payment is described as something given to discharge a debt or obligation and does not require the payment to be in the form of money.")
- *Time Ins. Co. v. Astrazeneca AB*, 52 F. Supp. 3d 705, 710 (E.D. Pa. 2014) ("In my opinion, reverse payments deemed anti-competitive pursuant to *Actavis* may take forms other than cash payments.")
- *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523, 543 (D.N.J. 2014) (finding that *Actavis* covers situations where "the non-monetary payment [can] be converted to a reliable estimate of its monetary value")
- *In re Niaspan Antitrust Litig*., 42 F. Supp. 3d 735, 751 (E.D. Pa. 2014) (holding "that the term 'reverse payment' is not limited to a cash payment")

Ninth Circuit

- *United Food & Commercial Workers v. Teikoku Pharma USA*, 74 F. Supp. 3d 1052, 1069-70 (N.D. Cal. 2014) (rejecting the theory that *Actavis* only applies to cash reverse payments as "[t]here are many plausible methods by which plaintiffs may calculate the value of non-monetary terms")

Part V: Difficulties of Valuing Non-Cash Payments

Two key courts of appeal have now ruled that non-cash reverse payment settlements are subject to antitrust scrutiny under *Actavis*, and the majority of district courts to consider the question have reached the same conclusion. Though it remains to be seen whether other courts of appeal will follow the First and Third Circuit's lead, it seems likely that pharmaceutical manufacturers will face increased exposure to significant liability from private antitrust plaintiffs claiming that the parties entered into noncash reverse payment settlements.

The question of whether *Actavis* applies to non-cash payments has been answered and the matter is effectively closed. But the resulting questions now is: how do plaintiffs sufficiently plead a reverse payment case that does not involve pure cash payments? Not only are there difficulties in valuing such agreements at the pleading stage, but plaintiffs also may not have access to much, if any, information about certain settlement terms, side agreements in particular. Valuing such deals becomes nearly impossible, especially at the crucial pleading stage. Some pharmaceutical companies are not U.S. public companies and therefore are not required to report deals they make with other companies. So, while class plaintiffs may suspect side deals as part of settlement agreements, unless first discovered by other means, like through an FTC or EC investigation, plaintiffs will not have access to the terms of those agreements and will be unable to adequately plead their value.

Already, several district courts have granted motions to dismiss because the value conferred by defendants in the alleged reverse payment was insufficiently quantified. In the cases discussed below, the district courts all agreed that *Actavis* applied to non-cash reverse payments, but dismissed the cases because the plaintiffs did not adequately alleged that the payments were "large."

Judge Sheridan from the District of New Jersey, in two separate but similar opinions, held that a reverse payment "must be converted to a *reliable estimate* of its monetary value so that it may be analyzed against the *Actavis* factors."[77] Judge Sheridan reasoned that, while the Supreme Court did not define what constituted a "large" cash payment, "[o]ne way to measure the 'largeness' of a reverse payment is to assess whether the amount is larger than what the generic would gain in profits if it won the Paragraph IV litigation and entered the market," which can be "'strong evidence' of anticompetitive activity."[78] Regarding the No-AG agreement, Judge Sheridan found that "[s]imply alleging some sort of value of a noauthorized generic agreement, absent a reliable foundation supporting that value, does not establish the plausibility required by Rule 12(b)(6).[79]

Helpfully, Judge Sheridan did lay out several factors to consider in valuing a non-cash reverse payment:

The payment prong involves the following steps: (a) valuing any consideration flowing from the patentee to the claimed infringer, which may be made over time and may take forms other than cash; (b) deducting from that payment the patent holder's avoided litigation costs; and (c) deducting from that payment the value of goods, services, or other consideration provided by the claimed infringer to the patent holder as part of the same transaction (or linked transactions). The resulting net payment is "otherwise unexplained"[80]

However, in both *Effexor* and *Lipitor*, Judge Sheridan dismissed the reverse payment claims because plaintiffs failed to adequately allege an estimate of the monetary value of the non-monetary payment.[81]

In *ACTOS*, the District Court for the Southern District of New York similarly dismissed a class of indirect purchasers' claims that Takata Pharmaceutical Company and its subsidiaries engaged in anticompetitive conduct to restrict generic entry of ACTOS and ACTO*plus*, drugs used to treat diabetes, through alleged pay-for-delay agreements with five manufacturers.[82] The court held that the plaintiffs failed to allege anticompetitive conduct under the rule of reason that would amount to the type of "large and unjustified" payment that would raise antitrust concerns under *Actavis*[83]. In discussing the Takeda settlement, the court concluded that even if the agreements were considered payments, the plaintiffs failed to plausibly allege that the payments were "large" and "unjustified."[84] Though plaintiffs need not

[77] *Effexor*, 2014 WL 4988410, at *20; *Lipitor*, 46 F. Supp. 3d at 543 (emphasis added).

[78] *Lipitor*, 46 F. Supp. 3d at 547.

[79] *Effexor*, 2014 WL 4988410, at * 21.

[80] *Effexor*, 2014 WL 4988410 at *20; *Lipitor*, 46 F. Supp. 3d at 544 (quoting Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *Activating Actavis*, 28 ANTITRUST 16 at 18(Fall 2013).

[81] *Effexor*, 2014 WL 4988410 at *22; *Lipitor*, 46 F. Supp. 3d at 546.

[82] *ACTOS*, 2015 WL 5610752, at *19-20.

[83] *Id.*

[84] *See id.* at *19.

provide a precise calculation of the size of the payment, "[p]laintiffs must plausibly allege a factual basis for the Court to reasonably estimate the value of the settlement terms."[85] Plaintiffs alleged that the licensing terms in the settlements were of "substantial value" and worth "tens" and "hundreds of millions" of dollars, but failed to explain the basis for those assertions or provide any method of calculating the value of the licensing terms.[86] These bare allegations, without additional factual support to aid the court in reasonably estimating the settlements' value, were insufficient.[87] The court was not persuaded by plaintiffs' argument that a valuation method was unnecessary simply because the payments were sufficiently large.[88]

Conclusion

While the argument that *Actavis* applies only to pure cash payment is nearly dead, many obstacles for class plaintiffs challenging non-cash reverse payment agreements remain. The First and Third Circuit rulings let plaintiffs put their foot in the door to successfully challenge non-cash pay-for-delay settlements, but the difficulty of identifying and quantifying the value of non-cash payments may result in the door quickly being slammed shut.

[85] *Id.*

[86] *Id.*

[87] *Id.*

[88] *Id.*