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ANTITRUST

Reverse Payments After *Actavis*: Fifteen Cases to Follow



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On June 17, 2013, the Supreme Court held in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013) (“*Actavis*”) that reverse payment settlements¹ in patent infringement litigation are not immune from antitrust attack, and that the anticompetitive effects of such “pay for delay” agreements will sometimes prove unjustified.² In doing so, it ruled that “the size of the unexplained reverse payment can provide a workable surrogate for a patent’s weakness, all without forcing a court

to conduct a detailed exploration of the validity of the patent itself.”³ It declined to follow the patentee-friendly “scope-of-the-patent test”⁴ and the challenger-friendly “quick look” test.⁵

Instead, the Court ruled that antitrust allegations involving reverse payments must be subject to the factually intensive rule-of-reason analysis,⁶ partly “because 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

¹ The Court explained reverse settlements as: “Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent’s term expires, and (2) Company A, the patentee, to pay B many millions of dollars.” *Actavis*, 133 S. Ct. at 2227).

² *Id.* at 2235-36.

³ *Id.* at 2236-37.

⁴ *Id.* at 2230-34.

⁵ *Id.* at 2237.

⁶ Cases applying the rule-of-reason analysis to antitrust violations often cite Justice Brandeis’ formulation of the rule: “The true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition. To determine that question the court must ordinarily consider the facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable. The history of the restraint, the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained, are all relevant facts. This is not because a good intention will save an otherwise objectionable regulation or the reverse; but because knowledge of intent may help the court to interpret facts and to predict consequences.” *Chicago Board of Trade v. United States*, 246 U.S. 231, 238 (1918).

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might represent payment, and the lack of any other convincing justification.”⁷

To root out these unjustified anticompetitive consequences, the Court noted “trial courts can structure antitrust litigation so as to avoid, on one hand, the use of antitrust theories too abbreviated to permit proper analysis, and on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question.”⁸ And with that, it left to the district courts “the structuring of present rule-of-reason antitrust litigation.”⁹ Chief Justice Roberts, in his dissent joined by Justices Scalia and Thomas, offered a few words for the district courts to help assess these settlements under the “unruly” rule of reason: “Good luck . . .”¹⁰

This article provides a factual survey of 15 ongoing cases applying (or soon applying) the rule of reason to alleged reverse payments under *Actavis*. Many of these cases are large, complex, and ongoing, and much of the information regarding these cases is not publicly available. However, the allegations and arguments may help illuminate the questions *Actavis* has left unresolved, and help practitioners and industry professionals identify litigation risks when settling patent cases.

***In re Lipitor Antitrust Litig.*, 12-cv-2389 (D.N.J.)**

Notable Issues: Whether *Actavis* applies to non-monetary reverse payments; whether release of liability in unrelated litigation can be a reverse payment; whether granting rights in foreign markets can be a reverse payment.

Lipitor was the first post-*Actavis* decision of note. On September 5, 2013, the Honorable Peter G. Sheridan in the District of New Jersey granted the direct purchaser class plaintiffs’ motions for leave to amend their complaints to focus solely on “reverse payment” allegations, after dismissing related *Walker Process* fraud, sham litigation, and sham citizen petition claims.¹¹

Actavis was decided while motions to dismiss were pending, and after the parties briefed the court, the direct purchaser class plaintiffs moved to amend their complaints to clarify their “reverse payment” allegations.¹² The defendants argued that these amendments would be futile, “because the amended allegations still fail to allege an actionable reverse payment under the Supreme Court’s standard in *Actavis*, which Defendants say only applies to settlements involving large monetary payments from the brand name manufacturer to the generic.”¹³ The court rejected this argument, noting “that nothing in *Actavis* strictly requires that the payment be in the form of money,” and thus amendments would not be futile on that basis.¹⁴

The plaintiffs’ amended complaints allege that Pfizer made various anticompetitive reverse payments to Ranbaxy in order to delay generic competition on *Lipitor*.

The agreements involving alleged reverse payments included the following terms:

- 1) Pfizer agreed to release potential generic competitor Ranbaxy from liability in a separate suit, which allegedly could have represented hundreds of millions of dollars in value. In exchange for this release from liability, Ranbaxy paid Pfizer \$1 million and Pfizer was released from its \$200 million injunction bond.¹⁵
 - 2) Pfizer granted Ranbaxy the exclusive right to sell *Lipitor* in 11 foreign markets, along with several licenses to Pfizer patents.¹⁶
 - 3) Ranbaxy agreed not to compete directly or indirectly with Pfizer prior to the agreed-upon entry date (November 30, 2011). Plaintiffs allege this is an agreement not to relinquish or waive Ranbaxy’s first-to-file 180-day marketing exclusivity,¹⁷ creating a bottleneck that prevents other generic competitors from obtaining regulatory approval.¹⁸
- Defendants have filed another round of motions seeking to dismiss the newly amended complaints.¹⁹
- Current Status:** Motions to dismiss pending.²⁰

***In re Effexor XR Antitrust Litig.*, 11-cv-5479 (D.N.J.)**

Notable Issues: Whether a “No AG” agreement constitutes a reverse payment under *Actavis*.

Effexor XR is also before the Honorable Peter G. Sheridan in the District of New Jersey, and thus there is some scheduling overlap between it and *Lipitor*.²¹ In addition to claims of *Walker Process* fraud and sham litigation,²² plaintiffs alleged Wyeth paid potential generic competitor Teva for delay by agreeing not to re-

¹⁵ *In re Lipitor Antitrust Litig.*, 2013 WL 4780496 at *11; Individual Plaintiffs’ Memorandum in Opposition to Defendants’ Motions to Dismiss Plaintiffs’ Amended Complaints at 6-7, *In re Lipitor Antitrust Litig.*, 12-cv-2389 (D.N.J. Jan. 17, 2014) ECF No. 508; Memorandum in Support of Ranbaxy Defendants’ Renewed Motion to Dismiss Direct Purchaser Plaintiffs’ Amended Complaints at 10, *In re Lipitor Antitrust Litig.*, 12-cv-2389 (D.N.J. Nov. 26, 2013) ECF No. 490-1.

¹⁶ *In re Lipitor Antitrust Litig.*, 2013 WL 4780496 at *11; Individual Plaintiffs’ Memorandum in Opposition to Defendants’ Motions to Dismiss Plaintiffs’ Amended Complaints at 7, *In re Lipitor Antitrust Litig.*, 12-cv-2389 (D.N.J. Jan. 17, 2014) ECF No. 508; Memorandum in Support of Ranbaxy Defendants’ Renewed Motion to Dismiss Direct Purchaser Plaintiffs’ Amended Complaints at 11-12, *In re Lipitor Antitrust Litig.*, 12-cv-2389 (D.N.J. Nov. 26, 2013) ECF No. 490-1.

¹⁷ *In re Lipitor Antitrust Litig.*, 2013 WL 4780496 at *11.

¹⁸ Individual Plaintiffs’ Memorandum in Opposition to Defendants’ Motions to Dismiss Plaintiffs’ Amended Complaints at 20-24, *In re Lipitor Antitrust Litig.*, 12-cv-2389 (D.N.J. Jan. 17, 2014) ECF No. 508.

¹⁹ See Memorandum in Support of Pfizer Defendants’ Motion to Dismiss All Direct Purchaser Amended Complaints, *In re Lipitor Antitrust Litig.*, 12-cv-2389 (D.N.J. Nov. 26, 2013) ECF No. 493-1.

²⁰ Letter Order, *In re Lipitor Antitrust Litig.*, 12-cv-2389 (D.N.J. Apr. 3, 2014) ECF No. 549.

²¹ Judicial Notice, *In re Lipitor Antitrust Litig.*, 12-cv-2389 (D.N.J. Apr. 10, 2014) ECF No. 551; *In re Effexor XR Antitrust Litig.*, 11-cv-5479 (D.N.J. Apr. 10, 2014) ECF No. 321.

²² Direct Purchaser Class Plaintiffs’ Second Amended Consolidated Class Action Complaint and Jury Demand at ¶¶ 407-20, *In re Effexor XR Antitrust Litig.*, 11-cv-5479 (D.N.J. Oct. 23, 2013) ECF No. 287.

⁷ *Actavis* at 2237.

⁸ *Id.* at 2238.

⁹ *Id.*

¹⁰ *Id.* at 2245 (C.J. Roberts, dissenting).

¹¹ *In re Lipitor Antitrust Litig.*, No. 12-cv-2389, 2013 WL 4780496 (D.N.J. Sept. 5, 2013).

¹² *Id.* at *25-26.

¹³ *Id.* at *26 (emphasis added).

¹⁴ *Id.*

lease its own authorized generic Effexor XR, also known as a “No AG” agreement.²³ The plaintiffs have argued that the “No AG” agreement was in effect a payment worth \$426 million to Teva.^{24, 25} The defendants argue that this “No AG” agreement is an early entry agreement and not a monetary reverse payment subject to review under *Actavis*.²⁶ The FTC has filed an *Amicus Curiae* brief arguing that “No AG” agreements are reverse payments.²⁷

Current Status: Motions to dismiss pending.

In re Nexium (Esomeprazole) Antitrust Litig., 12-md-2409 (D. Mass.)

Notable Issues: Which claims will survive summary judgment and potentially proceed to trial; whether “No AG” agreements are reverse payments; whether a generic defendant can cause anticompetitive harm when its launch is uncertain.

Nexium was the second case to issue a decision applying *Actavis*. On September 11, 2013, the District of Massachusetts ruled on a number of motions to dismiss.²⁸ In finding that the direct purchaser plaintiffs pleaded facts sufficient to establish antitrust violations, the Honorable William G. Young outlined the application of the rule of reason for reverse payment antitrust analysis.²⁹ The court found that the plaintiffs sufficiently alleged: (1) market power in the relevant market; (2) anticompetitive consequences; and (3) that the economic detriments of the agreement outweighed economic benefits, relying on the rule-of-reason test under *Stop & Shop Supermarket Co. v. Blue Cross & Blue Shield of R.I.*, 373 F.3d 57, 61 (1st Cir. 2004).³⁰

The court directly addressed the issue of whether reverse payments must be monetary, and held that using a broad interpretation of the word “payment” to include non-monetary consideration “serves the purpose of aligning the law with modern-day realities.”³¹ The agreements involving alleged reverse payments included the following terms:

- 1) AstraZeneca agreed not to release an authorized generic (“No AG”) during potential generic competitor Ranbaxy’s solely-held 180-day first-filer exclusivity period in exchange for a six-year delay

in entry.³² Ranbaxy also agreed to be a Nexium supplier as well as a distributor of two other AstraZeneca drugs.³³ This agreement purportedly created a “bottleneck” preventing non-first filers from challenging the patents at issue.³⁴

- 2) Both Teva and Dr. Reddy’s (non-first filer potential generic competitors) attempted to “uncork the FDA approval bottleneck” by filing declaratory judgment actions against AstraZeneca.³⁵ Before final judgments were reached in these actions, AstraZeneca released Teva and Dr. Reddy’s from contingent liabilities in litigation involving infringement of unrelated patents.³⁶

The court held that the consent agreement entered by the District of New Jersey memorializing these settlement agreements did not grant the defendants *Noerr-Pennington* antitrust immunity.³⁷

On February 12, 2014, the court granted partial summary judgment on several aspects of the case, including lack of causation for antitrust damages due to inadequate evidence that defendants Ranbaxy and Dr. Reddy’s would have been able to launch earlier, causing lower prices.³⁸ Two motions for summary judgment³⁹ were granted on the basis of the plaintiffs’ purported failure to prepare supplemental reports on damages calculations,⁴⁰ however these motions are under reconsideration after plaintiffs argued that the supplemental reports were created but not filed based on a clerical misunderstanding.⁴¹ The court is drafting a thorough written opinion on these and other summary judgments as other surviving aspects of the case proceed toward trial.⁴²

Current Status: Briefing on motion for reconsideration of two motions for summary judgment; two Fed. R. Civ. P. 23(f) Class Certification Interlocutory Appeals proceeding in the First Circuit Court of Appeals (Nos. 14-1521 and 14-1522);⁴³ written opinion on partial summary judgment pending; pretrial proceedings on surviving claims to be scheduled July 2014.⁴⁴

³² *Id.* at 381-82, 391.

³³ *Id.* at 382.

³⁴ *Id.* at 382-83.

³⁵ *Id.* at 382-84.

³⁶ *Id.*

³⁷ *Id.* at 394-98 (D. Mass. 2013). The court in *In re Androgel*, *infra*, came to a similar conclusion on the application of *Noerr-Pennington* immunity to consent agreements.

³⁸ *In re Nexium (Esomeprazole) Antitrust Litig.*, 2014 WL 585827 (D. Mass. Feb. 12, 2014).

³⁹ AstraZeneca Defendants’ Motion for Summary Judgment on All Claims Arising From AstraZeneca’s Settlements with Teva and DRL, *In re Nexium (Esomeprazole) Antitrust Litig.*, 12-md-2409 (D. Mass. Dec. 10, 2013) ECF No. 644; Teva’s Motion for Summary Judgment Based on Absence of Reverse Payment to Teva, *In re Nexium (Esomeprazole) Antitrust Litig.*, 12-md-2409 (D. Mass. Dec. 10, 2013) ECF No. 600.

⁴⁰ *In re Nexium (Esomeprazole) Antitrust Litig.*, 2014 WL 585827 at *1-2.

⁴¹ Plaintiffs’ Memorandum in Law in Support of Motion for Reconsideration *In re Nexium (Esomeprazole) Antitrust Litig.*, 12-md-2409 (D. Mass. Feb. 28, 2014) ECF No. 865.

⁴² *In re Nexium (Esomeprazole) Antitrust Litig.*, 2014 WL 585827 at *3.

⁴³ Notice of Appeal, *In re Nexium (Esomeprazole) Antitrust Litig.*, 12-md-2409 (D. Mass. May 15, 2014) ECF Nos. 926, 928.

⁴⁴ Electronic Clerk’s Notes, *In re Nexium (Esomeprazole) Antitrust Litig.*, 12-md-2409 (D. Mass. Apr. 16, 2014) ECF No. 902.

²³ *Id.* at ¶ 12; Direct Purchaser Class Plaintiffs’ Opposition to Defendants’ Motion to Dismiss the Second Amended Complaint, *In re Effexor XR Antitrust Litig.*, 11-cv-5479 (D.N.J. Jan. 24, 2014) ECF No. 316.

²⁴ Letter from Peter S. Pearlman, *In re Effexor XR Antitrust Litig.*, 11-cv-5479 (D.N.J. May 19, 2014) ECF No. 332.

²⁵ While not alleging an anticompetitive bottleneck outright, plaintiffs argued during oral argument that a change in royalty rates after the six-month first-filer exclusivity was indicative of bottlenecking. Transcript at 48:15-49:21, *In re Effexor XR Antitrust Litig.*, 11-cv-5479 (D.N.J. Jan. 7, 2014) ECF No. 312.

²⁶ Defendants’ Memorandum in Support of Motion to Dismiss Direct Purchaser Class Plaintiffs’ Second Amended Complaint at 6-9, *In re Effexor XR Antitrust Litig.*, 11-cv-5479 (D.N.J. Dec. 13, 2013) ECF No. 305-1.

²⁷ FTC Brief as *Amicus Curiae*, *In re Effexor XR Antitrust Litig.*, 11-cv-5479 (D.N.J. Sept. 13, 2013).

²⁸ *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 410 (D. Mass. Sept. 11, 2013).

²⁹ *Id.* at 387-93.

³⁰ *Id.* at 392.

³¹ *Id.*

In re Lamictal Direct Purchaser Antitrust Litig., 12-cv-995 (D.N.J.), 14-1243 (3d Cir.)

Notable Issues: Whether Actavis applies to non-monetary reverse payments; whether “No AG” agreements are reverse payments; whether determining a payment is “large and unjustified” is part of the rule-of-reason analysis or a preliminary requirement before reaching that analysis.

On January 24, 2014, the Honorable William H. Walls of the District of New Jersey again granted a motion to dismiss.⁴⁵ The agreements involving alleged reverse payments included the following terms:

- 1) GlaxoSmithKline granted potential generic competitor Teva a 37-month early entry to sell generic lamotrigine chewables, while supplying the chewable tablets to allow entry before the FDA approved Teva’s Abbreviated New Drug Application (ANDA).⁴⁶
- 2) GlaxoSmithKline granted Teva a six-month early entry for generic lamotrigine tablets, which depended on whether a pediatric exclusivity period was granted.⁴⁷
- 3) GlaxoSmithKline agreed not to launch its own generic versions of Lamictal products, i.e., a “No AG” agreement.⁴⁸

The *Lamictal* court’s interpretation of *Actavis* required a three-part test that differed from the test in *Nexium* in two respects.⁴⁹ For the first step, the court established a threshold inquiry asking “is there a reverse payment?”⁵⁰ The court took a more limited view on what would qualify as a payment, holding that *Actavis* only applies to monetary reverse payments. In effect, this means the court held that “No AG” agreements are not payments subject to rule-of-reason scrutiny.⁵¹ In doing so, the court directly addressed contrary holdings from *Lipitor* and *Nexium*, and found that they are “unsupported by the words of *Actavis* or are inapposite.”⁵²

For the second step, the court asked “is that reverse payment large and unjustified?”⁵³ If the first two steps are answered in the affirmative, only then would the court apply the rule-of-reason analysis to the payments at issue. In this third step, the court asked “whether the parties to an agreement creating a restraint of trade had market power and exercised it, whether the restraint had anticompetitive consequences and whether those consequences are otherwise justified.”⁵⁴ In this context, the district court suggested that *Actavis*’s “five sets of considerations,” which led the Supreme Court “to conclude that the FTC should have been given the opportu-

nity to prove its antitrust claim,”⁵⁵ were laid out “to guide district courts in applying the rule of reason . . .”⁵⁶

The district court acknowledged that there is “some overlap in the [three] steps” but held that deciding whether the settlement was a reverse payment and whether it was large and unjustified were preliminary steps and necessary precursors to rule-of-reason analysis.⁵⁷ Under this reading of *Actavis*, the alleged reverse payments did not qualify and the case was dismissed.⁵⁸ The case is on appeal to the Third Circuit.⁵⁹ Multiple *amicus curiae* briefs have been filed, with *amici* including the FTC, the AARP, 28 states, and 53 law, economics, and business professors.⁶⁰

Current Status: On appeal to the Third Circuit.

In re Modafinil Litigation, 06-cv-1797, 06-cv-1833, 06-cv-2768, 08-cv-2141 (E.D. Pa.)⁶¹

Notable Issues: Whether payment was fair price for goods or services; what preclusive effect do rulings from other trials have on antitrust liability; whether determining that a payment is “large and unjustified” is part of the rule-of-reason analysis or a preliminary requirement before reaching that analysis.

In *Modafinil*, end-payors, direct-purchasers, the FTC, and Apotex (a competing drug manufacturer) each alleged anticompetitive reverse payments occurred between Cephalon and four generic first-filers. The cases are before the Honorable Mitchell S. Goldberg in the Eastern District of Pennsylvania.⁶² Apotex also alleged, *inter alia*, *Walker Process* fraud, sham litigation, and illegal bottleneck.⁶³ The agreements involving alleged reverse payments included the following terms:

- 1) Teva, Ranbaxy, Barr, and Mylan agreed to delay marketing generic modafinil for up to six years, as long as another generic manufacturer did not enter the market first.⁶⁴
- 2) Cephalon entered into licenses to intellectual property held by potential generic competitors Teva, Ranbaxy, and Barr and its partner at prices that plaintiffs claim are higher than fair value.⁶⁵
- 3) Cephalon contracted to purchase active pharmaceutical ingredient (“API”) from Teva, Ranbaxy,

⁵⁵ *Actavis* at 2234.

⁵⁶ *In re Lamictal Direct Purchaser Antitrust Litig.*, 2014 WL 282755 at *5.

⁵⁷ *Id.* at *6.

⁵⁸ *Id.* at *6-7.

⁵⁹ *King Drug Co. of Florence Inc., v. Smithkline Beecham Co.*, appeal docketed, 14-1243 (3d Cir. Jan. 30, 2014).

⁶⁰ *Id.*

⁶¹ The authors of this article represent plaintiff Apotex in the *In re Modafinil Litigation*. All information reproduced here is drawn from publicly available sources and presented without opinion or argument.

⁶² See, e.g., Amended Consolidated Class Action Complaint, *Vista Healthplan, Inc. v. Cephalon, Inc.*, 06-cv-1833 (E.D. Pa. Aug. 10, 2009) ECF No. 74.

⁶³ See Apotex’s Second Amended Complaint at ¶¶ 2, 99, *Apotex v. Cephalon, Inc.*, 06-cv-2768 (E.D. Pa. Jan. 6, 2010) ECF No. 195.

⁶⁴ *Id.* at ¶¶ 127-37.

⁶⁵ Amended Consolidated Class Action Complaint at ¶¶ 103, 115, 123, *Vista Healthplan, Inc. v. Cephalon, Inc.*, 06-cv-1833 (E.D. Pa. Aug. 10, 2009) ECF No. 74.

⁴⁵ *In re Lamictal Direct Purchaser Antitrust Litig.*, 2014 WL 282755 at *1, 11 (D.N.J. Jan. 24, 2014). The court’s earlier grant of a motion to dismiss had been remanded for reconsideration in light of *Actavis*.

⁴⁶ *Id.* at *1-2.

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ *Id.* at *5.

⁵⁰ *Id.*

⁵¹ *Id.* at *7-9.

⁵² *Id.* at *9-10.

⁵³ *Id.*

⁵⁴ *Id.* (citing *United States v. Brown Univ.*, 5 F.3d 658, 679 (3d Cir. 1993)).

and Barr-Chemagis at prices plaintiffs claim are higher than fair value.⁶⁶

- 4) Cephalon entered into product development deals with potential generic competitors Mylan and Barr-Chemagis that the plaintiffs claim were reverse payments.⁶⁷

Before *Actavis* was decided, the district court denied motions to dismiss,⁶⁸ allowing discovery to progress to near completion. The court recently granted partial summary judgment for defendants on certain of plaintiffs' counts, "to the extent each is based on allegations of an overall conspiracy among all Defendants or between the Generic Defendants."⁶⁹ This grant of partial summary judgment did "not concern the legality of the individual, bilateral settlement agreements between Cephalon and each Generic Defendant," but rather "[p]laintiffs' claim that the separate settlement agreements were in fact the manifestation of a horizontal conspiracy between all Defendants—with Cephalon at the center—to restrain trade in the modafinil market."⁷⁰ The court focused on "whether there is sufficient evidence to allow a jury to consider whether all [d]efendants were parties to a single agreement."⁷¹ The court found that no direct evidence of such single agreement existed, and circumstantial evidence did "not support an inference of concerted, as opposed to independent, action."⁷² Currently, motions for summary judgment on the application of *Actavis* are before the court.⁷³

Unique to this case are earlier court determinations holding the patent at issue invalid, unenforceable, and not infringed by Apotex.⁷⁴ The Federal Circuit affirmed the judgments of invalidity and inequitable conduct in a *per curiam* opinion.⁷⁵ After the appeal, the district court granted summary judgment on the materiality element of the *Walker Process* fraud claim based on collateral estoppel,⁷⁶ but denied summary judgment on the intent element of that claim.⁷⁷ The latter denial is subject to a fully briefed motion for reconsideration.⁷⁸

⁶⁶ *Id.* at ¶¶ 104, 114, 121-122.

⁶⁷ First Amended Complaint for Injunctive Relief at ¶¶ 72, 77, *FTC v. Cephalon, Inc.*, 08-cv-2141 (E.D. Pa. Aug. 12, 2009) ECF No. 40.

⁶⁸ *See, e.g.*, Order, *Apotex v. Cephalon, Inc.*, 06-cv-2768 (E.D. Pa. Mar. 29, 2010) ECF No. 224.

⁶⁹ Order at 1 n.1, *Apotex v. Cephalon, Inc.*, 06-cv-2768 (E.D. Pa. June 23, 2014) ECF No. 793.

⁷⁰ Memorandum Opinion at 11, *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 06-cv-1797 (E.D. Pa. June 23, 1024) ECF No. 705.

⁷¹ *Id.*

⁷² *Id.* at 26.

⁷³ *See, e.g.*, Motion for Summary Judgment of Mylan Defendants on All Claims Under *FTC v. Actavis, Apotex, Inc. v. Cephalon, Inc.*, 06-cv-02768 (E.D. Pa. Apr. 4, 2014) ECF No. 690.

⁷⁴ *Apotex Inc. v. Cephalon, Inc.*, 2011 WL 6090696 at *1 (E.D. Pa. Nov. 7, 2011) *aff'd*, 500 F. App'x 959 (Fed. Cir. 2013).

⁷⁵ *Apotex Inc. v. Cephalon, Inc.*, 500 F. App'x 959 (Fed. Cir. 2013) *cert. denied*, 134 S. Ct. 825, 187 L. Ed. 2d 686 (2013). The judgment of non-infringement was not appealed.

⁷⁶ Memorandum Opinion at 24, *Apotex Inc. v. Cephalon, Inc.*, 06-cv-2768 (E.D. Pa. Mar. 13, 2014) ECF No. 674.

⁷⁷ *Id.* at 20.

⁷⁸ Apotex's Reply in Support of Its Motion for Reconsideration of the Court's Order of March 13, 2014 at 1, *Apotex, Inc. v. Cephalon, Inc.*, 06-cv-2768 (E.D. Pa. May 5, 2014) ECF No. 729-1.

Current Status: Replies and oral argument upon pre-trial evidentiary motions and motions for summary judgment pending; motion for reconsideration on preclusive effect of patent invalidity and unenforceability trial pending.

***In re Wellbutrin XL Antitrust Litig.*, 08-cv-2431, 08-cv-2433 (E.D. Pa.)**

Notable Issues: Whether a reverse payor's partner can be liable for making settlement possible; whether "No AG" agreements are reverse payments.

Wellbutrin XL was stayed awaiting resolution of *Actavis*,⁷⁹ and is now back before the Honorable Mary A. McLaughlin in the Eastern District of Pennsylvania. The settlements at issue were originally between Biovail, GlaxoSmithKline, and four generic manufacturers not named as defendants.⁸⁰ But on November 11, 2012, the court approved Biovail's settlement with the plaintiff class, leaving GlaxoSmithKline as the only defendant.⁸¹ The remaining agreement involving alleged reverse payments included the following terms:

GlaxoSmithKline waived its right to sell generic 150 mg Wellbutrin as Biovail's authorized generic during Anchen's 180-day first-to-file exclusivity period,⁸² allowing Biovail to secure a "No AG" agreement to prevent the generic manufacturers from launching.⁸³ Anchen had transferred this exclusivity to Teva two months before Biovail and Teva settled the Wellbutrin dispute.⁸⁴

Upon reopening the case, the court requested briefing on the application of *Actavis* before discovery.⁸⁵ The FTC attempted to file an *amicus curiae* brief to support the notion that *Actavis* applies to non-monetary "No AG" reverse payments,⁸⁶ but the brief was not accepted by the court.⁸⁷ After moving forward with briefing on the applicability of *Actavis* from both sides, the court found it was not yet prepared to accept that *Acta-*

⁷⁹ *See* Order, *In re Wellbutrin XL Antitrust Litig.*, 08-cv-2431 (E.D. Pa. Feb. 22, 2013) ECF No. 500.

⁸⁰ Consolidated Class Action Complaint, *In re Wellbutrin XL Antitrust Litig.*, 08-cv-2431 (E.D. Pa. July 10, 2008) ECF No. 21.

⁸¹ Order at 2, *In re Wellbutrin XL Antitrust Litig.*, 08-cv-2431 (E.D. Pa. Jan. 17, 2014) ECF No. 534; Final Order and Judgment Approving Settlement, *In re Wellbutrin XL Antitrust Litig.*, 08-cv-2431 (E.D. Pa. Nov. 7, 2012) ECF No. 485.

⁸² GSKs Memorandum on Applicability of *FTC v. Actavis* at 3-4, *In re Wellbutrin XL Antitrust Litig.*, 08-cv-2431 (E.D. Pa. Aug. 5, 2013) ECF No. 507.

⁸³ End-Payer [sic] Plaintiffs' Response to GSK's Memorandum of Law Regarding the Applicability of *FTC v. Actavis* at 11-12, *In re Wellbutrin XL Antitrust Litig.*, 08-cv-2433 (E.D. Pa. Sept. 26, 2013) ECF No. 479.

⁸⁴ *Id.* at 16-17.

⁸⁵ Order, *In re Wellbutrin XL Antitrust Litig.*, 08-cv-2431 (E.D. Pa. July 11, 2013) ECF No. 506.

⁸⁶ *See* Proposed Brief as *Amicus Curiae*, *In re Wellbutrin XL Antitrust Litig.*, 08-cv-2431 (E.D. Pa. Sept. 26, 2013) ECF No. 510-2.

⁸⁷ Order, *In re Wellbutrin XL Antitrust Litig.*, 08-cv-2431 (E.D. Pa. Oct. 3, 2013) ECF No. 522 (explaining that *amicus* briefs would not be appropriate or helpful, as the parties and their counsel can adequately argue on the interpretation of *Actavis*).

vis only applied to cash payments from the patentee to the generic, calling it “a close question.”⁸⁸

Current Status: Discovery scheduled to conclude December 29, 2014; dispositive motions and motions for summary judgment due February 5, 2015.⁸⁹

In re Androgel Antitrust Litig. (No. II), 09-cv-955 (N.D. Ga.)

Notable Issues: Whether payment was fair price for goods or services; whether determining that a payment is “large and unjustified” is part of the rule-of-reason analysis or a preliminary requirement before reaching that analysis.

Also known as *FTC v. Actavis*, this case is back before the Honorable Thomas W. Thrash, Jr. in the Northern District of Georgia after being vacated and remanded by the Supreme Court.⁹⁰ The agreements involving alleged reverse payments included the following terms:

- 1) Solvay agreed to share profits from its brand-name Androgel product with potential generic competitors Par, Paddock, and Watson.⁹¹
- 2) Par agreed to promote Androgel to primary care physicians and delay generic entry until 2015.⁹²
- 3) Paddock agreed to serve as an Androgel backup supplier and delay generic entry until 2015.⁹³
- 4) Watson agreed to promote Androgel to urologists and delay generic entry until 2015.⁹⁴

The defendants characterize these payments as legitimate compensation for services, while the plaintiffs argue that the payments were compensation for delayed competition.⁹⁵

Recently, the court denied a motion to dismiss based on *Noerr-Pennington* antitrust immunity.⁹⁶ Par, Paddock and Solvay argued that because their settlement agreements were memorialized by a court’s consent agreement, they constituted legitimate petitioning for government action and thus protected by the *Noerr-Pennington* doctrine.⁹⁷ The court rejected this argument because the consent agreement did not contain the full scope of the agreements between the parties and because “the full agreement between [Par, Paddock] and Solvay is precisely the sort of agreement the Supreme Court directed district courts to review with the rule of reason.”⁹⁸ The court has since denied Par

and Paddock’s request for interlocutory appeal on the matter.⁹⁹

Current Status: Discovery scheduled to conclude August 28, 2015; motions for summary judgment due October 28, 2015.¹⁰⁰

In re Loestrin 24 Antitrust Litig., 13-md-2472 (D.R.I.)

Notable Issues: Whether “No AG” agreements are reverse payments; whether payment was fair price for goods or services; whether Actavis applies to non-monetary reverse payments.

Loestrin 24 was filed October 3, 2013, before the Honorable William E. Smith in the District of Rhode Island. The agreements involving alleged reverse payments included the following terms:

- 1) Potential generic competitor Watson (now Actavis) agreed to delay launching generic *Loestrin 24* until the earliest of: (a) three years after the settlement; (b) 180 days before a third party’s approved generic entry; or (c) the date another generic version actually entered the market.¹⁰¹
- 2) Warner Chilcott agreed to not launch an authorized generic during Watson’s first 180 days of *Loestrin 24* sales, nor would it license a third party to do so.¹⁰²
- 3) Warner Chilcott gave Watson a worldwide license to *Loestrin 24* beginning in 2014.¹⁰³
- 4) Warner Chilcott paid Watson annual fees and royalties for promoting Warner Chilcott’s Femring hormone therapy product and the exclusive right to sell another branded oral contraceptive now named *Generess Fe*.¹⁰⁴
- 5) Potential generic competitor Lupin agreed to delay marketing generic *Loestrin 24* until the month that the patent at issue would expire.¹⁰⁵
- 6) Warner Chilcott granted Lupin a non-exclusive license to market *Femcon Fe* and *Asacol 400 mg*, supplied by Warner Chilcott, upon the entry of another generic version of each drug.¹⁰⁶

Plaintiffs also argue the defendants maintained an illegal bottleneck.¹⁰⁷ Motions to dismiss have been briefed, with the plaintiffs arguing that these settlements were large and unjustified payments,¹⁰⁸ and the

⁹⁹ Order Denying Motion for Appeal under 1292(b), *In re Androgel Antitrust Litig. (No. II)*, 09-cv-955 (N.D. Ga. May 20, 2014) ECF No. 297.

¹⁰⁰ Scheduling Order, *In re Androgel Antitrust Litig. (No. II)*, 09-cv-955 (N.D. Ga. June 11, 2014) ECF No. 307.

¹⁰¹ Consolidated Class Action Complaint at ¶¶ 88, 95, *In re Loestrin 24 Antitrust Litig.*, 13-md-2472 (D.R.I. Dec. 6, 2014) ECF No. 40.

¹⁰² *Id.* at ¶¶ 90, 94.

¹⁰³ *Id.* at ¶ 91.

¹⁰⁴ *Id.* at ¶¶ 92-93.

¹⁰⁵ *Id.* at ¶ 105.

¹⁰⁶ *Id.* at ¶¶ 107-108.

¹⁰⁷ End-Payor Plaintiffs’ Memorandum of Law in Opposition to Defendants’ Motion to Dismiss the Indirect Purchaser Plaintiffs’ Consolidated Class Action Complaint at 36, *In re Loestrin 24 Antitrust Litig.*, 13-md-2472 (D.R.I. Mar. 24, 2014) ECF No. 92-1.

¹⁰⁸ See *Id.* at 4-6.

⁸⁸ Order at 4, *In re Wellbutrin XL Antitrust Litig.*, 08-cv-2431 (E.D. Pa. June 12, 2014) ECF No. 547.

⁸⁹ Scheduling Order, *In re Wellbutrin XL Antitrust Litig.*, 08-cv-2431 (E.D. Pa. Feb. 11, 2014) ECF No. 537.

⁹⁰ *In re Androgel Antitrust Litig. (No. II)*, MDL 2084, 2014 WL 1600331 at *2-3 (N.D. Ga. Apr. 21, 2014).

⁹¹ *Id.* at *2.

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.* at *2 n.4.

⁹⁵ *Actavis* at 2229.

⁹⁶ *In re Androgel Antitrust Litig. (No. II)*, 2014 WL 1600331 at *2-3).

⁹⁷ *Id.* at *3.

⁹⁸ *Id.* at *6-9.

defendants urging the court to follow *Lamictal* and hold that *Actavis* only applies to monetary reverse payments.¹⁰⁹

Current Status: Motions to dismiss pending; oral arguments held June 27, 2014.¹¹⁰

In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., 14-md-2503 (D. Mass)

Notable Issues: Whether “No AG” agreements are reverse payments; how serial periods of generic exclusivity affect damages or liability.

At least 12 antitrust actions involving Medicis’s flagship *Solodyn* product were consolidated by the Judicial Panel on Multidistrict Litigation before the Honorable Denise J. Casper in the District of Massachusetts.¹¹¹ The agreements involving alleged reverse payments included the following terms:

- 1) Medicis allegedly paid potential generic competitor Impax at least \$55 million to delay marketing generic *Solodyn* for three years.¹¹²
- 2) Medicis granted potential generic competitors Teva, Sandoz, and Mylan serial, consecutive periods of generic exclusivity for *Solodyn*.¹¹³ Plaintiffs allege that these “seriatim periods” of sequential exclusivity delivered more profits to each of the generic manufacturers than if two or more generic manufacturers were competing.¹¹⁴
- 3) Medicis agreed not to distribute an authorized generic version of *Solodyn* to compete against Teva, Sandoz, or Mylan during each’s period of exclusivity.¹¹⁵
- 4) Medicis allegedly paid Teva to drop its challenge to 65 mg and 115 mg *Solodyn*, creating a bottleneck which it then allegedly paid potential generic competitors Ranbaxy, Mylan, and Lupin to not challenge.¹¹⁶
- 5) Medicis also allegedly paid Lupin to “park” its 180-day exclusivity with respect to 55 mg *Solodyn*.¹¹⁷

The plaintiffs also allege that Medicis fraudulently obtained the patent at issue and filed sham lawsuits, while using the delay in generic competition to switch patients away from patented products.¹¹⁸

¹⁰⁹ Reply Memorandum of Law in Further of Support of Motion to Dismiss at 12-15, *In re Loestrin 24 Antitrust Litig.*, 13-md-2472 (D.R.I. Apr. 23, 2014) ECF No. 97.

¹¹⁰ Notice of Hearing, *In re Loestrin 24 Antitrust Litig.*, 13-md-2472 (D.R.I. May 1, 2014).

¹¹¹ Transfer Order, *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 14-md-2503 (D. Mass Feb. 25, 2014) ECF No. 2.

¹¹² Complaint at ¶ 6, *Rochester Drug Co-Operative, Inc. v. Medicis Pharm. Corp.*, 1:14-cv-10438 (E.D. Pa. July 23, 2013) ECF No. 1. This case was consolidated in to the present *In re Solodyn* litigation.

¹¹³ *Id.* at ¶ 9.

¹¹⁴ *Id.* at ¶ 178.

¹¹⁵ *Id.* at ¶ 9.

¹¹⁶ *Id.* at ¶ 12.

¹¹⁷ *Id.*

¹¹⁸ Memorandum of Law in Support of Plaintiffs’ Motion to Consolidate the End-Payor Class Actions, Appoint Interim Co-Lead Counsel, and Enter Case Management Order No. 1 at 4,

Current Status: Consolidated amended complaints to be filed.

In re Cipro Cases I & II, S198616 (Cal.)

Notable Issues: *Actavis*’s impact on state antitrust claims.

The *Cipro Cases I & II* involve state law claims¹¹⁹ of contested reverse payments that were later ruled not in violation of the Sherman Act in federal court under the pre-*Actavis* scope-of-the-patent test.¹²⁰ The plaintiffs allege the reverse payment settlements are in violation of California’s Cartwright Act, Unfair Competition Law, and common law monopolization.¹²¹ The Court of Appeal in the Fourth District of California held that “unless a patent was procured by fraud, or a suit for its enforcement was objectively baseless, a settlement of the enforcement suit does not violate the Cartwright Act if the settlement restrains competition only within the scope of the patent.”¹²² The agreements involving alleged reverse payments included the following terms:

- 1) Potential generic competitor Barr agreed to amend its Paragraph IV certification to a Paragraph III certification, precluding Barr from obtaining FDA approval until the patent covering ciprofloxacin expired. Barr allegedly agreed to make this amendment in exchange for an immediate payment of \$49.1 million from Bayer, the owner of the branded *Cipro* product.
- 2) In a “supply agreement” with Bayer, potential generic competitors Barr and HMR agreed to not manufacture ciprofloxacin, giving Bayer the option of either supplying ciprofloxacin to Barr and HMR to distribute in the U.S. or making quarterly payments until the patent expired. Bayer chose the latter, and made total cash payments (including the \$49.1 million initial payment) of about \$398 million.¹²³

The court’s decision was appealed to the Supreme Court of California, where it was stayed awaiting the resolution of *Actavis*.¹²⁴ Weeks after *Actavis* was decided, brand manufacturer Bayer agreed to create a \$74 million settlement fund and cooperate with the plaintiffs in their continued litigation against the generic defendants.¹²⁵ The plaintiffs, remaining generic defendants, and several *amici* have filed briefs before the court, where the issue remains as to whether California

In re Solodyn Antitrust Litig., No. 14-md-2503 (D. Mass. Mar. 25, 2014) ECF No. 17.

¹¹⁹ *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 166 F. Supp. 2d 740, 757 (E.D.N.Y. 2001).

¹²⁰ *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1341 (Fed. Cir. 2008) *abrogated by* *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 186 L. Ed. 2d 343 (U.S. 2013) (“*Cipro III*”).

¹²¹ *In re Cipro Cases I & II*, 134 Cal. Rptr. 3d 165, 174 (Cal. Ct. App. 2011) *review granted* and opinion superseded, 269 P.3d 653 (Cal. 2012).

¹²² *Id.* at 184.

¹²³ *Id.* at 171.

¹²⁴ Order, *In re Cipro Cases I & II*, Case No. S198616 (Cal. Sept. 12, 2012).

¹²⁵ Joyce Cutler, “Bayer to Pay \$74 Million to Settle *Cipro* Pay-for-Delay Case; Other Lawsuits Continue,” *Pharmaceutical Law & Industry Report* (Sept. 6, 2013) (11 PLIR 1052, 9/6/13).

state antitrust claims may be brought to challenge reverse payments in pharmaceutical patent litigation.¹²⁶

Current Status: Supplemental briefing due before Supreme Court of California.

In re Aggrenox Antitrust Litig., 14-md-2516 (D. Conn.)

Notable Issues: Whether “No AG” agreements are reverse payments; whether payment was fair price for goods or services; whether settlement documents are protected work product.

The Judicial Panel on Multidistrict Litigation recently transferred 11 antitrust actions relating to Aggrenox to the Honorable Stefan R. Underhill in the District of Connecticut.¹²⁷ While the case is in its very early stages, the alleged reverse payments at issue appear to be:

- 1) Boehringer and potential generic competitor Barr entered a “co-promotion” agreement including up to \$120 million in upfront and continuing yearly royalty payments to Barr.¹²⁸
- 2) Boehringer agreed not to launch its own authorized generic version of Aggrenox once Barr launched generic Aggrenox in 2015.¹²⁹

In a separate but related case, the FTC sued Boehringer in the U.S. District Court of the District of Columbia to enforce a subpoena *duces tecum* requiring Boehringer to produce documents relating to the settlements at issue.¹³⁰ Boehringer succeeded in convincing the lower court that these documents were protected work product, but that case is currently on appeal awaiting oral argument before the D.C. Circuit Court.¹³¹

Current Status: Discovery is ongoing.¹³²

In re Adderall XR Antitrust Litig., 12-cv-3711 (S.D.N.Y.), 13-1232 (2d Cir.)

Notable Issues: Antitrust implications when a reverse payor does not perform contractual obligations; patentee’s unilateral refusal to deal.

The plaintiffs’ allegations in this case involve potential reverse payments, but the antitrust allegations focus on the “patentee’s unilateral refusal to deal in its pat-

ented product.”¹³³ Two related class action suits were consolidated before the Honorable Victor Marrero in the Southern District of New York.¹³⁴ The agreements involving alleged reverse payments included the following terms:

- 1) Potential generic competitors Teva and Impax agreed to delay launching their generic Adderall XR products for about three years.
- 2) Shire granted Teva and Impax patent licenses after that period, and further agreed to supply all of their Adderall XR supply needs under separate requirement contracts.¹³⁵

The plaintiffs alleged that Shire, as sole manufacturer of Adderall XR products, purposefully underperformed on these requirement contracts to keep supplies artificially low and prices artificially high, creating a “duty to deal” antitrust liability similar to that found in the *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985).¹³⁶ The district court dismissed the plaintiffs’ claims because the original agreements did not exceed the scope of the patents in question.¹³⁷

The plaintiffs appealed to the Second Circuit.¹³⁸ Plaintiff-Appellants argued that the district court’s reasoning relied on the scope-of-the-patent test from *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006), and was fatally undermined by *Acatvis’s* rejection of similar scope-of-the-patent tests and abrogation of *In re Tamoxifen*.¹³⁹ Defendant-Appellees argued that *Actavis* is inapposite because it does not apply “to a patentee’s unilateral refusal to deal.”¹⁴⁰

On June 9, 2014, the Second Circuit Court of Appeals affirmed the lower court’s dismissal for failure to state a claim.¹⁴¹ The court found that the plaintiffs expressly limited their argument to an antitrust “duty to deal” analysis and failed on that issue.¹⁴² In doing so, it fully avoided “the complexities that attend cases at the intersection of antitrust and patent law.”¹⁴³ The court did not weigh “the potentially anticompetitive effects, if any, of [the alleged reverse payments] against ‘patent law policy [and] procompetitive antitrust policies.’”¹⁴⁴

Current Status: Dismissal for failure to state a claim affirmed on appeal, June 9, 2014.

¹³³ Brief for Defendants-Appellees at 5 *In re Adderall XR Antitrust Litig.*, No. 13-1232 (2d Circuit Oct. 4, 2013) ECF No. 68.

¹³⁴ Consent Order Consolidating Related Actions, *In re Adderall XR Antitrust Litig.*, 12-cv-3711 (S.D.N.Y. Oct. 17, 2012) ECF No. 22.

¹³⁵ *Louisiana Wholesale Drug Co., Inc. v. Shire LLC*, 929 F. Supp. 2d 256, 258 (S.D.N.Y. 2013).

¹³⁶ *Id.* at 259.

¹³⁷ *Id.* at 265.

¹³⁸ Notice of Civil Appeal, *In re Adderall XR Antitrust Litig.*, No. 13-1232 (2d Cir. Apr. 3, 2013) ECF No. 1.

¹³⁹ Reply Brief of Plaintiffs-Appellants at 11-12, *In re Adderall XR Antitrust Litig.*, No. 13-1232 (2d Cir. Oct. 18, 2013) ECF No. 71.

¹⁴⁰ Brief for Defendants-Appellees at 22, *In re Adderall XR Antitrust Litig.*, 13-1232 (2d Cir. Oct. 4, 2013) ECF No. 68.

¹⁴¹ *In re Adderall XR Antitrust Litig.*, 13-1232, 2014 WL 2565832 at *7 (2d Cir. June 9, 2014).

¹⁴² *Id.* at *4-6.

¹⁴³ *Id.* at *4.

¹⁴⁴ *Id.* at *6.

¹²⁶ See *In re Cipro Cases I & II*, Case No. S198616, Case Information. http://appellatecases.courtinfo.ca.gov/search/case/mainCaseScreen.cfm?dist=0&doc_id=1999739&doc_no=S198616.

¹²⁷ Transfer Order at 1, *In re Aggrenox Antitrust Litig.*, No. 3:14-md-02516 (D.Conn. Apr. 3, 2014) ECF No. 1.

¹²⁸ Memorandum of Law in Support of End-Payor Plaintiffs’ Motion to Appoint Interim Co-Lead Counsel at 5, *In re Aggrenox Antitrust Litig.*, No. 3:14-md-02516 (D.Conn. May 19, 2014) ECF No. 61.

¹²⁹ *Id.*

¹³⁰ See Petition of the Federal Trade Commission for an Order Enforcing Subpoena *Duces Tecum* Issued in Furtherance of a Law Enforcement Investigation, *FTC v. Boehringer Ingelheim Pharm. Inc.*, 9-mc-564 (D.D.C. Oct. 23, 2009) ECF No. 1.

¹³¹ See *FTC v. Boehringer Ingelheim Pharm., Inc.*, No. 12-5393 (D.C. Cir.).

¹³² Scheduling Order, *In re Aggrenox Antitrust Litig.*, No. 3:14-md-02516 (D.Conn. May 30, 2014) ECF No. 83.

In re Niaspan Antitrust Litig., 13-md-2460 (E.D. Pa.)

Notable Issues: Whether payment was fair price for goods or services; whether “No AG” agreements are reverse payments.

Eight actions were consolidated before the Honorable Jan E. Dubois in the Eastern District of Pennsylvania.¹⁴⁵ The agreements involving alleged reverse payments included the following terms:

- 1) Potential generic competitor Barr agreed to delay entry from 2005 until 2013.
- 2) Barr agreed to develop an FDA-approved manufacturing process and stand as a back-up supplier for Niaspan, for which Kos would provide a start-up payment and quarterly stand-by payments.¹⁴⁶
- 3) Barr would co-promote Niaspan and Advicor (another Kos product) to doctors specializing in women’s health.¹⁴⁷
- 4) Kos agreed to pay Barr cash as a percentage of overall Niaspan sales, license its patents to Barr, and not launch authorized generic versions of Niaspan and Advicor.¹⁴⁸

Because Barr retained its 180-day first-filer exclusivity, plaintiffs have alleged a bottleneck preventing other generics from entering the market.¹⁴⁹

Current Status: Motions to dismiss pending.

In re Skelaxin (Metaxalone) Antitrust Litig., 12-md-2343 (E.D. Tenn.)

Notable Issues: Effect of reverse-bifurcated damages trial on settlement and future litigation; comparison of estimated damages to awarded damages; class certification.

Both federal and state antitrust claims are at issue here before the Honorable Curtis L. Collier in the Eastern District of Tennessee. Sherman Act violations were pleaded against King Pharmaceuticals, Inc., and Mutual Pharmaceutical Co., Inc., while additional state law claims were pleaded against these and other defendants.¹⁵⁰ The agreements involving alleged reverse payments included the following terms:

- 1) King agreed to pay potential generic competitor Mutual \$35 million and at least 10% of branded Skelaxin sales in exchange for intellectual property licenses on recently performed metabolism

¹⁴⁵ Order From Judicial Panel on Multidistrict Litigation, *In re Niaspan Antitrust Litig.*, No. 13-md-2460 (E.D. Pa. Sept. 17, 2013) ECF No. 1.

¹⁴⁶ Memorandum in Support of Defendants’ Joint Motion to Dismiss the Consolidated Amended Complaints at 5, *In re Niaspan Antitrust Litig.*, No. 13-md-2460 (E.D. Pa. Mar. 17, 2014) ECF No. 69.

¹⁴⁷ Plaintiffs’ Joint Opposition to Defendants’ Joint Motion to Dismiss the Consolidated Amended Complaints at 5-6, *In re Niaspan Antitrust Litig.*, No. 13-md-2460 (E.D. Pa. May 1, 2014) ECF No. 87.

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ Compare Amended Complaint, *In re Skelaxin (Metaxalone) Antitrust Litig.*, 12-md-2343 (E.D. Tenn. Nov. 2, 2012).

studies, while Mutual agreed to delay sales of generic metaxalone.¹⁵¹

- 2) Mutual and King allegedly filed multiple citizen petitions, concealed the details of their settlement, and stayed their litigation instead of settling it, in an attempt to create an extended bottleneck by delaying the case’s resolution beyond the FDA’s 30-month stay.¹⁵²

- 3) In exchange for a four-year delay in entry, King granted potential generic competitor CorePharma the right to enter the market as an authorized generic version of Skelaxin and supply CorePharma with API.¹⁵³

In what appears to be a coincidence, on the very same day *Actavis* was decided, the court in *Skelaxin* scheduled a damages-only trial to avoid expending “time, money, and energy on issues such as the conspiracy allegations . . . the sham FDA petitions. . . or the Orange Book and sham patent litigation issues in the complaint.”¹⁵⁴ The court has since denied class certification for the end-payor and indirect-purchaser plaintiffs,¹⁵⁵ while other classes of plaintiffs have settled.¹⁵⁶

A damages-only jury trial for individual plaintiffs concluded on June 12, 2014, although the court granted a motion to seal the verdict form.¹⁵⁷

Current Status: Damages-only jury trial concluded June 12, 2014; verdict sealed.¹⁵⁸

In re Opana ER (Oxymorphone Hydrochloride) Antitrust Litig., 159 14-cv-2630 (N.D. Cal.), 14-cv-3185, 14-cv-3190 (E.D. Pa.)

Notable Issues: Whether payment was fair price for goods or services; whether “No AG” agreements are reverse payments.

¹⁵¹ Amended Complaint at ¶¶ 173-80, *In re Skelaxin (Metaxalone) Antitrust Litig.*, 12-md-2343 (E.D. Tenn. Nov. 2, 2012) ECF No. 65.

¹⁵² *Id.* at ¶¶ 192-215.

¹⁵³ *Id.* at ¶¶ 216-17. See also *In re Skelaxin (Metaxalone) Antitrust Litig.*, 1:12-MD-2343, 2013 WL 2181185 at *6-10 (E.D. Tenn. May 20, 2013).

¹⁵⁴ Scheduling Order at 2-3 *In re Skelaxin (Metaxalone) Antitrust Litig.*, 12-cv-203 (E.D. Tenn. June 17, 2013) ECF No. 24.

¹⁵⁵ Order at 2, *In re Skelaxin (Metaxalone) Antitrust Litig.*, 12-md-2343 (E.D. Tenn. Jan. 20, 2014) ECF No. 509.

¹⁵⁶ Dominic Rivera, “\$2M Skelaxin Class Action Settlement Reached with Indirect Purchasers,” *Top Class Actions* (June 5, 2014) <http://www.topclassactions.com/lawsuit-settlements/lawsuit-news/29237-2m-skelaxin-class-action-settlement-reached-indirect-purchasers/>.

¹⁵⁷ Minute Entry, *In re Skelaxin (Metaxalone) Antitrust Litig.*, 12-md-2343 (E.D. Tenn. June 12, 2014) ECF No. 731.

¹⁵⁸ See Scheduling Order at 7, *In re Skelaxin (Metaxalone) Antitrust Litig.*, 12-cv-203 (E.D. Tenn. July 2, 2013) ECF No. 26; Docket, *In re Skelaxin (Metaxalone) Antitrust Litig.*, 12-md-2343 (E.D. Tenn.).

¹⁵⁹ These cases have not been consolidated under this name as they were filed very recently. The cases alleging the same issues and conduct surrounding the reverse settlements involving Endo’s Opana ER so far include: *Value Drug Co. v. Endo Health Solutions Inc.*, 14-cv-2630 (N.D. Cal.); *Rochester Drug Co-operative, Inc. v. Endo Health Solutions Inc.*, 14-cv-3185 (E.D. Pa.); and *Fraternal Order of Police v. Endo Health Solutions Inc.*, 14-cv-3190 (E.D. Pa.).

These cases in the Northern District of California and Eastern District of Pennsylvania were filed in the first week of June 2014, and accordingly only limited information is available from the initial complaints. The agreements involving alleged reverse payments included the following terms:

- 1) Endo ended litigation with potential generic competitor Impax, the first filer for five Opana ER dosages, in exchange for a future lump sum payment based on sales the quarter immediately prior to the delayed launch.¹⁶⁰
- 2) Endo and Impax entered into a “No AG” agreement preventing Endo from competing with Impax during its 180-day first-filer exclusivity period.¹⁶¹
- 3) Endo paid Impax \$10 million up front, with a \$30 million obligation to follow under a co-promotion agreement for an unapproved Parkinson’s disease medication.¹⁶²
- 4) Endo ended litigation against potential generic competitors Actavis, Barr, Sandoz, Watson, and Roxane (all of which are not named defendants) in exchange for early entry, the dates of which were allegedly rendered illusory in light of the regula-

¹⁶⁰ Class Action Complaint at ¶¶ 6, 138, *Rochester Drug Cooperative, Inc. v. Endo Health Solutions Inc.*, 14-cv-3185 (E.D. Pa June 4, 2014) ECF No. 1.

¹⁶¹ *Id.* at ¶¶ 6, 139.

¹⁶² *Id.* at ¶¶ 6, 140.

tory bottleneck created by the Endo-Impax agreements.¹⁶³

One novel element of the alleged reverse payment was that one reverse payment recipient (Impax) purportedly anticipated that Endo might attempt to switch patients from Opana ER to another product. Plaintiffs allege that Impax structured the agreement to insulate against this possibility of “product switching” or “product hopping” by basing it on Endo’s sales of branded Opana ER the quarter before generic entry.¹⁶⁴ If Opana ER sales were lower than a certain threshold in this quarter, Endo would provide a cash payment to Impax, which would grow larger the further the sales fell below the threshold.¹⁶⁵ Endo eventually switched products from Opana ER to a crush-proof formulation, allegedly netting Impax a cash payment of over \$100 million.¹⁶⁶

Current Status: Complaints filed.

Conclusion

In *Actavis*, the Supreme Court declined to apply a bright line scope-of-the-patent test to patent litigation settlement agreements. Instead, it called for a rule-of-reason analysis, leaving it to the district courts to structure the proper analysis. As seen in the conflicting analysis in *Nexium* and *Lamictal*, the contours of post-*Actavis* reverse payment analysis are not definitively established, creating uncertainty for pharmaceutical companies looking to settle ANDA litigation.

¹⁶³ *Id.* at ¶¶ 161-166.

¹⁶⁴ *Id.* at ¶¶ 144-48.

¹⁶⁵ *Id.* at ¶¶ 8, 145.

¹⁶⁶ *Id.* at ¶ 148.