United States Court of Appeals
For the First Circuit

Nos. 14-2071,
15-1250

IN RE: LOESTRIN 24 FE ANTITRUST LITIGATION

AMERICAN SALES COMPANY, LLC, on behalf of itself and all others similarly situated; ROCHESTER DRUG CO-OPERATIVE, INC., on behalf of itself and all others similarly situated,

Plaintiffs, Appellants,

CITY OF PROVIDENCE, RHODE ISLAND, individually and on behalf of itself and all others similarly situated; UNITED FOOD AND COMMERCIAL WORKERS LOCAL 1776 & PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND, individually and on behalf of all others similarly situated; NEW YORK HOTEL TRADES COUNCIL & HOTEL ASSOCIATION OF NEW YORK CITY, INC. HEALTH BENEFITS FUND, individually and on behalf of all others similarly situated; FRATERNAL ORDER OF POLICE, FORT LAUDERDALE LODGE 31, INSURANCE TRUST FUND, individually and on behalf of all others similarly situated; ELECTRICAL WORKERS 242 & 294 HEALTHCARE & WELFARE FUND, individually and on behalf of all others similarly situated; DENISE LOY, a resident citizen of the State of Florida, individually and on behalf of all others similarly situated; MELISA CHRESTMAN, a resident citizen of the State of Tennessee, individually and on behalf of all others similarly situated; MARY ALEXANDER, a resident citizen of the State of North Carolina, individually and on behalf of all others similarly situated; PAINTERS DISTRICT COUNCIL NO. 30 HEALTH & WELFARE FUND, individually and on behalf of all others similarly situated; TEAMSTERS LOCAL 237 WELFARE BENEFITS FUND, individually and on behalf of all others similarly situated; LABORERS INTERNATIONAL UNION OF NORTH AMERICA LOCAL 35 HEALTH CARE FUND, on behalf of itself and all others similarly situated; ALLIED SERVICES DIVISION WELFARE FUND, on behalf of itself and all others similarly situated; WALGREEN CO.; THE KROGER CO.; SAFEWAY, INC.; ALBERTSON'S, LLC; HEB GROCERY COMPANY L.P.,

Plaintiffs,

v.

WARNER CHILCOTT COMPANY, LLC; WARNER CHILCOTT PUBLIC LIMITED COMPANY; WARNER CHILCOTT HOLDINGS COMPANY III, LTD.; WARNER CHILCOTT CORPORATION, LLC, f/k/a Warner Chilcott Company, Inc.; WARNER CHILCOTT (US), LLC; WARNER CHILCOTT SALES (US), LLC; WARNER CHILCOTT LABORATORIES IRELAND LIMITED; WARNER CHILCOTT COMPANY; ACTAVIS, INC., f/k/a WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES, INC.; LUPIN LTD.; LUPIN PHARMACEUTICALS, INC.,

Defendants, Appellees.

APPEALS FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF RHODE ISLAND

[Hon. William E. Smith, U.S. District Judge]

Before

Torruella, Lynch, and Thompson,
Circuit Judges.

Thomas M. Sobol, with whom Kristen A. Johnson, Hagens Berman Sobol Shapiro, LLP, Joseph H. Meltzer, Terence S. Ziegler, Kessler Topaz Meltzer & Check, LLP, David F. Sorensen, Michael Kane, Berger & Montague, PC, Peter R. Kohn, Neill W. Clark, and Faruqi & Faruqi, LLP, were on brief, for Direct-Purchasers' appellants.

Mark S. Hegedus, Attorney, Office of the General Counsel, Federal Trade Commission, with whom Jonathan E. Nuechterlein, General Counsel, Joel Marcus, Director of Litigation, Deborah L. Feinstein, Director, Stephen Weissman, Deputy Director, Markus H. Meier, Assistant Director, Bradley S. Albert, Deputy Assistant Director, and Jamie R. Towey, Attorney, Bureau of Competition, were on brief, of the Federal Trade Commission as amicus curiae in support of appellants.

Steve D. Shadowen, Interim Co-Lead Counsel, with whom Elizabeth Arthur, Matthew C. Weiner, Hilliard & Shadowen LLP, Donald A. Migliori, Michael M. Buchman, John A. Ioannou, Motley

Rice LLC, J. Douglas Richards, Sharon K. Robertson, Cohen Milstein Sellers & Toll PLLC, Marvin A. Miller, Lori A. Fanning and Miller Law LLC, were on brief, for End-Payors' appellants.

Robert A. Milne, with whom Jack E. Pace III, Alison Hanstead, J. Mark Gidley, Peter J. Carney, White & Case LLP, John A. Tarantino, Nicole J. Benjamin and Adler Pollock & Sheehan P.C., were on brief, for appellees Warner companies.

Leiv Blad, Jr., with whom Zarema A. Jaramillo and Morgan, Lewis & Bockius LLP, were on brief, for appellees Lupin Limited and Lupin Pharmaceuticals, Inc.

Scott E. Perwin, Lauren C. Ravkind, Anna T. Neill, Kenny Nachwalter P.A., Paul J. Skiermont, Skiermont Puckett LLP, S. Michael Levin, Barry L. Refsin, Monica L. Rebuck and Hangley Aronchick Segal Pudlin & Schiller, on amicus brief of Walgreen Co., The Kroger Co., Safeway, Inc., Albertson's LLC, HEB Grocery Company, LP, Rite Aid Corporation and CVS Pharmacy, Inc.

Kenneth A. Wexler and Wexler Wallace LLP, on amicus brief on behalf of 70 Law, Economics, and Business Professors and the American Antitrust Institute.

Janet T. Mills, Attorney General of Maine, on amicus brief of the States of Maine, California, Alaska, Colorado, Connecticut, Delaware, District of Columbia, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Michigan Minnesota, Mississippi, Nebraska, New Hampshire, New Mexico, Oregon, Rhode Island, Tennessee, Texas, Utah, Vermont, and Washington.

Daniel S. Francis, D. Bruce Hoffman, Hunton & Williams LLP, Linda E. Kelly, Quentin Riegel, Manufacturers' Center for Legal Action, on amicus brief of National Association of Manufacturers.

Richard A. Samp, Mark S. Chenoweth, and Washington Legal Foundation, on amicus brief of Washington Legal Foundation.

Christopher T. Holding, William M. Jay, Brian T. Burgess, and Goodwin Procter LLP, on amicus brief of Generic Pharmaceutical Association.

Andrew Lazerow, Ashley Bass, Stephen Bartenstein and Covington & Burling LLP, on amicus brief of Pharmaceutical Research and Manufacturers of America.

Burt M. Rublin, Stephen J. Kastenberg, Jessica M. Anthony, Barbara A. Schwartz and Ballard Spahr LLP, on amicus brief of Antitrust Economists.

David A. Balto, James J. Kovacs and Law Offices of David A. Balto, on amicus brief of Consumer Action, AARP, U.S. Public Interest and Research Group, Public Citizen, Families USA, and Consumers Union.

February 22, 2016

TORRUELLA, **Circuit Judge**. This appeal arises from several pharmaceutical antitrust actions that were consolidated and transferred to the United States District Court for the District of Rhode Island by the United States Judicial Panel on Multidistrict Litigation.

Defendant Warner Chilcott ("Warner") is a brand-name drug manufacturer that owns the patent covering the oral contraceptive Loestrin 24 Fe ("Loestrin 24"). After defendant Watson Pharmaceuticals, Inc. ("Watson") notified Warner that it would seek to introduce a generic version of Loestrin 24, Warner sued Watson for patent infringement. The parties settled on conditions that Watson delay entry of its generic version of Loestrin 24 and, in exchange, Watson entered into favorable promotional deals with Warner and received promises that Warner would not introduce its own generic version of Loestrin 24, among other things. Shortly thereafter, defendant Lupin Pharmaceuticals, Inc. ("Lupin") announced that it would introduce a generic version of Loestrin 24. Warner brought a patent infringement suit against Lupin. Again, the parties settled on terms that Lupin wait to introduce its generic Loestrin 24 in exchange for attorneys' fees and Warner's agreement to enter into favorable side deals with Lupin.

Two putative classes of plaintiffs -- the Direct Purchaser Plaintiffs ("DPPs"), a group comprised of corporate entities that purchased Loestrin 24 directly from Warner, and End Payor Plaintiffs ("EPPs"), which consist of health and welfare benefit plans that have indirectly purchased, paid for, and provided reimbursement for their members' purchase of Loestrin 24, and individuals who purchased or paid for some or all of the purchase price of Loestrin 24 -- subsequently brought antitrust claims that the settlement agreements were violations of § 1 of the Sherman Act, 15 U.S.C. § 1.[1] They contend that these agreements constitute illegal restraints on trade under FTC v. Actavis, ___ U.S. ___, 133 S. Ct. 2223 (2013), which subjected certain patent settlement agreements between generic drug and brand-name drug manufacturers to antitrust scrutiny where they involve "reverse payments." As described in more detail herein, a reverse payment

[1] Section 1 of the Sherman Act provides:

> Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

15 U.S.C. § 1.

typically arises where a brand-name drug manufacturer pays the generic manufacturer to delay entry of its generic equivalent, thereby protecting the brand's market from generic competition.

Specifically, this antitrust case queries whether, following Actavis, such settlement agreements are subject to federal antitrust scrutiny where they do not involve reverse payments in pure cash form. The district court found that Actavis only applied to monetary reverse payments and dismissed on the basis that the EPPs and DPPs had alleged the existence of non-cash reverse payments only. Because we disagree with the district court's limited reading of Actavis, we vacate and remand. We begin with the relevant statutory and legal background, which provides the framework for understanding the facts in this appeal.

I. Regulatory Background

The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly known as the Hatch-Waxman Act, stipulates the process by which pharmaceutical firms may gain approval from the Food and Drug Administration ("FDA") to bring medications to the public marketplace. The Supreme Court in Actavis identified "four key

features of the relevant drug-regulatory framework" under the Hatch-Waxman Act. 133 S. Ct. 2227-29.

First, to market a new prescription drug, a brand-name drug manufacturer must submit a New Drug Application ("NDA") to the FDA and undergo a laborious and expensive approval process. 21 U.S.C. § 355(b)(1); see Actavis, 133 S. Ct. at 2228. Among other things, the NDA must include "the patent number and the expiration date of any patent which claims the drug . . . or which claims a method of using such drug." 21 U.S.C. § 355(b)(1). Upon receiving FDA approval, the brand manufacturer must publish a description of any patents associated with that drug in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. See Caraco Pharm. Labs., Ltd. V. Novo Nordisk A/S, ___ U.S. ___, 132 S. Ct. 1670, 1676 (2012).

Second, the Hatch-Waxman Act promotes the availability of cheaper generic alternatives by allowing generic drug manufacturers to bypass certain aspects of the NDA process. Instead of filing an NDA, a generic manufacturer may file a less cumbersome Abbreviated New Drug Application ("ANDA") "specifying that the generic has the 'same active ingredients as,' and is 'biologically equivalent' to, the already-approved brand-name drug." Actavis, 133 S. Ct. at 2228 (quoting Caraco Pharm. Labs., Ltd., 132 S. Ct. at 1676); 21 U.S.C. § 355(j)(2). But, "[b]ecause

the FDA cannot authorize a generic drug that would infringe a patent, the timing of an ANDA's approval depends on the scope and duration of the patents covering the brand-name drug." Caraco Pharm. Labs., Ltd., 132 S. Ct. at 1676.

Third, the Hatch-Waxman Act establishes procedures for resolving patent disputes between brand and generic drug manufacturers. 21 U.S.C. § 355(j)(2)(A)(vii); Actavis, 133 S. Ct. at 2228. When seeking FDA approval, the generic manufacturer must certify that it will not infringe the brand manufacturer's patents. 21 U.S.C. § 355(j)(2)(A)(vii); Actavis, 133 S. Ct. at 2228. It can make this certification in one of four ways:

> It can certify that the brand-name manufacturer has not listed any relevant patents. It can certify that any relevant patents have expired. It can request approval to market beginning when any still-in-force patents expire. Or, it can certify that any listed, relevant patent "is invalid or will not be infringed by the manufacture, use, or sale" of the drug described in the [ANDA].

Actavis, 133 S. Ct. at 2228 (quoting 21 U.S.C. § 355(j)(2)(A)(vii)(IV)).

The fourth alternative, also known as the Paragraph IV route, "counts as patent infringement and often 'means provoking litigation'" by the brand manufacturer. Id. (citation omitted) (quoting Caraco Pharm. Labs., Ltd., 132 S. Ct. at 1677). Should the brand manufacturer bring a patent suit within forty-five days of the generic manufacturer making a Paragraph IV certification,

the FDA may not approve the generic manufacturer's ANDA for a thirty-month period. 21 U.S.C. § 355(j)(5)(B)(iii); Actavis, 133 S. Ct. at 2228. Paragraph IV litigation between generic and brand-name drug manufacturers is particularly relevant here as it has led to the settlement arrangements identified in Actavis.

Fourth, the Hatch-Waxman Act provides incentives for the first generic manufacturer to file an ANDA through the Paragraph IV route: the generic will receive a 180-day period of exclusivity during which "no other generic can compete with the brand-name drug." Actavis, 133 S. Ct. at 2229; 21 U.S.C. § 355(j)(5)(B)(iv). This exclusivity period is potentially worth hundreds of millions of dollars to the first-filing generic manufacturer. See Actavis, 133 S. Ct. at 2229.[2] That said, the generic manufacturer may still face competition from a generic version of the drug produced by the brand manufacturer, also known as an authorized generic ("AG"), at any time, including during the exclusivity period. See Teva Pharm. Indus. Ltd. v. Crawford, 410 F.3d 51, 54-55 (D.C. Cir. 2005) (citing 21 U.S.C. § 355(j)(5)(B)(iv)).

II. Actavis

We turn to Actavis, where the Supreme Court analyzed settlement agreements arising from Paragraph IV litigation with

[2] This 180-day exclusivity period can be forfeited as provided under the Hatch-Waxman Act. 21 U.S.C. § 355(j)(5)(D).

terms requiring "(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. These types of settlements led to concerns that a brand manufacturer may be paying the generic manufacturer to abandon its patent challenge, thereby insulating the brand's market from competition and preventing consumers from accessing a more affordable generic version of the brand-name drug. The Court described this arrangement as a "reverse payment," explaining that "the basic question here is whether such an agreement can sometimes unreasonably diminish competition in violation of the antitrust laws." Id.

The Supreme Court answered in the affirmative. It rejected the argument that a settlement involving reverse payments is immune from antitrust scrutiny so long as any "anticompetitive effects [of the settlement] fall within the scope of the exclusionary potential of the patent," otherwise known as the "scope of the patent" test. Id. at 2230 (quoting FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1312 (11th Cir. 2012)).[3] The Court

[3] Before Actavis was decided, the circuits were split between the "scope of the patent test," see In re Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1332-36 (Fed. Cir. 2008), abrogated by Actavis, 133 S. Ct. 2223; In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 212-13 (2d Cir. 2006), abrogated by Actavis, 133 S. Ct. 2223, and the "quick look" test, under which reverse payments were considered "prima facie evidence of an

reasoned that Paragraph IV litigation does not begin with the baseline assumption that a patent is valid because "[t]he paragraph IV litigation . . . put[s] the patent's validity at issue, as well as its actual preclusive scope." Id. at 2231.

The Supreme Court acknowledged the "general legal policy" in favor of settlements,[4] but determined that "five sets of considerations" weighed in favor of subjecting reverse payment settlements to antitrust scrutiny. Id. at 2234-37. Specifically, the Court explained:

> [1] [A] reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; [2] one who makes such a payment may be unable to explain and to justify it; [3] such a firm or individual may well possess market power derived from the patent; [4] a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and [5] parties may well find ways to settle patent disputes without the use of reverse payments.

---

unreasonable restraint on trade," In re K-Dur Antitrust Litig., 686 F.3d 197, 218 (3d Cir. 2012), vacated, Upsher Smith Labs., Inc. v. La. Wholesale Drug Co., Inc., 133 S. Ct. 2849 (2013).

[4] The Court noted that it did not intend to disturb commonplace settlement forms. Whereas in a traditional settlement "a party with a claim (or counterclaim) for damages receives a sum equal to or less than the value of its claim," in a reverse payment settlement, "a party with no claim for damages (something that is usually true of a paragraph IV litigation defendant) walks away with money simply so it will stay away from the patentee's market." Actavis, 133 S. Ct. at 2233.

Id. at 2237. While the Supreme Court declined to adopt the Federal Trade Commission's ("FTC") suggestion that reverse payments be considered "presumptively unlawful," it determined that the potential anticompetitive effects of a reverse payment are subject to the rule of reason test. The "rule of reason" is a means of evaluating a restraint on trade and determining "whether under all the circumstances of the case the restrictive practice imposes an unreasonable restraint on competition." Arizona v. Maricopa Cty. Med. Soc'y, 457 U.S. 332, 343-44 (1982). To satisfy the rule of reason test, the plaintiff must demonstrate "that the alleged agreement involved the exercise of power in a relevant economic market, that this exercise had anti-competitive consequences, and that those detriments outweighed efficiencies or other economic benefits." Stop & Shop Supermarket Co. v. Blue Cross & Blue Shield of R.I., 373 F.3d 57, 61 (1st Cir. 2004); accord Sterling Merch., Inc. v. Nestlé, S.A., 656 F.3d 112, 123 (1st Cir. 2011).

Nevertheless, the Supreme Court acknowledged that Actavis left many questions unanswered as to how these cases would be litigated and "le[ft] to the lower courts the structuring of the present rule-of-reason antitrust litigation." Actavis, 133 S. Ct. at 2238.

III. Facts

"In reviewing the grant of a motion to dismiss, we recount the facts as alleged in the operative complaint[s]." Ruivo v. Wells Fargo Bank, N.A., 766 F.3d 87, 88 (1st Cir. 2014). This appeal involves two operative complaints that allege substantially the same facts, filed by the EPPs and DPPs, respectively.

Loestrin 24 contains the active ingredients norethindrone acetate and ethinyl estradiol, both of which the FDA has approved as oral contraceptives since the 1970s. Previous versions of Loestrin, including Loestrin 21 and Loestrin 1/20, contain twenty-one tablets taken on a daily basis. The patient would then take a week of placebo pills or skip tablets for a week, depending on the version of Loestrin.

Studies conducted in the 1990s examined whether taking Loestrin tablets for a longer duration than the twenty-one day period decreased the incidence of intermenstrual bleeding, or "spotting," a common side-effect of oral contraceptives. The studies yielded inconsistent results as to whether taking Loestrin tablets for longer periods actually reduced intermenstrual bleeding. Nevertheless, U.S. Patent No. 5,552,394 (the "'394 Patent"), entitled "Low Dose Oral Contraceptives with Less Breakthrough Bleeding and Sustained Efficacy," was granted for "a method of female contraception characterized by a reduced

incidence of breakthrough bleeding by administering a combination of estrogen and progestin for 23-25 consecutive days of a 28 day cycle."

Defendant Warner[5] currently owns the '394 Patent and, on April 15, 2005, submitted an NDA for approval to market the dosing regimen later known as Loestrin 24. On February 17, 2006, the FDA approved Loestrin 24 and the '394 Patent was listed in the Orange Book as covering Loestrin 24. As suggested by the '394 Patent, Loestrin 24 purports to reduce the incidence of intermenstrual bleeding by having the patient take the pills for twenty-four, as opposed to twenty-one, consecutive days.

A. Watson Litigation and Settlement

Only several months after the FDA approved Loestrin 24, on June 19, 2006, defendant Watson sent Warner a notice letter that it had filed an ANDA to market a generic of Loestrin 24. The notice letter contained a Paragraph IV certification that the commercial manufacture, use, or sale of Watson's generic Loestrin 24 would not infringe any valid claim of the '394 Patent. Predictably, Warner filed suit against Watson, alleging that

[5] Actavis acquired Warner in October 2013. In addition, Watson acquired Actavis in October 2012. Press Release, Watson Completes Actavis Acquisition, Allergan (Oct. 31, 2012). To avoid confusion with the Supreme Court case of the same name, we refer to the defendants as Warner and Watson, respectively.

Watson's generic product would infringe the '394 Patent.[6] By doing so, Warner triggered the thirty-month stay of FDA approval of Watson's ANDA for generic Loestrin 24. The stay was scheduled to expire in January 2009.

In January 2009, just before the expiration of the stay, Watson and Warner entered into a stipulation of dismissal and Exclusion Payment Agreement. Under the agreement, Watson agreed that it would delay selling its Loestrin 24 generic until the earliest of the following: (i) January 22, 2014; (ii) 180 days before Warner gave a third party the right to market a Loestrin 24 generic in the United States; (iii) the date another version of a Loestrin 24 generic entered the market; or (iv) the date on which a third party obtained a final, non-appealable judicial order that the '394 patent is invalid, unenforceable, or not infringed by the third party's generic Loestrin 24. In exchange, Warner agreed to several provisions:

> (1) Warner agreed not to market, supply, or license an AG version of Loestrin 24 during Watson's first 180 days of marketing, otherwise known as a "no-AG agreement."
> (2) Warner granted Watson a "non-exclusive, fully paid, worldwide, royalty-free irrevocable license" to market Loestrin 24 as of January 22, 2014.

[6] In response, Watson challenged the validity and enforceability of the '394 Patent based, in part, on the inconsistent studies regarding Loestrin 24's ineffectiveness in combatting intermenstrual bleeding. Those arguments need not be repeated here, as "it is normally not necessary to litigate patent validity to answer the antitrust question." Actavis, 133 S. Ct. at 2236.

(3) Warner would 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.
(4) Warner gave Watson the exclusive right to earn brand sales of a Warner oral contraceptive in late-stage development at the time of the agreement, now known as Generess Fe.
(5) 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.[7]
(6) 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. This "acceleration clause" allegedly was intended to deter other generic manufacturers from entering the marketplace before Watson.[8]

B. Lupin Litigation and Settlement

Six months after the announcement of Warner and Watson's agreement, on July 30, 2009, defendant Lupin[9] notified Warner that it had filed an ANDA to market a generic version of Loestrin 24. The notice letter contained a Paragraph IV certification. As expected, in September 2009, Warner sued Lupin, alleging infringement of the '394 Patent. Again, by virtue of Warner's

[7] Watson had otherwise forfeited its entitlement to a 180-day exclusivity period under the Hatch-Waxman Act because it had not obtained tentative FDA approval to market its generic Loestrin 24 within thirty months of submitting its ANDA.

[8] Only the EPPs allege that the acceleration clause constitutes a reverse payment under Actavis.

[9] The EPPs, but not the DPPs, list Lupin as a defendant.

filing suit within forty-five days, the FDA was prevented from approving the Lupin ANDA for thirty months.

Before the close of discovery, in October 2010, Warner entered into a non-competition agreement with Lupin and dismissed the suit. Under the agreement, Lupin forfeited its challenge to the '394 Patent and agreed to delay entry of its generic Loestrin 24 until July 22, 2014, the month that the '394 Patent was set to expire and six months after Watson was scheduled to enter the market with its Loestrin 24 generic. In exchange, Warner agreed to the following provisions:

(1) Warner granted Lupin a non-exclusive license as to Femcon Fe, another Warner branded oral contraceptive, which allowed Lupin to market an AG of Femcon Fe in the United States the earlier of (i) 180 days after Teva Pharmaceutical Industries, Ltd. (the Femcon Fe first filer) entered the market with its Femcon Fe generic, or (ii) January 1, 2013.
(2) 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.
(3) Warner paid Lupin an undisclosed amount toward attorney's fees.[10]

[10] The DPPs also allege that, six months after the announcement of the Warner-Lupin agreement, in April 2011, Mylan Pharmaceuticals ("Mylan") sent Warner a notice containing a Paragraph IV certification announcing that it had filed an ANDA to market a generic Loestrin 24. In June 2011, Warner sued Mylan for infringement of the '394 Patent. In July 2013, before a bench trial was scheduled to begin, Warner entered a settlement and license agreement with Mylan and the case was dismissed. Under the agreement, Mylan agreed to drop its challenge to the '394 Patent and delay entry of its generic Loestrin 24 until July 22,

IV. Procedural Background

In their complaint, the DPPs allege that Warner and Watson agreed to keep Watson's 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. The DPPs contend that this anticompetitive conduct insulated Loestrin 24 from generic competition, which would typically be priced far below the brand and eventually lead to reduced brand prices. In this way, Warner and Watson's conduct allegedly caused antitrust harm by subjecting the DPPs to artificially inflated prices.

The EPPs allege violations of § 1 of the Sherman Act as to both the Warner-Watson and Warner-Lupin agreements. They contend that the agreements required that Warner make payments to Watson and Lupin in exchange for Watson's and Lupin's promise not to market their versions of generic Loestrin 24 until January 22, 2014, and July 22, 2014, respectively. In addition, the EPPs bring state claims for unjust enrichment and allege that the Warner-

---

2014, again, the month that the '394 Patent was scheduled to expire. The DPPs do not detail the specific provisions of the agreement, nor do they allege that the Mylan agreement gives rise to independent antitrust claims.

Watson and Warner-Lupin agreements constituted unlawful restraints of trade in violation of various state antitrust laws.

The defendants filed two motions to dismiss, one as to the DPP complaint and the other as to the EPP complaint, under Federal Rules of Civil Procedure 12(b)(6) and 12(c). The defendants contended that Actavis was limited to reverse payments in cash. Nevertheless, they argued that the district court need not reach this question, as neither the DPPs nor the EPPs had plausibly pled the existence of a large and unjustified reverse payment under the pleading standards announced in Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007), and Ashcroft v. Iqbal, 556 U.S. 662 (2009). The defendants also asserted that the DPPs and EPPs had failed to allege monopoly power in a defined antitrust market as required under the rule of reason test and that their actions were barred on statute of limitations grounds.[11]

The district court granted the motions to dismiss in a single opinion and order on the basis that Actavis was limited to reverse payments in pure cash form. In re Loestrin 24 Fe Antitrust Litig., 45 F. Supp. 3d 180 (D.R.I. 2014) [In re Loestrin]. Scouring the language of Actavis, the district court noted that "[t]he discussion of patent settlements in Actavis fixates on the

[11] In addition, the defendants provided independent grounds for dismissing the state antitrust and unjust enrichment claims, none of which are relevant here.

one form of consideration that was at issue in that case: cash." Id. at 189. The district court also took into account the five considerations contemplated by the Supreme Court in its determination that subjecting reverse payments to antitrust scrutiny outweighed the benefits of settlement. In the district court's view, these considerations "guide the inquiry as to whether a settlement payment satisfies the rule of reason," and "require[], on the part of the plaintiff, and ultimately the reviewing court (or the jury), an ability to assess or calculate the true value of the payment made by the patentee to the generic competitor." Id. at 190. Whereas a court can measure the value of a cash settlement, "a non-cash settlement, particularly one that is multifaceted and complex . . . , is almost impossible to measure against these five factors." Id. at 191. In addition, the district court noted that "a cautious approach" was warranted as "Actavis marked a dramatic departure from the approach of the courts of appeal, and an important shift in the common law." Id. at 192.

Nevertheless, the district court candidly conceded that it had significant reservations about its holding: 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." Id. at 193.

The district court noted that "the Plaintiffs have asserted, in two robust complaints, facts demonstrating illegal contracts or combinations in restraint of trade undertaken by the Defendants." Id. However, because the district court dismissed the case on the basis that the reverse payments were not in cash form, it did not address the subsequent question of whether the individual provisions of the settlement agreements -- including the no-AG agreement, the acceleration clause, and the various side deals -- would have been adequately alleged as unlawful reverse payments were Actavis to extend to non-cash payments.

The district court entered final judgment as to the DPPs' claim under Rule 58 of the Federal Rules of Civil Procedure, noting that their case was "immediately appealable" as their complaint has been dismissed in its entirety. The district court entered final judgment as to the EPPs' federal antitrust claims under Rule 54(b) of the Federal Rules of Civil Procedure and stayed their remaining claims. The DPPs and EPPs timely appealed the district court's decision, and the parties now dispute whether the district court erred in determining that Actavis was limited to cash and, if so, whether the plaintiffs plausibly alleged that the no-AG

agreements, acceleration clause, and side deals constituted unlawful reverse payments.

V. Analysis

A. Standard of Review

We review a dismissal under Rule 12(b)(6) de novo. Ocasio-Hernández v. Fortuño-Burset, 640 F.3d 1, 7 (1st Cir. 2011). "For the purposes of our review, we accept as true all well-pled facts alleged in the complaint and draw all reasonable inferences in [the plaintiffs'] favor." Evergreen Partnering Grp., Inc. v. Pactiv Corp., 720 F.3d 33, 36 (1st Cir. 2013). "A motion for judgment on the pleadings [under Rule 12(c)] is treated much like a Rule 12(b)(6) motion to dismiss," with the court viewing "the facts contained in the pleadings in the light most favorable to the nonmovant and draw[ing] all reasonable inferences therefrom." Pérez-Acevedo v. Rivero-Cubano, 520 F.3d 26, 29 (1st Cir. 2008) (quoting R.G. Fin. Corp. v. Vergara-Núñez, 446 F.3d 178, 182 (1st Cir. 2006)).

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Iqbal, 556 U.S. at 678 (quoting Twombly, 550 U.S. at 570). The pleadings need not contain "detailed factual allegations" but must provide "more than labels and conclusions, and a formulaic recitation of the elements of the

cause of action will not do." Twombly, 550 U.S. at 555. Although the pleading standards articulated in Twombly are now ubiquitous in the legal world, it is important to note that Twombly addressed the specific question of "what a plaintiff must plead in order to state a claim under § 1 of the Sherman Act," id. at 554-55, and this court has cautioned against converting Twombly's mandates into a requirement that antitrust plaintiffs provide evidentiary support or set forth other "plus factors" to demonstrate the plausibility of their Sherman Act claims, Evergreen Partnering Grp., 720 F.3d at 46-47.

B. Actavis and Non-Cash Payments

As the district court addressed only the question of whether Actavis reached non-cash reverse payments, today we choose to limit ourselves to that query as well. For the reasons discussed herein, we conclude that the district court erred in determining that non-monetary reverse payments do not fall under Actavis's scope.

The district court reasoned that the reverse payments alleged in Actavis involved only cash payments, but that is not so: in Actavis, it was alleged that the reverse payments involved side deals in which the generic manufacturers agreed to promote the brand name drug at issue in exchange for multi-million dollar payments from the brand manufacturer. 133 S. Ct. at 2229; Watson

Pharm., Inc., 677 F.3d at 1305 (describing the terms of the settlement agreements). This fact alone demonstrates that the Supreme Court recognized that a disguised above-market deal, in which a brand manufacturer effectively overpays a generic manufacturer for services rendered, may qualify as a reverse payment subject to antitrust scrutiny and militates against limiting the Supreme Court's decision to pure cash payments.

The district court also analyzed the language of Actavis, noting that the Supreme Court was "fixated" on cash. But the district court overstates its case. Indeed, the Court in Actavis explained that, "in substance, the plaintiff agreed to pay the defendants many millions of dollars to stay out of its market." 133 S. Ct. at 2231 (emphasis added). This 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. Moreover, this approach is consistent with antitrust law, which has consistently prioritized substance over form. See, e.g., Am. Needle, Inc. v. Nat'l Football League, 560 U.S. 183, 191-92 (2010) ("'[W]e 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.'" (quoting United States v. Sealy, Inc.,

388 U.S. 350, 353 (1967))); 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"). As the district court itself acknowledged, a narrow construction of Actavis will give drug manufacturers carte blanche to negotiate anticompetitive settlements so long as they involve non-cash reverse payments:

> Many observers welcomed Actavis as a necessary step in confronting the scourge of pay for delay agreements that they contend benefit the pharmaceutical industry at the expense of consumers. But, ultimately, Actavis can only serve as the solution to anticompetitive pay for delay arrangements insofar as it encompasses both cash and these increasingly prevalent non-cash settlements. Of course, it is of relatively little import whether a payment for delay is made in the form of cash or some other form of consideration.

In re Loestrin, 45 F. Supp. 3d at 194 (footnote and citation omitted).

True, Actavis does contain references to money. See Actavis, 133 S. Ct. at 2233 (describing reverse payment settlements as an arrangement "in which A, the plaintiff, pays money to defendant B purely so B will give up the patent fight"); id. (explaining that, in reverse payment settlements, a party "walks away with money simply so it will stay away from the patentee's market"). But the key word used throughout the opinion is "payment," which connotes a much broader category of consideration

than cash alone. Black's Law Dictionary (10th ed. 2014) (defining "payment" as the "performance of an obligation by the delivery of money or some other valuable thing accepted in partial or full discharge of the obligation" and "the money or other valuable thing so delivered in satisfaction of an obligation" (emphases added)). As the Third Circuit observed,

> [t]he thrust of the Court's reasoning is not that it is problematic that money is used to effect an end to a patent challenge, but rather that the patentee leverages some part of its patent power . . . to cause anticompetitive harm -- namely, elimination of the risk of competition.

King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388, 406 (3d Cir. 2015); see also id. at 409 (holding, post-Actavis, that a no-AG agreement "is subject to antitrust scrutiny under the rule of reason").

Nor are we the first court to determine that Actavis should reach non-monetary reverse payments. Of the many district courts and the single court of appeals to have addressed this question, the overwhelming majority have declined to limit Actavis to cash payments. See King Drug Co. of Florence, Inc., 791 F.3d at 403 ("We do not believe Actavis's holding can be limited to reverse payments of cash."); In re Actos End Payor Antitrust Litig., No. 13-cv-9244(RA), 2015 WL 5610752, at *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."); United Food & Commercial Workers v. Teikoku Pharma USA, 74 F. Supp. 3d 1052, 1069-70 (N.D. Cal. 2014) (rejecting 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"); In re Effexor XR Antitrust Litig., No. 11-5479(PGS)(LHG), 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"); 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.").

To be sure, the district court was correct that the language of Actavis emphasizes that the value of a reverse payment is a key component in determining whether it is unlawful. In discussing how to apply the rule of reason analysis to reverse payments, the Supreme Court explained, "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 other convincing justification." Actavis, 133 S. Ct. at 2237. Such language emphasizes that the size of the reverse payment, particularly as it relates to potential litigation expenses, is central to the antitrust query and requires that the reviewing court or factfinder assess the value of the payment.

Similarly, as the district court noted, the five considerations set forth by the Supreme Court[12] require that the

[12] There is some dispute as to how the five considerations should factor into antitrust litigation going forward. Whereas the district court construed the five considerations as "guid[ing] the inquiry as to whether a settlement payment satisfies the rule of reason," In re Loestrin, 45 F. Supp. 3d at 190, the DPPs contend

court or factfinder measure the payment's size. The Supreme Court stated that a reverse payment may be justified where it "reflects traditional settlement considerations, such as avoided litigation costs or fair value for services." Id. at 2236. And, for the market power inquiry, the Court explained that "the size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power." Id. (internal quotation marks omitted). Again, both statements assume that the value of the reverse payment is ascertainable.

On this basis, the district court determined that it was "almost impossible" to measure non-cash settlements such as those

---

that these considerations were proffered only as justifications for why subjecting reverse payments to antitrust scrutiny outweigh the public policy in favor of settlements. We agree with the DPPs that the five considerations should not overhaul the rule of reason, nor should they create a new five-part framework in antitrust cases.

We note, however, that there is overlap between the five considerations and the preexisting elements of the rule of reason. For example, the First Circuit's rule of reason analysis queries, among other things, whether the "agreement involved the exercise of power in a relevant economic market." Stop & Shop Supermarket Co., 373 F.3d at 61. In that same vein, Actavis explains how to evaluate the market power question: "the size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power." Actavis, 133 S. Ct. at 2236 (internal quotation marks omitted). Similarly, the First Circuit rule of reason includes as an element the anticompetitive consequences of the alleged agreement, and the first of the five considerations articulated by the Supreme Court explains that a reverse payment may have significant anticompetitive effects where it "amounts to a purchase by the patentee of the exclusive right to sell its product." Id. at 2234.

at issue here. In re Loestrin, 45 F. Supp. 3d at 191. Although the value of non-cash reverse payments may be much more difficult to compute than that of their cash counterparts, antitrust litigation often requires an "elaborate inquiry into the reasonableness of a challenged business practice" and, as a result, is "extensive and complex." Maricopa Cty. Med. Soc'y, 457 U.S. at 343. In other words, antitrust litigation already requires courts to make intricate and complex judgments about market practices.

We agree with those courts that, rather than rejecting wholesale Actavis's applicability to non-cash payments, have required that the plaintiffs plead information sufficient "to estimate the value of the term, at least to the extent of determining whether it is 'large' and 'unjustified.'" In re Actos End Payor Antitrust Litig., 2015 WL 5610752, at *13. Consistent with Twombly, which declined to "require heightened fact pleading of specifics," Twombly, 550 U.S. at 570, we do not require that the plaintiffs provide precise figures and calculations at the pleading stage, In re Actos End Payor Antitrust Litig., 2015 WL 5610752, at *13. Requiring such a high burden would impose a nearly insurmountable bar for plaintiffs at the pleading stage because "very precise and particularized estimates of fair value and anticipated litigation costs may require evidence in the exclusive possession of the defendants, as well as expert

analysis." In re Aggrenox Antitrust Litig., 94 F. Supp. 3d at 244-45. Nevertheless, the plaintiffs must allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under Actavis. See In re Niaspan Antitrust Litig., 42 F. Supp. 3d at 753 (describing Twombly's applicability to the Actavis inquiry).

On appeal, the defendants do not strenuously argue that Actavis should be limited to cash payments, instead focusing their briefing on whether the plaintiffs adequately pled that the provisions at issue in the Warner-Watson and Warner-Lupin settlement agreements are unlawful reverse payments under Actavis. As the district court did not address these issues, we remand for the district court to evaluate these remaining questions in the first instance. The Supreme Court acknowledged that Actavis had opened the door to a new landscape of litigation and "le[ft] to the lower courts the structuring of the present rule-of-reason antitrust litigation." Actavis, 133 S. Ct. at 2238. At this juncture, we feel that the most prudent course is to proceed one step at a time, and we therefore leave for another day the question of whether the EPPs and DPPs adequately alleged that the individual

provisions of the settlement agreements warranted antitrust scrutiny as unlawful reverse payments.

VI. Conclusion

For the foregoing reasons, the judgment is vacated and the case is remanded for further proceedings consistent with this opinion. No costs are awarded.

Vacated and Remanded.