PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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Nos. 14-4202, 14-4203, 14-4204, 14-4205, 14-4206, &
14-4602

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In re: LIPITOR ANTITRUST LITIGATION

RITE AID CORPORATION;
RITE AID HDQTRS CORPORATION; JCG (PJC)
USA, LLC; MAXI DRUG, INC. d/b/a Brooks Pharmacy;
ECKERD CORPORATION,

Appellants in No. 14-4202

WALGREEN COMPANY; THE KROGER
COMPANY; SAFEWAY, INC.; SUPERVALU, INC.;
HEB GROCERY COMPANY L.P.,

Appellants in No. 14-4203

GIANT EAGLE, INC.,

Appellant in No. 14-4204

MEIJER INC.; MEIJER DISTRIBUTION, INC.,

Appellants in No. 14-4205

ROCHESTER DRUG CO-OPERATIVE, INC.; STEPHEN L. LAFRANCE PHARMACY, INC. d/b/a SAJ DISTRIBUTORS; BURLINGTON DRUG COMPANY, INC.; VALUE DRUG COMPANY; PROFESSIONAL DRUG COMPANY, INC.; AMERICAN SALES COMPANY LLC,

Appellants in No. 14-4206

A.F.L.-A.G.C. BUILDING TRADES WELFARE PLAN; MAYOR AND CITY COUNCIL OF BALTIMORE, MARYLAND; NEW MEXICO UNITED FOOD AND COMMERCIAL WORKERS UNION'S AND EMPLOYERS' HEALTH AND WELFARE TRUST FUND; LOUISIANA HEALTH SERVICE INDEMNITY COMPANY, d/b/a BLUE CROSS/BLUE SHIELD OF LOUISIANA; BAKERS LOCAL 433 HEALTH FUND; TWIN CITIES BAKERY WORKERS HEALTH AND WELFARE FUND; FRATERNAL ORDER OF POLICE, FORT LAUDERDALE LODGE 31, INSURANCE TRUST FUND; INTERNATIONAL BROTHERHOOD

OF ELECTRICAL WORKERS LOCAL 98; NEW YORK HOTEL TRADES COUNSEL & HOTEL ASSOCIATION OF NEW YORK CITY, INC., HEALTH BENEFITS FUND; EDWARD CZARNECKI; EMILIE HEINLE; FRANK PALTER; ANDREW LIVEZEY; EDWARD ELLENSON; JEAN ELLYNE DOUGAN; NANCY BILLINGTON, ON BEHALF OF THEMSELVES AND ALL OTHERS SIMILARLY SITUATED,

Appellants in No. 14-4602

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Nos. 15-1184, 15-1185, 15-1186, 15-1187, 15-1274, 15-1323 & 15-1342

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IN RE: EFFEXOR XR ANTITRUST LITIGATION

WALGREEN, CO.; THE KROGER, CO.; SAFEWAY, INC.; SUPERVALU, INC.; HEB GROCERY COMPANY LP; AMERICAN SALES COMPANY, INC.,

Appellants in No. 15-1184

RITE AID CORPORATION; RITE AID HDQTRS., CORPORATION; JCG (PJC) USA, LLC; MAXI DRUG, INC. d/b/a BROOKS PHARMACY; ECKERD CORPORATION; CVS CAREMARK CORPORATION,

Appellants in No. 15-1185

GIANT EAGLE, INC.,

Appellant in No. 15-1186

MEIJER, INC.; MEIJER DISTRIBUTION, INC.,

Appellants in No. 15-1187

PROFESSIONAL DRUG COMPANY, INC.; ROCHESTER DRUG CO-OPERATIVE, INC.; STEPHEN L. LAFRANCE HOLDINGS, INC.; STEPHEN L. LAFRANCE PHARMACY, INC. d/b/a SAJ DISTRIBUTORS; UNIONDALE CHEMIST, INC.,

Appellants in No. 15-1274

PAINTERS DISTRICT COUNCIL NO. 30 HEALTH & WELFARE FUND; MEDICAL MUTUAL OF OHIO,

Appellants in No. 15-1323

A.F. of L.-A.G.C. BUILDING TRADES WELFARE PLAN; DARYL DEINO; IBEW-NECA LOCAL 505 HEALTH & WELFARE PLAN; LOUISIANA HEALTH SERVICE INDEMNITY COMPANY d/b/a BLUE CROSS/BLUE SHIELD OF LOUISIANA; MAN-U SERVICE CONTRACT TRUST FUND; MC-UA LOCAL 119 HEALTH & WELFARE PLAN; NEW MEXICO UNITED FOOD AND COMMERCIAL WORKERS UNION'S AND EMPLOYERS' HEALTH AND WELFARE TRUST FUND; PLUMBERS AND PIPEFITTERS LOCAL 572 HEALTH AND WELFARE FUND; SERGEANTS BENEVOLENT ASSOCIATION HEALTH AND WELFARE FUND; PATRICIA SUTTER (TOGETHER "END-PAYOR CLASS PLAINTIFFS") ON BEHALF OF THEMSELVES AND ALL OTHERS SIMILARLY SITUATED,

Appellants in No. 15-1342

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On Appeal from the United States District Court
for the District of New Jersey
(MDL 2332) / (D.N.J. No. 3-12-cv-02389) /
(D.N.J. No. 3-12-cv-02478) / (D.N.J. No. 3-12-cv-04115)
/ (D.N.J. No. 3-12-cv-04537) / (D.N.J. No. 3-12-cv-
05129) / (D.N.J. No. 3-12-cv-06774) / (D.N.J. No. 3-12-
cv-07561) / (D.N.J. No. 3-11-cv-05479) / (D.N.J. No. 3-
11-cv-05590) / (D.N.J. No. 3-11-cv-05661) /

(D.N.J. No. 3-11-cv-06985) / (D.N.J. No. 3-11-cv-07504) / (D.N.J. No. 3-12-cv-03116) / (D.N.J. No. 3-12-cv-03523)
District Judge: The Honorable Peter G. Sheridan

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Argued May 19, 2017

Before: SMITH, *Chief Judge,* AMBRO, and FISHER, *Circuit Judges*

(Filed: August 21, 2017)

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OPINION

SMITH, *Chief Judge*.

This opinion addresses two sets of consolidated appeals concerning two pharmaceutical drugs: Lipitor and Effexor XR. In both sets of consolidated appeals, plaintiffs allege that the companies holding the patents related to Lipitor and Effexor XR fraudulently procured and enforced certain of those patents. Plaintiffs further allege that those companies holding the patents entered into unlawful, monopolistic settlement agreements with potential manufacturers of generic versions of Lipitor and Effexor XR. The same District Court Judge dismissed the complaints in the Lipitor litigation and dismissed certain allegations in the Effexor litigation. Those decisions relied on plausibility determinations that are now challenged on appeal.

We begin with a brief summary of the relevant regulatory scheme applicable to pharmaceutical drugs and then detail the factual and procedural backgrounds of these two sets of consolidated appeals. The remainder of the opinion broadly covers two issues. First, in *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), the Supreme Court concluded that payments from patentees to infringers

through "reverse payment settlement agreements" are subject to antitrust scrutiny. *Id.* at 2227. In both sets of consolidated appeals, plaintiffs allege that the companies holding the pharmaceutical patents and the generic manufacturers entered into such agreements. We are asked to decide whether those allegations are plausible. We conclude, as to both sets of appeals, that they are. Second, regarding only the Lipitor consolidated appeals, we address whether plaintiffs in those appeals pled plausible allegations of fraudulent patent procurement and enforcement, as well as other related misconduct. We again determine that those allegations are indeed plausible. Accordingly, we will reverse the District Court's dismissal of the complaints in the Lipitor litigation, reverse its dismissal of the allegations in the Effexor litigation, and remand for further proceedings.

I

The 1984 Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Act"), 98 Stat. 1585, as amended, provides a regulatory framework designed in part to (1) ensure that only rigorously tested pharmaceutical drugs are marketed to the consuming public, (2) incentivize drug manufacturers to invest in new research and development, and (3) encourage generic drug entry into the marketplace. As we have noted previously, the Hatch-Waxman Act contains four key relevant features. *See In re Lipitor Antitrust Litig.*, 855 F.3d 126, 135 (3d Cir. 2017) (*Lipitor III*), *as amended* (Apr. 19,

2017); *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 394 (3d Cir. 2015), *cert. denied*, 137 S. Ct. 446 (2016).

First, the Hatch-Waxman Act requires a drug manufacturer wishing to market a new brand-name drug to first submit a New Drug Application ("NDA") to the Food and Drug Administration ("FDA"), *see* 21 U.S.C. § 355, and then undergo a long, complex, and costly testing process, *see* 21 U.S.C. § 355(b)(1) (requiring, among other things, "full reports of investigations" into safety and effectiveness; "a full list of the articles used as components"; and a "full description" of how the drug is manufactured, processed, and packed). If this process is successful, the FDA may grant the drug manufacturer approval to market the brand-name drug.

Second, after that approval, a generic manufacturer can obtain similar approval by submitting an Abbreviated New Drug Application ("ANDA") that "shows that the generic drug has the same active ingredients as, and is biologically equivalent to, the brand-name drug." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012) (citing 21 U.S.C. §§ 355(j)(2)(A)(ii), (iv)). This way, a generic manufacturer does not need to undergo the same costly approval procedures to develop a drug that has already received FDA approval. *Actavis*, 133 S. Ct. at 2228 ("The Hatch-Waxman process, by allowing the generic to piggy-back on the pioneer's approval efforts, 'speed[s] the introduction of low-cost generic drugs to

market,' *Caraco*, [566 U.S. at 405], thereby furthering drug competition." (first alteration in original)).

Third, foreseeing the potential for conflict between brand-name and generic drug manufacturers, the Hatch-Waxman Act "sets forth special procedures for identifying, and resolving, related patent disputes." *Id.* The Hatch-Waxman Act, as well as federal regulations, requires brand-name drug manufacturers to file information about their patents with their NDA. *Id.* The brand-name manufacturer "is required to list any patents issued relating to the drug's composition or methods of use." *Lipitor III*, 855 F.3d at 135. That filing must include the patent number and expiration date of the patent. *See Caraco*, 566 U.S. at 405 (quoting 21 U.S.C. § 355(b)(1)). Upon approval of the brand-name manufacturer's NDA, the FDA publishes the submitted patent information in its "Orange Book," more formally known as the Approved Drug Products with Therapeutic Equivalence Evaluations. *Id.* at 405–06.

Once a patent has been listed in the Orange Book, the generic manufacturer is free to file an ANDA if it can certify that its proposed generic drug will not actually violate the brand manufacturer's patents. *Id.* at 405; *see also id.* (The FDA "cannot authorize a generic drug that would infringe a patent."). A generic manufacturer's ANDA certification may state:

> (I) that such patent information has not been filed,
>
> (II) that such patent has expired,
>
> (III) . . . the date on which such patent will expire, or
>
> (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

21 U.S.C. § 355(j)(2)(A)(vii). "The 'paragraph IV' route[], automatically counts as patent infringement . . . ." *Actavis*, 133 S. Ct. at 2228 (citing 35 U.S.C. § 271(e)(2)(A)). As a result, a paragraph IV certification often "means provoking litigation" instituted by the brand manufacturer. *Caraco*, 566 U.S. at 407.

If the brand-name manufacturer initiates a patent infringement suit within 45 days of the ANDA filing, the FDA must withhold approval of the generic for at least 30 months while the parties litigate the validity or infringement of the patent. *Actavis*, 133 S. Ct. at 2228 (citing 21 U.S.C. § 355(j)(5)(B)(iii)). If a court decides the infringement claim within this 30-month period, then the FDA will follow that determination. *Id.* However, if the litigation is still proceeding at the end of the 30-month period, the FDA may give its approval to the generic drug

manufacturer to begin marketing a generic version of the drug. *Id.* The generic manufacturer then has the option to launch "at risk," meaning that, if the ongoing court proceeding ultimately determines that the patent was valid and infringed, the generic manufacturer will be liable for the brand-name manufacturer's lost profits despite the FDA's approval. *See King Drug Co.*, 791 F.3d at 396 n.8.

Fourth, to incentivize generic drug manufacturers to file an ANDA challenging weak patents, the Hatch-Waxman Act provides that the first generic manufacturer to file a paragraph IV certification will enjoy a 180-day exclusivity period. 21 U.S.C. § 355(j)(5)(B)(iv). This exclusivity period prevents any other generic from competing with the brand-name drug, *see Actavis*, 133 S. Ct. at 2229, which is an opportunity that can be "worth several hundred million dollars," to the first-ANDA filer, *id.* (quoting C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1579 (2006)). This 180-day exclusivity period belongs only to the first generic manufacturer to file an ANDA; if the first-ANDA filer forfeits its exclusivity rights, no other generic manufacturer is entitled to it. *Id.* (citing 21 U.S.C. § 355(j)(5)(D)). Importantly, the brand-name manufacturer is not barred from entering the generic market with its own generic version of the drug—a so-called "authorized generic"—during the 180-day exclusivity period. *See Lipitor III*, 855 F.3d at 135–36

(citing cases).

II

These consolidated appeals concerning Lipitor and Effexor XR involve antitrust challenges related to that pharmaceutical regulatory scheme. This panel previously detailed much of the factual background and procedural history of these appeals. *See Lipitor III*, 855 F.3d at 136–42. In relevant part, we repeat and expand on much of that earlier recitation.

A

In *In re Lipitor Antitrust Litigation*, Nos. 14-1402 et al., plaintiffs are a putative class of direct purchasers of branded Lipitor, a putative class of end payors, and several individual retailers asserting direct-purchaser claims.[1] We will refer to these plaintiffs collectively as the "*Lipitor* plaintiffs." Defendants are Pfizer Inc., Ranbaxy Inc., and their respective corporate affiliates; they will be referred to collectively as the "*Lipitor* defendants." We proceed by

[1] Earlier this year, the action of a fourth group of plaintiffs—California-based pharmacists raising claims under California law—was remanded to the District Court for a federal subject-matter jurisdiction determination. See Lipitor III, 855 F.3d at 151–52. We retained jurisdiction over their appeal. Id.

outlining the factual background behind those consolidated appeals and then describing their procedural history.

1

Lipitor is a brand-name drug designed to reduce the level of LDL cholesterol in the bloodstream. In 1987, the U.S. Patent and Trademark Office (PTO) granted Pfizer the original patent for Lipitor.[2] That patent—designated U.S. Patent No. 4,681,893 (the '893 Patent)—claimed protection for atorvastatin, Lipitor's active ingredient. Although initially set to expire on May 30, 2006, the '893 patent received an extension from the FDA, lengthening the patent's term through March 24, 2010.

Pfizer obtained additional, follow-on patent protection for Lipitor in December 1993 when the PTO issued U.S. Patent No. 5,273,995 (the '995 Patent). That patent claimed protection for atorvastatin calcium, the specific salt form of the active atorvastatin molecule in Lipitor. *Lipitor* plaintiffs assert that Pfizer committed fraud in the procurement and enforcement of the '995 Patent. They allege that Pfizer submitted false and misleading data to the PTO to support its claim that the cholesterol-synthesis inhibiting activity of atorvastatin calcium was surprising and unexpected. Specifically,

[2] Pfizer merged with Warner-Lambert Co. in 2002. We refer to the two entities collectively as "Pfizer."

Lipitor plaintiffs claim that Pfizer chemists informed senior management that the '893 Patent already covered atorvastatin calcium; Pfizer produced a misleading chart and other data, purportedly cherry-picked, to support its claim that atorvastatin calcium was several times more effective than expected; and, in order to avoid undermining its claim of surprising results, Pfizer intentionally withheld another dataset that contradicted its claim as to the surprising effectiveness of atorvastatin calcium. The PTO originally denied the patent application for atorvastatin calcium as "anticipated" by the '893 Patent. In response, Pfizer submitted a declaration from one of its chemists claiming even greater, i.e., more surprising, results from testing atorvastatin calcium. The PTO again rejected the patent application for atorvastatin calcium based on its contents being covered by the '893 Patent. Pfizer appealed that determination to the PTO's Patent Trial and Appeal Board (PTAB). The PTAB reversed the rejection of Pfizer's patent application, concluding that the application was not anticipated by the '893 Patent. It, however, required further proceedings on Pfizer's application, noting that "[a]n obviousness rejection . . . appear[ed] to be in order." Lipitor JA353 (DPP Orig. Am. Compl. ¶¶ 157–58).[3] Nevertheless, as

[3] We refer to the joint appendix in *Lipitor* as "Lipitor JA." Also, as *Lipitor* plaintiffs' complaints contain substantively identical factual allegations, we cite only to the direct purchasers' complaints, referring to their

noted above, the PTO concluded that the patent application claimed nonobvious material and issued the '995 Patent. The '995 Patent expired on June 28, 2011.

After obtaining the '893 and '995 Patents, Pfizer launched Lipitor in 1997. Following Lipitor's 1997 launch, Pfizer obtained five additional patents, none of which, according to *Lipitor* plaintiffs, could delay further generic versions of the drug from coming to market. Pfizer listed all Lipitor patents in the FDA's Orange Book, with the exception of certain "process" patents, which could not be listed. *Lipitor* plaintiffs allege fraud only as to the procurement and enforcement of the '995 Patent.

In August 2002, Ranbaxy obtained ANDA first-filer status for a generic version of Lipitor. Sometime later in 2002, Ranbaxy notified Pfizer of its paragraph IV certifications, which asserted that Ranbaxy's sale, marketing, or use of generic Lipitor would not infringe any valid Pfizer patent. Pfizer subsequently sued Ranbaxy for patent infringement in the District of Delaware within the 45-day period prescribed by the Hatch-Waxman Act. Pfizer alleged that Ranbaxy's generic would infringe the '893 and '995 Patents. As a result of Pfizer's lawsuit, the

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original amended complaint as "DPP Orig. Am. Compl." and the second amended complaint as "DPP Sec. Am. Compl."

FDA withheld approval of Ranbaxy's ANDA for 30 months pursuant to the Hatch-Waxman Act.

After a bench trial, the Delaware District Court ruled that Pfizer's patents were valid and enforceable and would be infringed by Ranbaxy's generic. *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 405 F. Supp. 2d 495, 525–26 (D. Del. 2005). In doing so, it rejected Ranbaxy's argument that the '995 Patent was procured by inequitable conduct. *Id.* at 520–25. On appeal, the Federal Circuit affirmed the District Court's ruling that the '893 Patent would be infringed. *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1286 (Fed. Cir. 2006). But, the Federal Circuit reversed in part, holding that claim 6 of the '995 Patent was invalid. *Id.* at 1291–92. On remand, the District Court enjoined FDA approval of Ranbaxy's ANDA until March 24, 2010, the date of the '893 Patent's expiration.

In July 2005, as the 30-month statutory window barring Ranbaxy's generic market entry was closing, Pfizer filed a citizen petition with the FDA stating that the amorphous noncrystalline form of atorvastatin used in generic Lipitor (including in Ranbaxy's, as identified in its ANDA) may be "inferior in quality" to branded Lipitor's crystalline form. Lipitor JA1851. *Lipitor* plaintiffs claim that this citizen petition was a sham. In particular, they allege that Pfizer's citizen petition ignored both a decade-old FDA policy and FDA statements expressing the immateriality of drug form (i.e., crystalline versus amorphous), ignored Pfizer's own use of the amorphous

form of branded Lipitor in its clinical studies, and lacked any evidence to support its claims. In May 2006, the FDA informed Pfizer that it had not yet reached a decision on the petition, citing the need for further review and analysis given the "complex issues" it raised. Lipitor JA1877. The FDA eventually denied the citizen petition in a 12-page decision issued on November 30, 2011.

In 2007, following the Federal Circuit's ruling invalidating claim 6 of the '995 Patent, Pfizer applied for a reissuance of the '995 Patent to cure the relevant error. Ranbaxy filed an objection to the reissuance with the PTO. As explained below, however, Ranbaxy withdrew its objection, and the PTO reissued the '995 Patent in April 2009, relying on Lipitor's "commercial success," without addressing whether Pfizer first obtained the patent using allegedly fraudulent submissions.

During their Lipitor patent dispute, Pfizer and Ranbaxy also litigated a patent-infringement suit regarding a separate drug, Accupril. Pfizer owned the patent on Accupril, enjoying annual sales of over $500 million. Teva Pharmaceuticals first filed an ANDA seeking approval to market a generic version of Accupril. Ranbaxy subsequently filed an ANDA for Accupril as well. Pfizer sued Teva, resulting in Teva being enjoined from selling its generic until expiration of Pfizer's Accupril patent. Meanwhile, Ranbaxy still sought to sell its version of generic Accupril but could not do so because of the 180-day exclusivity period (not yet triggered)

available to Teva under the Hatch-Waxman Act. With Teva enjoined from selling its generic Accupril and Ranbaxy prevented from selling its generic because of Teva's first-filer exclusivity right, Teva and Ranbaxy entered into an agreement through which Teva became the exclusive distributor of Ranbaxy's generic. The parties agreed to split the profits from the sales, and Ranbaxy agreed to indemnify Teva for any liability related to the launch of its generic. Ranbaxy received approval for its generic version of Accupril in 2004.

Shortly after receiving that approval, Ranbaxy launched its generic Accupril, and Pfizer brought suit almost immediately, seeking treble damages for willful infringement. Pfizer also sought a preliminary injunction against Ranbaxy and Teva, informing the court that Ranbaxy's generic sales "decimated" its Accupril sales. The District Court in Pfizer's Accupril action granted the injunction halting Ranbaxy's generic sales, and the Federal Circuit affirmed the grant. *Pfizer Inc. v. Teva Pharm. USA, Inc.*, 429 F.3d 1364, 1383 (Fed. Cir. 2005). Pfizer posted a $200 million bond in conjunction with the District Court's entry of the injunction. After entry of the injunction, Pfizer expressed confidence that it would succeed in obtaining a substantial monetary judgment from Ranbaxy. On June 13, 2007, in light of the disputed Accupril patent's expiration, the District Court vacated the preliminary injunction. The only issues that remained contested were Pfizer's claims for past damages and

Ranbaxy's counterclaim as secured by the preliminary injunction bond.

In March 2008, Pfizer again sued Ranbaxy in the District of Delaware over Lipitor; this time, Pfizer claimed that Ranbaxy's generic Lipitor would infringe Pfizer's two Lipitor-related process patents. *Lipitor* plaintiffs contend that this litigation was a sham because no imminent threat of harm to Pfizer existed and because Pfizer knew Ranbaxy's generic would not violate those patents. They assert that the actual purpose of Pfizer's suit was to create "the illusion of litigation" so that the parties could enter a settlement agreement. Lipitor JA254 (DPP Sec. Am. Compl. ¶ 137).

Not long after Pfizer brought suit against Ranbaxy, on June 17, 2008, Pfizer and Ranbaxy executed a near-global litigation settlement—which *Lipitor* plaintiffs allege constituted an unlawful reverse payment—regarding scores of patent litigations around the world, including the Lipitor and Accupril disputes. The settlement ended the Accupril litigation with prejudice, and brought to a close not only all domestic patent infringement litigation between Pfizer and Ranbaxy pertaining to Lipitor, but also all foreign litigation between the two companies over Lipitor. By the settlement's terms, Ranbaxy agreed to delay its entry in the generic Lipitor market until November 30, 2011. In addition, Pfizer and Ranbaxy negotiated similar market entry dates for generic Lipitor in several foreign jurisdictions.

Ranbaxy also paid $1 million to Pfizer in connection with the Accupril litigation, and Pfizer's $200 million injunction bond from the Accupril litigation was released. Ranbaxy further agreed to cease its protests on the '995 Patent's reissuance. (As noted above, the PTO subsequently issued the '995 Patent in March 2009.) Although not alleged in their complaints, the settlement also created a Canadian supply arrangement for generic Lipitor between the parties and resolved other litigation regarding the pharmaceutical drug Caduet.

Ranbaxy delayed generic entry until November 2011, thus extending Pfizer's exclusivity in the Lipitor market twenty months beyond the expiration of the '893 Patent and five months beyond the expiration of what Ranbaxy alleged was the fraudulently procured '995 Patent. As a result, Ranbaxy's delayed entry created a bottleneck in the entry of generic Lipitor from later ANDA filers. Due to its ANDA first-filer status, Ranbaxy was entitled to the first-filer 180-day generic market exclusivity. Under the settlement agreement, though, Ranbaxy would not trigger that period by entering the generic market until November 2011. That meant that any other would-be generic manufacturer that wanted Ranbaxy's 180-day period to begin earlier than November 2011 needed a court to hold that all of Pfizer's Lipitor patents listed in the Orange Book were invalid or not infringed. Pfizer helped to forestall this possibility, *Lipitor* plaintiffs assert, through a combination of lawsuits

against subsequent ANDA filers. The FDA ultimately approved Ranbaxy's Lipitor ANDA on November 30, 2011, the day Ranbaxy's license to the unexpired Lipitor patents with Pfizer commenced.

2

Beginning in late 2011, *Lipitor* direct purchasers and end payors filed separate antitrust actions in various federal district courts. The cases were subsequently referred to the Judicial Panel on Multidistrict Litigation ("JPML") for coordination. The JPML transferred each case to the District of New Jersey, assigning the matters to District Judge Peter G. Sheridan. *See In re Lipitor Antitrust Litig.*, 856 F. Supp. 2d 1355 (J.P.M.L. 2012).

Thereafter, the direct-purchaser and end-payor plaintiffs filed amended class action complaints; *Lipitor* individual-retailer plaintiffs likewise filed complaints joining the consolidated proceedings. The complaints raise two substantively identical claims: (1) a monopolization claim under Section 2 of the Sherman Act (15 U.S.C. § 2) or a state analogue against Pfizer, asserting that the company engaged in an overarching anticompetitive scheme that involved fraudulently procuring the '995 Patent from the PTO (*Walker Process*[4] fraud), falsely listing that patent in the FDA's Orange

[4] *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965).

Book, enforcing the '995 Patent and certain process patents through sham litigation, filing a sham citizen petition with the FDA, and entering into a reverse payment settlement agreement with Ranbaxy; and (2) a claim under Section 1 of the Sherman Act (15 U.S.C. § 1) or a state analogue against both Pfizer and Ranbaxy, challenging the settlement agreement as an unlawful restraint of trade.

Lipitor defendants filed motions to dismiss all the complaints under Rule 12(b)(6) of the Federal Rules of Civil Procedure. During the pendency of those motions, on May 16, 2013, the District Court stayed proceedings, awaiting the Supreme Court's decision in *Actavis.* Following that decision on June 17, 2013, the District Court reopened the case and permitted the parties to file supplemental briefs on the pending motions to dismiss.

On September 5, 2013, the District Court dismissed *Lipitor* plaintiffs' complaints to the extent they were based on anything other than the reverse payment settlement agreement. *In re Lipitor Antitrust Litig.*, 2013 WL 4780496, at *27 (D.N.J. Sept. 5, 2013) (*Lipitor I*). The Court specifically rejected the *Walker Process* fraud, false Orange Book listing, sham litigation, sham FDA citizen petition, and overall monopolistic scheme allegations related to *Lipitor* plaintiffs' monopolization claims against Pfizer. *Id.* at *15–23. However, the Court granted leave to file amended complaints focused solely on the reverse payment settlement agreement between Pfizer and Ranbaxy. *Id.* at *25–27.

Lipitor plaintiffs filed amended complaints in October 2013. The direct purchasers and end payors attached their prior complaints as exhibits to their new complaints to preserve the allegations that had been dismissed for appeal. Similarly, the independent retailers stated in the first paragraph of their new complaints that they were also preserving the previously dismissed allegations. In November 2013, *Lipitor* defendants moved to dismiss the amended complaints.

On September 12, 2014, the District Court dismissed the direct purchaser's amended complaint with prejudice, rejecting the remaining allegations relating to the reverse payment settlement agreement between Pfizer and Ranbaxy. *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523 (D.N.J. 2014) (*Lipitor II*). The complaints of the end payor and individual retailers were dismissed that same day in light of the District Court's dismissal of the direct purchasers' complaint.

On October 10, 2014, the direct purchasers filed a motion to amend the judgment and for leave to file an amended complaint, contending that the District Court applied "a new, heightened pleading standard." Lipitor JA151. That motion was denied on March 16, 2015. These timely appeals followed.

B

In *In re Effexor XR Antitrust Litigation*, Nos. 15-

1184 et al., plaintiffs are a putative class of direct purchasers of branded Effexor XR, a putative class of end payors, two individual third-party payors, and several individual retailers asserting direct-purchaser claims. We will refer to these parties collectively as the "*Effexor* plaintiffs." Defendants are Wyeth, Inc., Teva Pharmaceutical Industries Ltd., and their respective corporate affiliates. We will likewise refer to these parties collectively as the "*Effexor* defendants." As with the *Lipitor* appeals, we proceed by outlining the factual background behind these consolidated appeals and then describing their procedural history.

1

Effexor is a brand-name drug used to treat depression. In 1985, the PTO issued American Home Products, Wyeth's predecessor, a patent for Effexor's active ingredient—the compound venlafaxine hydrochloride. The patent for that compound expired on June 13, 2008.

In 1993, the FDA granted Wyeth approval to begin marketing Effexor, which Wyeth did with respect to an instant-release version of the drug (or "Effexor IR"). Four years later, the FDA granted Wyeth approval for Effexor XR, an extended-release, once-daily version of the drug. Wyeth obtained three patents for Effexor XR, all of which expired on March 20, 2017. *Effexor* plaintiffs contend that Wyeth obtained the Effexor XR patents through fraud on

the PTO, improperly listed those patents in the FDA's Orange Book, and enforced those patents through serial sham litigation.[5]

On December 10, 2002, Teva obtained ANDA first-filer status for a generic version of Effexor XR. Teva's ANDA included paragraph IV certifications, asserting that Teva's sale, marketing, or use of generic Effexor would not infringe Wyeth's patents or that those patents were invalid or unenforceable. As the first company to file an ANDA with a paragraph IV certification for generic Effexor XR, Teva was entitled to the Hatch-Waxman Act's 180-day period of marketing exclusivity. Within the 45-day period prescribed by the Hatch-Waxman Act, Wyeth brought suit against Teva for patent infringement in the District of New Jersey.

In October 2005, shortly after the District Court held a *Markman*[6] hearing on patent claim construction, Wyeth and Teva reached a settlement. *Effexor* plaintiffs allege that the District Court's ruling at the *Markman* hearing spurred the parties to reach a settlement

[5] As explained below, the District Court did not dismiss *Effexor* plaintiffs' allegations related to Wyeth's fraudulent procurement and enforcement of the Effexor patents. Because those allegations are thus not at issue on appeal, we do not detail them here.

[6] Named after *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996).

agreement, as Wyeth feared that it would lose the litigation. A loss would have enabled other generic manufacturers to then enter the Effexor XR market. Under the terms of the settlement, Wyeth and Teva agreed to vacate the *Markman* ruling. They further agreed to a market entry date of July 1, 2010, for Teva's generic Effexor XR, nearly seven years before the expiration of Wyeth's patents. Wyeth further agreed that it would not market an authorized-generic Effexor XR during Teva's 180-day exclusivity period (the "no-AG agreement"). *Effexor* plaintiffs allege that Wyeth's promise to stay out of the generic Effexor XR market was worth more than $500 million, observing that Teva would gain all the sales of generic Effexor XR during Teva's generic exclusivity period. Wyeth also agreed to allow Teva to sell a generic version of Wyeth's Effexor IR before the original patent for Effexor expired in June 2008, and Wyeth promised not to launch an authorized generic to compete with Teva's instant-release generic.

In return, and in addition to the delayed entry date for generic Effexor XR, Teva agreed to pay royalties to Wyeth. With regard to its generic Effexor XR sales, Teva would pay Wyeth royalties beginning at 15% during its 180-day exclusivity period. If Wyeth chose not to introduce an authorized generic after 180 days and no other generic entered the market, Teva was required to pay Wyeth 50% royalties for the next 180 days and 65% royalties thereafter for up to 80 months. As to Teva's sales

of generic Effexor IR, Teva agreed to pay Wyeth 28% royalties during the first year and 20% during the second year.

In November 2005, Wyeth and Teva filed the settlement agreement with the District Court presiding over the patent-infringement litigation. As required by a 2002 consent decree, Wyeth submitted the agreement to the Federal Trade Commission ("FTC"), which possessed the right to weigh in on and raise objections to Wyeth's settlements. The FTC offered no objection but reserved its right to take later action. The settlement was also submitted to the U.S. Department of Justice, and again to the FTC, pursuant to Section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, 117 Stat. 2066, 2461–63 (2003) (codified at 21 U.S.C. § 355 note). The District Court thereafter entered orders vacating its prior *Markman* rulings, dismissing the case, and adopting in summary fashion the terms of the settlement as a consent decree and permanent injunction. Effexor JA1298.[7]

Following the Wyeth-Teva settlement, between April 2006 and April 2011, Wyeth brought patent-infringement suits against sixteen other companies that sought to market a generic version of Effexor XR. Each

[7] We refer to the joint appendix in the *Effexor* consolidated appeals as "Effexor JA."

lawsuit ended in settlement and without a court order regarding the validity or enforceability of Wyeth's patents.

2

Beginning in May 2011, several direct purchasers of Effexor XR filed class action complaints raising various antitrust claims in the U.S. District Court for the Southern District of Mississippi. Those cases were consolidated and, on September 21, 2011, that Court transferred the action to District Judge Peter G. Sheridan in the U.S. District Court for District of New Jersey.

After the consolidation and transfer, the direct purchasers filed an amended consolidated class action complaint, a group of end payors joined the case with a consolidated class action complaint, several individual retailers filed complaints, and two individual third-party payors together filed their own complaint. As with the consolidated *Lipitor* appeals, their complaints each raise two substantively identical claims: (1) a monopolization claim under Section 2 of the Sherman Act (15 U.S.C. § 2) or a state analogue against Wyeth, asserting that Wyeth fraudulently induced the PTO to issue the three patents covering Effexor XR (*Walker Process* fraud), improperly listed those patents in the Orange Book, enforced those patents through serial sham litigation, and entered into a reverse payment settlement with Teva; and (2) a claim under Section 1 of the Sherman Act (15 U.S.C. § 1) or a state analogue against both Wyeth and Teva, alleging the

reverse payment settlement agreement between them was an unlawful restraint of trade.[8]

In April 2012, *Effexor* defendants filed motions to dismiss under Rule 12(b)(6). During the pendency of those motions, the District Court stayed proceedings in October 2012 pending the Supreme Court's decision in *Actavis*. Following the *Actavis* ruling, the District Court vacated the stay, reopened the case, and called for supplemental briefing on the pending motions to dismiss. On October 23, 2013, the direct purchasers (but no other party) filed an amended complaint. That amended complaint was met with a renewed motion to dismiss.

On October 6, 2014, the District Court granted in part and denied in part *Effexor* defendants' motions to dismiss. *In re Effexor XR Antitrust Litig.*, No. CIV.A. 11-5479 PGS, 2014 WL 4988410 (D.N.J. Oct. 6, 2014). It granted the motions to dismiss, with prejudice, as to *Effexor* plaintiffs' challenges to the reverse payment settlement agreement between Wyeth and Teva under Section 1 of the Sherman Act (or its state analogue). *Id.* at *19–24. The District Court denied the motions as they related to the remaining allegations of *Effexor* plaintiffs against Wyeth. *Id.* at *24–26. At *Effexor* plaintiffs' request, the District Court directed entry of a final judgment as to the Section 1 claims (or their state

[8] The individual third-party payors' operative complaint names only Wyeth and its affiliates as defendants.

analogues) against Wyeth and Teva under Rule 54(b) of the Federal Rules of Civil Procedure. These timely appeals followed.

III

The District Court had subject-matter jurisdiction with respect to the *Lipitor* and *Effexor* direct purchasers and independent retailers under 28 U.S.C. §§ 1331 and 1337(a), the *Lipitor* and *Effexor* end payors under 28 U.S.C. § 1332(d), and the *Effexor* independent third-party payors under 28 U.S.C. § 1332(a)(3).

We have appellate jurisdiction pursuant to 28 U.S.C. § 1291. In April 2017, this Court concluded that the *Lipitor* and *Effexor* consolidated actions did not "arise under" patent law and consequently denied *Lipitor* and *Effexor* plaintiffs' request for a transfer to the U.S. Court of Appeals for the Federal Circuit. *In re Lipitor Antitrust Litig.*, 855 F.3d at 145–46; *see also* 28 U.S.C. § 1338(a) (providing district courts with original jurisdiction over actions "arising under" federal patent law); 28 U.S.C. § 1295(a) (providing the U.S. Court of Appeals for the Federal Circuit with "exclusive jurisdiction" over "an appeal from a final decision . . . in any civil action arising under" federal patent law). Appellate jurisdiction, therefore, is proper in this Court, not the Federal Circuit.

We review dismissals under Rule 12(b)(6) of the Federal Rules of Civil Procedure de novo. *See Phillips v.*

County of Allegheny, 515 F.3d 224, 230 (3d Cir. 2008). We accept all factual allegations in the complaint as true and, examining for plausibility, "determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Bronowicz v. Allegheny County*, 804 F.3d 338, 344 (3d Cir. 2015) (quoting *Powell v. Weiss*, 757 F.3d 338, 341 (3d Cir. 2014)). As part of that review, we may consider documents "integral to or explicitly referred to in the complaint" without turning a motion to dismiss into a motion for summary judgment. *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997)).

With allegations of fraud, "a party must state with particularity the circumstances constituting fraud or mistake," although "intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b); *see also U.S. ex rel. Moore & Co., P.A. v. Majestic Blue Fisheries, LLC*, 812 F.3d 294, 307 (3d Cir. 2016) ("A plaintiff alleging fraud must therefore support its allegations 'with all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where and how of the events at issue.'" (quoting *In re Rockefeller Ctr. Props., Inc. Securities Litig.*, 311 F.3d 198, 217 (3d Cir. 2002))); *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 695 (2d Cir. 2009) (requiring that allegations of fraudulent procurement of a patent be pled

with particularity). In doing so, "a party must plead [its] claim with enough particularity to place defendants on notice of the 'precise misconduct with which they are charged.'" *United States ex rel. Petras v. Simparel, Inc.*, 857 F.3d 497, 502 (3d Cir. 2017) (quoting *Lum v. Bank of Am.*, 361 F.3d 217, 223–24 (3d Cir. 2004), *abrogated on other grounds by Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007)).

IV

In *F.T.C. v. Actavis*, the Supreme Court held that reverse payments made pursuant to settlement agreements ("reverse payment settlement agreements") may give rise to antitrust liability. 133 S. Ct. at 2227. Often arising from pharmaceutical drug litigation, reverse payment settlement agreements operate counter to conventional settlement norms. As traditionally understood, settlements involve an agreement by a defendant (i.e., a patent infringer in the pharmaceutical drug context) to pay a plaintiff (i.e., the patentee) to end a lawsuit. A reverse payment settlement agreement instead "requires the patentee to pay the alleged infringer," in return for the infringer's agreement not to produce the patented item. *Id.* To make that abstract explanation more concrete, the Supreme Court gave the following unadorned example: "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." *Id.*

Prior to *Actavis*, several courts had held that such settlement agreements "were immune from antitrust scrutiny so long as the asserted anticompetitive effects fell within the scope of the patent." *King Drug Co.*, 791 F.3d at 399. That categorical rule, known as the "scope of the patent" test, relied on the premise that, because a patentee possesses a lawful right to keep others out of its market, the patentee may also enter into settlement agreements excluding potential patent challengers from entering that market. *Actavis*, 133 S. Ct. at 2230.

The Supreme Court rejected that approach. Its main concern was the use of reverse payments "to avoid the risk of patent invalidation or a finding of noninfringement." *Id.* at 2236. It reasoned that "to refer . . . simply to what the holder of a valid patent could do does not by itself answer the antitrust question. The patent . . . may or may not be valid, and may or may not be infringed." *Id.* at 2230–31. Therefore, "determin[ing] antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well," would be "incongruous." *Id.* at 2231. Instead, "patent and antitrust policies are both relevant in determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent." *Id.* Hence, patent-related "reverse payment settlements . . .

can sometimes violate the antitrust laws[.]" *King Drug Co.*, 791 F.3d at 399 (first alteration in original) (quoting *Actavis*, 133 S. Ct. at 2227).

In determining that reverse payment settlement agreements may violate antitrust laws, the Supreme Court offered limited guidance as to when such settlements should be subject to antitrust scrutiny. It exempted "commonplace forms" of settlement from scrutiny. *Actavis*, 133 S. Ct. at 2233. One such settlement is a payment where "a party with a claim (or counterclaim) for damages receives a sum equal to or less than the value of its claim." *Id.* at 2233 ("[W]hen Company A sues Company B for patent infringement and demands, say, $100 million in damages, it is not uncommon for B (the defendant) to pay A (the plaintiff) some amount less than the full demand as part of the settlement—$40 million, for example."). Another such settlement is a payment by a plaintiff (i.e., the patent holder) settling a counterclaim made by a defendant (i.e., the alleged patent infringer). *Id.* ("[I]f B has a counterclaim for damages against A, the original infringement plaintiff, A might end up paying B to settle B's counterclaim.").

In contrast to those commonplace forms of settlement, a reverse payment in pharmaceutical drug litigation occurs when "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." *Id.* At base, reverse

payments violate antitrust law when they unjustifiably seek "to prevent the risk of competition." *Id.* at 2236. "If the basic reason [for the payment] is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement." *Id.* at 2237; *see also id.* at 2236 ("[T]he payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm."). Stated differently, a reverse payment may demonstrate "that the patentee seeks to induce the . . . challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market." *Id.* at 2235.

Reverse payment settlement agreements give rise to those antitrust concerns—that is, the concern that a settlement seeks "to eliminate risk of patent invalidity or noninfringement," *King Drug Co.*, 791 F.3d at 411—when the payments are both "large and unjustified." *Actavis*, 133 S. Ct. at 2237.

Consideration of the size of the reverse payment serves at least two functions in assessing that payment's lawfulness. First, the Supreme Court observed that a large reverse payment may indicate that "the patentee likely possesses the power to bring [an unjustified anticompetitive] harm about in practice." *Id.* at 2236; *see also King Drug Co.*, 791 F.3d at 403 ("[T]he size of a reverse payment may serve as a proxy for [the power to

bring about anticompetitive harm] because a firm without such power (and the supracompetitive profits that power enables) is unlikely to buy off potential competitors."). That is, a large reverse payment may signal that the patentee possessed "the power to charge prices higher than the competitive level" and may be using that power to keep others from entering its market. *Actavis*, 133 S. Ct. at 2236. Second, a large reverse payment may signify that the payment seeks to avoid invalidation of the disputed underlying patent. *Id.* at 2236. A patent holder may be concerned about the validity of its patent, and so the size of the payment may very well correspond with the magnitude of that concern. *See id.* at 2236–37 ("In a word, the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness . . . .").

The justifications underlying the reverse payment also play a role in determining whether that payment will give rise to antitrust liability. The Supreme Court observed, on the one hand, that "[w]here a reverse payment reflects traditional settlement considerations, . . . there is not the same concern [as with other reverse payments] that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement." *Id.* at 2236. Those legitimate justifications for a reverse payment include those where the payment is "a rough approximation of the litigation expenses saved through settlement" or a reflection of "compensation for other services the generic has promised

to perform." *Id*. The Supreme Court did not exclude other possible legitimate explanations from also justifying reverse payment settlement agreements. *Id.* On the other hand, in the absence of a legitimate justification or explanation, the reverse payment "likely seeks to prevent the risk of competition" in that its "objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market." *Id.*

"In sum, a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects . . . ." *Id.* at 2237. Therefore, to survive a motion to dismiss when raising an antitrust violation under *Actavis*, "plaintiffs must allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under *Actavis.*" *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 552 (1st Cir. 2016). If plaintiffs do so, they may proceed to prove their allegations under the traditional antitrust rule-of-reason analysis. *See Actavis*, 133 S. Ct. at 2237.

Since *Actavis*, this Court has had occasion to assess the plausibility of allegations raising an unlawful reverse payment settlement agreement. In *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, we reached two conclusions relevant here regarding the parameters of antitrust claims brought under *Actavis.*

First, we held that a reverse payment underlying an *Actavis* antitrust claim need not be in cash form. 791 F.3d at 403–09. The allegedly unlawful reverse payment took the form of a "no-AG agreement," a brand-name manufacturer's promise not to produce an authorized generic to compete with the generic manufacturer. *Id.* at 397. There, the direct purchasers of a drug (Lamictal) sued both GlaxoSmithKline (GSK), the brand-name manufacturer, and Teva, the generic manufacturer, for violating Sections 1 and 2 of the Sherman Act. *Id.* at 393. The direct purchasers alleged that GSK and Teva entered into an agreement settling GSK's patent infringement suit, which contained a no-AG agreement. *Id.* at 397. The no-AG agreement provided that GSK would not produce an authorized generic version of Lamictal for 180 days after Teva started marketing its generic. *Id.* The *King Drug Co.* plaintiffs argued that the no-AG agreement could constitute an anticompetitive reverse payment under *Actavis* because it worked to maintain supracompetitive prices in the Lamictal market. *Id.* at 397, 410. We agreed, holding "that a no-AG agreement, when it represents an unexplained large transfer of value from the patent holder to the alleged infringer, may be subject to antitrust scrutiny under the rule of reason." *Id.* at 403.

We also determined that the plaintiffs in *King Drug Co*. plausibly alleged that the no-AG agreement was a large and unjustified reverse payment sufficient to support antitrust scrutiny under *Actavis*. *Id*. at 409–10. The

allegations giving rise to antitrust review were that (1) "GSK agreed not to launch a competing authorized generic during Teva's 180-day exclusivity period"; (2) "GSK had an incentive to launch its own authorized generic versions of tablets"; (3) GSK's promise could be "worth many millions of dollars of additional revenue"; (4) "Teva had a history of launching 'at risk'"; and (4) the relevant "patent was likely to be invalidated." *Id.* Given those allegations, we reasoned that the complaint plausibly alleged that the reverse payment was large and unjustified and attempted to prevent the risk of competition through the sharing of monopoly profits: "Because marketing an authorized generic was allegedly in GSK's economic interest, its agreement not to launch an authorized generic was an inducement—valuable to both it and Teva—to ensure a longer period of supracompetitive monopoly profits based on a patent at risk of being found invalid or not infringed." *Id.* at 410.

In reaching that conclusion, we specifically rejected GSK and Teva's argument that the reverse payment was justified because Teva was given permission in the settlement agreement to enter a different pharmaceutical drug market early. We observed that, according to the complaint, the early-entry provision allowed access to a market worth "only $50 million annually," which "was orders of magnitude smaller than the alleged $2 billion . . . market the agreement is said to have protected." *Id.* The early-entry provision thus failed to justify the large reverse

payment from the patentee GSK to the alleged infringer Teva. *Id.* Because the complaint in *King Drug Co.* plausibly alleged a large and unjustified reverse payment, the plaintiffs there could proceed to prove their claim through "the traditional rule-of-reason approach." *Id.* at 411; *see also id.* at 412 (providing a three-step rule-of-reason approach by which antitrust plaintiffs could demonstrate that the reverse payment settlement agreement imposed an unreasonable restraint on competition).

Applying *Actavis* and *King Drug Co.*, we next address whether the complaints in the Lipitor and Effexor consolidated appeals plausibly allege an actionable reverse payment settlement agreement.

A

We conclude that *Lipitor* plaintiffs have plausibly pled an unlawful reverse payment settlement agreement.[9] Their allegations sufficiently allege that Pfizer agreed to release the *Accupril* claims against Ranbaxy, which were likely to succeed and worth hundreds of millions of

[9] This conclusion renders unnecessary the need to address the *Lipitor* direct purchasers' argument that they should be granted leave to submit a new complaint with economic calculations to bolster their allegations of an unlawful reverse payment.

dollars, in exchange for Ranbaxy's delay in the release of its generic version of Lipitor.

As part of their effort to allege an unlawful reverse payment settlement agreement, *Lipitor* plaintiffs plead, among other factual averments, the following: Ranbaxy launched a generic version of Pfizer's brand drug Accupril "at risk," Lipitor JA257 (DPP Sec. Am. Compl. ¶ 149); Pfizer had annual Accupril sales over $500 million prior to Ranbaxy's launch, *id.*; Pfizer brought suit and sought to enjoin Ranbaxy's generic sales, Lipitor JA260 (DPP Sec. Am. Compl. ¶ 160); the District Court granted the injunction halting Ranbaxy's sales of generic Accupril, which the Federal Circuit affirmed, *Pfizer Inc. v. Teva Pharm. USA, Inc.*, 429 F.3d 1364, 1383 (Fed. Cir. 2005); Pfizer posted "a $200 million bond in conjunction with" the injunction and informed the Court that Ranbaxy's generic sales "decimated" its Accupril sales, Lipitor JA260 (DPP Sec. Am. Compl. ¶ 160); more specifically, Pfizer's Accupril sales dropped from $525 million in 2004 to $71 million in 2005 following Ranbaxy's launch of the generic version of Accupril, Lipitor JA260 (DPP Sec. Am. Compl. ¶ 160); Pfizer's suit was likely to be successful, Lipitor JA262–63 (DPP Sec. Am. Compl. ¶¶ 167–70); and Pfizer itself made statements about Ranbaxy's exposure, estimating that Ranbaxy faced "very, very substantial damages in the way of lost profits," Lipitor JA263 (DPP Sec. Am. Compl. ¶ 170).

Despite the large expected damages arising from the Accupril suit and the high likelihood of its success, Pfizer subsequently released its *Accupril* claims as part of a settlement agreement with Ranbaxy. Ranbaxy paid $1 million to Pfizer in connection with the Accupril litigation and also agreed to the release of Pfizer's $200 million injunction bond. *Lipitor* plaintiffs allege that the release of the *Accupril* claims was unjustified, as the release of potential liability in *Accupril* "far exceeded" any of Pfizer's saved litigation costs or any services provided by Ranbaxy. Lipitor JA265 (DPP Sec. Am. Compl. ¶¶ 180, 285). Pfizer's alleged agreement to release the *Accupril* claims, therefore, "was an inducement—valuable to both it and [Ranbaxy]—to ensure a longer period of supracompetitive monopoly profits based on [the Lipitor patent, which was] at risk of being found invalid or not infringed." *King Drug Co.*, 791 F.3d at 410. Those allegations sufficiently plead that the value of the *Accupril* claims was large and their release was unjustified. *See Actavis*, 133 S. Ct. at 2236 ("[T]he payment (if otherwise unexplained) likely seeks to prevent the risk of competition. . . . [T]hat consequence constitutes the relevant anticompetitive harm.").

Notwithstanding *Lipitor* plaintiffs' allegations, the District Court determined their complaints were wanting. It required that they plead a "reliable" monetary estimate of the dropped *Accupril* claims so that they "may be analyzed against the *Actavis* factors" to determine whether

the value of those claims "is 'large' once the subtraction of legal fees and other services provided by generics occurs." *See Lipitor II*, 46 F. Supp. 3d at 543. That "reliable" monetary estimate, according to the Court, necessitated a series of calculations: a valuation of Pfizer's damages in the Accupril litigation incorporating both Pfizer's probability of success in that action and an estimation of Pfizer's lost profits; a discounting of Pfizer's damages based on its saved litigation costs and Pfizer's various litigation risks; and an accounting of various other provisions within the settlement agreement, including the arrangement to allow Ranbaxy into several foreign markets, the parties' agreement resolving other pharmaceutical litigation, and a supply arrangement between Ranbaxy and Pfizer related to generic Lipitor sales in Canada. Without these various calculations, the District Court determined that *Lipitor* plaintiffs had failed to allege a plausible large and unjustified reverse payment under *Actavis*.

Lipitor defendants largely echo the reasoning of the District Court. Their contentions broadly fall into two categories. First, and similar to the District Court, *Lipitor* defendants maintain that, even if the settlement could be characterized as an unlawful reverse payment, *Lipitor* plaintiffs insufficiently alleged the payment was "large" and "unjustified." Second, they argue that the settlement here was no more than the sort of commonplace settlement

that the Supreme Court excluded from antitrust scrutiny. Neither of these arguments withstands careful review.

Both the District Court and *Lipitor* defendants offer a heightened pleading standard contrary to *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). *Twombly* and *Iqbal* require only plausibility, a standard "not akin to a 'probability requirement.'" *Iqbal*, 556 U.S. at 678. While *Twombly* and *Iqbal* require that "[f]actual allegations . . . be enough to raise a right to relief above the speculative level," *Twombly*, 550 U.S. at 555, "those cases make it clear that a claimant does not have to 'set out *in detail* the facts upon which he bases his claim.'" *Covington v. Int'l Ass'n of Approved Basketball Officials*, 710 F.3d 114, 118 (3d Cir. 2013) (quoting *Twombly*, 550 U.S. at 555 n.3); *see also Connelly v. Lane Const. Corp.*, 809 F.3d 780, 786 (3d Cir. 2016) ("[D]etailed pleading is not generally required.").

Applying that pleading standard, neither the Supreme Court in *Actavis* nor this Court in *King Drug Co.* demanded the level of detail the District Court and *Lipitor* defendants would require. For its part, the Supreme Court in *Actavis* was deliberately opaque about the parameters of reverse payment antitrust claims. We take note, though, of the allegations in *Actavis* regarding the size of the reverse payment. There, the FTC alleged simply that a patentee "agreed to pay [a generic manufacturer] $10 million per year for six years," "agreed to pay [another generic manufacturer] $2 million per year for six years,"

and "projected that it would pay [a third generic manufacturer] about $19 million during the first year of its agreement, rising to over $30 million annually by the end of the deal." Second Amended Complaint for Injunctive and Other Equitable Relief ¶¶ 66, 77, *In re Androgel Antitrust Litig.*, No. 1:09-CV-00955-TWT (N.D. Ga. May 28, 2009), ECF No. 134. The FTC's complaint did not preemptively negate justifications for the reverse payments. It simply alleged that the payments were meant to, and did, induce delay of likely successful patent challenges through the sharing of monopoly profits. *Id.* ¶¶ 67, 86; *see also Actavis*, 133 S. Ct. at 2229. The Supreme Court did not require the advanced valuations asked for by *Lipitor* defendants and required by the District Court.

Perhaps equally striking in their simplicity are the allegations we concluded were sufficient to state an *Actavis* claim in *King Drug Co.* There, we elucidated no special valuation requirement in examining the alleged reverse payment. Rather, the allegations were simply that a no-AG agreement provided the alleged infringer with "many millions of dollars of additional revenue" and that the patentee otherwise had "an incentive to launch its own authorized generic." *King Drug Co.*, 791 F.3d at 409–10. The no-AG agreement resultantly induced the alleged infringer to agree to delay the launch of its generic drug that would compete with the patentee's drug, which

purportedly relied on an invalid patent. *Id*. Nothing more was necessary to plausibly plead a claim under *Actavis*.

The allegations here, as outlined above, easily match, if not exceed, the level of specificity and detail of those in *Actavis* and *King Drug Co*. The alleged reverse payment here was "large" enough to permit a plausible inference that Pfizer possessed the power to bring about an unjustified anticompetitive harm through its patents and had serious doubts about the ability of those patents to lawfully prevent competition.[10] *Actavis*, 133 S. Ct. at 2236. Pfizer purportedly suffered hundreds of millions of dollars in lost sales following Ranbaxy's entry into the Accupril market. Lipitor JA260 (DPP Sec. Am. Compl. ¶ 160). Upon suing Ranbaxy, Pfizer sought treble damages, Lipitor JA263–64 (DPP Sec. Am. Compl. ¶¶ 159, 172–74), and posted a $200 million bond to secure an injunction, "demonstrating that Pfizer placed great value on preserving its Accupril franchise," Lipitor JA260 (DPP Sec. Am. Compl. ¶ 160). That claim had some likelihood of success given the entry of the injunction, which was affirmed on appeal. *See Pfizer*, 429 F.3d at 1383. Pfizer itself told shareholders that it was likely to succeed on the merits of the case. Lipitor JA263 (DPP Sec. Am. Compl.

[10] Notably, *Lipitor* plaintiffs do not allege the size or value of Pfizer's grant to Ranbaxy of early access into several foreign markets for Lipitor.

¶ 170). Despite those losses and the likely success of that litigation against Ranbaxy, Pfizer released its claim worth "hundreds of millions of dollars." JA264 (DPP Sec. Am. Compl. ¶ 175). Those allegations sufficiently allege a large reverse payment; more detailed, advanced calculations related to those allegations may come later.[11]

[11] As explained *infra*, not only does *Lipitor* defendants' request for detailed economic analyses go beyond what is required at this stage of the litigation, but that request also attempts to require *Lipitor* plaintiffs to disprove what *Lipitor* defendants must prove. *Lipitor* defendants suggest that the size of the reverse payment must be determined by the *net* reverse payment, which accounts for litigation costs and other discounting measures and justifications for the payment. In doing so, *Lipitor* defendants seem to conflate the *Actavis* requirement that the reverse payment be "large" with the requirement that the payment be "unjustified." Their proposed economic valuation demands that *Lipitor* plaintiffs disprove proffered justifications for the reverse payment settlement agreement. *Lipitor* plaintiffs, though, need not do so at the pleading stage. *Actavis*, 133 S. Ct. at 2236 ("*An antitrust defendant* may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason." (emphasis added)).

The alleged reverse payment here was also "unjustified." As noted earlier, avoiding litigation costs, providing payment for services, or other consideration may justify a large reverse payment. *See Actavis*, 133 S. Ct. at 2236. To plausibly allege an unjustified reverse payment, an antitrust plaintiff need only allege the absence of a "convincing justification" for the payment. *Id.* at 2236–37 (observing that, if such considerations are present, "there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement"); *see also King Drug Co.*, 791 F.3d at 412 (observing that, in the first step of the rule-of-reason analysis, a plaintiff must "prove a payment for delay, or, in other words, payment to prevent the risk of competition," and then citing *Actavis* for the proposition that the "likelihood of a reverse payment bringing about anticompetitive effects" depends on its size, anticipated litigation costs, its independence from other services rendered, and other justifications).

Lipitor plaintiffs' complaints state that the value of the released *Accupril* claims "far exceed[s] any litigation costs (in any or all cases) Pfizer avoided by settling." Lipitor JA265 (DPP Sec. Am. Compl. ¶ 180). While *Lipitor* defendants speculate as to the actual saved litigation costs, all that need be alleged, at this juncture, is that those costs fail to explain the hundreds of millions of dollars of liability released by Pfizer. *Lipitor* plaintiffs have alleged just that, and the finely calibrated litigation

cost estimates requested by *Lipitor* defendants and the District Court are unnecessary at this stage in the litigation.

Lipitor defendants also argue that the alleged reverse payment was pled out of context, as the Accupril litigation settlement was part of a larger, global settlement agreement between Pfizer and Ranbaxy. Specifically, they point out that the complaints do not address other aspects of the settlement agreement, namely a supply arrangement in Canada and resolution of litigation over another pharmaceutical drug, Caduet.[12] They are correct that the complaints make little mention of those aspects of

[12] The *Lipitor* parties differ as to whether, under the Sherman Act, foreign or out-of-market procompetitive effects of the settlement agreement, like the Canadian supply arrangement and settlement of the Caduet litigation, can justify the domestic or in-market anticompetitive effects of the settlement, namely Ranbaxy's delayed entry into the U.S. Lipitor market. We need not decide that issue, as *Lipitor* plaintiffs have, at least at this point in the litigation, plausibly alleged the absence of justifications for the reverse payment. *See King Drug Co.*, 791 F.3d at 410 n.34 ("It may also be (though we do not decide) that procompetitive effects in one market cannot justify anticompetitive effects in a separate market." (citation and quotation marks omitted)).

the settlement. We disagree that the absence of those allegations is fatal.

Lipitor defendants have the burden of justifying the rather large reverse payment here, and they offer no reason why those other elements of the settlement agreement do so. *Actavis* does not require antitrust plaintiffs to come up with possible explanations for the reverse payment and then rebut those explanations in response to a motion to dismiss. The Supreme Court clearly placed the onus of explaining or justifying a large reverse payment on *antitrust defendants*. In examining allegations of a reverse payment at the pleading stage, the Supreme Court acknowledged that, even if there is an explanation for a reverse payment, "that possibility d[id] not justify dismissing the [antitrust plaintiff's] complaint. *An antitrust defendant* may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason." *Id*. at 2236 (emphasis added). The Supreme Court emphasized this point later, in *Actavis*, stating that the "one who makes [the reverse] payment" needs "to explain and to justify it." *Id*. at 2237. We noted as much in *King Drug Co.*, where we observed that the antitrust defendant has the burden "to show 'that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.'" 791 F.3d at 412 (quoting

Actavis, 133 S. Ct. at 2235–36); *see also In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 753 (E.D. Pa. 2014) ("While it is possible that defendants will be able to supply evidence to rebut plaintiffs' allegations regarding the true value of the services . . . , *Twombly* does not require an antitrust plaintiff to plead facts that, if true, definitively rule out all possible innocent explanations."). Here, *Lipitor* plaintiffs sufficiently alleged the absence of a convincing justification for the reverse payment and were not required to plead more than that.

Our conclusion here is consistent with the persuasive decisions of other courts facing similar challenges to pleadings raising an antitrust claim under *Actavis*. For example, in *In re Loestrin 24 Fe Antitrust Litigation*, a patentee entered into a no-AG agreement with a generic manufacturer, providing the generic manufacturer with favorable promotion deals in exchange for the generic manufacturer's delaying entry into the patentee's market. 814 F.3d at 541. Addressing the specificity necessary for allegations raising an antitrust claim under *Actavis*, the First Circuit held: "Consistent with *Twombly*, which declined to 'require heightened fact pleading of specifics' [in an antitrust suit], we do not require that the plaintiffs provide precise figures and calculations at the pleading stage." *Id.* at 552 (citations omitted). To conclude otherwise "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." *Id.* (quoting *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 243 (D. Conn. 2015)). The First Circuit concluded that plaintiffs must simply "allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under *Actavis.*" *Id.* (citation omitted).

Finally, *Lipitor* defendants contend that the reverse payment here was no more than a commonplace settlement. That argument is unpersuasive. As they would have it, the exchange of Ranbaxy's $1 million payment to Pfizer for Pfizer's release of the claim in the *Accupril* action (allegedly worth hundreds of millions of dollars) constituted a lawful compromise warranting no antitrust scrutiny. *Lipitor* defendants rely on the Supreme Court's warning in *Actavis* that its opinion "should not be read to subject to antitrust scrutiny 'commonplace forms' of settlement, such as tender by an infringer of less than the patentee's full demand." *King Drug Co.*, 791 F.3d at 402 (quoting *Actavis*, 133 S. Ct. at 2233). We doubt that the $1 million payment from Ranbaxy to Pfizer, in exchange for an agreement not to enter a patentee's market, insulates review of the settlement agreement here. If parties could shield their settlements from antitrust review by simply including a token payment by the purportedly infringing generic manufacturer, then otherwise unlawful reverse payment settlement agreements attempting to eliminate

the risk of competition would escape review. That result simply cannot be squared with *Actavis*.

More importantly, *Lipitor* defendants' argument that the settlement agreement here is a commonplace one does not withstand *Lipitor* plaintiffs' plausible allegations and the reasonable inferences arising therefrom. As referenced above, the *Lipitor* complaints plausibly allege that, while Ranbaxy gave Pfizer $1 million, Pfizer's release of the *Accupril* claims was given "[i]n exchange for Ranbaxy's agreement to delay its launch of (and not to authorize another ANDA filer to launch) generic Lipitor until November 30, 2011," not in exchange for the $1 million. Lipitor JA257 (DPP Sec. Am. Compl. ¶ 48). Bolstering that allegation is *Lipitor* plaintiffs' contention that the *Accupril* claims were worth hundreds of millions of dollars to Pfizer and were likely to be successful. The $1 million payment is paltry by comparison. Given those allegations, Pfizer's release of the *Accupril* claims plausibly sought to induce Ranbaxy to delay its entry into the Lipitor market and was not in exchange for Ranbaxy's $1 million. *Cf. Actavis*, 133 S. Ct. at 2229 ("The companies described these payments as compensation for other services the generics promised to perform, but the FTC contends the other services had little value. According to the FTC the true point of the payments was to compensate the generics for agreeing not to compete . . . until 2015."). Pfizer and Ranbaxy's settlement agreement is therefore properly subject to antitrust scrutiny.

B

Applying the same analysis to the *Effexor* consolidated appeals as we applied above compels the same result. We conclude that *Effexor* plaintiffs plausibly allege a reverse payment settlement agreement under *Actavis*.

As with the *Lipitor* appeals, we begin with a brief recitation of key allegations. *Effexor* plaintiffs allege that, after Teva filed an ANDA seeking approval of its generic version of Effexor XR, Wyeth brought suit. Following a ruling adverse to Wyeth, the parties entered into a settlement agreement. As part of that agreement, Wyeth agreed it would not compete with Teva by producing an authorized generic of either Effexor XR or Effexor IR. That no-AG agreement allegedly "constituted a substantial, net payment by Wyeth to Teva in exchange for Teva agreeing to delay generic entry much later than it otherwise would have." Effexor JA210 (DPP Sec. Am. Compl. ¶ 281).[13] More specifically, *Effexor* plaintiffs claim that the promise "amount[ed] to over $500 million in value" given to Teva. *Id.* In return for that value, Teva agreed it would delay entry into the Effexor XR market by not selling its generic version of the drug until a specified

[13] Because *Effexor* plaintiffs' complaints contain substantively identical factual allegations, we cite only to the direct purchasers' complaint, referring to their second amended complaint as "DPP Sec. Am. Compl."

date. According to *Effexor* plaintiffs, Teva's promise to delay entry of its generic Effexor XR "meant that U.S. drug purchasers paid *billions of dollars* more for extended-release venlafaxine than they otherwise would have absent the Wyeth-Teva agreement." Effexor JA210 (DPP Sec. Am. Compl. ¶ 279). Wyeth was thus able to profit substantially from Teva's promise to delay the entry of its generic into the Effexor XR market.

The District Court concluded that those allegations insufficiently pled a large and unjustified reverse payment. It determined that *Effexor* plaintiffs had not alleged that the reverse payment here was "large" because their "analysis . . . [did] not have a reliable foundation."[14] *In re*

[14] Reliability is often associated with the evidentiary standard applicable to expert testimony, *see* Rule 702(c) of the Federal Rules of Evidence, not the pleading standard required to survive a motion to dismiss. As the Amicus Brief submitted by the American Antitrust Institute points out, the District Court even seems to have suggested that *Effexor* plaintiffs at the pleading stage should have produced *evidence* in order to make their allegation plausible: "Since the Direct Purchaser Plaintiffs fail to provide *appropriate evidence* for the Court to determine the value of the payment, the allegations in the Complaint do not reach the plausibility standard established in *Iqbal* and *Twombly*." *In re Effexor XR*

Effexor XR Antitrust Litig., 2014 WL 4988410, at *23. Lacking that reliable foundation, their allegation of a large reverse payment was, in the District Court's view, implausible. *Effexor* defendants make this same argument on appeal. *Effexor* plaintiffs purportedly failed to allege the specific benefit accruing to Teva from the settlement agreement and instead relied on "various general assumptions about generic penetration rates and pricing impacts." Wyeth Br. 46. *Effexor* defendants also argue the reverse payment was not large because the complaints here failed to sufficiently allege that Wyeth would have released an authorized generic but for its settlement agreement with Teva. Finally, they argue that the reverse payment may be explained by another provision in the settlement agreement that requires Teva to pay Wyeth certain royalties for its Effexor sales. Those arguments, though, ask too much of *Effexor* plaintiffs at this stage of the litigation. Their allegations, as outlined above, sufficiently allege a reverse payment settlement agreement as laid out by the Supreme Court in *Actavis*.

Similar to the *Lipitor* appeals, the District Court and *Effexor* defendants request a level of pleading exceeding what *Twombly* and *Iqbal* require. *See Iqbal*, 556 U.S. at 678; *Twombly*, 550 U.S. at 555. Moreover, neither the Supreme Court in *Actavis* nor this Court in *King Drug Co.*

Antitrust Litig., 2014 WL 4988410, at *23 (emphasis added); American Antitrust Institute Amicus Br. 10.

required such detailed allegations at the pleading stage. The complaint in *Actavis* simply alleged that the patentee paid various sums of money to generic manufacturers to induce them to delay their entry into the patentee's pharmaceutical drug market. *See Actavis*, 133 S. Ct. at 2229. Likewise, in *King Drug Co.*, this Court viewed as sufficient allegations that the patentee agreed not to market an authorized generic to compete with a generic manufacturer, with that promise worth "many millions of dollars of additional revenue," thereby inducing the generic manufacturer to delay its entry into the patentee's market. *King Drug Co.*, 791 F.3d at 410. The facts alleged by *Effexor* plaintiffs similarly, and thus plausibly, allege that Wyeth leveraged its extremely valuable promise not to enter the generic market with an authorized generic in exchange for Teva's promise to delay entry into the Effexor XR market. *See King Drug Co.*, 791 F.3d at 409 (allegations that patentee "sought to induce [the generic manufacturer] to delay its entry into the [relevant pharmaceutical drug] market by way of an unjustified no-AG agreement" sufficiently stated a claim "under *Twombly* and *Iqbal* for violation of the Sherman Act"); *see also Loestrin*, 814 F.3d at 552 ("[P]laintiffs must allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under *Actavis*.").

First, the alleged reverse payment, here in the form of Wyeth's no-AG agreement, is plausibly large. The no-

AG agreement used by Wyeth to induce Teva to stay out of the Effexor XR market was alleged to have been worth more than $500 million. *Effexor* plaintiffs note that the Effexor XR market is a multi-billion dollar market annually, and, with the no-AG agreement, "Teva would (a) garner all of the sales of generic Effexor XR during Teva's generic exclusivity period . . . and (b) charge higher prices than it would have been able to charge if it was competing with Wyeth's authorized generic." Effexor JA211 (DPP Sec. Am. Compl. ¶ 282). *Effexor* plaintiffs further cite several aggregate studies noting that, historically, authorized-generic versions of a drug bring down the price of the generic drug, with one study observing that the entry "of an authorized generic causes generic prices to be 16% lower than when there is no authorized generic." Effexor JA147 (DPP Sec. Am. Compl. ¶¶ 58–60). Those allegations plausibly allege a large reverse payment, with Wyeth's no-AG agreement "allow[ing] Teva to maintain a supra-competitive generic price as the only generic manufacturer on the market, and to earn substantially higher profits than it otherwise would have earned." Effexor JA214–15 (DPP Sec. Am. Compl. ¶ 292).

Effexor defendants nevertheless respond that the payment in this case cannot plausibly constitute a large reverse payment because of *Effexor* plaintiffs' "failure to plead that Wyeth plausibly would have introduced an AG absent the settlement." Wyeth Br. 36. They argue that Wyeth has rarely introduced authorized generics in

response to the entry of a generic into one of their branded drugs' markets and that, according to an FTC study, Wyeth "lack[ed] an 'AG Strategy.'" *Id.* at 34; *see also* Effexor JA1756–77 (a FTC study indicating that Wyeth released few authorized generics). *Effexor* defendants thus contend that Wyeth's no-AG agreement really gave Teva little value in return for the latter's delay because Wyeth was not going to produce an authorized generic anyway. Wyeth's behavior in the absence of the agreement is certainly disputed. Yet *Effexor* plaintiffs state facts plausibly alleging that Wyeth would have produced an authorized generic but for the no-AG agreement. They claim that "[t]ypically, once a drug goes generic, the branded manufacturer sells both the branded version and an 'authorized' generic version, usually selling the same exact pills in different bottles." Effexor JA206 (DPP Sec. Am. Compl. ¶ 265). More specifically, they allege, "Wyeth could have launched (and, but for its anticompetitive deal, would have launched) its own authorized generic at or about the time that Teva launched its generic." Effexor JA208–09 (DPP Sec. Am. Compl. ¶ 276). Moreover, while the FTC study cited by *Effexor* defendants notes that Wyeth introduced only one authorized generic between 2001 and 2008, the study does not specifically analyze Wyeth or suggest that Wyeth would not have introduced an authorized generic with respect to Effexor. And even *Effexor* defendants admit that Wyeth had introduced at least one authorized generic in the past. Wyeth Br. 36 & n.11. So, the FTC study is, at

best, evidence that Wyeth may not have introduced an authorized generic here, but it does not make *Effexor* plaintiffs' allegations implausible at the pleading stage where we again consider plausibility, not probability. *Effexor* defendants have not—by merely arguing that Wyeth does not typically introduce authorized generics into the market—rendered the allegations about the value of the no-AG agreement implausible.

Second, the alleged reverse payment made through Wyeth's no-AG agreement is plausibly unjustified. As alleged, the no-AG agreement "cannot be excused as a litigation cost avoidance effort by Wyeth." Effexor JA212 (DPP Sec. Am. Compl. ¶ 285). *Effexor* plaintiffs' complaint states that Wyeth's litigation costs with Teva would have totaled only between $5 million to $10 million, and those costs "would have been the tiniest of a fraction the size of the payment likely over $500 million effectuated by Wyeth to Teva." *Id.* They allege further that the no-AG agreement is not "justified on any procompetitive basis," asserting that no exchange of goods or services or any explanation justifies the delay of Teva's entry into the Effexor XR market other than the settlement agreement. Effexor JA212 (DPP Sec. Am. Compl. ¶¶ 286–87).

Effexor defendants respond that the settlement agreement is not subject to antitrust scrutiny because the agreement is "traditional" in that it is justified by Teva's payment of royalties to Wyeth. *Effexor* defendants further

argue that the complaints do not include allegations about the settlement agreement's royalty licensing agreements when alleging Teva's receipt of the $500 million no-AG agreement. Wyeth Br. 49–51. These arguments do not undermine the plausibility of the complaints' allegations that the no-AG agreement was entered into in exchange for the delayed entry of Teva into the Effexor markets. As the agreement indicates, Teva paid Wyeth only 15% of its profits for the first 6 months. The rate then jumped to 50% and then 65% after that. Thus, while the royalty licensing provisions may show that the no-AG agreement is ultimately worth less than it otherwise would have been, *Effexor* plaintiffs' allegations are still plausible. *See King Drug Co.*, 791 F.3d at 410 (concluding that a settlement agreement provision allowing access to a market worth "only $50 million annually" failed to make plaintiffs' *Actavis* allegations implausible because the value of that provision "was orders of magnitude smaller than the alleged $2 billion . . . market the agreement [was] said to have protected"). Although the royalty licensing provisions will perhaps be a valid defense, they require factual assessments, economic calculations, and expert analysis that are inappropriate at the pleading stage. *Effexor* plaintiffs, again, need not allege any more at this stage of the litigation.[15]

[15] The procedural history related to the royalty licensing provisions further supports our conclusion. The *Effexor*

direct purchasers filed a motion for leave to file a second amended consolidated complaint on August 28, 2013, attaching their proposed complaint. A week after receiving this proposed second amended complaint, *Effexor* defendants sent *Effexor* plaintiffs a copy of the un-redacted agreement containing details about the royalties, coming mere days before oral argument on *Effexor* plaintiffs' request to amend. Despite the timing of its disclosure, *Effexor* defendants would have this panel affirm the dismissal of all the complaints, without giving any *Effexor* plaintiffs, even those other than the direct purchasers, a chance to amend. Given this procedural background, dismissal based on the absence of detailed, expert-derived allegations explaining the royalty licenses—as requested by *Effexor* defendants—would be inappropriate. This procedural history serves to underscore the concern that requiring the heightened level of specificity requested here would make settlement agreements like this one nearly impossible to challenge because the details of the agreements are closely guarded by the parties entering into them. American Antitrust Institute Amicus Br. 6–7. Accordingly, it was appropriate to look to general assumptions about authorized generics to determine the value of the agreement based on the information available to *Effexor* plaintiffs. They need not have brought in experts to assess the settlement based on the limited information they had.

In sum, *Effexor* plaintiffs need not have valued the no-AG agreement beyond their allegations summarized above. *See Loestrin*, 814 F.3d at 552; *King Drug Co.*, 791 F.3d at 409–10. Nor were they required to counter potential defenses at the pleading stage. *Actavis*, 133 S. Ct. at 2236. Their complaints contain sufficient factual detail about the settlement agreement between Teva and Wyeth to plausibly suggest that Wyeth paid Teva to stay out of the market by way of its no-AG agreement; that is the very anticompetitive harm that the Supreme Court identified in *Actavis*. *Id.* ("[T]he payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm."); *see also id.* (identifying the anticompetitive harm as "the payment's objective . . . to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market"). While *Effexor* defendants may ultimately be able to show that the payments were not in fact large or unjustified, that determination should not have been made at the pleading stage given the plausible allegations here.

Effexor defendants also attempt to support the District Court's decision to grant their motion to dismiss on two other, independent grounds. First, they argue that the FTC's failure to object to their settlement agreement prevents *Effexor* plaintiffs from now bringing an antirust challenge to that agreement. Second, they contend that the

Noerr-Pennington doctrine immunizes their settlement agreement from antitrust scrutiny. Neither argument prevails.

1

Effexor defendants argue that "Wyeth [could] not possibly have sought to illicitly 'pay' Teva [because] it submitted the settlement in full to the District Court for antitrust review and the District Court specifically invited the FTC to voice concerns, and then the FTC raised no objections." Wyeth Br. 55. Essentially, *Effexor* defendants contend that (1) by submitting the agreement to the FTC in 2005, Wyeth lacked any anticompetitive intent; (2) while not dispositive, the lack of anticompetitive intent is "useful in determining whether a settlement should be viewed as" an unlawful reverse payment settlement agreement or a traditional settlement agreement, *id.*; and (3) the FTC's failure to object effectively sanctioned the settlement agreement. The District Court agreed, explaining that "any alleged antitrust intent held by the parties is negated by the fact that the settlement and license agreements were forwarded to the FTC." *In re Effexor XR Antitrust Litig.*, 2014 WL 4988410, at *24. And, although the FTC reserved its rights in response to Wyeth's submission, the District Court found that reservation of rights "unconvincing," concluding that "when a governmental agency receives an invitation from the Court to intercede in a matter *by way of an Order*, that agency should respond appropriately, not

simply reserve that right for the future." *Id.* We disagree—the submission of the settlement agreement to the FTC here does not protect the settlement agreement from antitrust scrutiny under *Actavis*.

First, the District Court failed to draw all reasonable inferences in *Effexor* plaintiffs' favor. Wyeth's compliance with the 2002 consent decree fails to demonstrate that Wyeth somehow lacked anticompetitive intent. It was complying with a legal obligation, not acting altruistically. Similarly, in addition to Wyeth's submission to the FTC from the 2002 consent decree, Teva and Wyeth had to submit the settlement to the FTC for review under the MMA. § 1112, 117 Stat. at 2461–63. Therefore, taking reasonable inferences in *Effexor* plaintiffs' favor, compliance with the 2002 consent decree and the MMA through the submission of the settlement agreement simply indicates mere compliance with the law, not the lack of antitrust intent.

Even if the submission of the settlement agreement to the FTC could create an inference that Wyeth somehow lacked antitrust intent, that intent is not an element of an antitrust claim, and benign intent does not shield anticompetitive conduct from liability. A party's "good intention" cannot "save an otherwise objectionable [restraint of trade]." *Chicago Bd. of Trade v. United States*, 246 U.S. 231, 238 (1918). The antitrust inquiry "is confined to a consideration of impact on competitive conditions," *Nat'l Soc'y of Prof'l Eng'rs v. United States*,

435 U.S. 679, 690 (1978), and "good motives will not validate an otherwise anticompetitive practice," *NCAA v. Bd. of Regents of the Univ. of Okla.*, 468 U.S. 85, 101 n.23 (1984). Accordingly, the District Court erred in giving significant weight to the parties' compliance with the 2002 consent decree and MMA.

Finally, it is erroneous to conclude that the FTC's inaction equates to a determination that the settlement agreement does not run afoul of the Sherman Act, especially given the circumstances here. Generally, an agency decision on whether to act in a particular matter or at a particular time "often involves a complicated balancing" of factors: the agency must "assess whether a violation has occurred," "whether agency resources are best spent" on that matter, whether that particular action "best fits the agency's overall policies, and indeed whether the agency has enough resources to undertake the action at all." *Heckler v. Chaney*, 470 U.S. 821, 831 (1985). Reading agency tea leaves is therefore a vexing prospect, made all the more difficult given the limited scope of review on a motion to dismiss.

The circumstances here bear out that observation. Following the submission of the settlement agreement in 2005, the FTC offered no objection but explicitly reserved its rights to take later action on the agreement. That express reservation alone raises the plausible inference that the FTC had not accepted the legality of the agreement. Moreover, the MMA includes a savings clause

which explains that the FTC's failure to object does not prevent later litigation over the agreement:

> Any action taken by . . . the [FTC], or any failure of . . . the [FTC] to take action, under this subtitle shall not at any time bar any proceeding or any action with respect to any agreement between a brand name drug company and a generic drug applicant, or any agreement between generic drug applicants, under any other provision of law, nor shall any filing under this subtitle constitute or create a presumption of any violation of any competition laws.

§ 1117, 117 Stat. at 2463. Thus, even though the FTC expressly reserved its rights, it did not have to do so under the law. Again, drawing all reasonable inferences in *Effexor* plaintiffs' favor, the FTC's failure to object here constitutes no waiver of objection to or affirmance of the settlement agreement.

Thus, the District Court erred in concluding that the submission of the settlement agreement to the FTC and the FTC's lack of response immunized *Effexor* defendants' settlement agreement from antitrust scrutiny under *Actavis*.

Effexor defendants finally contend that "[d]ismissal is appropriate for the independent reason that the [settlement agreement] became operative only after the district court overseeing the patent case incorporated the terms into a court order requested by the parties." Wyeth Br. 61. They cite the District Court's one-page consent decree adopting the terms of the settlement. According to them, "the operation of the settlement . . . *result[s] from* government action—stemming from constitutionally protected petitioning activity." *Id*.

Essentially, *Effexor* defendants argue that, because they submitted the proposed settlement agreement to the District Court for confirmation, *Noerr-Pennington*[16] immunity inoculates the settlement agreement from antitrust scrutiny. "Rooted in the First Amendment and fears about the threat of chilling political speech," *Noerr-Pennington* immunity provides "immun[ity] from antitrust liability" to parties "who petition[ ] the government for redress." *A.D. Bedell Wholesale Co. v. Philip Morris Inc.*, 263 F.3d 239, 250 (3d Cir. 2001). That immunity "applies to actions which might otherwise violate the Sherman Act because '[t]he federal antitrust laws do not regulate the conduct of private individuals in seeking anticompetitive action from the government.'" *Id*. at 250–51 (quoting *City*

[16] Named after *Eastern Railroad Presidents Conference v. Noerr Motor Freight*, 365 U.S. 127 (1961); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965).

of Columbia v. Omni Outdoor Advert., Inc., 499 U.S. 365, 379–80 (1991)).

However, "[t]he scope of *Noerr-Pennington* immunity . . . depends on the 'source, context, and nature of the competitive restraint at issue.'" *Id.* at 251 (quoting *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 499 (1988)). On the one hand, parties may be immune from liability for "the antitrust injuries which result from the [government] petitioning itself" or "the antitrust injuries *caused by* government action which results from the petitioning." *Id.* (emphasis added). On the other hand, "[i]f the restraint directly results from private action there is no immunity." *Id.* That is, immunity will not categorically apply to private actions somehow involving government action. "Passive government approval is insufficient. Private parties cannot immunize an anticompetitive agreement merely by subsequently requesting legislative approval." *Id.* A distinction therefore exists between merely urging the government to restrain trade and asking the government to adopt or enforce a private agreement. Government advocacy is protected by *Noerr-Pennington* immunity; seeking governmental approval of a private agreement is not.

Effexor defendants argue that the effect of the settlement agreement at issue "was dependent entirely on the action of the court" and is therefore protected. Wyeth Br. 63. We are not persuaded. The Supreme Court

explained in *Local No. 93, International Association of Firefighters v. City of Cleveland*, 478 U.S. 501 (1986), that, while consent decrees are at some level judicial acts, a court's role in entering a consent judgment differs fundamentally from its role in actually adjudicating a dispute. *Id.* at 519–22. When parties pursue litigation, courts reach determinations of facts and applicable law via the adversary process. But when courts enter consent decrees, "it is the agreement of the parties, rather than the force of the law upon which the complaint was originally based, that creates the obligations embodied in the consent decree." *Id*. at 522. "Indeed, it is the parties' agreement that serves as the source of the court's authority to enter any judgment at all." *Id*. That is because consent decrees "closely resemble contracts." *Id*. at 519. Their "most fundamental characteristic" is that they are *voluntary agreements* negotiated by the parties for their own purposes. *Id*. at 521–22; *see id*. at 522 ("[T]he *decree* itself cannot be said to have a purpose; rather the *parties* have purposes . . . ." (quoting *United States v. Armour & Co.*, 402 U.S. 673, 681 (1971))). Consequently, when parties seek to enforce agreements adopted in consent orders, courts construe terms of the settlement based on the intent of the parties, not of the court. *See, e.g.*, *United States v. ITT Cont'l Baking Co.*, 420 U.S. 223, 238 (1975) ("[A] consent decree or order is to be construed for enforcement purposes basically as a contract[.]"); *United States v. New Jersey*, 194 F.3d 426, 430 (3d Cir. 1999) ("[A]s consent decrees have many of the attributes of contracts, we

interpret them with reference to traditional principles of contract interpretation."); *Fox v. U.S. Dep't of Hous. & Urban Dev.*, 680 F.2d 315, 319–21 (3d Cir. 1982) (examining evidence regarding "the intention of the parties").

Effexor defendants nevertheless attempt to distinguish this case from a mere "rubberstamping of a private settlement." Wyeth Br. 64. They point to four facts they believe distinguish this case from the typical unprotected settlement approval: (1) the full terms of the settlement agreement were presented to the District Court; (2) the District Court solicited feedback from the FTC; (3) the FTC was provided with time and notice of the settlement prior to its effectiveness; and (4) the full terms of the settlement agreement between Teva and Wyeth were included in the consent order. *Id.* at 65.

Those differences fail to convert the otherwise passive government approval of a private settlement agreement into a protected government action. As discussed earlier, the FTC's inaction did not represent approval of the settlement agreement. In addition, court approval of a settlement agreement, even with access to the agreement's full terms, is simply not akin to a corporation's petition of the government for a monopoly or the government's grant of an exclusive license to a corporation. *Cf. Cantor v. Detroit Edison Co.*, 428 U.S. 579, 602 (1976) (refusing to allow "state action which amounts to little more than approval of a private proposal"

to immunize otherwise anticompetitive conduct). Instead, court approval of a settlement agreement of the kind alleged here is commercial activity not protected by the First Amendment right to petition the government. *See In re Androgel Antitrust Litig.*, No. 1:09-cv-955, 2014 WL 1600331, at *6–9 (N.D. Ga. Apr. 21, 2014) ("Indeed, providing the consent judgment with *Noerr-Pennington* immunity would largely eviscerate the ruling in *Actavis* and the Court can be sure that subsequent patent settlements would always include a consent judgment."); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 394–98 (D. Mass. 2013) ("The ways in which parties maneuver to transform a settlement agreement into a judicially approved consent judgment, then, cannot be fairly characterized as direct 'petitioning'—at least not as that word is commonly understood in the context of the political process."); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 212–13 (E.D.N.Y. 2003) ("Even if signing the Consent Judgment could be construed as approving the Settlement Agreements, government action that 'amounts to little more than approval of a private proposal' is not protected." (quoting *Cantor*, 428 U.S. at 602)). Finally, we note that accepting *Effexor* defendants' argument would have the practical effect of insulating many (if not most) potentially collusive settlement agreements from legal challenge. If *Effexor* defendants' actions were sufficient to garner *Noerr-Pennington* immunity, then almost every settlement agreement would be submitted to a court for entry of a

consent decree, and court approval would be likely to result given that no party before the court would be challenging the entry of the order. Effectively, then, no third party harmed by a collusive agreement could bring an antitrust lawsuit.

Accordingly, *Effexor* defendants' actions in submitting their private agreement to the District Court for entry of a consent decree are not sufficient to grant that agreement *Noerr-Pennington* immunity.

V

In the consolidated *Lipitor* appeals, the District Court not only dismissed *Lipitor* plaintiffs' allegations regarding an unlawful reverse payment but rather dismissed the entirety of the complaints in those appeals. In doing so, it also rejected allegations relating to Pfizer's fraudulent procurement and enforcement of the '995 Patent. More specifically, it dismissed as implausible allegations that Pfizer fraudulently procured the '995 Patent (*Walker Process* fraud), wrongfully listed that patent in the FDA's Orange Book, conducted sham litigation as the basis for entering into the reverse payment settlement agreement, filed a sham "citizen petition," and entered into an overall monopolistic scheme. We now address the dismissal of those additional allegations and revive each set of allegations.

A

The District Court dismissed *Lipitor* plaintiffs' allegations of Pfizer's fraudulent patent procurement and enforcement. That was error.[17]

Fraudulent procurement of a patent or the enforcement of a patent obtained by fraud, i.e., *Walker Process* fraud, can provide the basis for antitrust liability. *See Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965). To prove *Walker Process* fraud, a plaintiff must, in part, demonstrate

> (1) a false representation or deliberate omission of a fact material to patentability, (2) made with the intent to deceive the patent examiner, (3) on which the examiner justifiably relied in granting the patent, and (4) but for which misrepresentation or deliberate omission the patent would not have been granted.

C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1364 (Fed. Cir. 1998); *see also TransWeb, LLC v. 3M Innovative Props. Co.*, 812 F.3d 1295, 1306 (Fed. Cir. 2016)

[17] Because we reverse the dismissal of *Lipitor* plaintiffs' *Walker Process* fraud allegations, we will also reverse the District Court's limitation on *Lipitor* plaintiffs' potential damages period, *Lipitor I*, 2013 WL 4780496, at *25, as that limitation was predicated on the dismissal of the *Walker Process* fraud allegations.

(observing that, in addition to proving that the patent was obtained through fraud, an antitrust plaintiff must show "all the other elements necessary to establish a Sherman Act monopolization claim").

Lipitor plaintiffs claim that Pfizer obtained the '995 Patent by fraud and then used it to continue to sell Lipitor exclusively. To summarize those allegations, Pfizer obtained the '995 Patent, claiming protection for atorvastatin calcium, as a follow-on patent to the '893 Patent. To obtain the '995 Patent, Pfizer purportedly submitted false and misleading data to the PTO showing the cholesterol-synthesis inhibiting activity of atorvastatin calcium was surprising and unexpected. More specifically, Pfizer submitted a chart with selectively misleading data and intentionally failed to submit another set of data that undermined its '995 Patent application. Pfizer provided the PTO with that information despite its own scientists informing it that its prior '893 Patent already covered atorvastatin calcium. After once denying Pfizer's patent application for atorvastatin calcium as "anticipated" by the '893 Patent and allegedly receiving even more fraudulent data from Pfizer as a result, the PTO eventually issued the '995 Patent.

Neither Pfizer nor the District Court challenges the sufficiency or specificity of those allegations based on the face of the complaint. The District Court even stated that its "decision d[id] not rest on any failure on [*Lipitor*] Plaintiffs' part under Fed. R. Civ. P. 8(a) or 9(b) to spell

out these allegations." *Lipitor I*, 2013 WL 4780496, at *18. Despite disavowing reliance on the pleading standards set forth in the Federal Rules of Civil Procedure, the District Court nonetheless ruled that the *Walker Process* fraud allegations were implausible because they "were presented at trial in the litigation before [another district court judge], in Australia and Canada, and in reissue proceedings before the PTO." *Id.* More specifically, the District Court reasoned that the *Walker Process* fraud allegations were implausible because (1) a prior District Court Judge had already determined that similar allegations were implausible, (2) the outcomes of foreign litigation addressing the fraud allegations failed to substantiate those allegations, and (3) the PTO's reissuance of the '995 Patent in 2009, despite its awareness of the fraud allegations, meant that the PTO determined that Pfizer had committed no fraud in its original procurement of the patent. *Id.* at *19–20. Individually or in combination, none of those reasons renders the *Walker Process* fraud allegations implausible. We address them each in turn.

1

In concluding that *Lipitor* plaintiffs' allegations of *Walker Process* fraud were implausible, the District Court first relied on a District Court's decision in another case. That court had determined that Pfizer had committed no wrongdoing in the procurement of the '995 Patent. Reliance on that prior decision functionally amounted to

the application of collateral estoppel and was therefore improper because *Lipitor* plaintiffs were not parties in that prior case.

As described above, Pfizer sued Ranbaxy in 2002 for infringement of the '893 and '995 Patents following Ranbaxy's ANDA filing. *Pfizer*, 405 F. Supp. 2d at 499. In that litigation, Ranbaxy defended against Pfizer's infringement suit by arguing in part that, because Pfizer engaged in inequitable conduct in the procurement of the '995 Patent before the PTO, the '995 Patent was unenforceable. *Id.* at 520–21. Similar to the allegations here, Ranbaxy contended that Pfizer withheld information from the PTO and misrepresented the results of testing related to atorvastatin calcium. *Id.* Following a bench trial, however, the District Court in that litigation determined that Pfizer committed no inequitable conduct in its procurement of the '995 Patent. *Id.* at 520–25.

Relying on that determination, the District Court here concluded that *Lipitor* plaintiffs' *Walker Process* fraud allegations were implausible. In doing so, it effectively bound *Lipitor* plaintiffs to the other Court's prior determination in the other case. That is the essence of collateral estoppel.[18] *See Doe v. Hesketh*, 828 F.3d 159,

[18] The District Court also appeared to rely on the law of the case doctrine, citing case law applying that doctrine. The law of the case doctrine does not apply here because it only applies within a single litigation. *See Hamilton v.*

171 (3d Cir. 2016) ("Collateral estoppel prevents the re-litigation of a factual or legal issue that was litigated in an earlier proceeding.").

Applying collateral estoppel against *Lipitor* plaintiffs based on the prior litigation between Pfizer and Ranbaxy constitutes reversible error. Invocation of the collateral estoppel doctrine is appropriate only where "the party against whom the bar is asserted was a party or in privity with a party to the prior adjudication[] and . . . had a full and fair opportunity to litigate the issue in question." *Id.* (quoting *Del. River Port Auth. v. Fraternal Order of Police*, 290 F.3d 567, 573 n.10 (3d Cir. 2002)). Here, none of the *Lipitor* plaintiffs was a party in that prior litigation. Ruling that their allegations are implausible in light of that litigation would thus improperly estop *Lipitor* plaintiffs from raising *Walker Process* fraud. *See S. Cross Overseas Agencies, Inc. v. Wah Kwong Shipping Grp. Ltd.*, 181 F.3d 410, 426 (3d Cir. 1999) ("[O]n a motion to dismiss, we may take judicial notice of another court's opinion—*not for the truth of the facts recited therein*, but for the existence of the opinion, which is not subject to reasonable dispute over its authenticity." (emphasis added) (citations

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Leavy, 322 F.3d 776, 786–87 (3d Cir. 2003) ("The law of the case doctrine 'limits relitigation of an issue once it has been decided' in an earlier stage of the same litigation." (quoting *In re Continental Airlines, Inc.*, 279 F.3d 226, 232 (3d Cir. 2002))).

omitted)); *Gen. Elec. Capital Corp. v. Lease Resolution Corp.*, 128 F.3d 1074, 1083 (7th Cir. 1997) ("[I]f a court could take judicial notice of a fact simply because it was found to be true in a previous action, the doctrine of collateral estoppel would be superfluous. A plaintiff cannot be collaterally estopped by an earlier determination in a case in which the plaintiff was neither a party nor in privity with a party." (citations omitted)); *United States v. Jones*, 29 F.3d 1549, 1553 (11th Cir. 1994) ("If it were permissible for a court to take judicial notice of a fact merely because it has been found to be true in some other action, the doctrine of collateral estoppel would be superfluous." (citation omitted)); *see also DDAVP*, 585 F.3d at 692 (concluding that the District Court improperly relied on the record in an earlier case to dismiss *Walker Process* fraud allegations and noting "the record in this case could be different following discovery").[19]

2

The District Court also cited the presentment of similar allegations to Australian and Canadian courts as a

[19] Pfizer cites several cases, but none supports the District Court's functional application of collateral estoppel here. *See, e.g.*, *CBS Outdoor Inc. v. New Jersey Transit Corp.*, No. CIV.A.06-2428HAA, 2007 WL 2509633, at *2, *15 (D.N.J. Aug. 30, 2007) (concluding that plaintiff's allegations were implausible, as that *same plaintiff's* allegations had been rejected in state court).

basis for dismissal. It concluded that the results of that foreign litigation did "nothing to alter" its conclusion that *Lipitor* plaintiffs' *Walker Process* fraud allegations were implausible. *Lipitor I*, 2013 WL 4780496, at *19–20. We agree only that the past foreign litigation has no bearing on the plausibility of the *Walker Process* fraud allegations here. Even if the District Court were permitted to consider it, the rulings in that litigation fail to make *Lipitor* plaintiffs' allegations implausible.

As stated above, the factual resolution of issues in prior litigation (foreign or otherwise) should not dictate the plausibility of *Lipitor* plaintiffs' allegations when they were not parties to that litigation. *See S. Cross Overseas Agencies*, 181 F.3d at 426 ("[O]n a motion to dismiss, we may take judicial notice of another court's opinion—not for the truth of the facts recited therein, but for the existence of the opinion, which is not subject to reasonable dispute over its authenticity."); *Werner v. Werner*, 267 F.3d 288, 295 (3d Cir. 2001) ("Taking judicial notice of the truth of the contents of a filing from a related action could reach, and perhaps breach, the boundaries of proper judicial notice.").

Even if consideration of that other foreign litigation were appropriate, *Lipitor* plaintiffs' allegations are still plausible. In the Australian litigation, the Australian trial court found that Pfizer was guilty of "false suggestion" because the record there raised "[t]he clear inference . . . that the claim of surprising and unexpected inhibition of

the synthesis of cholesterol . . . is an artificial and unsupported claim." *Ranbaxy Australia Pty Ltd v Warner-Lambert Co LLC (No. 2)* [2006] FCA 1787 (20 December 2006) ¶ 357 (Austl.). On appeal, another Australian court concluded that Pfizer's assertion that its results were surprising was "a false representation" and that the patent "was obtained by false suggestion or misrepresentation." *Ranbaxy Australia Pty Ltd (ACN 110 781 826) v. Warner-Lambert Co LLC* [2008] FCAFC 82 (28 May 2008) ¶ 140 (Austl.). While the District Court and Pfizer note that the Australian courts did not go so far as to say Pfizer intentionally committed fraud, those rulings would, if anything, seem to support the plausibility of *Lipitor* plaintiffs' *Walker Process* allegations here.

In the Canadian litigation, a Canadian court determined that Pfizer's data and statements in support of its Canadian patent (the equivalent of the '995 patent) were "incorrect" and based on "false suggestion." *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2007 F.C. 91, paras. 122, 124 (Can. Ont. F.C.). On appeal, a Canadian appeals court reversed, concluding Pfizer's data and statements were not misleading. *Pfizer Canada Inc. v. Canada (Minister of Health)* (2008), [2009] 1 F.C.R. 253, paras. 53–55 (Can. Ont. C.A.). That decision, though, appears to have largely avoided the issue of Pfizer's alleged misrepresentations. *Id*. paras. 56–58 (applying one section of a Canadian patent statute and noting that "[t]he requirement that the specification of a patent be

truthful and not be misleading" was in another section of the patent statute, which was not at issue). Were these decisions a proper basis to evaluate the plausibility of *Lipitor* plaintiffs' allegations, they would do little to suggest implausibility.

In short, the factual resolution of similar *Walker Process* fraud allegations in foreign litigation not involving *Lipitor* plaintiffs has no bearing on the current litigation. Even assuming consideration of that foreign litigation was proper, it fails to suggest the implausibility of *Lipitor* plaintiffs' allegations.

3

The District Court finally relied on the reissuance of the '995 Patent in 2009 to dismiss the *Walker Process* fraud allegations. It concluded that, because the PTO reissued the '995 Patent in 2009 despite being made aware of the fraud allegations, the reissuance "suggest[ed] that [*Lipitor* plaintiffs' allegation] that the PTO would not have issued the patent but for the alleged misrepresentations or omissions [was] implausible." *Lipitor I*, 2013 WL 4780496, at *20. We disagree.

To the extent that the District Court's decision implies that a patent reissuance precludes a finding of *Walker Process* fraud, such reasoning is incorrect. A patent's reissuance by the PTO does not bar a later finding that the patent was originally procured by fraud. *See*

Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1288 (Fed. Cir. 2011) (en banc) ("[I]nequitable conduct cannot be cured by reissue . . . ."). Rather, a fact finder may conclude that inequitable conduct or fraud occurred in the patent's prosecution despite the patent's reissuance by the PTO. *See Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1236–37, 1242 (Fed. Cir. 2003) (upholding district court's finding of inequitable conduct in patent prosecution despite the PTO's reissuance of patent); *see also Hoffman-La Roche Inc. v. Lemmon Co.*, 906 F.2d 684, 688–89 (Fed. Cir. 1990) ("[I]f the district court finds that there was inequitable conduct in the prosecution of the original patent[,] then the reissue patent is invalid . . . .").

Assuming the District Court did not conclude that the patent reissuance precluded a finding of fraud but that it only "suggested" that such a finding was implausible, the District Court failed to draw inferences in *Lipitor* plaintiffs' favor. *Lipitor* plaintiffs allege that, were it not for Pfizer's fraud on the PTO in procuring the '995 Patent in 1993, the PTO would not have originally issued the '995 Patent. *See* Lipitor JA375 (DPP Original Compl. ¶ 242 ("Were it not for Pfizer's fraud on the PTO in the context of procuring the '995 patent, there would never have been a '995 patent in the first place.")). Drawing reasonable inferences in their favor, *Lipitor* plaintiffs' allegation is plausible. Initially, the PTO issued the '995 Patent based on data alleged to be fraudulent. Rather than rely on that

data during the reissuance proceedings before the PTO, Pfizer based its request for reissuance entirely on Lipitor's "commercial success," a basis that was clearly not available before Lipitor's launch in 1997. By Pfizer's own request, the PTO did not base its 2009 decision on the allegedly fraudulent data. During the reissuance proceedings, Pfizer told the PTO that the information it previously submitted in 1993 was "inaccurate," that it was not "necessary to consider such evidence," and that Pfizer was no longer relying on that data. Lipitor JA371–72 (DPP Orig. Am. Compl. ¶¶ 225–28). Finally, no allegations suggest that the PTO's reissuance made an express determination regarding Pfizer's lack of fraud during the original patent proceeding. These allegations plausibly allege that the PTO would not have issued the '995 Patent during the original patent proceedings in 1993 but for the allegedly fraudulent and misleading submissions by Pfizer.

Pfizer's arguments to the contrary are unpersuasive. First, Pfizer would have us conclude that the PTO definitively determined that Pfizer committed no past fraud based on the PTO's Manual of Patent Examining Procedure ("MPEP"), and therefore the reissuance should prevent *Lipitor* plaintiffs from raising *Walker Process* fraud allegations. As we have already observed, the PTO's reissuance of a patent does not bar a later finding that the patent was first procured by fraud. *See Therasense*, 649 F.3d at 1288; *PIC Inc. v. Prescon Corp.*,

485 F. Supp. 1302, 1303 (D. Del. 1980) ("[A] result favorable to a patentee in a PTO reissue proceeding on issues of invalidity by reason of prior art and fraud is not entitled to preclusive effect in the courts.").

Moreover, Pfizer's reliance on the MPEP is misplaced. Pfizer cites language from the MPEP that states, "Clearly, if a reissue patent would not be enforceable after its issue because of 'fraud' . . . during the prosecution of the patent sought to be reissued, the reissue patent application should not issue." MPEP § 2012 (9th ed., Nov. 2015). Pfizer fails to include the next part of that same section of the manual, though, which tells the patent examiner "*not to make any investigation* as to lack of deceptive intent requirement in reissue applications. Applicant's statement (in the oath or declaration) of lack of deceptive intent will be accepted as dispositive except in special circumstances such as *an admission or judicial determination* of fraud." *Id.* (emphasis added). Pfizer also points out that Ranbaxy filed protests raising the fraud allegations before the PTO during the reissuance proceeding. It argues that the PTO was "required to consider such arguments" under the MPEP. Pfizer Br. 50 (citing MPEP § 1901.6). Section 1901.6 of the MPEP, however, states that the patent examiner receiving a protest raising issues of fraud must enter the protest into "the application file, generally without comments on those issues." MPEP § 1901.6(I)(B). Given Pfizer's request that the PTO not consider its allegedly fraudulent data, the

PTO's reissuance of the '995 Patent on a basis other than those fraudulent submissions, the lack of any explicit fraud determination by the PTO in its reissuance of the '995 Patent, and the MPEP seemingly limiting patent examiners' investigations into past fraud, we conclude that the complaint plausibly alleges that the PTO did not find a lack of fraud in initial patent proceedings through its reissuance of the '995 Patent.

Second, Pfizer contends that its disclosures of information to the PTO during the reissuance proceedings undermine the allegations that Pfizer intended to deceive the PTO in 1993. During the reissuance proceedings, Pfizer provided information on the Australian and Canadian litigations and, as noted earlier, informed the PTO that the data previously submitted in support of the '995 Patent was "inaccurate." Pfizer's actions in 2007 before the PTO during reissuance proceedings, though, shed little light on Pfizer's intent to deceive the PTO back in 1993 when Pfizer first sought issuance of the '995 patent.[20] *See Bristol-Myers Squibb Co.*, 326 F.3d at 1241 ("[T]he issue is [the patentee's] intent during the prosecution of the original application. Thus, [the patentee's] disclosure during reissue is irrelevant to the inquiry of whether [the patentee] acquired the . . . patent

[20] For a similar reason, Pfizer's later disclosures of information in the foreign litigation fail to make *Lipitor* plaintiffs' allegations of fraudulent intent implausible.

by engaging in inequitable conduct."). At the very least, Pfizer's disclosures do not make *Lipitor* plaintiffs' allegations implausible.

In sum, the PTO's reissuance fails to render *Lipitor* plaintiffs' allegations implausible. *See Therasense*, 649 F.3d at 1288; *Bristol-Myers Squibb Co.*, 326 F.3d at 1236–37, 1242.

B

After dismissing *Lipitor* plaintiffs' *Walker Process* fraud allegations, the District Court also dismissed allegations that Pfizer falsely listed the '995 Patent in the FDA's Orange Book. It rejected those allegations of the false Orange Book listing based on its dismissal of the *Walker Process* fraud allegations. Because we conclude that *Lipitor* plaintiffs plausibly allege *Walker Process* fraud, we also reinstate their allegations regarding Pfizer's false Orange Book listing.

C

The District Court next dismissed *Lipitor* plaintiffs' allegations that Pfizer conducted sham litigation. The Court concluded that those allegations were implausible largely because the *Walker Process* fraud allegations were implausible. Again, because we conclude the *Walker Process* fraud allegations are plausible, that is not a ground for dismissal. The District Court also offered several other

reasons for dismissing the sham litigation allegations related to Pfizer's suit against Ranbaxy in 2008, but those additional grounds fail to persuade.

Filing a lawsuit essentially petitions the government for redress and is therefore generally protected from antitrust liability by *Noerr-Pennington* immunity. *See Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119, 122 (3d Cir. 1999). But *Noerr-Pennington* immunity will not shield lawsuits that are a "mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." *Id.* (quoting *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961)). To demonstrate the applicability of that exception to *Noerr-Pennington* immunity, a plaintiff must show that the defendant's lawsuit was both "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits" and "an attempt to interfere *directly* with the business relationships of a competitor." *Id.* at 122–24 (quoting *Prof'l Real Estate Inv'rs, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993)).

In March 2008, Pfizer sued Ranbaxy, claiming that Ranbaxy's generic Lipitor would infringe Pfizer's two Lipitor-related process patents. *Lipitor* plaintiffs allege that Pfizer's 2008 lawsuit was a sham. They assert that Pfizer knew Ranbaxy's generic would not violate those patents and that Pfizer simply used the 2008 suit as a way to enter into the reverse payment settlement agreement.

The District Court first concluded that those allegations were implausible because the court in the alleged sham litigation "permitted jurisdictional discovery" on subject-matter jurisdiction and because *Lipitor* plaintiffs failed to explain why subject-matter jurisdiction in that litigation was lacking. *Lipitor I*, 2013 WL 4780496, at *21. *Lipitor* plaintiffs, though, alleged that Pfizer's 2008 suit was not justiciable because Ranbaxy was already enjoined from selling its generic Lipitor for several more years given the earlier litigation between the parties. The grant of jurisdictional discovery is also not a determination of the action's underlying merits and certainly has limited, if any, bearing on the plausibility of *Lipitor* plaintiffs' allegations. Indeed, *Lipitor* plaintiffs explicitly provide allegations as to why Pfizer's 2008 suit lacked merit and was thus a sham. *See* Lipitor JA255–56 (DPP Sec. Am. Compl. ¶¶ 140–44).

Second, the District Court observed that the timing of Pfizer's litigation "was consistent with the typical duration for litigation infringement claims." Lipitor JA51–52. Given the pleading standard, it should not have been drawing inferences in Pfizer's favor regarding the timing of Pfizer's 2008 litigation. *See In re Asbestos Prod. Liab. Litig.* (No. VI), 822 F.3d 125, 131 (3d Cir. 2016) ("[W]e must accept as true all plausible facts alleged in her amended complaint and draw all reasonable inferences in her favor."). *Lipitor* plaintiffs thus plausibly allege that Pfizer conducted sham litigation in its 2008 lawsuit

against Ranbaxy.

D

The District Court next dismissed *Lipitor* plaintiffs' allegations that Pfizer submitted a sham citizen petition to the FDA to prevent Ranbaxy's entrance into the Lipitor market. It reasoned that Pfizer's petition was not objectively baseless because it was supported by science and the FDA believed it had merit. Dismissal on those grounds was improper.

Beyond immunizing certain petitioning in the judicial system, *Noerr-Pennington* immunity also protects petitioning of "all types of government entities." *Cheminor Drugs*, 168 F.3d at 122. Petitions to administrative agencies are consequently also immune from antitrust liability. *See id*. But as with the immunity extended for filing a lawsuit, *Noerr-Pennington* protection will not apply to petitions that are a "mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." *Id*. (quoting *Noerr*, 365 U.S. at 144). Petitioning that is "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits" and "an attempt to interfere *directly* with the business relationships of a competitor" will not be immune from antitrust liability. *Id*. at 122–24 (quoting *Prof'l Real Estate Inv'rs*, 508 U.S. at 60).

Analyzing this exception to *Noerr-Pennington* immunity, the District Court first concluded that the citizen petition to the FDA could not have been "objectively baseless" because it was supported by science. That conclusion is incorrect given the pleading standard here. *Lipitor* plaintiffs contend that Pfizer filed a sham citizen petition raising baseless concerns about Ranbaxy's use of amorphous atorvastatin calcium in its generic version of Lipitor. *Lipitor* plaintiffs allege Pfizer's petition was a sham because (1) it "ignored more than a decade of FDA policy, the FDA's 2002 rejection of a similar argument in relation to the drug Ceftin, subsequent FDA pronouncements reinforcing that the polymorphic form of the drug (i.e., crystalline versus amorphous) [were] immaterial to ANDA approval," Lipitor JA242 (DPP Sec. Am. Compl. ¶ 95), (2) it ignored Pfizer's own use of the amorphous form of atorvastatin in its clinical studies "to support the safety and efficacy of Lipitor," *id.*, (3) it lacked any evidence that amorphous atorvastatin calcium "would not be pharmaceutically equivalent or bioequivalent to branded Lipitor," Lipitor JA241 (DPP Sec. Am. Compl. ¶ 96), and (4) the FDA ultimately denied Pfizer's citizen petition. Those allegations plausibly allege Pfizer submitted a sham petition not supported by science. To conclude otherwise requires an evaluation of

the scientific merit of Pfizer's petition. Such an inquiry is unsuitable for resolution on a motion to dismiss.[21]

The District Court also determined the citizen petition was not "objectively baseless" because the FDA considered the petition on its merits. To reach that factual conclusion, it observed that the FDA took several years to reach a decision on the petition and that the FDA described the petition as "complex." Neither of those observations, however, leads to the conclusion that *Lipitor* plaintiffs' sham citizen petition allegations are implausible. All citizen petitions are granted or denied by the FDA. *See* 21 C.F.R. § 10.30(e)(1) ("The Commissioner shall . . . rule upon each petition . . . ."). Mere consideration of a petition by an agency, even lengthy consideration, does not immunize that petition. *See Hanover 3201 Realty*,

[21] Pfizer also argues that its mere submission of data to the FDA in support of its petition renders implausible allegations that the petition was a sham. Reading the complaints in the light most favorable to *Lipitor* plaintiffs, a reasonable inference is that the data submitted with the petition only perpetuated Pfizer's baseless attempt to prevent Ranbaxy's entry into Lipitor's market. At the very least, the mere submission of data in support of a petition raises no inference that the petition itself possessed merit. Put simply, Pfizer's submission of data with its petition does not make *Lipitor* plaintiffs' sham petition allegations implausible.

LLC v. Vill. Supermarkets, Inc., 806 F.3d 162, 180–83 (3d Cir. 2015) (applying the sham exception to *Noerr-Pennington* to defendants' permit objections and observing "[t]hat the [government agency] was required to consider Defendants' challenge does not mean that their arguments had any bite"). Equating delay in consideration of a petition or its complexity with the petition's underlying merits also fails to draw inferences in *Lipitor* plaintiffs' favor. Reasonable inferences from those facts are that the FDA's delay in deciding the petition had no connection to the petition's merits and that the petition's "complexity" also reflected little about its actual merits. Moreover, according to *Lipitor* plaintiffs, the FDA delayed in reaching a decision on the citizen petition, in part, because it knew of the settlement agreement between Ranbaxy and Pfizer. Lipitor JA269 (DPP Sec. Am. Compl. ¶ 193 ("[O]nce [the] FDA learned of the fact that the first generic for Lipitor, *i.e.*, Ranbaxy's, would not be marketed until November 30, 2011, [the] FDA shifted assets away from Ranbaxy's ANDA and the Pfizer petition . . . .")).

The District Court's dismissal of *Lipitor* plaintiffs' sham citizen petition allegations was error.

E

The District Court finally dismissed *Lipitor* plaintiffs' allegations that Pfizer participated in an overall monopolistic scheme. It dismissed those allegations based

on its dismissal of all the above allegations (i.e., the allegations concerning *Walker Process* fraud, the false Orange Book listing, sham litigation, and the sham citizen petition). Because we conclude that those allegations are plausible, we conclude that the District Court's dismissal of *Lipitor* plaintiffs' allegations that Pfizer participated in an overall scheme of monopolistic conduct was also error.

VI

For the reasons stated, we will reverse the District Court's dismissals in both the *Lipitor* and *Effexor* consolidated appeals. We will remand those consolidated cases for further proceedings consistent with this opinion.