APPENDIX

TABLE OF APPENDICES

Appendix A

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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

IN RE: LIPITOR ANTITRUST LITIGATION

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

IN RE: EFFEXOR XR ANTITRUST LITIGATION

On Appeal from the United States District Court
for the District of New Jersey
Nos. 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

Argued: May 19, 2017
Filed: August 21, 2017

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

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 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

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[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.

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

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, *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

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

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factual allegations, we cite only to the direct purchasers' complaints, referring to their original amended complaint as "DPP Orig. Am. Compl." and the second amended complaint as "DPP Sec. Am. Compl."

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 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)

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

(*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 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,

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[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).

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 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

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

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.

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

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 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 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

[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.

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. ¶ 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]

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[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.

[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

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

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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)).

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

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[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)).

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 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 Effexor XR Antitrust*

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[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."

[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

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

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

in *King Drug Co.* 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]

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[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

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

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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.

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*.

2

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 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

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[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).

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) (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").

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[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.

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, 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

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[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. 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))).

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 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]

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[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-

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

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).

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 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.

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[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.

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]

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[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

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, 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,

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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.

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.

Appendix B

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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

IN RE: LIPITOR ANTITRUST LITIGATION

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

IN RE: EFFEXOR XR ANTITRUST LITIGATION

On Appeal from the United States District Court
for the District of New Jersey
Nos. 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

Argued: September 27, 2016
Filed: April 13, 2017

Before: AMBRO, SMITH* and FISHER,**
Circuit Judges.

OPINION

FISHER, *Circuit Judge.*

A pharmaceutical company holding the patent on a drug sues the manufacturer of a generic version of that drug for patent infringement. The patent-holder and the generic manufacturer later settle, with the former paying the latter not to produce a generic until the patents at issue expire. In *FTC v. Actavis, Inc.*, 133 S. Ct. 2233 (2013), the Supreme Court recognized that such a settlement—commonly known as a "reverse payment"—where large and unjustified, can sometimes unreasonably diminish competition in violation of the antitrust laws. To answer the antitrust question, *Actavis* explained, "it is not normally necessary to litigate patent validity" because "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness." *Id.* at 2236-37.

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* Honorable D. Brooks Smith, United States Circuit Judge for the Third Circuit, assumed Chief Judge status on October 1, 2016.

** Honorable D. Michael Fisher, United States Circuit Judge for the Third Circuit, assumed senior status on February 1, 2017.

These two sets of consolidated appeals involve allegations that the companies holding the patents for Lipitor and Effexor XR delayed entry into the market of generic versions of those drugs. The companies did so, plaintiffs say, by engaging in an overarching monopolistic scheme that involved fraudulently procuring and enforcing the underlying patents and then entering into a reverse-payment settlement agreement with a generic manufacturer. With a single exception, every complaint asserts one of these monopolization claims against the patent-holders. The cases were assigned to the same district judge, who ultimately dismissed the bulk of plaintiffs' claims.

In this opinion, we address two questions of federal jurisdiction. First, do plaintiffs' allegations of fraudulent procurement and enforcement of the patents require us to transfer these appeals to the Court of Appeals for the Federal Circuit? That court has exclusive jurisdiction over appeals from civil actions "arising under" patent law. 28 U.S.C. § 1295(a)(1). But not all cases presenting questions of patent law necessarily arise under patent law. *See Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800 (1986). Where, as here, patent law neither creates plaintiffs' cause of action nor is a necessary element to any of plaintiffs' well-pleaded claims, jurisdiction lies in this Court, not the Federal Circuit.

The second jurisdictional question we confront is confined to one of the *Lipitor* appeals, *RP Healthcare, Inc. v. Pfizer, Inc.*, No. 14-4632. That case, brought by a group of California pharmacists, involves claims solely under California law and was filed in California state court. Following removal the District Court

declined to remand the case to state court, citing potential patent defenses. That was error, as federal jurisdiction depends on the content of the plaintiff's complaint, not a defendant's possible defenses. Before final judgment, however, the remaining non-diverse defendants were voluntarily dismissed, thus raising the possibility that, notwithstanding the District Court's failure to remand the case, it possessed diversity jurisdiction before the time it entered judgment. *See Caterpillar Inc. v. Lewis*, 519 U.S. 61 (1996). But because the state of the record before us is unclear with regard to the citizenship of the parties, we cannot reach the merits of this appeal until that question is resolved. We will accordingly remand the *RP Healthcare* appeal to the District Court so it can conduct jurisdictional discovery and address the matter in the first instance.

I

It is necessary to begin by discussing the regulatory framework that forms the foundation for the issues presented by these appeals.

A

"Apparently most if not all reverse payment settlement agreements arise in the context of pharmaceutical drug regulation, and specifically in the context of suits brought under statutory provisions allowing a generic drug manufacturer (seeking speedy marketing approval) to challenge the validity of a patent owned by an already-approved brand-name drug owner." *Actavis*, 133 S. Ct. at 2227. With the Drug Price Competition and Patent Term Restoration Act, 98 Stat. 1585, as amended, known as the Hatch-Waxman Act, Congress "attempted to balance the goal

of 'mak[ing] available more low cost generic drugs' with the value of patent monopolies in incentivizing beneficial pharmaceutical advancement." *King Drug Co. v. SmithKline Beecham Corp.*, 791 F.3d 388, 394 (3d Cir. 2015) (alteration in original) (quoting H.R. Rep. No. 98-857, pt. 1, at 14-15 (1984)), *cert. denied*, 137 S. Ct. 446 (2016). "The Act seeks to accomplish this purpose, in part, by encouraging 'manufacturers of generic drugs . . . to challenge weak or invalid patents on brand name drugs so consumers can enjoy lower drug prices.'" *Id.* (alteration in original) (quoting S. Rep. No. 107-167, at 4 (2002)). In *Actavis*, the Supreme Court identified four relevant features of Hatch-Waxman's regulatory framework. 133 S. Ct. at 2227-29; *see also King Drug*, 791 F.3d at 394-96.

First, a drug manufacturer seeking to market a new, "pioneer" prescription drug must obtain approval from the Food and Drug Administration (FDA). *See* 21 U.S.C. § 355(b)(1). This approval process involves testing that is "long, costly, and comprehensive." *Actavis*, 133 S. Ct. at 2228.

Second, following FDA approval of a brand-name drug, a generic manufacturer can file an Abbreviated New Drug Application (ANDA) indicating that the generic "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)(iv)). The ANDA process furthers drug competition "by allowing the generic to piggy-back on the pioneer's approval efforts." *Actavis*, 133 S. Ct. at 2228.

Third, the Hatch-Waxman Act "sets forth special procedures for identifying, and resolving, related patent disputes." *Id.* The new drug applicant is required to list any patents issued relating to the drug's composition or methods of use. *See* 21 U.S.C. § 355(b)(1). If the FDA approves the new drug, it publishes this patent information, without verification, in its Orange Book (officially known as Approved Drug Products with Therapeutic Equivalence Applications). *King Drug*, 791 F.3d at 395 & n.5 (citing *Caraco*, 566 U.S. at 405-06). In its ANDA, the generic manufacturer must "assure the FDA that its proposed generic drug will not infringe the brand's patents." *Caraco*, 566 U.S. at 406. One method of assurance is known as "paragraph IV certification," whereby the generic may assert that the relevant listed patents are "invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The filing of a paragraph IV certification "means provoking litigation," *Caraco*, 566 U.S. at 407, as the patent statute treats it as an act of automatic infringement, *see* 35 U.S.C. § 271(e)(2)(A). If the brand-name patentee brings an infringement suit within 45 days, the FDA is required to withhold approving the generic for a 30-month period. If the courts decide the matter during that period, the FDA will follow that determination; if not, the FDA may move forward on its own. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

Fourth, "Hatch-Waxman provides a special incentive for a generic to be the first to file an [ANDA] taking the paragraph IV route." *Actavis*, 133 S. Ct. at 2228-29. From the time it begins marketing its generic, the first-filer enjoys a 180-day exclusivity

period during which no other generic can compete with the brand-name drug. *See* 21 U.S.C. § 355(j)(5)(B)(iv). This exclusivity period "can prove valuable, possibly 'worth several hundred million dollars.'" *Actavis*, 133 S. Ct. at 2229 (quoting C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1579 (2006)). The right to exclusivity belongs to the first-filer alone and is nontransferable. *See* 21 U.S.C. § 355(j)(5)(D). However, Hatch-Waxman does not preclude the underlying patent-holder from marketing a brand-generic version of its drug—known as an "authorized generic"—during the 180-day exclusivity period. *See Mylan Pharm., Inc. v. FDA*, 454 F.3d 270, 276-77 (4th Cir. 2006); *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 55 (D.C. Cir. 2005); *see also King Drug*, 791 F.3d at 393; *Sanofi-Aventis v. Apotex Inc.*, 659 F.3d 1171, 1174-75 (Fed. Cir. 2011).

B

In *Actavis*, the Supreme Court addressed whether reverse-payment settlements in the Hatch-Waxman context are subject to antitrust scrutiny. The Court concluded that such settlements "can sometimes violate the antitrust laws." 133 S. Ct. at 2227. That is so, the Court held, because "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival," thus "suggest[ing] that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market." *Id.* at 2237.

Actavis rejected an approach known as the "scope of the patent" test, a near-categorical rule that "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012), *rev'd sub nom. Actavis*, 133 S. Ct. 2223. The Court concluded that it would be "incongruous to determine 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." *Actavis*, 133 S. Ct. at 2231. Instead, the Court's precedents "indicated that 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.* The Court viewed these cases as "seek[ing] to accommodate patent and antitrust policies, finding challenged terms and conditions unlawful unless patent law policy offsets the antitrust law policy strongly favoring competition." *Id.* at 2233; *see id.* at 2244 (Roberts, C.J., dissenting) ("The majority seems to think that *even if* the patent is valid, a patent holder violates the antitrust laws merely because the settlement took away some chance that his patent would be declared invalid by a court."). Finally, the Court observed, among other things, that "it is normally not necessary to litigate patent validity to answer the antitrust question (unless, perhaps, to determine whether the patent litigation is a sham)." *Id.* at 2236 (majority opinion). Such antitrust

questions are to be addressed under the traditional rule-of-reason analysis. *See id.* at 2237-38.

II

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 four individual-retailers asserting direct-purchaser claims. We will refer to these three groups of 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." There is also a fourth group of plaintiffs—several California-based pharmacists raising claims under California law—that we will refer to independently as the "*RP Healthcare* plaintiffs." In addition to suing the *Lipitor* defendants, the *RP Healthcare* plaintiffs also named additional parties as defendants whose relevance we will explore in Part V, *infra*.

1

Warner-Lambert Co. developed atorvastatin, the active ingredient in its blockbuster brand-name drug Lipitor. One of the best-selling pharmaceutical products of all time, Lipitor reduces the level of bad LDL cholesterol in the bloodstream. Warner-Lambert, in partnership with Pfizer, launched Lipitor in 1997. The two companies merged in 2002, and we will refer to them collectively as "Pfizer."

In 1987, Pfizer obtained the original patent for Lipitor. That patent—designated U.S. Patent No. 4,681,893 (the '893 Patent)—claims protection for

atorvastatin. Initially scheduled to expire in May 2006, Pfizer eventually secured extensions on the '893 Patent's term through March 24, 2010. Pfizer obtained additional, follow-on patent protection for Lipitor in December 1993, when the Patent and Trademark Office (PTO) issued U.S. Patent No. 5,273,995 (the '995 Patent). That patent claims atorvastatin calcium, the specific salt form of the active atorvastatin molecule in Lipitor. The *Lipitor* plaintiffs assert that Pfizer committed fraud with regard to the procurement and enforcement of the '995 Patent. In particular, the *Lipitor* plaintiffs 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. The '995 Patent expired on June 28, 2011. Following Lipitor's 1997 launch, Pfizer obtained five additional patents, all of which, according to the *Lipitor* plaintiffs, could not block 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 the process patents, which cannot be listed. The *Lipitor* plaintiffs allege fraud only with regard to the procurement and enforcement of the '995 Patent.

After obtaining ANDA first-filer status for generic Lipitor in August 2002, Ranbaxy notified Pfizer of its paragraph IV certifications, which contended that none of the valid patent claims that covered Lipitor would be infringed by the sale, marketing, or use of its generic. Pfizer sued Ranbaxy in the District Court for the District of Delaware within the 45-day period prescribed by Hatch-Waxman, alleging that Ranbaxy's generic would infringe the '893 and '995

Patents. Pursuant to Hatch-Waxman, the filing of Pfizer's lawsuit stayed FDA approval of Ranbaxy's ANDA for 30 months.

After a bench trial, the 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). On appeal, the Federal Circuit largely agreed, affirming 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). The Federal Circuit reversed in part, however, holding that claim 6 of the '995 Patent was invalid due to what amounted to a scrivener's error in the drafting of the claim. *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. Also in response to the Federal Circuit's ruling, Pfizer applied for a reissuance of the '995 Patent to cure the drafting error. Ranbaxy filed an objection to the reissuance with the PTO.

In July 2005, as the 30-month statutory window halting 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 Ranbaxy's, as identified in its ANDA) may be "inferior in quality" to branded Lipitor's crystalline form. *Lipitor* J.A. 1851. The *Lipitor* plaintiffs claim that this citizen petition was a sham. In May 2006, the FDA informed Pfizer that it had not yet reached a decision, citing the need for further review and analysis. The FDA denied the

petition in a 12-page decision issued on November 30, 2011.

Around the same time as their Lipitor patent dispute, Pfizer and Ranbaxy were also locked in patent-infringement litigation regarding a separate drug called Accupril. After Ranbaxy received ANDA approval and began marketing a generic Accupril product in conjunction with Teva Pharmaceuticals, Pfizer sued Ranbaxy and Teva in the District of New Jersey. On March 25, 2005, the district court issued a preliminary injunction halting Ranbaxy's sales of generic Accupril, subject to Pfizer posting a $200 million bond to cover Ranbaxy's damages in the event the injunction was improvidently granted. The Federal Circuit affirmed without prejudice to an ultimate resolution of the merits. *Pfizer Inc. v. Teva Pharm. USA, Inc.*, 429 F.3d 1364, 1383 (Fed. Cir. 2005). On June 13, 2007, in light of the disputed patent's expiration, the district court vacated the preliminary injunction. The only issues that remained contested were Pfizer's limited 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, this time claiming that Ranbaxy's generic Lipitor would infringe Pfizer's two Lipitor-related process patents. Not long after, on June 18, 2008, Pfizer and Ranbaxy publically announced that they had reached a near-global litigation settlement—which the *Lipitor* plaintiffs allege constituted an unlawful reverse payment—regarding scores of patent litigations around the world, including the Lipitor and Accupril disputes. In

particular, the settlement ended the Accupril litigation with prejudice, all domestic patent infringement litigation between Pfizer and Ranbaxy pertaining to Lipitor, and all foreign litigation between the two companies over Lipitor. As a result of the settlement, Ranbaxy received a licensed entry date of November 30, 2011 for generic Lipitor, Pfizer and Ranbaxy negotiated similar market entry dates for generic Lipitor in several foreign jurisdictions, Ranbaxy paid $1 million to Pfizer in connection with the Accupril litigation, and Pfizer's $200 million injunction bond from the Accupril litigation was cancelled. Ranbaxy also withdrew its objection to the '995 Patent's reissuance. The PTO reissued the '995 Patent in March 2009.

As part of the agreement, Ranbaxy delayed entry of its generic to March 2010, when the '983 Patent was set to expire. Due to its ANDA first-filer status, Ranbaxy was entitled to 180 days of market exclusivity. The Pfizer-Ranbaxy agreement consequently had the effect of maintaining a bottleneck over the entry of generic Lipitor from later ANDA filers. Any other would-be generic manufacturer that wanted the 180-day period to begin earlier than November 2011 would need a court to hold that all of Pfizer's Orange Book-listed patents were invalid or not infringed. Pfizer helped to forestall this possibility, the *Lipitor* plaintiffs say, through a combination of several lawsuits against subsequent ANDA filers. The FDA approved Ranbaxy's Lipitor ANDA on November 30, 2011, the day Ranbaxy's license to the unexpired Lipitor patents commenced.

2

Beginning in November 2011, the *Lipitor* direct-purchasers and end-payors, as well as the *RP Healthcare* plaintiffs, filed separate antitrust actions in various federal jurisdictions. The cases were referred to the Judicial Panel on Multidistrict Litigation (JPML) for coordination. In January 2012, the *RP Healthcare* plaintiffs withdrew their federal suit and refiled in California state court raising claims solely under California law. That suit was removed to federal court two months later.

The JPML transferred each case to the District of New Jersey, and assigned the matters to Judge Peter G. Sheridan. *See In re Lipitor Antitrust Litig.*, 856 F. Supp. 2d 1355 (J.P.M.L. 2012); *In re Lipitor Antitrust Litig.*, 2012 WL 4069565 (J.P.M.L. Aug. 3, 2012). Thereafter, the direct-purchaser and end-payor plaintiffs filed amended class action complaints; the individual-retailer plaintiffs likewise filed complaints joining the consolidated proceedings. The complaints are substantively identical, raising the same two claims: First, 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* fraud), 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 with Ranbaxy. Second, the *Lipitor* plaintiffs raise 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 reverse-payment settlement as an unlawful restraint of trade. We will refer to these claims, respectively, as the "section 2 monopolization claim" and the "section 1 restraint of trade claim."

The *RP Healthcare* plaintiffs' amended complaint raises an altogether different claim under California's antitrust statute, the Cartwright Act, Cal. Bus. & Prof. Code § 16700 *et seq*. They allege that Pfizer, Ranbaxy, a Japanese company called Daiichi Sankyo (and an affiliate), and two large pharmacies entered into a *per se* unlawful market allocation agreement regarding Lipitor. This agreement, according to the *RP Healthcare* plaintiffs, extended the life of Pfizer's Lipitor-related patents and fixed prices for Lipitor and its generic equivalents at supracompetitive levels.

The *Lipitor* defendants filed motions to dismiss all complaints under Federal Rule of Civil Procedure 12(b)(6). On October 19, 2012, the District Court denied the *RP Healthcare* plaintiffs' motion to remand to California state court, reasoning that "there may be many patent issues raised as defenses in this case which would engender federal jurisdiction." *Lipitor* J.A. 2. And on May 16, 2013, the District Court stayed proceedings pending the Supreme Court's decision in *Actavis*. In light of *Actavis*, 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 the *Lipitor* plaintiffs' complaints to the extent they were based on anything other than the reverse-payment settlement. *In re Lipitor Antitrust Litig.*, 2013 WL 4780496 (D.N.J. Sept. 5, 2013). In

particular, the District Court rejected the *Walker Process*, sham litigation, and sham FDA citizen petition aspects of the *Lipitor* plaintiffs' monopolization claims. *Id.* at *15-23. The court also granted leave to file amended complaints focused solely on the Pfizer-Ranbaxy reverse payment. *Id.* at *25-27.

The *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 for appeal the allegations that had been dismissed. For their part, the independent-retailers stated in the first paragraph of their new complaints that they were also preserving the previously dismissed claims.

In November 2013, the *Lipitor* defendants once again moved to dismiss. On September 12, 2014, the District Court dismissed with prejudice the *Lipitor* direct-purchasers' remaining argument that the Pfizer-Ranbaxy settlement was unlawful under *Actavis*. *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523 (D.N.J. 2014). The complaints of the end-payor, individual-retailer, and *RP Healthcare* plaintiffs were subsequently dismissed with prejudice in light of the District Court's opinion.

The direct-purchasers filed a motion to amend the judgment and for leave to file an amended complaint, arguing that the District Court applied a novel pleading standard. That motion was denied on March 17, 2015. *Lipitor* J.A. 151-52. 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 four 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."

1

In 1985, the PTO issued a patent for the compound venlafaxine hydrochloride. That patent was assigned to American Home Products, Wyeth's predecessor. Eight years later, in 1993, the FDA granted Wyeth approval to begin marketing Effexor, a drug used to treat major depression. Effexor's active ingredient is venlafaxine hydrochloride; the patent for that compound expired on June 13, 2008. In 1997, Wyeth introduced Effexor XR, an extended release, once-daily version. Wyeth obtained three patents for Effexor XR, all of which expired on March 20, 2017. The *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.

On December 10, 2002, Teva filed a paragraph IV certification challenging the validity of Wyeth's Effexor XR patents. As the first company to file an ANDA with a paragraph IV certification for generic Effexor XR, Teva was entitled to Hatch-Waxman's

180-day period of marketing exclusivity. 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* hearing on claim construction, Wyeth and Teva reached a settlement. Under the settlement, which the *Effexor* plaintiffs allege constitutes an unlawful reverse payment, Wyeth and Teva reached an agreed-upon entry date of July 1, 2010 for generic Effexor XR, nearly seven years before the expiration of Wyeth's patents related to that drug. Wyeth further agreed that it would not market an authorized-generic Effexor XR during Teva's 180-day exclusivity period. In return, Teva would pay Wyeth royalties for the license, beginning at 15% during the 180-day 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% thereafter for up to 80 months. Moreover, in accordance with the settlement, Wyeth granted Teva a license to begin selling generic immediate release Effexor (Effexor IR) for two years prior to the June 2008 expiration of the original venlafaxine hydrochloride patent and agreed that it would not compete with Teva's marketing of generic Effexor IR during that two-year period. Teva, for its part, would pay Wyeth 28% royalties during the first year and 20% during the second year.

Wyeth and Teva filed the settlement agreement with the district court presiding over the patent infringement litigation. In accordance with a 2002 consent decree, the Federal Trade Commission (FTC) had the right to weigh in on Wyeth's settlements and

to raise objections in advance. It offered no objection. The settlement was also submitted to the FTC and the U.S. Department of Justice pursuant to section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 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 the terms of the settlement as a consent decree and permanent injunction. *Effexor* J.A. 1298.

Following the Wyeth-Teva settlement, between April 2006 and August 2011, Wyeth brought patent infringement suits against sixteen other companies that sought to market a generic Effexor XR. All suits settled under terms stipulating that Wyeth's patents were valid and infringed.

2

Beginning in May 2011, several direct-purchasers of Effexor XR filed class action complaints in the Southern District of Mississippi challenging the lawfulness of the Wyeth-Teva settlement agreement. The cases were consolidated and, on September 21, 2011, the court transferred the action to the District of New Jersey.

After 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 of their own, four individual-retailers filed complaints, and two individual third-party payors together filed their own complaint. The complaints are substantially similar: Each alleges a monopolization claim against Wyeth under section 2

of the Sherman Act or analogous state statutes, asserting that Wyeth fraudulently induced the PTO to issue the three patents covering Effexor XR (*Walker Process* fraud), wrongfully listed those patents in the Orange Book, enforced those patents through serial sham litigation, and entered into a reverse-payment settlement with Teva. The complaints also raise a claim under section 1 of the Sherman Act or a state analogue against both Wyeth and Teva, challenging the reverse-payment settlement as an unlawful restraint of trade. As with the *Lipitor* appeals, we will refer to these claims, respectively, as the "section 2 monopolization claim" and the "section 1 restraint of trade claim." (Though otherwise similar to the other complaints, the individual third-party payors' complaint names only Wyeth and its affiliates as defendants. They also raise additional claims not relevant to these appeals.)

The *Effexor* defendants filed motions to dismiss under Rule 12(b)(6), but the District Court stayed proceedings pending the Supreme Court's decision in *Actavis*. After *Actavis* was issued, 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.

On October 6, 2014, the District Court granted in part and denied in part the *Effexor* defendants' motions to dismiss. *In re Effexor XR Antitrust Litig.*, 2014 WL 4988410 (D.N.J. Oct. 6, 2014). It rejected the *Effexor* plaintiffs' challenges to the Wyeth-Teva reverse-payment settlement and dismissed with prejudice the section 1 restraint of trade claims. *Id.* at

*19-24. However, the District Court declined to dismiss the *Effexor* plaintiffs' *Walker Process* allegations against Wyeth. *Id.* at *24-26. At the *Effexor* plaintiffs' request, the court granted final judgment on the restraint of trade claims under Federal Rule of Civil Procedure 54(b).

These timely appeals followed. On February 27, 2015, the *Effexor* defendants moved this Court to transfer the *Effexor* appeals to the Federal Circuit on the ground that the *Effexor* plaintiffs' complaints assert claims that arise under patent law. We denied the motion without prejudice to the *Effexor* defendants raising the jurisdictional argument in their merits briefs.

III

The District Court possessed subject-matter jurisdiction, at a minimum, under the following statutes: With respect to the *Lipitor* and *Effexor* direct-purchasers and independent-retailers, the District Court had jurisdiction under 28 U.S.C. §§ 1331 and 1337(a). With respect to the *Lipitor* and *Effexor* end-payors, the District Court had jurisdiction under 28 U.S.C. § 1332(d). And with respect to the *Effexor* independent third-party payors, the District Court had jurisdiction under 28 U.S.C. § 1332(a)(1) and (3).

The *Lipitor* and *Effexor* defendants contend that the District Court also had jurisdiction over each of these cases under 28 U.S.C. § 1338(a), thus necessitating transfer of these appeals to the Federal Circuit. The *RP Healthcare* plaintiffs, for their part, argue that the District Court did not possess subject-

matter jurisdiction at all; they say their case properly belongs in California state court.

Though our jurisdiction to reach the merits of these appeals is disputed, "it is familiar law that a federal court always has jurisdiction to determine its own jurisdiction." *United States v. Ruiz*, 536 U.S. 622, 628 (2002); *see also Bender v. Williamsport Area Sch. Dist.*, 475 U.S. 534, 542 (1986); *Brown v. Keene*, 33 U.S. (8 Pet.) 112, 116 (1834). We therefore, for purposes of this opinion, have jurisdiction under 28 U.S.C. § 1291. Our review of the jurisdictional questions at issue is plenary. *In re NFL Players Concussion Injury Litig.*, 775 F.3d 570, 576 (3d Cir. 2014).

IV

Like all other federal courts, we are a court of limited jurisdiction, possessing "only that power authorized by Constitution and statute." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994). As an Article III court established by Congress, our appellate jurisdiction is "purely statutory." *Heike v. United States*, 217 U.S. 423, 428 (1910).

The United States Courts of Appeals have general appellate jurisdiction over "appeals from all final decisions of the district courts of the United States." 28 U.S.C. § 1291. But carved out of § 1291's jurisdictional grant is the Court of Appeals for the Federal Circuit. Congress vested that court with "exclusive jurisdiction of an appeal from a final decision of a district court of the United States . . . in any civil action *arising under* . . . any Act of Congress relating to patents." *Id.* § 1295(a)(1) (emphasis added). The federal district courts, in turn, "have original

jurisdiction of any civil action arising under any Act of Congress relating to patents." *Id.* § 1338(a). "Thus, the Federal Circuit's jurisdiction is fixed with reference to that of the district court, and turns on whether the action arises under federal patent law." *Holmes Grp., Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 829 (2002). So if the District Court here had jurisdiction over at least one claim in a particular case under § 1338(a), the Federal Circuit has exclusive jurisdiction of that appeal. *See Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1342 (Fed. Cir. 2003); *see also* 19 James Wm. Moore & George C. Pratt, *Moore's Federal Practice* § 208.10[2], p. 208-16 (3d ed. 2017) ("The minimum jurisdictional requirement is the existence of at least one claim under the patent . . . statutes, and in a mixed case, the Federal Circuit has jurisdiction to decide all of the issues involved in the appeal." (footnote omitted)). In that circumstance, we would lack jurisdiction and be required to transfer these appeals to the Federal Circuit. *See* 28 U.S.C. § 1631; *In re Arunchalam*, 812 F.3d 290, 293-94 (3d Cir. 2016) (per curiam).

The discussion that follows applies to both sets of appeals. Consequently, unless otherwise indicated, we will refer to the *Lipitor* and *Effexor* plaintiffs collectively as the "plaintiffs" and the *Lipitor* and *Effexor* defendants collectively as the "defendants."

A

The Supreme Court's pathmarking decision addressing the Federal Circuit's patent-law jurisdiction is *Christianson v. Colt Industries Operating Corp.*, 486 U.S. 800 (1986). At the time, the Federal Circuit's jurisdictional statute vested that

court with "exclusive jurisdiction of an appeal from a final decision of a district court of the United States . . . if the decision of a district court was based, in whole or in part, on [28 U.S.C.] § 1338." 28 U.S.C. § 1295(a)(1). Then, as now, § 1338(a) granted the district courts "original jurisdiction of any civil action arising under any Act of Congress relating to patents." Section 1338(a) uses the same operative language as 28 U.S.C. § 1331, the statute that gives the district courts "original jurisdiction of all civil actions *arising under* the Constitution, laws, or treaties of the United States." (Emphasis added.).

Christianson held that "[l]inguistic consistency" requires that courts apply the same jurisdictional test to determine whether a case arises under § 1331 as it would under § 1338(a). 486 U.S. at 808. Under § 1338(a), then, jurisdiction extends "only to those cases in which a well-pleaded complaint establishes either that federal patent law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims." *Id.* at 809. As in the § 1331 context, the determination whether a claim "arises under" patent law must be made in accordance with the time-honored well-pleaded-complaint rule. And as "appropriately adapted to § 1338(a)," that rule provides that the answer to whether a claim "arises under" patent law "must be determined from what necessarily appears in the plaintiff's statement of his own claim in the bill or declaration, unaided by anything alleged in anticipation or avoidance of defenses which it is thought the defendant may interpose." *Id.* (quoting

Franchise Tax Bd. of Cal. v. Constr. Laborers Vacation Trust, 463 U.S. 1, 10 (1983)).

For those cases in which federal patent law does not create the cause of action, it is not "necessarily sufficient that a well-pleaded claim alleges a single theory under which resolution of a patent-law question is essential." *Id.* at 810. Rather, if "'on the face of a well-pleaded complaint there are . . . reasons completely unrelated to the provisions and purposes of [the patent laws] why the [plaintiff] may or may not be entitled to the relief it seeks,' then the claim does not 'arise under' those laws." *Id.* (alterations in original) (quoting *Franchise Tax Bd.*, 463 U.S. at 26). "Thus," *Christianson* explained, "a claim supported by alternative theories in the complaint may not form the basis for § 1338(a) jurisdiction unless patent law is essential to each of those theories." *Id.*

The complaint in *Christianson* contained an antitrust count that the Court understood as raising a monopolization claim under section 2 of the Sherman Act and a group-boycott claim under section 1. *See id.* Even though the claims included allegations of patent invalidity, the Court held that the Federal Circuit lacked jurisdiction because the "patent-law issue, while arguably necessary to at least one theory under each claim, [was] not necessary to the overall success of either claim." *Id.*

As to the complaint's section 2 monopolization claim, the Court first identified the "thrust" of the allegations, namely, that Colt, the defendant, "embarked on a course of conduct to illegally extend its monopoly position with respect to the described patents and to prevent" plaintiffs from competing. *Id.*

But because the well-pleaded-complaint rule "focuses on claims, not theories," the Court emphasized that "just because an element that is essential to a particular theory might be governed by federal patent law does not mean that the entire monopolization claim 'arises under' patent law." *Id.* at 811. One such theory involved allegations that certain Colt trade secrets were not protected under state law because their underlying patents were invalid. But after parsing the complaint, the Court observed that this monopolization theory was "only one of several, and the only one for which the patent-law issue is even arguably essential." *Id.* Because there were "'reasons completely unrelated to the provisions and purposes' of federal patent law why [the plaintiffs] 'may or may not be entitled to the relief they [sought]' under their monopolization claim, the claim [did] not 'arise under' patent law." *Id.* at 812 (quoting *Franchise Tax Bd.*, 463 U.S. at 26).

The same result obtained with regard to the plaintiffs' section 1 group-boycott claim. That claim involved allegations that Colt engaged in a group-boycott to protect its trade secrets. And like the section 2 monopolization claim, one theory of recovery involved assertions that Colt's patents protecting its trade secrets were invalid. "Whether or not the patent-law issue was an 'essential' element of that group-boycott *theory*," the Court noted, plaintiffs "could have supported their group-boycott *claim* with any of several theories having nothing to do with the validity of Colt's patents." *Id.* at 813. Instead, "the appearance on the complaint's face of an alternative, non-patent theory compel[led] the conclusion that the group-boycott claim [did] not 'arise under' patent law." *Id.*

Four working principles underlie the Court's decision in *Christianson*. First, whether a claim "arises under" federal patent law is made by reference to the well-pleaded complaint. *See Holmes Grp.*, 535 U.S. at 829-30. Second, for jurisdictional purposes, regardless of how a complaint labels its claims or counts, courts are to look to the complaint and its allegations as a whole to identify the plaintiff's claims and any theories undergirding those claims. Third, in the antitrust context, courts must attend to the thrust of the plaintiff's allegations and then determine the theories that explain why certain alleged conduct was anticompetitive. And finally, after distinguishing between claims and theories, courts then must ascertain whether each theory supporting a claim necessarily requires the resolution of a substantial question of patent law. If one theory does not, the Federal Circuit lacks appellate jurisdiction. *See ClearPlay, Inc. v. Abecassis*, 602 F.3d 1364, 1369 (Fed. Cir. 2010) ("*Christianson* embraces a distinctly non-holistic approach to 'arising under' jurisdiction. It is not enough that patent law issues are in the air. Instead, resolution of a patent law issue must be necessary to *every theory of relief* under at least one claim in the plaintiff's complaint." (emphasis added)).

B

Applying these principles, we conclude that the actions brought by the *Lipitor* and *Effexor* plaintiffs do not "arise under" patent law. We note at the outset a clear and undisputed aspect of our jurisdictional inquiry. Federal and state *antitrust* law, not federal patent law, creates plaintiffs' claims. This case, like *Christianson* itself, turns on the second head of

"arising under" jurisdiction. And so we must decide whether plaintiffs' well-pleaded complaints state at least one claim upon which their "right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims." *Christianson*, 486 U.S. at 809.

Defendants do not argue that plaintiffs' section 1 restraint of trade claims arise under patent law. Those claims relate only to the Pfizer-Ranbaxy and Wyeth-Teva reverse-payment settlements. Defendants instead home in on plaintiffs' section 2 monopolization claims. Recall that the thrust of those claims is that Pfizer and Wyeth each engaged in an overall scheme to monopolize the markets for their respective branded Lipitor and Effexor XR drugs. Those schemes, plaintiffs allege, were furthered in part by the companies' fraudulent procurement and enforcement of certain patents relating to the drugs. But the schemes were also furthered by the reverse-payment settlements (and, in the *Lipitor* appeals, the filing of a sham FDA citizen petition).

The fraudulent procurement of a patent—known as *Walker Process* fraud, *see Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965) (recognizing that a patentee's knowing and willful misrepresentation of facts to the PTO can strip the patentee of immunity under the antitrust laws)—requires a plaintiff to show, among other things, that the patentee committed fraud before the PTO, that the fraud caused the patent to issue, and that the patentee enforced the fraudulently procured patent, *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 375 F.3d 1341,

1355 (Fed. Cir. 2004), *rev'd on other grounds*, 546 U.S. 394 (2006). *Walker Process* fraud has for some time been considered by courts to present a substantial question of patent law. *See In re DDAVP Antitrust Litig.*, 585 F.3d 677, 685 (2d Cir. 2009); *In re Ciprofloxacin Antitrust Litig.*, 544 F.3d 1323, 1330 n.8 (Fed. Cir. 2008) ("[T]he determination of fraud before the PTO necessarily involves a substantial question of patent law."); *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998) (en banc in relevant part) ("[W]hether conduct in procuring or enforcing a patent is sufficient to strip a patentee of its immunity from the antitrust laws is to be decided as a question of Federal Circuit law."). And to the extent plaintiffs' sham litigation and false Orange Book listing theories depend on a successful showing of *Walker Process* fraud, they too could present substantial questions of patent law. *See DDAVP*, 585 F.3d at 685; *Nobelpharma*, 141 F.3d at 1071-72. We recognize as well that the substantiality of these theories may be open to debate following *Gunn v. Minton*, 133 S. Ct. 1059 (2013). That case held, in the context of a state legal malpractice claim, that hypothetical, backward-looking, case-within-a-case questions of patent law that do not change the real-world result of prior federal patent litigation do not present a substantial patent-law issue. *Id.* at 1067-68. We need not definitively address the substantiality of plaintiffs' *Walker Process*, sham litigation, and false Orange Book listing theories in light of *Gunn*. For even assuming that these theories do present substantial questions of patent law, plaintiffs' right to relief on their section 2 monopolization claims does not depend upon them.

Here, plaintiffs could obtain relief on their section 2 monopolization claims by prevailing on an alternative, non-patent-law theory, namely, that Pfizer and Wyeth monopolized the market in their respective branded drugs by engaging in a reverse-payment settlement. And in *Lipitor* the plaintiffs could also prevail on the additional non-patent law theory that Pfizer filed a sham citizen petition with the FDA. *See DDAVP*, 585 F.3d at 686 ("[W]hether [a FDA] petition was a sham is an issue independent of patent law."); *see also Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 59 (2d Cir. 2016).

Actavis teaches that reverse-payment antitrust claims do not present a question of patent law. *See* 133 S. Ct. at 2236-37 ("[T]he size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself."). The Court did acknowledge, however, that questions of patent validity may still arise from time to time. *See id.* at 2236 ("[I]t is normally not necessary to litigate patent validity to answer the antitrust question (unless, perhaps, to determine whether the patent litigation is a sham)."). But even where patent-law questions are presented, it does not follow that patent law is necessary for relief on every theory of liability supporting an antitrust claim. In the present appeals, "[s]ince there are reasons completely unrelated to the provisions and purposes of federal patent law why [plaintiffs] may or may not be entitled to the relief they seek under their monopolization claim, the claim does not 'arise under' federal patent law." *Christianson*, 486 U.S. at 812 (brackets, citation, and some internal quotation marks omitted). These

considerations lead us to conclude that the presence of non-patent-law theories of liability supporting the *Lipitor* and *Effexor* plaintiffs' monopolization claims vests jurisdiction over their appeals in this Court, not the Federal Circuit.

C

Defendants do not quarrel with any of the principles that guide our analysis. They instead assert that plaintiffs' reverse-payment settlement allegations constitute monopolization claims separate and apart from the *Walker Process* fraud, sham litigation, and false Orange Book listing theories. The allegations of fraudulent procurement and enforcement of the Lipitor and Effexor patents, in defendants' view, involve distinct anticompetitive conduct that occurred years before the reverse-payment settlements (and, in *Lipitor*, the sham FDA citizen petition).

We reject this divide-and-conquer approach to "arising under" jurisdiction. Defendants in effect ask that we rewrite plaintiffs' complaints, which plead patent-law related theories as aspects of an overall monopolistic scheme. A monopolization claim under section 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power. *LePage's Inc. v. 3M*, 324 F.2d 141, 146 (3d Cir. 2003) (en banc) (citing *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966)). But to be condemned as exclusionary, a monopolist's anticompetitive conduct must have an anticompetitive effect. "The relevant inquiry," we have held, "is the anticompetitive effect of [a defendant's] exclusionary practices considered

together." *Id.* at 162. Thus, "courts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation." *Id.* (citing *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962)); *see id.* ("[I]t would not be proper to focus on specific individual acts of an accused monopolist while refusing to *consider their overall combined effect* . . . . We are dealing with what has been called the 'synergistic effect' of the mixture of the elements." (alterations in original) (internal quotation marks omitted)).

Defendants contend that the patent-law theories of monopolization liability in plaintiffs' complaints are distinct "claims." But that runs headlong into traditional antitrust principles. Plaintiffs' monopolization claims encompass the totality of the allegedly anticompetitive conduct—from defendants' fraudulent procurement and enforcement of their patents on through to the reverse-payment settlements. We will not permit the defendants to commandeer these complaints, of which plaintiffs are master.

Nor do we accept the argument that certain statements made by the *Effexor* plaintiffs in the District Court somehow estop them from arguing that the patent-law allegations constitute theories of relief. Principles of estoppel cannot confer jurisdiction where it otherwise does not exist. *See Ins. Corp. of Ireland, Ltd. v. Compagnie des Bauxites de Guinee*, 456 U.S. 694, 702 (1982); *Semper v. Gomez*, 747 F.3d 229, 247 (3d Cir. 2014). And in any event, our jurisdictional inquiry is confined solely to the plaintiffs' well-pleaded complaints, not subsequent events. *See Christianson*,

486 U.S. at 814 ("Since the district court's jurisdiction is determined by reference to the well-pleaded complaint, not the well-tried case, the referent for the Federal Circuit's jurisdiction must be the same.").

D

Our jurisdictional holding is consistent, we think, with two of the Second Circuit's pre-*Actavis* reverse-payment cases. In one case, the court transferred an appeal to the Federal Circuit and retained jurisdiction over others. The Second Circuit explained: "The indirect purchaser plaintiffs amended their complaint to add state-law, *Walker Process* antitrust claims . . . . Because the *Walker Process* claims are preempted by patent law, we transferred the indirect purchaser plaintiffs' appeal to the Federal Circuit, while retaining jurisdiction over the direct purchaser plaintiffs' appeals." *Arkansas Carpenters Health & Welfare v. Bayer AG*, 604 F.3d 98, 103 n.10 (2d Cir. 2010); *see In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 2007 U.S. App. LEXIS 30732, at *1 (2d Cir. Nov. 7, 2007) (order transferring indirect purchaser plaintiffs' appeal to the Federal Circuit). The Second Circuit and the Federal Circuit therefore each independently assessed the lawfulness of the same reverse-payment settlement. *See Arkansas Carpenters*, 604 F.3d at 103 & n.10; *Ciprofloxacin*, 544 F.3d at 1333. But unlike the *Lipitor* and *Effexor* appeals before us, the appeal transferred from the Second Circuit to the Federal Circuit involved stand-alone *Walker Process* claims. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 544 (E.D.N.Y. 2005) ("[I]ndirect plaintiffs' Count V [raising state-law *Walker Process* claims] not only

arises out of patent law, but *rests entirely on patent law*" (emphasis added)), *aff'd*, 544 F.3d 1232 (Fed. Cir. 2008), *and aff'd sub nom. Arkansas Carpenters*, 604 F.3d 98.

And in *DDAVP*, 585 F.3d 677, the Second Circuit retained jurisdiction over a reverse-payment case. The *DDAVP* plaintiffs alleged four theories of liability in a Sherman Act monopolization claim against a branded drug manufacturer based upon theories nearly identical to those the *Lipitor* and *Effexor* plaintiffs bring against Pfizer and Wyeth: *Walker Process* fraud, sham Orange Book listing, sham litigation against generic competitors, and a sham FDA citizen petition. *Id.* at 685. The Second Circuit acknowledged that, while the plaintiffs' first three theories turned on substantial questions of patent law, the fourth theory—the filing of a sham FDA citizen petition—did not. *Id.* at 685-86. Because the citizen-petition theory did not raise any question of patent law, the court exercised jurisdiction over the entirety of the plaintiffs' monopolization claim. *Id.* at 686.

A final, prudential consideration tips in favor of our Court exercising jurisdiction over these appeals. Under the Federal Circuit's choice-of-law rules, it would apply *Third Circuit* antitrust jurisprudence—including our recent decision in *King Drug*, 791 F.3d 388—when reviewing whether plaintiffs' complaints state plausible claims for relief under *Actavis*. *See Nobelpharma*, 141 F.3d at 1059 (Federal Circuit "appl[ies] the law of the appropriate regional circuit to issues involving other elements of antitrust law such as relevant market, market power, damages, etc., as those issues are not unique to patent law"). Now that

the Supreme Court has confirmed that it is usually unnecessary to litigate these patent-law issues to determine antitrust liability, the development of post-*Actavis* jurisprudence is, in the ordinary case, left to the regional Courts of Appeals.

Christianson establishes that not all cases involving patent law fall within the Federal Circuit's jurisdiction. Congress has left a role for our Court to play in adjudicating patent-law issues over which we possess jurisdiction. Our holding requires us to fulfill that role in these appeals.

V

The appeal of the *RP Healthcare* plaintiffs requires a separate jurisdictional inquiry. That case was filed by a group of California pharmacists in the Superior Court of California, Sonoma County, but Pfizer removed it to federal district court, citing federal-question jurisdiction under 28 U.S.C. § 1331 and patent-law jurisdiction under § 1338(a). *RP Healthcare* J.A. 26-27; *see* 28 U.S.C. § 1441(a). In denying the *RP Healthcare* plaintiffs' remand motion, the District Court reasoned that "there may be patent issues raised as defenses in this case which would engender jurisdiction." *Lipitor* J.A. 2. We disagree. "Under the well-pleaded complaint rule . . . whether a claim 'arises under' patent law 'must be determined from what necessarily appears in the plaintiff's statement of his own claim in the bill or declaration, unaided by anything alleged in anticipation or avoidance of defenses which it is thought the defendant may interpose.'" *Christianson*, 486 U.S. at 809 (quoting *Franchise Tax Bd.*, 463 U.S. at 8); *see Louisville & Nashville R.R. Co. v. Mottley*, 211 U.S.

149 (1914); *N.J. Carpenters v. Tishman Constr. Corp. of N.J.*, 760 F.3d 297, 302 (3d Cir. 2014) ("The existence or expectation of a federal defense is insufficient to confer federal jurisdiction.").

Pfizer and Ranbaxy nevertheless argue that the *RP Healthcare* case belongs in federal court because it "arises under" patent law pursuant to § 1338(a). They also say the District Court possessed diversity jurisdiction before final judgment entered as a result of the *RP Healthcare* plaintiffs' voluntary dismissal of the only two non-diverse defendants. We reject the first argument but find the record insufficient to decide the second.

A

The *RP Healthcare* plaintiffs do not challenge the Pfizer-Ranbaxy settlement as an unlawful reverse payment. Rather, they allege that the settlement constitutes a *per se* unlawful market allocation agreement in violation of California's Cartwright Act. Two years after *Actavis*, the California Supreme Court held that reverse-payment settlements can be challenged under that Act and are to be analyzed under a structured rule-of-reason. *In re Cipro Cases I & II*, 348 P.3d 845 (Cal. 2015). But the California court has yet to recognize the kind of *per se* market allocation claim proposed by the *RP Healthcare* plaintiffs.

To the extent their claim exists under California law (a question we do not decide), as pled by the *RP Healthcare* plaintiffs that claim would not "arise under" federal patent law. Pfizer and Ranbaxy latch onto a single sentence in the *RP Healthcare* plaintiffs' state court complaint making an express allegation of

Walker Process fraud. *See RP Healthcare* Pls.' Compl. ¶ 114, *RP Healthcare* J.A. 57 ("The Agreement between Defendants extending the length of the Lipitor patents constitutes fraudulent procurement and enforcement of a patent . . . ." (citing *Walker Process*, 382 U.S. 172)). But like the complaints of the *Lipitor* and *Effexor* plaintiffs discussed above, we conclude that there are alternative non-patent-law theories through which the *RP Healthcare* plaintiffs could prevail on their state-law antitrust claim. *See Christianson*, 486 U.S. at 809-10. The *RP Healthcare* plaintiffs' complaint includes theories of liability other than *Walker Process* fraud. *See id.* ¶ 105, *RP Healthcare* J.A. 56 ("The Agreements between the Defendants, which artificially extended the length of the Lipitor-related patents, *allocated markets between them, artificially postponed price reductions, and restrained trade in the provision of Lipitor and its generic alternatives*, are a violation of the Cartwright Act . . . ." (emphasis added)). Thus, the *RP Healthcare* plaintiffs could obtain relief on the market allocation claim all without addressing the validity of Pfizer's Lipitor patents. The oblique mention of *Walker Process* fraud in their complaint does not land this case in the "special and small category" of state-law claims "in which arising under jurisdiction still lies." *Gunn*, 133 S. Ct. at 1064 (internal quotation marks omitted).

B

While the District Court did not possess jurisdiction over the *RP Healthcare* case under § 1338(a), the possibility exists that the court had diversity jurisdiction by the time it entered final

judgment. Article III of the Constitution provides that "[t]he judicial Power [of the United States] shall extend . . . to Controversies . . . between Citizens of different States; . . . and between a State, or the Citizens thereof, and foreign States, Citizens or Subjects." Beginning with the Judiciary Act of 1789, ch. 20, § 11, 1 Stat. 78, Congress has authorized the federal courts to exercise jurisdiction based on the parties' diversity of citizenship. In its current form, the diversity statute vests in the federal district courts original jurisdiction of "all civil actions where the matter in controversy exceeds the sum or value of $75,000, . . . and is between . . . citizens of different States and in which citizens or subjects of a foreign state are additional parties." 28 U.S.C. § 1132(a)(3). Since *Strawbridge v. Curtis*, 7 U.S. (3 Cranch) 267 (1806), the Supreme Court has interpreted the diversity statute to require "complete diversity" of citizenship: "[i]n a case with multiple plaintiffs and multiple defendants, the presence in the action of a single plaintiff from the same State as a single defendant deprives the district court of original diversity jurisdiction over the entire action," *Exxon Mobil Corp. v. Allahpattah Servs., Inc.*, 545 U.S. 546, 553 (2005).

Though "[i]t had long been the case that 'the jurisdiction of the court depends upon the state of things at the time of the action brought,'" *Grupo Dataflux v. Atlas Global Grp., L.P.*, 541 U.S. 567, 570 (2004) (quoting *Mollan v. Torrance*, 22 U.S. (9 Wheat.) 537, 539 (1824)), this time-of-filing rule is subject to a few discrete exceptions. One such "method of curing a jurisdictional defect [that has] long been an exception to the time-of-filing rule" is when a jurisdictional

defect is "cured by the dismissal of the party that had destroyed diversity." *Id.* at 572. As the Supreme Court recognized in *Caterpillar Inc. v. Lewis*, "a district court's error in failing to remand a case improperly removed is not fatal to the ensuing adjudication if federal jurisdictional requirements are met at the time judgment is entered." 529 U.S. 61, 64 (1996).

Pfizer and Ranbaxy urge us to apply that exception here. After all, the *RP Healthcare* plaintiffs voluntarily dismissed the only two non-diverse defendants prior to entry of final judgment. Before this Court, however, the parties expressed uncertainty regarding the state of the record as it pertains to the citizenship of two parties—defendants Pfizer Ireland Pharmaceuticals and Warner-Lambert Co., LLC, both unincorporated entities and wholly owned subsidiaries of Pfizer. *See Lipitor* Tr. of Oral Arg. 23-24, 44-47; *RP Healthcare* Pls.' Reply Br. 17-18. Like all unincorporated entities, partnerships and limited liability companies (LLCs) bear the citizenship of each of their members. *See Americold Realty Trust v. ConAgra Foods, Inc.*, 136 S. Ct. 1012, 1016-17 (2016); *Carden v. Arcoma Assocs.*, 494 U.S. 185, 195-96 (1990); *Zambelli Fireworks Mfg. Co. v. Wood*, 592 F.3d 412, 420 (3d Cir. 2010).

As the parties asserting diversity jurisdiction, Pfizer and Ranbaxy bear the burden of proving diversity of citizenship by a preponderance of the evidence. *See Freidrich v. Davis*, 767 F.3d 374, 377 (3d Cir. 2014). Since this case was removed to federal court, diversity must have existed both at the time the *RP Healthcare* plaintiffs' state court complaint was filed and at the time of removal. *See Pullman Co. v.*

Jenkins, 305 U.S. 534, 537 (1939); *Johnson v. SmithKline Beecham Corp.*, 724 F.3d 337, 346 (3d Cir. 2013). But no changes in citizenship after the time of filing (and, as relevant here, the time of removal) can create or destroy diversity. *See Grupo Dataflux*, 541 U.S. at 574-75; *Conolly v. Taylor*, 27 U.S. (2 Pet.) 556, 565 (1829).

In calling for diversity jurisdiction Pfizer and Ranbaxy made no effort before this Court or the District Court to demonstrate that complete diversity was in fact present before final judgment. That is especially puzzling, since an unincorporated association "is in the best position to ascertain its own membership," *Lincoln Benefit Life Co. v. AEI Life, LLC*, 800 F.3d 99, 108 (3d Cir. 2015), and the entities in question are Pfizer subsidiaries. While we have previously observed that, "where the unincorporated association is the proponent of diversity jurisdiction, there is no reason to excuse it of its obligation to plead the citizenship of each of its members," *id.* at 108 n.36, that statement was made in the context of an unincorporated association asserting diversity *as a plaintiff*. It does not address the situation in this case, where the removing parties are asserting diversity as a result of the plaintiffs' own voluntary post-removal actions. We therefore consider it premature to direct that the *RP Healthcare* case be sent back to California state court. Rather, we will remand the matter to the District Court to give the parties the opportunity to clarify the record with regard to diversity of citizenship. The District Court should also ensure that the amount in controversy alleged in the *RP Healthcare* plaintiffs' state-court complaint exceeds

$75,000. *See* 28 U.S.C. § 1332(a); *Angus v. Shiley*, 989 F.2d 142, 145-46 (3d Cir. 1993).

Our remand applies as well to the Daiichi Sankyo defendants. Before the District Court, they moved to dismiss the *RP Healthcare* plaintiffs' complaint on three grounds: lack of Article III standing, lack of personal jurisdiction, and failure to state a claim upon which relief can be granted. The District Court dismissed the Daiichi Sankyo defendants under Rule 12(b)(6) for failure to state a plausible claim. *Lipitor* J.A. 65, 3543-44. But "a federal court generally may not rule on the merits of a case without first determining that it has jurisdiction over the category of claim in suit (subject-matter jurisdiction) and the parties (personal jurisdiction)." *Sinochem Int'l Co. v. Malaysia Int'l Shipping Corp.*, 549 U.S. 422, 430-31 (2007); *see Steel Co. v. Citizens for Better Environment*, 523 U.S. 83, 93-102 (1998). The District Court should have resolved the standing and personal jurisdictional arguments before dismissing Daiichi Sankyo on the merits. In the event that the District Court concludes on remand that the parties were completely diverse at the time of judgment, it should address those arguments to determine whether it had the power to reach the merits of the *RP Healthcare* plaintiffs' claim against Daiichi Sankyo.

It is a common practice among the Courts of Appeals to retain jurisdiction over an appeal while making a limited remand for additional findings or explanations. Basic illustrations include a "controlled remand to determine whether there is federal subject-matter jurisdiction," as well as "remands to determine justiciability or personal jurisdiction." 16 Charles

Alan Wright, Arthur R. Miller, & Edward H. Cooper, *Federal Practice & Procedure* § 3937.1, pp. 847-48 (3d ed. 2012) (footnote omitted); *see, e.g.*, *Friery v. Los Angeles Unified Sch. Dist.*, 448 F.3d 1146, 1150 (9th Cir. 2006) (limited remand for Article III standing determination); *Fort Knox Music Inc. v. Baptiste*, 203 F.3d 193, 197 (2d Cir. 2000) (limited remand for personal jurisdiction determination); *Jason's Foods, Inc. v. Peter Eckrich & Sons, Inc.*, 768 F.2d 189, 190-91 (7th Cir. 1985) (limited remand for diversity-of-citizenship determination). We will follow that practice and retain jurisdiction over the *RP Healthcare* plaintiffs' appeal. It is expected that the District Court and the parties will move expeditiously on remand to resolve the diversity-of-citizenship issue and, if necessary, jurisdiction over the Daiichi Sankyo defendants.

VI

For the reasons stated, we conclude that, with a single exception, we have jurisdiction to reach the merits of these appeals. In one of the *Lipitor* appeals, *RP Healthcare, Inc. v. Pfizer, Inc.*, No. 14-4632, because it is unclear whether the District Court had jurisdiction at the time judgment was entered, we will order a limited remand for the parties to clarify the record in this regard. Any further proceedings in these appeals will be heard by this panel.

Appendix C

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

No. 11-5479 (PGS) (LHG)

IN RE: EFFEXOR XR ANTITRUST LITIGATION

Filed: October 6, 2014

MEMORANDUM

SHERIDAN, U.S.D.J.

This matter comes before the Court on Defendants Wyeth LLC, Wyeth Pharmaceuticals, Inc., Wyeth-Whitehall Pharmaceuticals LLC, and Wyeth Pharmaceuticals Company's (collectively, "Wyeth Defendants" or "Wyeth") and Teva Pharmaceuticals USA, Inc., and Teva Pharmaceuticals Industries Ltd.'s (collectively, "Teva Defendants" or "Teva") Motion to Dismiss Plaintiffs Professional Drug Company, Inc., Rochester Drug Co-Operative, Inc., Stephen L. LaFrance Holdings, Inc., Stephen L. LaFrance Pharmacy, Inc. d/b/a SAJ Distributors, and Uniondale Chemists, Inc.'s (collectively, "Direct Purchaser Class Plaintiffs") Second Amended Consolidated Class Action Complaint for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6) (ECF Nos. 136, 138, 305). Direct Purchaser Class Plaintiffs allege that Defendant Wyeth engaged in an anticompetitive

scheme to prevent and delay the approval and marketing of generic versions of its antidepressant drug Effexor XR, an extended release version of the compound venlafaxine hydrochloride, in violation of the Sherman Antitrust Act, 15 U.S.C. §§ 1-2. Specifically, Plaintiffs allege that Wyeth: (1) fraudulently procured three patents for extended release formulations of venlafaxine hydrochloride; (2) wrongfully listed those patents in the FDA Orange Book as covering Effexor XR; (3) engaged in sham litigation to block and delay multiple generic companies from entering the generic Effexor XR market; (4) entered into an illegal horizontal market-allocation and price-fixing reverse settlement agreement with Defendant Teva through which Wyeth paid Teva value worth over $500 million in exchange for Teva's agreement not to market its own generic version of Effexor XR until an agreed-upon entry date; and (5) negotiated settlements with subsequent generic applicants for the sole purpose of preserving and protecting its alleged monopoly and market-division agreement with Teva. The Court held oral argument in this matter on September 10, 2013, April 3, 2014 and June 5, 2014. For the reasons set forth herein, Defendants' Motion to Dismiss is granted in part and denied in part.

I. BACKGROUND

A. Parties

1. Plaintiffs

Plaintiff Professional Drug Company, Inc. ("Professional Drug") is a corporation organized under the laws of the State of Mississippi with its principal place of business in Biloxi, Mississippi. (Direct

Purchaser Class Pls.' Second Am. Consolidated Class Action Complaint ("Second Am. Compl.") at ¶ 17). It purchased Effexor XR directly from Wyeth during the class period. (*Id*.).

Plaintiff Rochester Drug Co-Operative, Inc. ("RDC") is a stock corporation organized under the laws of the State of New York with its principal place of business in Rochester, New York. (*Id*. at ¶ 18). It purchased Effexor XR directly from Wyeth, and generic Effexor XR directly from Teva, during the class period. (*Id*.).

Plaintiff Stephen L. LaFrance Holdings, Inc. is a holding company with interests in retail and wholesale distribution whose corporate office is located in Pine Bluff, Arkansas. (*Id*. at ¶ 19.).Plaintiff Stephen L. LaFrance Pharmacy, Inc. d/b/a SAJ Distributors (collectively with Stephen L. LaFrance Holdings, Inc., "LaFrance") is a wholly owned subsidiary of Stephen L. LaFrance Holdings, Inc. which operates as its distribution company. (*Id*.). Its corporate office is similarly located in Pine Bluff, Arkansas. (*Id*.). LaFrance is the assignee of McKesson Corporation which purchased Effexor XR directly from Wyeth during the class period. (*Id*.).

Plaintiff Uniondale Chemists, Inc. is a retail pharmacy located in Uniondale, New York. (*Id*. at ¶ 20). Uniondale Chemists is the assignee of QK Healthcare, Inc. which purchased Effexor XR directly from Wyeth during the class period. (*Id*.).

2. Defendants

Defendant Wyeth—a/k/a Wyeth LLC, f/k/a Wyeth, Inc., f/k/a American Home Products—is a corporation organized under the laws of the State of Delaware

with its principal place of business in Madison, New Jersey. (*Id.* at ¶ 21). It operates as a wholly owned subsidiary of Pfizer. (*Id.*).

Defendant Wyeth Pharmaceuticals, Inc. is a corporation organized under the laws of the State of Delaware with its principal place of business in Collegeville, Pennsylvania. (*Id.* at ¶ 22.). Wyeth Pharmaceuticals, Inc. is a member of Wyeth Pharmaceuticals Division and is a wholly owned subsidiary of Wyeth. (*Id.*).

Defendant Wyeth-Whitehall Pharmaceuticals ("Wyeth-Whitehall") is a corporation organized under the laws of the Commonwealth of Puerto Rico with its principal place of business in Guayama, Puerto Rico. (*Id.* at ¶ 23.). Wyeth-Whitehall is in the business of pharmaceutical preparation and is a subsidiary of Wyeth. (*Id.*).

Defendant Wyeth Pharmaceuticals Company ("WPC") is a corporation organized under the laws of the Commonwealth of Puerto Rico with its principal place of business in Guayama, Puerto Rico. (*Id.* at ¶ 24.). WPC is in the business of pharmaceutical wholesale products and is a subsidiary of Wyeth. (*Id.*).

Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized under the laws of the State of Delaware with its principal place of business in North Wales, Pennsylvania. (*Id.* at ¶ 27). Teva USA, which is a wholly owned subsidiary of Teva Pharmaceutical Industries Ltd., is in the business of developing, manufacturing and marketing pharmaceutical products in the United States. (*Id.*).

Defendant Teva Pharmaceutical Industries Ltd. is an international corporation headquartered in

Petach Tivka, Israel which is in the business of developing, manufacturing and marketing pharmaceutical products. (*Id.* at ¶ 28). It has major manufacturing operations in the United States and conducts a large portion of its sales in the United States through its subsidiaries. (*Id.*).

B. Regulatory Framework

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers who create a new drug product must obtain the approval of the United States Food and Drug Administration ("FDA") to sell the new drug by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. §§ 355(a)-(b). When the FDA approves a brand name manufacturer's NDA, the brand manufacturer may list any patents that the brand manufacturer believes could reasonably be asserted against a generic manufacturer who makes, uses, or sells a generic version of the brand name drug prior to the expiration of the listed patents in the FDA's book of Approved Products with Therapeutic Equivalence Evaluations (the "Orange Book").

The Hatch-Waxman Amendments to the FDCA simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (the "Hatch-Waxman Act"). Pursuant to Hatch-Waxman, a generic manufacturer seeking approval to sell a generic version of a brand name drug may file an Abbreviated

New Drug Application ("ANDA") with the FDA. An ANDA relies on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA, but must show that the generic drug is bioequivalent to the brand name drug. The FDA assigns generic drugs that are bioequivalent to branded drugs an "AB" rating.

To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under Hatch-Waxman, a generic manufacturer's ANDA must contain one of four certifications. Most relevant for purposes of this action is a Paragraph IV certification in which the generic manufacturer certifies that the patent for the brand name drug "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)(IV).

If a generic manufacturer files a Paragraph IV certification, a brand name manufacturer has the ability to delay FDA approval of an ANDA by suing the ANDA applicant for patent infringement. If the brand name manufacturer brings a patent infringement action against the generic filer within forty-five (45) days of receiving notification of the Paragraph IV certification, the FDA may not grant final approval to the ANDA until the earlier of (1) the passage of thirty (30) months, or (2) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. *See* 21 U.S.C. § 355(j)(5)(B)(iii). As an incentive to encourage generic companies to seek approval of generic

alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification is entitled to a 180-day exclusivity period to market its generic version of the drug. *See* 21 U.S.C. § 355(j)(5)(B)(iv).

Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute less-costly AB-rated generic equivalents for branded prescriptions. (Second Am. Compl. at ¶ 44). As a result, the launch of AB-rated generics usually results in a rapid decline in price and a large-scale shift in sales from the branded to the generic manufacturer. (*Id*.). According to Plaintiffs, once a generic equivalent hits the market, the generic quickly captures sales of the branded drug, often in excess of 80 percent of the market within the first six months. (*Id*.). In a recent study, the Federal Trade Commission ("FTC") found that, within a year of generic entry, generics had, on average, captured 90 percent of branded sales and that prices had dropped 85 percent with multiple generics on the market.[1] (*Id*.). In the end, total payments to brand manufacturers for the drug decline to a small fraction of the amounts paid prior to generic entry.

While later ANDA-approved generic manufacturers must wait six months after the first filer's market entry to seek FDA approval, a branded

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[1] *See* FTC, Pay-For-Delay: How Drug Company Pay-Offs Cost Consumers Billions: A Federal Trade Commission Staff Study (Jan. 2010), *available at* http://www.ftc.gov/reports/pay-delay-how-drug-company-payoffs-cost-consumers-billions-federal-trade-commission-staff.

manufacturer's "authorized generic" may enter the market at any time. Authorized generics are essentially prescription drugs manufactured by brand pharmaceutical companies that are marketed under a private label and sold at generic prices. Authorized generics compete with generics on price and are usually marketed to consumers during the first filer's 180-day exclusivity period. A 2006 study sponsored by the Pharmaceutical Research and Manufacturers of America found that generic prices were 16 percent lower when an authorized generic was marketed. (*Id.* at 58).So, while the first ANDA filer enjoys the exclusive right to sell the only ANDA-approved generic product during its 180-day exclusivity period, the prices at which it may do so are often lowered by price competition from authorized generics. (*Id.* at ¶ 61). Without the entry of an authorized generic, the first filer is essentially left with all generic sales during that time period.

C. Factual Background

1. Prosecution History of Effexor XR Patents

On August 13, 1985, the United States Patent and Trademark Office ("PTO") issued a patent for the compound venlafaxine hydrochloride ("venlafaxine"), U.S. Patent No. 4,535,186 (the "Husbands patent" or the "'186 patent"). (*Id.* at ¶ 62) The inventor of the patent, G.E. Morris Husbands, subsequently assigned the Husbands patent to Wyeth's predecessor American Home Products. (*Id.*). Eight years later, in December 1993, the FDA approved Wyeth's New Drug Application ("NDA") for Effexor, an antidepressant whose active pharmaceutical ingredient is

venlafaxine.[2] (*Id*. at ¶ 63). According to Plaintiffs, "[t]he Husbands patent protected venlafaxine generally, and thus it protected any kind of Wyeth venlafaxine products from generic competition before June 13, 2008."[3] (*Id*. at ¶ 64). As a result, Wyeth had market exclusivity for venlafaxine products—whether instant release or extended release—for fourteen and a half years. (*Id*. at ¶ 65).

In 1991, spurred by drawbacks associated with the immediate release form of the drug, Wyeth's marketing department requested development of an extended release version of venlafaxine hydrochloride. (*Id*. at ¶ 67). According to Plaintiffs, Wyeth sought development of an extended release version because early clinical trials showed that some patients who took the instant release form of Effexor reported experiencing negative side effects such as nausea and vomiting. (*Id*.). A group of Wyeth chemists from upstate New York initially attempted to create an extended release venlafaxine formulation using hydrogel tablet technology through which the active ingredient is combined with cellulose ethers and then

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[2] Effexor is a tablet that dissolves rapidly, resulting in a rapid increase in blood plasma levels of venlafaxine shortly after administration. (Second Am. Compl. at ¶ 63). Compounds with such rapid dissolution profiles are referred to as "instant release" formulations. (*Id*.). Levels of venlafaxine in the blood gradually decrease, reaching sub-therapeutic levels in about twelve hours. (*Id*.).

[3] The Husbands patent would have expired much earlier than 2008, but Wyeth "received a significant extension to reflect the time it took the FDA to approve its NDA for Effexor and an additional six month extension for having conducted pediatric studies[]." (*Id*.).

compressed into a tablet. (*Id.* at ¶ 70). According to Plaintiffs, Inventor Deborah M. Sherman "had previous experience with this approach, and in the second half of 1991 set out to make an extended release hydrogel tablet containing venlafaxine." (*Id.*). By December 1991, however, Wyeth abandoned its hydrogel approach "because the tablets were dissolving too rapidly." (*Id.*).

Following its failed attempt at using hydrogel tablet technology, Wyeth: (1) began in-house development of a conventional coated spheroid approach based on its prior experience with extending the release of a similar chemical, propanolol, which it marketed as Inderal[4] and (2) entered into a business venture with Alza, a pharmaceutical company specializing in extended release technology that possessed an available "OROS" technology that could potentially be used to extend the release of venlafaxine. (*Id.* at ¶¶ 71-72). Plaintiffs contend that the Effexor XR inventors implemented the coated spherical approach by simply substituting venlafaxine for the propanolol in Wyeth's Inderal LA formulation. (*Id.* at ¶ 75). In 1992, within six months of implementing the spheroid approach, Wyeth deemed the approach successful. (*Id.* at ¶ 77).

At the same time Wyeth pursued the spheroid approach, it also sought to develop an osmotic shell extended release venlafaxine through the use of Alza's OROS technology. (*Id.* at ¶ 78). In 1992, Wyeth entered into a cooperation agreement with Alza to

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[4] Inderal LA, a "longer acting" or extended release product, had been formulated over a decade earlier and received marketing approval from the FDA in April 1983. (*Id.* at ¶ 72).

develop an extended release formulation of venlafaxine hydrochloride using Alza's proprietary drug delivery system. (*Id*.). The collaboration agreement granted Alza ownership rights in any information generated or acquired during the collaboration and the patents resulting from the collaboration. Alza also retained the right to use, disclose, and license information obtained through the collaboration to third parties. (*Id*.). By the end of 1992, Alza was also successful in developing an extended release formulation of venlafaxine. (*Id*. at ¶ 80). Wyeth, however, "chose to pursue its own, encapsulated spheroid approach." (*Id*. at ¶ 81).

Following development of the encapsulated spheroid extended release venlafaxine, Wyeth conducted clinical studies to establish the efficacy and safety of its new formulation. (*Id*. at ¶ 82). In some studies, Wyeth compared the extended release formulation to the instant release formulation; in others, it compared the extended release to a placebo. (*Id*.). According to Plaintiffs, "[w]hile the studies established the FDA minima of efficacy as compared to a placebo, the studies failed to establish any statistically significant improvement of the extended release over the instant release with respect to side effects such as nausea." (*Id*. at ¶ 82). As a result, Plaintiffs contend that "Wyeth could not truthfully claim [that] there was any valid scientific basis for claiming that the extended release version reduced side effects when compared to the instant release." (*Id*.).

In addition to clinical testing of its extended release form of venlafaxine, Wyeth "began some early

efforts to secure further patent protection for venlafaxine."[5] (*Id.* at ¶ 83). In June 1993, a group of Wyeth employees based in eastern Pennsylvania filed a patent application seeking a method-of-use patent for using venlafaxine for a number of medical conditions. (*Id.*). The application claimed as the "invention . . . a method of treating obesity, generalized anxiety disorder, post-traumatic stress disorder, late luteal phase disphoric disorder (premenstrual syndrome), attention deficit disorder, with and without hyperactivity, Gilles de la Tourette syndrome, bulimia nervosa or Shy Dragger Syndrome . . . by administering . . . an effective amount of [venlafaxine]." (*Id.* at ¶ 83). In 1995, after abandoning the original application, Wyeth filed a series of applications which reiterated that "sustained release compositions" of venlafaxine were the likely favored form of administering venlafaxine. (*Id.* at ¶ 85). These applications eventually led to several

[5] In the early 1990s, Alza also sought patent protection for its extended release osmotic approach for venlafaxine. On May 27, 1993, Alza filed patent application No. 08/068,480 listing the inventors as Edgren, *et al.* (the "Edgren application"). (*Id.* at ¶ 88). On August 27, 2002, the Edgren application issued as U.S. Patent No. 6,440,457 (the "Edgren patent" or the "'457 patent"). On December 8, 1994, the World Intellectual Property Organization in Geneva, Switzerland published WO 94/27589, assigned to Alza (the "'589 PCT application"). (*Id.* at ¶ 89). According to Plaintiffs, the '589 PCT application "claims priority to the Edgren application and disclosed to the public all features of the Edgren application." (*Id.*). Alza's '589 PCT application allegedly "describes, repeatedly, the broader notion that the use of extended release venlafaxine would reduce the daily spiking in blood plasma levels that result from multiple daily usage of venlafaxine." (*Id.* at ¶ 90).

method-of-use patents for specific medical conditions. (*Id*.).

In January 1995, several of the Wyeth employees based in eastern Pennsylvania filed Patent Application No. 08/380,093 (the "Upton application") which sought a method-of-use patent for using venlafaxine to treat hypothalamic menopause in non-depressed woman. (*Id*. at ¶ 86). According to Plaintiffs, the Upton application "did not seek approval of any formulations of venlafaxine[,]" but disclosed a "sustained oral administration form or time-release form [of venlafaxine], which may be used to spread the dosage over time, such as for one-a-day applications." (*Id*.).

In late 1995 or early 1996, the PTO allegedly notified Wyeth that the Upton application would soon issue as a patent. According to Plaintiffs, "Wyeth knew that particular disclosures that would appear in this patent—those describing extended release venlafaxine as a method to smooth the dosage over time—would be prior art relevant to later patent applications seeking to claim as a new invention the use of extending the release of venlafaxine as a method to control dose rates." (*Id*. at ¶ 109). On March 25, 1996, therefore, the Wyeth applicants filed a provisional utility patent application, No. 60/014,006 (the "'006 application"), with the PTO that included method-of-use claims for decreasing incidences of nausea and vomiting and for minimizing the troughs and peaks in drug concentration in a patient's blood plasma. (*Id*. at ¶ 110). According to Plaintiffs, the Wyeth applicants did so "to avoid the Upton [p]atent standing as prior art to future

extended release venlafaxine claims." (*Id*.). On April 9, 1996, following the filing of the '006 application, the Upton application issued as U.S. Patent No. 5,506,270 (the "Upton patent" or the "'270 patent"). (*Id*. at ¶ 87). According to Plaintiffs, "[t]he Upton patent contained the same reference to sustained and time release forms of venlafaxine to spread the dosage over time[.]" (*Id*.). One month later, on May 16, 1996, Wyeth sought FDA approval to sell an encapsulated extended release formulation of venlafaxine hydrochloride called Effexor XR. (*Id*. at ¶ 97).

On March 20, 1997, within a year of filing the provisional '006 application, the Wyeth applicants filed a non-provisional application, No. 08/821,137 (the "'137 application") which claimed priority to the '006 application. (*Id*. at ¶ 100). The '137 application was assigned to Examiner Amy Hulina. (*Id*. at ¶ 119). According to Plaintiffs, the '137 application was "virtually identical to the '006 [provisional application] in all respects, setting forth the Wyeth-developed, encapsulated film-coated spheroid formulation to extend the release of venlafaxine." (*Id*. at ¶ 120). The '137 application also set forth the same eight formulation claims as the '006 application as well as two method-of-use claims. (*Id*.). Claim 1 recited an extended release formulation of venlafaxine hydrochloride with spheroids. (*Id*. at ¶ 121). Claim 9 recited a method-of-use claim for reducing incidences of nausea and vomiting associated with venlafaxine. (*Id*. at ¶ 122). Claim 10 recited a method-of-use claim for reducing the disparities in concentration of venlafaxine in a patient's blood serum. (*Id*. at ¶ 123).

On July 10, 1997, the Wyeth applicants submitted an information disclosure statement ("IDS") to the PTO which listed five U.S. patents. (*Id.* at ¶ 125). According to Plaintiffs, Wyeth did not list the original Husbands patent on the IDS, but rather, referenced it in the specification. (*Id.*). Furthermore, Plaintiffs contend that Wyeth neglected to list or otherwise disclose both the Upton patent and Alza's '589 PCT application to Examiner Hulina. (*Id.* at ¶ 126). Despite the Wyeth applicants' alleged failure to disclose the existence of the Upton patent, Examiner Hulina discovered the patent when conducting her own prior art search.[6] (*Id.* at ¶ 127). During a telephone interview on July 30, 1997, Examiner Hulina informed Wyeth that its two method-of-use claims were not patentable as independent claims in light of the disclosure of extended release formulations of venlafaxine in the Upton patent. (*Id.* at ¶ 128). She further informed Wyeth that these method-of-use claims would be patentable if Wyeth amended them to depend on the specific encapsulated spheroid formulation of extended release venlafaxine recited in Claim 1 of the '137 application. (*Id.*). Based on Examiner Hulina's conclusion, Wyeth authorized the examiner to amend the method-of-use claims to depend on Wyeth's encapsulated spheroid formulation. (*Id.* at ¶ 130). On August 5, 1997, Examiner Hulina issued a notice of allowance for the

[6] According to Wyeth, because Examiner Hulina had identified the Upton patent during her independent search for prior art and rejected certain claims over it, "the Upton patent . . . was known to the PTO from the very beginning of the prosecution." (Defs.' Mem. in Supp. of Wyeth Defs. Mot. to Dismiss All Direct Purchaser Compls. ("Wyeth Br.") at 6) (ECF No. 138).

two amended method-of-use claims. (*Id*. at ¶ 131). The examiner also allowed the seven remaining formulation claims that described the encapsulated film-coated spheroid extended release venlafaxine invention. (*Id*.). According to Plaintiffs, despite having received the notice of allowance, the Wyeth applicants allegedly "decided to abandon the '137 application . . . in the hopes that a new application might draw a different examiner . . . unfamiliar with the Upton patent's disclosure of extended release venlafaxine [who] . . would [potentially] . . . allow independent nausea/vomiting and 'troughs and peaks' method-of-use claims." (*Id*. at ¶ 133). In the meantime, the FDA approved Wyeth's NDA for Effexor XR on October 20, 1997. (*Id*. at ¶ 97).

On November 5, 1997, prior to abandoning their '137 application, the Wyeth applicants filed a continuation-in part application, No. 08/964,328 (the "'328 application), which claimed priority to the '137 and '006 applications. (*Id*. at ¶¶ 101-02). The application was assigned to Examiner James Spear and proposed sixteen formulation claims. (*Id*. at ¶¶ 137-38). The '328 application also contained two independent method-of-use claims which, according to Plaintiffs, were nearly identical to the two method-of-use claims of the '137 application rejected by Examiner Hulina.

On February 9, 1998, the Wyeth applicants submitted an IDS identifying the same five U.S. patents identified in the IDS for the '137 application. (*Id*. at ¶ 140). On August 13, 1998, they submitted a supplemental IDS, listing three foreign patent documents. (*Id*.). According to Plaintiffs, while the

Wyeth applicants listed the Upton patent and '589 PCT application in these IDSs, they failed to identify Examiner Hulina's prior rejection of the broad method-of-use claims recited in the '137 patent application despite their knowledge that such a rejection constituted material information required to be disclosed to the PTO.[7] (*Id*. at ¶ 141).

After reviewing the application, Examiner Spear issued a first office action on October 14, 1998. (*Id*. at ¶ 143). Examiner Spear (1) found that the formulation claims that quantified the amount and ratio of materials to be used for film-coating of the venlafaxine spheroids would be patentable; (2) allowed Claim 11 because, as an independent claim that quantified those amounts, it was a patentable formulation; and (3) rejected Claim 1 because its general formulation claim of using any amounts of materials to extend the release of venlafaxine was obvious. (*Id*.). According to Plaintiffs, "[i]n allowing the encapsulated extended release formulation of venlafaxine in Claim 11, [Examiner Spear] also allowed Claims 13 and 14, the two claims for methods of diminishing

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[7] Wyeth contends that the "family history of the '137 application (before Examiner Hulina) . . . was [actually] before Examiner Spear, including the fact that Examiner Hulina had initially rejected claims in view of Upton and the proposed amendment of the claims, [since] the history is listed in each Effexor XR application and on the first page of each Effexor XR Patent." (*Id*. at 6-7). Wyeth further contends that it disclosed Alza's '589 PCT application in each of its patent applications beginning with the '328 application. (*Id*. at 8). Moreover, according to Wyeth, "[b]eginning with the '137 application, in each of its patent applications Wyeth disclosed . . . [the] patent covering Inderal LA[.]" (*Id*. at 9).

nausea/vomiting or eliminating troughs/peaks by 'adminstering . . . an encapsulated extended release formulation . . . [of] venlafaxine.'" (*Id.*). In doing so, Examiner Spear essentially "allowed the method-of-use claims (claims 13 and 14) to issue as independent claims" despite Wyeth's previous agreement to amend those very same claims to be dependent. (*Id.* at ¶ 144). While Wyeth obtained allowance of the method-of-use claims as a result of the first office action, as previously mentioned, the examiner rejected the general formulation in Claim 1 of the '328 application. The Wyeth applicants allegedly responded to that rejection by "canceling, amending, and adding new claims." (*Id.* at 146). After Examiner Spear again rejected Claim 1 as obvious on July 21, 1999, the Wyeth applicants ultimately abandoned the '328 application. (*Id.*).

On January 20, 2000, several weeks prior to abandoning the '328 application, the Wyeth applicants filed a continuation-in-part application, No. 09/488,629 (the "'629 application), that claimed priority to the '328 application, the '137 application, and the '006 application. (*Id.* at ¶¶ 103, 147). The '629 application was again assigned to Examiner Spear. According to Plaintiffs, the '629 application "contained a nearly identical specification to the '328 application." (*Id.* at ¶ 148). Specifically, "Claim 1, again, recited an extended release version of venlafaxine hydrochloride in spheroids that was substantially similar to the claim rejected by Examiner Spear during the prosecution of the '328 application in light of the prior art." (*Id.*). Moreover, "Claims 21 and 22, again recited the same independent method-of-use claims originally presented in (rejected) claims 9 and 10 of the '137

application and (allowed but abandoned) claims 13 and 14 in the '328 application[.]" (*Id.*). Plaintiffs allege that Wyeth informed Examiner Spear of neither Examiner Hulina's prior rejection of those method-of-use claims nor its agreement to amend those claims to be dependent.

On January 4, 2001, Examiner Spear allowed the two method-of-use claims. (*Id.* at ¶ 149). In response, the Wyeth applicants added additional method-of-use claims which, according to Plaintiffs, were again "substantially similar" to those claims rejected by Examiner Hulina. (*Id.* at ¶ 150). The additional independent claims were similarly allowed by Examiner Spear and, on August 14, 2001, the '629 application issued as U.S. Patent No. 6,274,171 B1 (the "'171 patent"). (*Id.* at ¶¶ 150-51). The '171 patent contains twenty-five claims in total, including claims for (1) an extended release form of venlafaxine hydrochloride using spheroids; (2) method-of-use claims for decreasing incidences of nausea and vomiting; and (3) method-of-use claims for minimizing the troughs and peaks in drug concentration in a patient's blood plasma. (*Id.* at ¶ 104). It is assigned to Wyeth and expires on March 20, 2017. (*Id.*).

On June 19, 2001, two months prior to the issuance of the '171 patent, the Wyeth applicants filed a divisional application, No. 09/884,412 (the "'412 application), which claimed priority to the '629 application (which resulted in the '171 patent), the '328 application, the '137 application, and the '006 application. (*Id.* at ¶ 105). The application was again assigned to Examiner Spear. According to Plaintiffs, Examiner Spear rejected some claims within the

application, the Wyeth applicants canceled one claim and added new claims that were "substantially similar to claims issued in the '171 patent." (*Id*.). Again, Plaintiffs allege that the Wyeth applicants never informed Examiner Spear that the Upton patent had identified the existence of an extended release formulation of venlafaxine hydrochloride that rendered their method-of-use claims unpatentable. (*Id*. at 154). Moreover, according to Plaintiffs, the Wyeth applicants never disclosed that "a previous examiner [had] determined [that] the method-of use claims [which were] virtually identical to claims 23 and 24 [in the '412 application] were unpatentable . . . [or] that they had agreed to amend virtually identical claims in order to avoid a rejection over the prior art disclosed by . . . [the] Upton patent." (*Id*.).

On January 13, 2002, Examiner Spear rejected claims 23 and 24 as being unpatentable over claims 20 and 21 of the '171 patent. (*Id*. at ¶ 155). The Wyeth applicants subsequently contested that claims 23 and 24 were obvious in light of the '171 patent, but filed a terminal disclaimer confirming that Wyeth would not seek an additional time period of patent protection beyond that afforded by the '171 patent—that is, through March 20, 2017. (*Id*. at ¶¶ 106, 155). The Wyeth applicants also added additional independent method-of-use claims which recited methods to decrease incidences of nausea and vomiting and minimize the troughs and peaks in drug concentration in a patient's blood plasma. (*Id*. at ¶¶ 106, 156). Those claims were similarly allowed by Examiner Spear and, on July 16, 2002, the '412 application issued as U.S.

Patent No. 6,419,958 B2 (the "'958 patent"). (*Id*. at ¶¶ 156-57).

Two months later, on September 12, 2001, Wyeth filed a continuation-in-part application, No. 09/950,965 (the "'965 application") that claimed priority to the '412 application (which resulted in the '958 patent), the '629 application (which resulted in the '171 patent), the '328 application, the '137 application, and the '006 application. (*Id*. at ¶ 107). The application was again assigned to Examiner Spear. The '965 application allegedly "contained the same specification and claims as the '412 application (and corresponding '958 patent)." (*Id*. at ¶ 159). Specifically, the Wyeth applicants canceled claims 2-22 and added new claims 23-34. (*Id*.). According to Plaintiffs, "Claim 23 recited a method-of use claim for diminished incidences of nausea and vomiting . . . [that was] substantially similar to rejected claim 9 of the '137 application[.]" (*Id*.). As they had allegedly done with their prior applications, the Wyeth applicants failed to disclose to Examiner Spear that a previous examiner had determined that a claim substantially similar to claim 23 was unpatentable. (*Id*. at ¶ 160). In addition, the Wyeth applicants allegedly never disclosed that Wyeth had agreed to amend a substantially similar claim in order to avoid rejection due to prior art disclosed in Wyeth's own Upton patent. (*Id*.). Examiner Spear allowed claim 23 and objected to claims 24-34. (*Id*.). After Wyeth amended claims 24 and 25 to depend on the previously allowed claim 23, the amended claims were also allowed by the examiner. (*Id*. at ¶ 161). On June 11, 2002, the '965 application issued as U.S. Patent No. 6,403,120 B1 (the "'120 patent"). Similar to the '171

and '958 patents, the '120 patent also expires on March 20, 2017. (*Id.* at ¶ 108).

In total, Wyeth filed information for seven patents with the FDA in connection with Effexor XR, including the original compound patent (the '186 patent) and the three Effexor XR patents (the '171, '958, and '120 patents). The '186 patent covering the venlafaxine hydrochloride molecule expired on June 13, 2008. As previously mentioned, the three Effexor XR patents expire on March 20, 2017.

2. Wyeth's Settlement Agreement with Teva

On December 10, 2002, Teva filed an ANDA seeking approval of a generic version of Effexor XR. (*Id.* at ¶ 264). Teva USA's ANDA included Paragraph IV certifications that Wyeth's '171, '120, and '958 patents were invalid, unenforceable, and would not be infringed by its generic extended release venlafaxine capsules. (*Id.* at ¶ 264). Pursuant to the Hatch-Waxman Act, as the first ANDA applicant to submit a substantially complete ANDA, Teva USA was entitled to be the only non-authorized generic on the market during the statutorily prescribed 180-day exclusivity period. (*Id.* at 265).

On March 24, 2003, Wyeth brought suit against Teva in the United States District Court for the District of New Jersey for infringement of the '171, '120, and '958 patents. (*Id.* at ¶ 266). In its Complaint, Wyeth alleged that Teva's proposed manufacture, marketing and sale of a generic version of Effexor XR would infringe claims 20-25 of the '171 patent, claims 1,2 13, and 14 of the '120 patent, and claims 1-6 of the '958 patent. (*Id.*). All of these are method-of-use claims

for either reducing the incidences of nausea and vomiting or smoothing out the troughs and peaks in a patient's blood serum. (*Id*.). According to Plaintiffs, Wyeth "did not assert [that] Teva infringed any of the formulation claims . . . [or] infringed any other patents." (*Id*.). In its June 2, 2003 Answer to Wyeth's Complaint, Teva denied the allegations and asserted that the patents in issue were invalid and not infringed. (*Id*. at ¶ 267).

Throughout the course of the litigation, the parties disputed the term "extended release formulation"—the term that defines the method-of-use claims broadly or limits those claims to the spheroid formulation developed by Wyeth. (*Id*. at ¶ 268). After conducting a *Markman* hearing on August 29, 2005, the Hon. William J. Martini, U.S.D.J ("Judge Martini") issued an Opinion on September 6, 2005 concluding that "[w]hen the term 'extended release formulation' is looked at in its proper context in the specification, . . . one of ordinary skill in the art would construe the term to include specific ingredients." *Wyeth v. Teva Pharms. USA, Inc.*, 2005 U.S. Dist. LEXIS 20034, at *18 (D.N.J. Sept. 6, 2005). According to Plaintiffs, "Wyeth knew this ruling meant that loss of the litigation was right around the corner." (Second Am. Compl. at ¶ 269).

In October 2005, one month after the Court issued its *Markman* ruling, Wyeth and Teva entered into an agreement (the "Wyeth-Teva agreement") to settle the litigation. (*Id*. at ¶ 270). As part of the agreement, Wyeth and Teva agreed that the prior *Markman* ruling of the *Teva* court would be vacated. (*Id*. at ¶ 272). In addition, with respect to the instant release

version of Effexor ("Effexor IR"), Wyeth: (1) permitted Teva to sell a generic version of Effexor IR before the original compound patent for venlafaxine expired in June 2008 and (2) agreed that it would not compete with Teva's marketing of a generic version of Effexor IR by launching its own authorized generic during that period. (*Id.* at ¶ 273). According to Plaintiffs, Wyeth also agreed "to refrain from selling an authorized generic version of [Effexor IR] until the Husbands patent expired—giving Teva at least a year and a half of being the *only* instant release generic on the market."[8] (*Id.* at ¶ 275). Plaintiffs contend that by the end of 2007, approximately 96 percent of Wyeth's sales of instant release Effexor tablets worth about $100 million had converted to Teva generic instant release venlafaxine tablets. (*Id.* at ¶ 294).

Also under the Wyeth-Teva agreement, Teva allegedly agreed to delay market entry for its ANDA-approved, AB-rated extended release venlafaxine ("Effexor XR") until as late as July 2010, two years after the expiration of the original venlafaxine compound patent.[9] (*Id.* at 276). According to Plaintiffs, to induce Teva to agree to the delay period, Wyeth promised Teva that Wyeth would not market an authorized generic version of Effexor XR during Teva's

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[8] In October 2006, with Wyeth's permission, Teva obtained FDA approval and began selling generic instant release venlafaxine. (Second Am. Compl. at ¶ 274). In June 2008, the Husbands patent expired. (*Id.*).

[9] The agreement to delay included a provision for an earlier launch by Teva if another generic entered earlier than July 2010, or if another generic was successful in invalidating the '171, '120 and '958 patents. (*Id.* at ¶ 276).

180-day exclusivity period. (*Id.*).[10] Teva, in turn, allegedly "agreed to delay the launch of generic Effexor XR until two years after the expiration of the only Wyeth patent actually capable of blocking generic competition to Effexor XR"—namely, the original venlafaxine compound patent. (*Id.* at ¶ 277). By performing its contractual obligation not to compete with Teva, Wyeth allegedly "provided Teva with a substantial financial inducement amounting to over $500 million in value in exchange for Teva's agreement to delay selling its generic version of Effexor XR for two years." (*Id.* at ¶ 281). According to Plaintiffs, "Wyeth's fulfillment of its contractual obligation not to compete with Teva constituted a [reverse] payment to Teva[,]" and, as a result of that payment, the Direct Purchasers and members of the class were deprived of the price-reducing benefits of timely generic competition.[11] (*Id.* at 281-281).

In October 2005, Wyeth and Teva submitted the proposed terms of the Settlement and License Agreements to Judge Martini and asked that those terms be embodied in a consent order resolving the

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[10] According to Defendants, pursuant to the Wyeth-Teva agreement, Wyeth granted Teva an exclusive license to sell generic versions of Effexor years before expiry of the relevant patents—seven years early in the case of Effexor XR and two years early in the case of Effexor IR. (Defs.' Mem. in Supp. of Mot. to Dismiss Direct Purchaser Class Pls.' Second Am. Compl. ("Defs.' Supp. Br.") at 6) (ECF No. 305).

[11] Defendants, in contrast, contend that "Wyeth did not pay one dollar to Teva . . . so that the generic challenger would 'stay out.'" (*Id.*). Rather, according to Defendants, "Teva *paid Wyeth* for the procompetitive right to sell generic versions of Effexor, through substantial royalties." (*Id.*)

litigation. On October 24, 2005, Judge Martini issued a scheduling order requiring the parties to provide the FTC with the proposed settlement and associated license agreements and soliciting the FTC's views on any antitrust issues concerning the proposed settlement.[12] The scheduling order stated, in relevant part: "(2) The execution-ready Definitive Agreements shall be delivered to the Federal Trade Commission for its review not later than November 2, 2005; (3) If the Federal Trade Commission has any objection to the Definitive Agreements, it shall file such objection with the Court not later than December 2, 2005[.]" *Wyeth v. Teva Pharms. USA, Inc.*, No. 03-cv-1293 (D.N.J. Oct. 24, 2005) (ECF No. 156). Judge Martini also established a briefing schedule for addressing such objections and indicated that he would hold a hearing if needed to address any objections raised by the FTC. Wyeth provided this information to the FTC

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[12] The court hearing the underlying patent case solicited the FTC's views pursuant to a 2002 Consent Decree in which the FTC had secured the right to weigh in on Wyeth's settlements and to raise objections in advance. *See In the Matter of Schering-Plough Corp., Upsher-Smith Labs, Inc., & Am. Home Prods. Corp.*, Decision and Order, Docket No. 9297 (Apr. 2, 2002). According to Defendants, "the Consent Decree required Wyeth to (1) produce to the FTC not only the settlement and all related agreements themselves, but also a variety of additional materials, including documents prepared internally at Wyeth for the evaluation of the settlement, (2) provide the patent court with a copy of the Consent Decree and Analysis to Aid Public Comment, and (3) 'not oppose any effort by the Commission to participate, in any capacity permitted by the [patent] court, in the court's consideration' of the settlement." (Letter from Liza M. Walsh, Connell Foley LLP to Judge Peter G. Sheridan, U.S. Dist. Ct. for the Dist. of N.J., at 2 (June 13, 2014) (ECF No. 320).

and furnished Judge Martini with both a stipulation of dismissal and a full copy of the proposed settlement documents.

On December 1, 2005, the FTC responded in a letter signed by Acting Assistant Director of the Bureau of Competition David R. Pender. Assistant Director Pender wrote:

> We have received Wyeth's notice of its proposed settlement with Teva, as required by the Federal Trade Commission's Decision and Order. We understand that Wyeth and Teva do not intend to independently raise with the Court the competitive implications of their proposed settlement agreement. As a consequence, you may advise the Court that we will not file an objection to the Court entering an injunction based on the joint stipulation of the parties. (Letter from David R. Pender, Acting Asst. Dir., Bureau of Competition, FTC to Michael N. Sohn, Esq., Arnold & Porter (Dec. 1, 2005) (ECF No. 339-1)

The FTC further emphasized that "[its] decision to not file an objection with the Court is not to be construed as a determination that the proposed settlement agreement does not violate Section 5 of the FTC Act[.]" (*Id.*). Moreover, the Commission "reserve[d] the right to take such further action as the public interest may require." (*Id.*).

After the FTC chose not to object to the proposed settlement, the parties moved before Judge Martini for a Stipulated Order and permanent injunction requiring Wyeth and Teva to abide by the terms of the

agreement. On December 7, 2005, Judge Martini entered the proposed order. *See* Stipulated Order, *Wyeth v. Teva Pharms. USA, Inc.*, No. 03-1293 (D.N.J. Dec. 7, 2005) (ECF No. 169). The parties also moved to vacate the prior *Markman* decision, which Judge Martini granted on January 12, 2006. *See* Order Vacating Markman Rulings, *Wyeth v. Teva Pharms. USA, Inc.*, No. 03-1293 (D.N.J. Jan. 12, 2006) (ECF No. 168). On January 20, 2005, Judge Martini entered an order dismissing the action.

3. Wyeth's Settlements with Other Generic Manufacturers

According to Plaintiffs, "[t]he agreement between Wyeth and Teva was structured to encourage Wyeth to resolve all subsequent challenged to the '171, '120, and '958 patents prior to a court finding of invalidity, non-infringement, or unenforceability." (Second Am. Compl at ¶ 293). As such, between April 2006 and April 2011, Wyeth brought infringement suits against sixteen additional generic companies which sought to market a generic version of Effexor XR.[13] (*Id.* at

[13] The sixteen additional patent infringement suits instituted by Wyeth are as follows: (1) *Wyeth v. Impax Labs, Inc.*, Civ. Action No. 06-0222 (D. Del. 2006); (2) *Wyeth v. Anchen Pharms., Inc.*, Civ. Action No. 06-0386 (C.D. Cal. 2006); (3) *Wyeth v. Lupin Ltd.*, Civ. Action No. 07-0632 (D. Md. 2007); (4) *Wyeth v. Osmotica Pharm. Corp.*, Civ. Action No. 07-0067 (E.D.N.C. 2007); (5) *Wyeth v. Sandoz, Inc.*, Civ. Action No. 07-0234 (E.D.N.C. 2007); (6) *Wyeth v. Mylan Pharms., Inc.*, Civ. Action No. 07-0091 (N.D.W. Va. 2007); (7) *Wyeth v. Wockhardt Ltd.*, Civ. Action No. 07-5166 (C.D. Cal. 2007); (8) *Wyeth v. Biovail Corp.*, Civ. Action No. 08-0390 (D. Del. 2008); (9) *Wyeth v. Apotex, Inc.*, Civ. Action No. 08-22308 (S.D. Fla. 2008); (10) *Wyeth v. Torrent Pharms., Ltd.*, Civ. Action No. 09-0019 (D. Del. 2009); (11) *Wyeth v. Cadila Healthcare Ltd.*, Civ. Action No. 09-0239 (D. Del. 2009); (12)

¶ 364). In answering Wyeth's claims of infringement, each of the generic companies claimed that the patents were invalid. (*Id*.). Several of the generic companies also alleged that the patents were unenforceable due to inequitable conduct. (*Id*.). Wyeth subsequently settled each and every Effexor XR infringement suit before a federal court could render an opinion on the validity or enforceability of Wyeth's Effexor XR patents. (*Id*. at ¶ 365).

D. Procedural History

On May 2, 2011, Direct Purchaser Plaintiff Professional Drug Company, Inc. filed a Class Action Complaint against Defendant Wyeth, Inc. in the United States District Court for the Southern District of Mississippi. (ECF No. 1). On May 5, 2011, Direct Purchaser Plaintiffs Stephen L. LaFrance Holdings, Inc. and Stephen L. LaFrance Pharmacy, Inc. filed a similar lawsuit against the Wyeth Companies in the Mississippi District Court. Direct Purchaser Plaintiff Rochester Drug Co-Operative, Inc. also filed suit against Wyeth on May 27, 2011. On June 21, 2011, the Mississippi Court granted an unopposed motion to consolidate the three actions pursuant to Fed. R. Civ. P. 42. (ECF No. 18). Pursuant to the Court's Consolidation Order, Direct Purchaser Plaintiffs filed a Consolidated Class Action Complaint and Jury

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Wyeth v. Orgenus Pharma, Inc., Civ. Action No. 09-3235 (D.N.J. 2009); (13) *Wyeth LLC v. Aurobindo Pharma Ltd.*, Civ. Action No. 10-2084 (D.N.J. 2010); (14) *Wyeth, LLC v. Intellipharmaceutics Int'l Inc.*, Civ. Action No. 10-5072 (S.D.N.Y. 2010); (15) *Wyeth LLC v. Dr. Reddy's Labs., Ltd.*, Civ. Action No. 10-cv-4551 (D.N.J. 2010); and (16) *Wyeth LLC v. Nostrum Pharms., LLC*, Civ. Action No. 11-2280 (D.N.J. 2011).

Demand on June 22, 2011. (ECF No. 19). On July 5, 2011, Direct Purchaser Plaintiff Uniondale Chemists, Inc. also filed a lawsuit against Wyeth which was subsequently consolidated with the other three actions. On September 21, 2011, the Mississippi Court approved a transfer of venue of the consolidated action to the United States District Court for the District of New Jersey. (ECF No. 44).

Following the transfer, twelve Indirect Purchaser (or End-Payer) class actions and one additional Individual Direct Purchaser action were filed in the New Jersey District Court. On December 13, 2011, this Court issued a Case Management Order consolidating all Direct Purchaser Class Actions and designating *Professional Drug Co., Inc. v. Wyeth, Inc.*, Civ. Action No. 11-cv-5479 as the Lead Direct Purchaser Class Action. (ECF No. 86). The following day, on December 14, 2011, the Direct Purchaser Class Plaintiffs filed a First Amended Consolidated Class Action Complaint and Jury Demand. (ECF No. 91). On April 6, 2012, Defendants Wyeth and Teva filed separate Motions to Dismiss the Direct Purchaser Class Plaintiffs' First Amended Consolidated Class Action Complaint pursuant to Fed. R. Civ. P. 12(b)(6). (ECF Nos. 136, 138).

On July 16, 2012, the United States Court of Appeals for the Third Circuit issued its decision in *In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3d Cir. 2012), which involved an antitrust challenge to a patent litigation settlement agreement between a brand-name pharmaceutical manufacturer and a generic manufacturer. In light of the Third Circuit's decision, and the likelihood that the United States

Supreme Court would grant *certiorari*, Defendants filed a Motion to Stay the instant action pending the Supreme Court's decision on September 10, 2012 (ECF No. 184). On October 23, 2012, this Court granted Defendants' motion and stayed this action pending the conclusion of proceedings in the Supreme Court. (ECF No. 191).

On June 17, 2013, the Supreme Court issued a decision in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), which set forth the standard to assess the legality of reverse payment settlement agreements between branded and generic pharmaceutical companies. Based on the *Actavis* decision, the Supreme Court vacated and remanded *In re K-Dur Antitrust Litigation* for further consideration. *See Merck & Co., Inc. v. Louisiana Wholesale Drug Co., Inc.*, 133 S. Ct. 2849 (2013). One month later, on July 17, 2013, this Court vacated the stay in this matter and reopened the case. (ECF No. 211). The Court also granted the parties' request to file supplemental briefs on the pending Motions to Dismiss in light of the Supreme Court's decision in *Actavis*. (ECF No. 222).

On August 14, 2013, the FTC filed a Motion for Leave to appear *amicus curiae*. (ECF No. 236).[14] The FTC's motion was opposed by both the Wyeth and Teva Defendants. (ECF Nos. 249-50). On August 28, 2013, Direct Purchaser Class Plaintiffs filed a Motion for Leave to file a Second Amended Consolidated Class

[14] The FTC had previously filed a motion for leave to appear *amicus curiae* in this matter on August 10, 2012. (ECF No. 173). That motion was denied by the Hon. Joel A. Pisano on October 3, 2012. (ECF No. 187). Judge Pisano ruled without the Supreme Court's decision in *Activas*.

Action Complaint. (ECF No. 248). On September 10, 2013, this Court heard oral argument on the pending Motions to Dismiss as well as the FTC's and the Direct Purchaser Class Plaintiffs' motions. (ECF No. 265). On September 12, 2013, the Court granted the FTC's motion to appear *amicus curiae*. (ECF No. 263). The FTC's brief was filed the following day and all parties subsequently responded. (ECF Nos. 264, 271-74).

On October 23, 2013, the Court granted the Direct Purchaser Class Plaintiff's Motion for Leave to File a Second Amended Consolidated Class Action Complaint. (ECF No. 282). The Second Amended Consolidated Class Action Complaint was filed later that day. (ECF No. 287).

On December 13, 2013, pursuant to a December 5, 2013 Letter Order issued by the Court (ECF No. 303), Defendants filed the instant Motion to Dismiss the Direct Purchaser Class Plaintiffs' Second Amended Consolidated Class Action Complaint pursuant to Fed. R. Civ. P. 12(b)(6). (ECF No. 305). Direct Purchaser Plaintiffs filed their Opposition to Defendants' motion on January 24, 2014 and Defendants replied on February 14, 2014. (ECF Nos. 316-17). The Court held additional argument on Defendants' Motions to Dismiss on April 3, 2014 and June 5, 2014.

II. DISCUSSION[15]

A. Fed. R. Civ. P. 12(b)(6) Standard of Review

Fed. R. Civ. P. 12(b)(6) provides for the dismissal of a complaint if the plaintiff "fail[s] to state a claim

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[15] Several sections herein are the same or similar to those set forth in *In Re Lipitor*, as they were written simultaneously. (Cite)

upon which relief can be granted[.]" The Supreme Court explained the standard for addressing a motion to dismiss under Rule 12(b)(6) in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007). The *Twombly* Court stated that, "[w]hile a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, . . . a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do[.]" *Id.* at 555 (internal citations and quotations omitted); *see also Baraka v. McGreevey*, 481 F.3d 187, 195 (3d Cir. 2007) (stating that the standard of review for a motion to dismiss does not require courts to accept as true "unsupported conclusions and unwarranted inferences" or "legal conclusion[s] couched as factual allegation[s]") (internal quotation marks omitted). Therefore, for a complaint to withstand a motion to dismiss under 12(b)(6), the "[f]actual allegations must be enough to raise a right to relief above the speculative level, . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact) . . . ." *Twombly*, 550 U.S. at 555 (internal citations and quotations omitted).

In *Ashcroft v. Iqbal,* 556 U.S. 662, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009), the Court built upon its decision in *Twombly*. The Court acknowledged that although a complaint need only contain a "short and plain statement of the claim showing that the pleader is entitled to relief" *id.* at 677-78 (quoting Fed. R. Civ. P. 8(a)(2)), this statement must nevertheless contain "factual content that allows the court to draw the reasonable inference that the defendant is liable for

the misconduct alleged." *Id.* at 678. *Iqbal* reiterated two benchmarks of *Twombly*. That is, "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting *Twombly,* 550 U.S. at 570). Plausibility, as explained by the court, "is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* at 678 (quoting *Twombly*, 550 U.S. at 556.

Thus, when assessing the sufficiency of a complaint, a district court must distinguish betwen factual contentions and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Id.* at 678. When evaluating a motion to dismiss for failure to state a claim, district courts must conduct a three-part analysis:

> First, the court must "tak[e] note of the elements a plaintiff must plead to state a claim." *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S. Ct. 1937, 1947, 173 L. Ed. 2d 868 (2009). Second, the court should identify allegations that, "because they are no more than conclusions, are not entitled to the assumption of truth." *Id.* at 1950. Third, "whe[n] there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief." *Id.* This means that our inquiry is normally broken into three parts: (1) identifying the elements of the claim, (2) reviewing the complaint to strike

> conclusory allegations, and then (3) looking at the well-pleaded components of the complaint and evaluating whether all of the elements identified in part one of the inquiry are sufficiently alleged.

Malleus v. George, 641 F.3d 560, 563 (3d Cir. 2011) (alterations in original).

A complaint will be dismissed unless it "contain[s] sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). "Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679. A plaintiff may not be required to plead every element of a *prima facie* case, but he must at least make allegations that "'raise a reasonable expectation that discovery will reveal evidence of' the necessary element." *Phillips v. Cnty of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008) (quoting *Twombly*, 550 U.S. at 556).

Significantly, the dilemma the Supreme Court faced in deciding *Twombly* is before the Court now, because, as in *Twombly*, the Court is concerned with antitrust cases. *Twombly,* 550 U.S. at 558-59. The Supreme Court explained "that something beyond the mere possibility of loss causation must be alleged, lest a plaintiff with 'a largely groundless claim' be allowed to 'take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value.'" *Id.* at 557-558 (quoting *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 125 S. Ct. 1627, 161 L. Ed. 2d 577 (2005)). Most

notably, "'this basic deficiency should . . . be exposed at the point of minimum expenditure of time and money by the parties and the court.'" *Twombly*, 550 U.S. at 558 (quoting 5 Wright & Miller, Federal Practice & Procedure - Civil Rules: 2010 Quick Reference Guide, Vol. 12B, § 1216, at 233-34). As one treatise has acknowledged, "this standard is best understood as a flexible pleading benchmark that varies depending on the type of claim chosen and the type of allegations pleaded: a 'plausible' auto accident may be very concisely pleaded, whereas a 'plausible' antitrust or RICO case may demand a far fuller factual presentation." Wright & Miller, 2010 Quick Reference Guide, Vol. 12B, at 152 (2014).

This Court must apply the *Twombly* and *Iqbal* standards against the factors of *Actavis* in analyzing the Plaintiff's complaint. Specifically, where the anticompetitive effects of a settlement agreement might fall within the scope of the exclusionary potential of a patent, a court must determine whether there was a reverse payment that is large and unjustified.

B. Summary of Supreme Court's Decision in *Actavis*

The Supreme Court has described a reverse payment settlement agreement ("RPSA") as "unusual" because "where only one party owns a patent, it is virtually unheard of outside of pharmaceuticals for that party to pay an accused infringer to settle a lawsuit." *FTC v. Actavis, Inc.* 133 S. Ct. 2223, 2235 (2013) (quoting 1 H. Hovenkamp, M. Janis, M. Lemley, & C. Leslie, IP and Antitrust § 15.3, p. 15-45,

n. 161 (2d ed. Supp. 2011)). The Court explained that a RPSA occurs as follows:

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

"Because the settlement requires the patentee to pay the alleged infringer, rather than the other way around, it is often called a 'reverse payment' settlement agreement. *Id.* Some of this atypical behavior occurs due to the workings of the Hatch-Waxman Act, wherein the first generic to file enjoys the 180-day exclusivity period during which the "vast majority of potential profits for a generic drug manufacturer materialize[.]" *Id.* at 2229 (internal citation and quotation omitted).

Prior to the *Actavis* decision, there was a dispute within the circuits as to the standard for analyzing a RPSA. Some circuits applied the scope-of-the-patent test, under which antitrust attack will be dismissed so long as the anticompetitive effects fall within the exclusionary potential of the patent. *See, e.g.*, *FTC v. Watson Pharms.*, 677 F.3d 1298 (11th Cir. 2012). In contrast, the Third Circuit implemented a "quick look" approach wherein a RPSA is considered *prima facie* evidence of an unreasonable restraint of trade. *See In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3d Cir. 2012), vacated, *Merck & Co. v. La. Wholesale Drug Co.,* 133 S. Ct. 2849 (2013); *Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co.,* 133 S. Ct. 2849 (2013). This

essentially shifts to "a defendant the burden to show empirical evidence of [the settlement's] procompetitive effects." *Actavis*, 133 S. Ct. at 2237 (quoting *Cal. Dental Ass'n. v. FTC*, 526 U.S. 756, 776 n.12, 119 S. Ct. 1604, 143 L. Ed. 2d 935 (1999).

In *Actavis*, the Supreme Court rejected both camps and, in lieu thereof, instructed courts to employ a rule-of-reason approach in order to strike a balance "between the lawful restraint on trade of the patent monopoly and the illegal restraint prohibited broadly by the Sherman Act." *Actavis*, 133 S. Ct. at 2231. The basic question before the Supreme Court was "whether . . . an agreement [between a patentee and a generic] can sometimes unreasonably diminish competition in violation of the antitrust laws." *Id*. at 2227; *see also* 15 U.S.C. § 1 (Sherman Act prohibition of "restraint[s] of trade or commerce").

In *Actavis*, Solvay Pharmaceuticals initiated patent litigation against Actavis, Inc. and Paddock Laboratories, in response to their Paragraph IV certifications that Solvay's listed patent for its drug AndroGel was invalid and not infringed. *See Actavis*, 133 S. Ct. at 2229. Par Pharmaceutical did not file an ANDA with the FDA, but agreed to share the litigation costs with Paddock in exchange for a share of profits if Paddock gained approval for its generic drug. *Id*. FDA approved Actavis' first-to-file generic product, but in 2006, within the thirty month litigation period, all the parties settled. *Id*. The terms of the settlement between Solvay and Actavis were that (1) Actavis agreed to not bring its generic to market sixty-five (65) months before Solvay's patent expired (unless someone else marketed a generic sooner); and

(2) Actavis agreed to promote AndroGel to urologists. *Id*. The other two manufacturers made similar promises. *Id*. In return, Solvay agreed to pay millions of dollars to each generic—$12 million in total to Paddock; $60 million in total to Par; and an estimated $19-$30 million annually for nine years, to Actavis. *Id*.

The FTC subsequently filed suit against Solvay and the three generics alleging a violation of § 5 of the Federal Trade Commission Act, 15 U. S. C. § 45, by unlawfully agreeing "to share in Solvay's monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years." *Id*. at 2229-30 (internal quotation and citation omitted). The District Court, later affirmed by the Eleventh Circuit, applied the scope-of-the-patent test and found that the FTC had no standing because "absent sham litigation or fraud in obtaining the patent, a [RPSA] is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." *Watson Pharms., Inc.*, 677 F.3d at 1312.

In rejecting the Eleventh Circuit's "scope-of-the-patent" test, the Supreme Court noted that there was "reason for concern" that RPSAs "tend to have significant adverse effects on competition." *Actavis,* 133 S. Ct. at 2231. While the court conceded that settlement on terms of permitting the patent challenger to enter the market before the expiration of the patent bring about competition, it also noted that a payment for staying out of the market causes anticompetitive harm. *Id.* at 2234-35. Such arrangement "simply keeps prices at patentee-set

levels" at the consumers' expense, *i.e.*, the resulting benefit is shared only between the patentee and the challenger. *Id*.

The scope-of-the-patent test finds support in a general policy favoring settlements and thus, truncates any inquiry into patent validity or infringement regardless of the merits of the patent. *Id.* at 2230-31. The Supreme Court cautioned that "whether a particular restraint lies beyond the limits of the patent monopoly is a *conclusion* . . . not its starting point." *Id.* at 2231- 32 (emphasis as original). An invalid patent confers its owner no right to exclude others from the market. Even if a patent is valid, it does not carry with it the power to exclude products or processes that do not infringe upon it. *Id.* at 2231. While recognizing that settling parties may have other reasons to prefer RPSA, the Supreme Court found that the scope-of-the-patent test overlooked the possibility that "the patentee has serious doubts about the patent's survival" and "the payment's objective is to maintain supracompetitive prices." *Id.* at 2235-3737. The majority opinion wrote:

> In our view, these considerations, taken together, outweigh the single strong consideration—the desirability of settlements—that led the Eleventh Circuit to provide near-automatic antitrust immunity to reverse payment settlements. *Id.* at 2237.

On the other hand, the Supreme Court was cognizant of the value of settlements and the strong interest in settling complex and expensive patent infringement litigations. *Id*. at 2234 (citing *Schering-Plough Corp. v. FTC,* 402 F.3d 1056, 1074-75 (11th

Cir. 2005); *In re Tamoxifen Citrate,* 466 F.3d 187, 202 (2d Cir. 2006) (noting public's "strong interest in settlement" of complex and expensive cases). The Court made clear that "it is not normally necessary to litigate patent validity to answer the antitrust question." *Actavis,* 133 S. Ct. at 2236. Rather, the court proposed to initially look at the size of a reverse payment. *Id*. According to the Supreme Court, an "unexplained large reverse payment" may "provide strong evidence" of antitrust activity, because it "can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." *Id.* at 2235-37. The Court further noted that the size of a reverse payment can also serve as "a strong indicator of power" possessed by the patentee to bring about anticompetitive harm. *Id.* at 2236.

The Supreme Court in *Actavis* further rejected the presumptively illegal "quick look" approach advocated by the Third Circuit in *K-Dur*. *Id.* at 2237. Because some reverse payments could be justified under antitrust analysis, the court held that a finding of reverse payment alone is insufficient to conclude its illegality. *Id.* The court reasoned that:

> the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification. The existence and degree of any anticompetitive consequence may also vary as among

> industries. These complexities lead us to conclude that the FTC must prove its case as in other rule-of-reason cases. *Id.*

Additionally, the Court commented that presumptive rules like the "quick look" approach are appropriate only where "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets." *Id.* (internal quotation marks omitted). Since the complexity of a RPSA is far beyond "rudimentary," the Court determined that the "quick-look" approach was not applicable. *Id.*

In formulating the rule of reason analysis, the Supreme Court enumerated several factors to consider: (1) there must be a "payment"; (2) it must be a "reverse" payment, *i.e.*, the payment must be from the alleged patentee to the alleged infringer; (3) it must be "large" which to the Supreme Court is a "surrogate for a patent's weakness" and a "strong indicator of power—namely, "the power to charge prices higher than the competitive level"; and (4) the large reverse payment must be "unexplained." *Id.* at 2236-37. Regarding the fourth factor, valid explanations include the cost of litigation, payments for other services promised to be rendered by the generic challenger and "any other convincing justification." *Id.* at 2237.

Sometimes there are types of settlements that do not fall within the *Actavis* rationale. The Supreme Court provided two types of "commonplace forms" of settlement that are not subject to *Actavis* scrutiny. The first one is when A sues B for patent infringement

and demands $100 million in damages; and then B pays A $40 million as settlement. *Actavis*, 133 S. Ct. at 2233. The "implicit net payment" or reduction in demand of $60 million by A does not trigger antitrust scrutiny. *Id.* The second situation occurs when B has a counterclaim for damages against A, the patentee, and A pays B to settle B's counterclaim. *Id.* Such settlements between a patentee and a generic manufacturer are permissible.

Furthermore, the Supreme Court specifically raised the following five sets of considerations to guide its rule of reason analysis: (1) whether the restraint at issue has the "potential for genuine adverse effects on competition"; (2) whether there are justifications for the anticompetitive consequences; (3) whether the patentee has the market power to bring about the anticompetitive harm, which tends to be true when a reverse payment threatens to work unjustified anticompetitive harm; (4) whether the size of the unexplained settlement payment suggests a workable surrogate for the patent's weakness, which in turn suggests the intent of the patentee to maintain supracompetitive prices; and (5) whether the parties could have settled in a way that did not involve the use of reverse payment. *Id.* at 2234-2237.

The Supreme Court left "to the lower courts the structuring of the present rule-of-reason antitrust litigation." *Id.* at 2238. With this new *Actavis* framework in mind, this Court will analyze Defendants' Motions to Dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure.

1. Payment

In providing the rule of reason analysis for reverse payment settlement agreements, *Actavis* does not define payment or provide clarity as to whether a payment can be something other than a monetary payment. Since the *Actavis* decision, there has been much discussion by other courts, the parties, and commentators regarding the question of what constitutes a payment.

The common use of the term payment is described as something given to discharge a debt or obligation and does not require the payment to be in the form of money. *See Hill v. United States*, 263 F.2d 885, 886 (3d Cir. 1959); *Staff Builders of Philadelphia, Inc. v. Koschitzki*, 989 F.2d 692, 695 (3d Cir. 1993). In Black's Law Dictionary, payment is defined as "performance of an obligation by the delivery of money or some other valuable thing accepted in partial or full discharge of the obligation". Black's Law Dictionary (9th ed. 2009). Payment may also be defined as "the discharge of a pecuniary obligation by money or what is accepted as the equivalent of a specific sum of money." 60 Am. Jur. 2d Payment § 1. Furthermore, it is widely held that a payment may refer to a transfer of something of value other than money. *See* 60 Am. Jur. 2d Payment § 26; *Sousa v. First Cal. Co.*, 101 Cal. App. 2d 533, 540, 225 P.2d 955, 960 (1950); *Dynair Electronics, Inc. v. Video Cable, Inc.,* 55 Cal. App. 3d 11, 18, 127 Cal. Rptr. 268, 272 (Cal. Ct. App. 1976). A non-monetary payment includes something of value that can be converted to a concrete, tangible or defined amount which yields a reliable estimate of a monetary payment.

Other courts have reviewed whether *Actavis* requires that the payment must be cash. One court held that "[n]owhere in *Actavis* did the Supreme Court explicitly require some sort of monetary transaction to take place for an agreement between a brand and generic manufacturer to constitute a reverse payment." *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013).[16] Another decision (by one of my esteemed New Jersey colleagues) found otherwise and held that "the Supreme Court considered a reverse payment to involve an exchange of money" and therefore did "not extend the holding of *Actavis* to the non-monetary

[16] In *In re Nexium*, AstraZeneca and three generic defendants—Ranbaxy, Teva, and Dr. Reddy's, were alleged to have entered into reverse payment agreements to keep a generic version of Nexium off the market. All three generic defendants agreed to refrain from selling generic versions of Nexium until May 27, 2014 when some (but not all) of the patents had expired, though this was years after the generic defendants were initially proposing in their Paragraph IV certifications and arguing in the resulting litigations. In return, AstraZeneca agreed to not to produce its own authorized generic version of Nexium during Ranbaxy's 180-day exclusivity period, allegedly accruing a value to Ranbaxy of over $1 billion. It is unclear from the opinion if there was a cash payment made to Ranbaxy. Also, AstraZeneca forgave contingent liabilities of both Teva and Dr. Reddy's related to "at risk" launches of generic versions of non-related products. The generic defendants urged the court to read *Actavis* to apply only to monetary payments and the court declined. At the motion to dismiss stage, the *In re Nexium* court found the allegations sufficient to allege an antitrust violation. *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013). Later, at the summary judgment stage, the court denied summary judgment made on similar grounds. *In re Nexium (Esomeprazole) Antitrust Litig.*, 12-md-02409-WGY (D. Mass. Sept. 4, 2014) (ECF No. 977).

facts before it." *In re Lamictal Direct Purchaser Antitrust Litig.*, No. 12-0995, 2014 WL 282755, at *6-7 (D.N.J. Jan. 24, 2014)[17]. This Court somewhat agrees with the analysis of both cases. That is, it is true that *Actavis* never indicated that a reverse payment had to be a cash payment; but it is also true that *Actavis* emphasized cash payments. In applying *Actavis* here, the non-monetary payment must be converted to a reliable estimate of its monetary value so that it may be analyzed against the *Actavis* factors.

The Supreme Court's general concern is to determine if there are "genuine adverse effects on competition." *Actavis,* 133 S. Ct. at 2234 (quoting *FTC v. Indiana Federation of Dentists*, 476 U.S. 447, 460-461, 106 S. Ct. 2009, 90 L. Ed. 2d 445 (citing 7 Areeda ¶ 1511, at 429 (1986))). Although *Actavis* addressed cash payments, reading the opinion as a whole, it is clear that the Supreme Court focuses on the antitrust intent of the settling parties rather than the manner of payment. For example, Justice Breyer stated: "the relevant antitrust question is: What are [the] reasons

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[17] In this case, GlaxoSmithKline ("GSK") and the generic defendant Teva are alleged to have entered into reverse payment agreements to keep a generic version of Lamictal off the market. GSK allowed certain generic forms of Lamictal to enter the market before all patent claims had expired, though later than Teva was initially proposing in its Paragraph IV certification and arguing in the resulting litigation. In return, GSK agreed to not to produce its own authorized generic version of Lamictal during Teva's 180-day exclusivity period. The court held that application of *Actavis* did require a monetary payment to have occurred in the settlement and the no-authorized generic agreement was not a payment within *Actavis.* The court concluded that "the settlement was reasonable and not the sort that requires *Actavis* scruitiny."

[for preferring reverse payment settlements]? If the basic reason 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." *Actavis,* 133 S. Ct. at 2237.

The distinction between non-monetary and cash payments impacts the plausibility standard of Rule 12(b)(6). When Justice Breyer explained RPSA through the use of a simple hypothetical "Company A, the patentee, to pay [Company] B [the claimed infringer] many millions of dollars," it is easy to identify the reverse payment; however, in a non-monetary payment it is not as easily recognized. *Actavis,* 133 S. Ct. at 2227. The pleading must show some reliable foundation for estimating the alleged reverse payment. *Cf.* IIA Phillip E. Areeda, Herbert Hovenkamp, et al., Antitrust Law: An Analysis of Antitrust Principles and Their Application ¶ 397, at 417 (3d ed. 2007).

As previously noted, *Twombly* and *Iqbal* establish a flexible pleading benchmark, and in a case where a non-monetary payment is alleged in an antitrust suit, the pleading must demonstrate the reliable foundation showing a reliable cash value of the non-monetary payment through the use of more facts upon which Plaintiff depends. As the Third Circuit noted in an antitrust case:

> [i]t is, of course, true that judging the sufficiency of a pleading is a context-dependent exercise. Some claims require more factual explication than others to state a plausible claim for relief. For example, it

> generally takes fewer factual allegations to state a claim for simple battery than to state a claim for antitrust conspiracy.

W. Penn Allegheny Health Sys., Inc. v. Univ. Pittsburg Medical Center, 627 F.3d 85, 98 (3d Cir. 2010) (internal citations omitted). It is not like changing plausibility to probability; it simply requires a showing of a reliable foundation used within the industry to convert the non-monetary payment to a monetary value.

The FTC has concluded that "[a]llowing pharmaceutical companies to sidestep antitrust review by using non-cash payments to purchase delayed generic entry would significantly undermine the holding in *Actavis*." (FTC *Amicus Curiae* Br. "FTC Br.") at 18). The FTC has performed recent studies on the competitive effects of authorized generic drugs and found that no-authorized generic agreements have become commonplace and "a recognized mode of compensation to generics for restrictions on entry."[18] Though a no-authorized generic agreement does have value, in order to be assessed, it must be converted to a specific value. When an alleged reverse payment involves a non-monetary payment of any kind, it must be valued in terms of a monetary amount in order to determine if it is "large" within the meaning of *Actavis*.

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[18] FTC, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact: A Report of the Federal Trade Commission, at 145-46 (August 2011), *available at* http://www.ftc.gov/reports/authorized-genericdrugs- short-term-effects-long-term-impact-report-federal-trade-commission.

In the instant case, Direct Purchaser Plaintiffs allege that the reverse payment was an agreement "that Wyeth would not launch an authorized generic version of Effexor XR during the 180-day exclusivity period." (Second Am. Compl. at ¶ 12). Plaintiffs believe that by not having to compete with an authorized generic during this time period, "Teva would realize about double the volume of generic sales at significantly higher, supra-competitive prices than Teva otherwise would receive absent Wyeth's promise." (*Id.*). Plaintiffs value this benefit at over $500 million. (*Id.* at ¶¶ 12, 281, 285, 292).

The value of the no-authorized generic agreement in the Complaint appears to be based on a comparison between the $2.39 billion in reported sales of Effexor in 2009 (the year before generic competition) and the $2.31 billion in reported sales of a similarly situated drug, Paxil. The first-filer generic manufacturer of that drug, Apotex Corp., allegedly informed the FDA that the presence of an authorized generic for Paxil cost the company approximately $400 million in sales during its 180-day exclusivity period. (*Id.* at ¶ 292). While this comparison is useful for purposes of showing that a no-authorized generic agreement has value, it does not specifically value the monetary amount of the no-authorized generic agreement in the instant case.[19]

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[19] The FTC Authorized Generic Study has data on the revenue share that transfers from the brand manufacturer to the first-filer generic manufacturer during the exclusivity period, even amongst those without authorized generic competition, even amongst those with a similar market size. *FTC AG Study* at 60, Figure 3-6. The Complaint fails to sufficiently explain why a generic version of Effexor XR would have a similar revenue share

While the Direct Purchaser Plaintiffs' Complaint provides some background on the effect of generic competition and provides estimates of the expected market sales of a generic, it does not provide any explanation as to how those estimations are used to formulate the approximate value of the no-authorized generic agreement. Simply alleging some sort of value of a no-authorized generic agreement, absent a reliable foundation supporting that value, does not establish the plausibility required by Rule 12(b)(6).[20] In essence, Plaintiffs' calculation of the monetary value of the no-authorized generic agreement is vague and amorphous. In this Court's view, in order to raise a right to relief above the speculative level, Plaintiffs must provide some reliable foundation to show that a reverse payment agreement was actually entered and present specific facts showing how the alleged non-monetary payment was calculated. For example, in one article explaining the *Actavis* analysis, the

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as a generic version of Paxil or why the presence of an authorized generic would have a similar impact on the revenue of a generic manufacturer.

[20] While the Plaintiffs later submitted a letter to the Court on May 19, 2014 discussing a methodology used to calculate the no authorized generic agreement having a value of over $500 million, this methodology was not included in the second amended complaint and therefore does not constitute the allegations on which this motion can be based and the Court has not ruled on whether the methodology is plausible. Letter from Peter S. Pearlman, May 19, 2014 (ECF No. 332). It was filed very late and beyond the scope of what the Court had requested to be submitted and, accordingly, it will not be considered. Plaintiffs were provided the opportunity to amend the complaint in light of *Actavis* and re-brief their opposition to the motion to dismiss and did not include the details of the calculation of the payment.

authors noted that a plaintiff must "valu[e] the consideration flowing from the patentee to the claimed infringer."[21] The use of the term "value" contemplates that it is based on a reliable foundation used within the industry.

The Court sees the "payment" between Wyeth and Teva as including more than the no-authorized generic agreement. The *Actavis* decision provides that a payment could be made in exchange for "avoided litigation costs or fair value for services". *Actavis,* 133 S. Ct. at 2236. To establish the payment, the Court finds it appropriate to apply the following analysis:

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

Activating *Actavis*, 16 Antitrust, Vol. 28, at 18. Therefore, the total payment here is seen as the value of the no authorized generic promise for Effexor XR for eleven months (as Plaintiffs also allege that Wyeth kept all other generic companies off the market until

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[21] Aaron S. Edlin, Scott Hemphill, Herbert Hovencamp & Carl Shaprio, *Activating Actavis*, Antitrust, Vol. 28, No. 1 (Fall 2013).

June 2011), added to the value of the allowing Teva to release a generic of Effexor IR before the expiration of the Husbands patent, subtracted by the value of the avoided litigation costs and the royalties Teva would pay to Wyeth during those eleven months.

A rough approximation of the value of the no-authorized generic agreement could be based upon the difference in market expectations with and without an authorized generic. That calculation would include assumptions such as the share of the market that converts from the brand to the generic, the retail price of the generic during the 180-day exclusivity period, with and without an authorized generic, and the share of the generic market that would have been retained by the authorized generic if there had been one. Those assumptions must be analyzed in the Complaint and, in the view of this Court, Plaintiffs are obligated to explain why they provide a reasonable foundation. While Plaintiffs' counsel argues that the Court should accept Plaintiffs' allegation as true, the Court is reluctant to do so because Plaintiffs do not set forth a reliable foundation substantiating their claim. The Complaint simply does not rely on any knowledge of business practitioners in the pharmaceutical industry. As such, more focused allegations are necessary.

Direct Purchaser Plaintiffs allege that, in approximate sixteen months following Teva's release of Effexor IR, Wyeth's sales of Effexor IR that had converted to Teva generic IR venlafaxine tablets were likely worth about or less than $100 million. (Second Am. Compl. at ¶ 294). Again, the Complaint provides no reliable foundation of this value or any explanation for the calculation of this amount. This is an

insufficient allegation for the Court to simply accept as true. Plaintiffs also project that Wyeth's litigation costs for the *Teva* litigation "could not have been larger than a range of about $5 million to $10 million". (*Id*. at ¶ 285). Plaintiffs, however, again fail to provide any reasonable foundation. In contrast, the Complaint could have alleged that a reliable foundation is what is set forth in *Actavis*—that is "[o]ne study found that the cost of litigation in this specific context—a generic challenging a brand name pharmaceutical patent—was about $10 million per suit." *Actavis,* 133 S. Ct. at 2243-44 (citing *Herman* at 1795, n. 41 (citing M. Goodman, G. Nachman, & L. Chen, Morgan Stanley Equity Research, Quantifying the Impact from Authorized Generics 9 (2004)). Such an allegation may have met the reliable foundation standard. In addition, the Complaint also does not allege the value of the royalty payments paid by Teva to Wyeth. In the view of the Court, at the very least, some general industry guidelines should have been alleged in order to be used as a reliable foundation.

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*.

2. Reverse

Actavis provides two examples of settlements that take "commonplace forms" and then provides that there is "something quite different" about reverse payment settlements where "a party with no claim for damages (something that is usually true of a paragraph IV litigation defendant) walks away with

money simply so it will stay away from the patentee's market." *Actavis,* 133 S. Ct. at 2233. Therefore, within the context of pharmaceutical patent cases, a payment is reverse when a net positive payment flows from the patentee to the alleged infringer. *Id.*

According to the Plaintiffs, Wyeth's no-authorized generic promise 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. (Second Am. Compl. at ¶ 281). The Court views the payment as including more than just the no-authorized generic promise, as described above. Defendants argue that there was no reverse payment because "[n]othing in *Actavis* supports treating an early-entry settlement as a 'reverse payment settlement' simply because there is consideration supporting the agreement on both sides". (Defs.' Br. at ¶ 7). Using the three-step methodology to formulate the payment may have still resulted in a net reverse payment. Since the Plaintiffs' conclusion about the value of the payment cannot be supported without sufficient factual matter provided in the Complaint, the value of the non-monetary payment cannot be determined and, therefore, the direction of the payment cannot be established.

3. Large

Throughout the *Actavis* opinion, the Court repeatedly states that the payment must be "large." *Actavis,* 133 S. Ct. at 2236-2237. *Actavis* again does not define what makes a payment "large" and provides only slight guidance for making this determination. Perhaps, at the extreme, a "large" payment is "a sum even larger than what the generic would gain in

profits if it won the paragraph IV litigation and entered the market." *Id.* at 2235. At the other extreme, perhaps a "large" payment is anything more than the value of the avoided litigation costs, when there are no other services provided from the generic to the brand manufacturer. *See Activating Actavis* at 18. The question still remains how large of a payment creates a suspicion that "[t]he rationale behind a payment of this size cannot . . . be supported by traditional settlement considerations." *Actavis,* 133 S. Ct. at 2235.

The Court cannot plausibly establish the value of the non-monetary payment in order to determine if it is large, whether the value of the non-monetary payment was a substantial amount of annual sales of the brand product maybe an appropriate fact, as it must be a payment that appears to be large from the perspective of the brand company making the payment. During oral argument, the discussion turned to the definition of "large." Plaintiffs' counsel noted that $500 million "may not be an awful lot of money to . . . Wyeth. I'll bet it's a lot of money to Teva." Tr. 60:8-60:14, April 3, 2014 (ECF No. 339-2). The problem with Plaintiff's counsel's analysis is that it does not have a reliable foundation. "Betting" it is a large number to Teva is not a sufficient plausible fact to withstand Defendants' motion to dismiss.

4. Unexplained

Actavis has provided examples of valid explanations that account for the payment and, therefore, do not invite antitrust scrutiny. These include the cost of anticipated litigation, payments for other services promised to be rendered by the generic challenger and "any other convincing justification."

Actavis, 133 S. Ct. at 2237. Other convincing justifications are left open to interpretation by the district courts. *Actavis* also suggests that a justification can be seen in the intent of the parties in settling, "[i]f the basic reason 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. Here, any alleged antitrust intent held by the parties is negated by the fact that the settlement and license agreements were forwarded to the FTC evidencing the parties' willingness to submit those agreement for review prior to the settlement becoming effective. The steps ordered by Judge Martini show that the proposed settlement of the patent case was in light of appropriate antitrust concerns. Judge Martini's Scheduling Order does far more than simply inform the FTC of the settlement, as would a submission to the FTC under the MMA. His entry of the Order and signing of the Consent Decree shows strong judicial intervention in the antitrust inquiry. The FTC's letter would lead Judge Martini to conclude that the agency had no interest in the case. With such forethought by Judge Martini, it is difficult for this Court to set aside the settlement agreement contained in the consent decree.

The FTC responded to Judge Martini that they reserved the right to take further action regarding the settlement. The Court finds such a reservation to be unconvincing. 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. Here the FTC filed an amicus brief. There is no

reason suggested therein that FTC's position or knowledge of this case differed between the time of the Consent Decree and the filing of the amicus brief. As such, the comprehensive review suggested by the judiciary makes the FTC's lackluster response to same distinguishable from the settlement discussed in *Actavis* and is a sufficient justification that the agreement between Wyeth and Teva did not constitute an unexplained payment.

Walker Process Claim

In *Walker Process Equipment Inc. v. Food Machinery and Chemical Corp.*, 382 U.S. 172, 86 S. Ct. 347, 15 L. Ed. 2d 247 (1965), the Supreme Court specifically addressed monopoly allegations linked to patents that were allegedly procured by fraud. The Court held that proof that a patent holder knowingly and willfully misrepresented facts to the PTO which would have prevented issuance of the patent. *Id.* at 176-80. Courts have stated the elements of a *Walker Process* claim as:

> (1) the patent at issue was procured by knowing or willful fraud on the USPTO; (2) the defendant was aware of the fraud when enforcing the patent; (3) there is independent evidence of a clear intent to deceive the examiner; (4) there is unambiguous evidence of reliance, i.e., that the patent would not have issued but for the misrepresentation or omission; and (5) the necessary additional elements of an underlying violation of the antitrust laws are present.

Jersey Asparagus Farms, Inc. v. Rutgers Univ., 803 F. Supp. 2d 295, 306 n.9 (D.N.J. 2011) (quoting

Nobelpharma AB v. Implant Innov., Inc., 141 F.3d 1059 (Fed.Cir. 1998)). Hence, in addition to alleging that the patent-holder obtained the patent through an actual fraud perpetrated on the PTO, a *Walker Process* plaintiff "'must also [allege] the basic elements of an antitrust violation defined by the regional circuit's law." *Id.* (quoting *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1346-48 (Fed. Cir. 2007).

Plaintiffs allege that Wyeth "engaged in distinct *Walker Process* frauds." (ECF No. 298, ¶ 416). Plaintiffs allege four different instances where *Walker Process* fraud occurred; the Court mentions two of them. They are:

1. By fraudulently claiming that extended release venlafaxine reduced the incidence of nausea and vomiting, when it did not. (ECF No. 276, ¶ 417.) According to Plaintiffs, Wyeth conducted clinical studies to establish the efficacy of Effexor XR and the studies failed to demonstrate any statistically significant decline in the incidence of nausea. (see *supra*, p. 9).

2. By failing to disclose to a second patent examiner (Spear) that a prior examiner (Hulina) had found all method-of-use claims of Effexor XR unpatentable in light of the Upton patent which had been issued earlier. (ECF 287, ¶ 418.) (See *supra*, p. 10-11).

In response to Plaintiffs' *Walker Process* claims, Wyeth refutes the factual contentions. For example, at oral argument, Wyeth's attorney (Mr. Drivas) focused on the second claim wherein he argued that the interview summary of Examiner Hulina as set forth in the prosecution history concerning method-of-use

claims and the Upton patent did not show that Wyeth concealed Examiner Hulina's action from Spear, when Examiner Spears initialed that he reviewed Examiner Hulina's work. (Effexor T. 21, 6 through T. 23, 24). Similarly, Mr. Drivas attacked the "materiality" of the Upton patent. (Effexor T. 24, L. 5) since the Upton patent does not deal with depression and there is "no disclosure of a sustained release." (Effexor T. 24, L. 5-T. 25, L. 3). Wyeth's arguments appeared to be more like summary judgment than a motion to dismiss on the *Walker Process* claim. As noted in the standard of review section (see *supra*, p. 25-27) Plaintiffs' obligation is to provide grounds of his entitlement to relief, meaning that the "factual allegations must be enough to raise a right to relief above the speculative level . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact) . . . *Twombly*, 550 U.S. at 555. Here, the facts in the Complaint are plausible, and even if one was skeptical about the truth of the facts, they survive on a motion to dismiss. The Complaint sets forth in a clear and plain statement of facts showing that the pleader is entitled to relief. *Iqbal*, 556 U.S. at 677-78.

Wyeth also argues that the plaintiffs failed to show intent, i.e. Wyeth knowingly and willfully undertook the above actions to defraud the Patent Office. Such an intent is an element of proof to ascertain a *Walker Process* claim. Generally, lack of proof of intent within the four corners of the pleading is not a reason to dismiss a complaint. In order to dismiss on such a ground, the defendant must show that the Plaintiff has failed to allege any facts that can support an inference of bad faith or an intent to deceive. *See Wechsler v. Steinberg*, 733 F. 2d 1054,

1057-58 (2d Cir. 1984). Scienter or intent to defraud is usually an issue of fact that should not typically be resolved on a pretrial motion. *Lau v. Mezei*, 2012 U.S. Dist. LEXIS 116608, *11 (S.D.N.Y. 2012). The facts concerning Wyeth's interactions with the Patent Office, *e.g.* failing to disclose the Upton patent, and failing to advise Spear about Hulina's findings, are sufficient to infer fraudulent intent.

III. CONCLUSION

For the reasons stated above, Defendants' Motion to Dismiss the Direct Purchaser Plaintiffs' Second Amended Consolidated Class Action Complaint is granted in part and denied in part. An appropriate Order follows.

s/Peter G. Sheridan

PETER G. SHERIDAN, U.S.D.J.

October 6, 2014