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

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

IN RE EFFEXOR XR ANTITRUST LITIGATION

On Appeal from the United States District Court for the
District of New Jersey, Judge Peter G. Sheridan

BRIEF *AMICI CURIAE* OF 48 LAW, ECONOMICS, AND BUSINESS PROFESSORS AND THE AMERICAN ANTITRUST INSTITUTE IN SUPPORT OF APPELLANTS

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CORPORATE DISCLOSURE STATEMENT OF AMERICAN ANTITRUST INSTITUTE

Pursuant to Fed. R. App. P. 26.1, American Antitrust Institute states that it is a nonprofit corporation and, as such, no entity has any ownership interest in it.

Dated: November 17, 2015

/s/ Steve D. Shadowen
Steve D. Shadowen

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INTEREST OF AMICI CURIAE

The academic *amici* are professors of economics, business, innovation, antitrust law, and intellectual property law. (A list of signatories is attached as Addendum A.) Their sole interest in this case is to ensure that patent and antitrust law develop in a way that serves the public interest and public health by promoting both innovation and competition.

Amicus American Antitrust Institute (AAI) is an independent and non-profit education, research, and advocacy organization devoted to advancing the role of competition in the economy, protecting consumers, and sustaining the vitality of the antitrust laws. AAI is managed by its Board of Directors with the guidance of an Advisory Board consisting of more than 130 prominent antitrust lawyers, law professors, economists, and business leaders.[1]

[1] All parties have consented to the filing of this brief. Pursuant to Fed. R. App. P. 29(c)(5), *amici* state that no counsel for a party has authored this brief in whole or in part; and no party, party's counsel, or any other person or entity—other than *amici* or their counsel—has contributed money that was intended to fund preparing or submitting this brief. AAI's Board of Directors has approved this filing for AAI. Individual views of members of the Board of Directors or Advisory Board may differ from AAI's positions. Certain members of AAI's Board of Directors and Advisory Board are among the counsel for the plaintiffs and were recused from involvement in AAI's deliberations with respect to the brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

Amici offer this brief because exclusion-payment settlements, by which brands pay generics to delay entering the market, are one of the most harmful forms of anticompetitive business behavior in today's economy. These agreements cause enormous harm, requiring consumers to overpay by billions of dollars and to miss dosages by splitting pills in half or not taking needed medications.

The court below erred in requiring plaintiffs to produce, at the motion-to-dismiss stage, evidence typically considered at summary judgment or trial. Just as concerning, the court required plaintiffs to introduce evidence the Supreme Court expected *defendants* to introduce in justifying payment. These requirements are inconsistent with *FTC v. Actavis*, 133 S. Ct. 2223 (2013); this Court's ruling in *King Drug Co. of Florence v. Smithkline Beecham Corp. (Lamictal)*, 791 F.3d 388 (3d Cir. 2015); and pleading standards articulated in *Bell Atlantic v. Twombly*, 550 U.S. 544 (2007), *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), and this Court's precedents.

The Court in *Actavis* found that a large transfer of consideration from a brand to a generic, in exchange for the latter's delayed entry, could have "significant anticompetitive effects" and violate the antitrust laws. 133 S. Ct. at 2237. This watershed ruling would be significantly undermined if courts could impose excessive standards at the motion-to-dismiss stage that effectively make it

impossible for plaintiffs to succeed on a claim despite allegations of conduct that violates the antitrust laws and costs consumers hundreds of millions of dollars.

The excessive pleading requirements imposed by the court below are also not consistent with this Court's subsequent ruling in *Lamictal*. In that case, this Court made clear that *Actavis* applies to non-cash payments, in particular settlements in which brands agree not to introduce their own version of generics (known as "authorized generics" or "AGs") that would compete with true generics. Entry by an authorized generic threatens to cut true generics' revenues in half in the ("valuable," according to the Supreme Court) 180-day exclusivity period reserved for the first generic to challenge a brand firm's patent, claiming invalidity or infringement. For that reason, it is common business practice in the pharmaceutical industry to recognize that brands' promises not to introduce authorized generics are extremely valuable to generics and entail sacrifice by the brand that cedes the revenue it would gain from selling generics.

Finally, in manufacturing heightened pleading thresholds, the court below misread *Twombly*, *Iqbal*, and this Court's opinions. It charted a course that violated the "common sense" required by *Twombly* and multiple decisions that recognized the realities of exclusion-payment litigation in finding complaints to survive motions to dismiss. And it ignored the well-pleaded components of a complaint that alleged: (1) an 11-month delay in marketing an authorized generic; (2) well-

documented findings of the effects of AGs on first-filing generics; (3) reference to a drug with similar revenues for which an AG reduced revenues by hundreds of millions of dollars in a period roughly half as long; and (4) a lopsided comparison of the value provided by the no-AG agreement with litigation costs.

ARGUMENT

I. *ACTAVIS* ARTICULATED A STREAMLINED RULE-OF-REASON FRAMEWORK, NOT A RESTRICTIVE NEW PLEADING STANDARD

The district court adopted heightened pleading requirements not found in—and in fact directly contrary to—the Supreme Court's landmark *Actavis* decision.[2] In that case, the Supreme Court for the first time considered the antitrust legality of agreements by which brands pay generics to delay entering the market. The Court forcefully held that such agreements could be "unjustified," 133 S. Ct. at 2235-36; have the potential for "significant adverse effects on competition," *id.* at 2234; and "violate the antitrust laws," *id.* at 2227.

The Court emphasized the significant antitrust harms that result when a brand pays a generic to stay out of the market. The payment "in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were

[2] *See* Michael A. Carrier, *Pleading Standards: The Hidden Threat to Actavis*, 91 N.Y.U. L. Rev. Online __, draft at 1-2 (forthcoming 2016), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2683704.

held invalid or not infringed by the generic product." *Id.* at 2234. In fact, payment can "provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market." *Id.* at 2235.

In analyzing competitive effects, the Court "le[ft] to the lower courts the structuring of the present rule-of-reason antitrust litigation." *Id.* at 2238. Such a framework was to "consider traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations." *Id.* at 2231. The Court also instructed lower courts to "structure antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question—that of the presence of significant unjustified anticompetitive consequences." *Id.* at 2238. In short, it had in mind a Rule-of-Reason analysis, albeit one structured to avoid detailed, exhaustive analysis that is unnecessary when agreements are so clearly anticompetitive. *See, e.g.*, *id*. at 2234 ("the specific restraint at issue has the 'potential for genuine adverse effects on competition'") (citation omitted); *id*. at 2236 (manufacturer that makes an exclusion payment "likely possesses [market] power"); *id*. at 2237-38 (plaintiffs need not "present every possible supporting fact or refute every possible pro-defense theory").

The application of the Rule of Reason is particularly important for non-cash payments. In the past several years, settlements have migrated away from naked cash transfers towards complex non-cash transactions involving, for example, brand payments for licenses, materials, or promotion, or brand promises not to introduce generics. In the setting of a motion to dismiss, plaintiffs cannot delineate the precise contours of such agreements, which are revealed only through discovery.

Importantly, the Court concluded that *defendants* bear the burden of demonstrating a payment's justifications. It explained that "[a]n 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." *Actavis*, 133 S. Ct. at 2236. And it noted that "one who makes such a payment may be unable to explain and to justify it." *Id.* at 2237.

Specifically, *Actavis* allows the settling parties to explain their payment by showing that it was no larger than litigation costs or was fair value for services provided by the generic, rather than delayed entry. Placing this burden on the patent litigants makes sense given their likely possession of evidence relating to the payment's justifications. As the California Supreme Court recognized in *In re Cipro Cases I & II,* 348 P.3d 845, 867 (Cal. 2015), "a settling party's own

litigation costs and the existence and value of any collateral products or services provided as part of a patent settlement" are "matters about which the settling parties will necessarily have superior knowledge." Similarly, the court in *In re Aggrenox Antitrust Litigation*, 2015 WL 1311352, at *13 (D. Conn. Mar. 23, 2015), explained that "very precise and particularized estimates of fair value and anticipated litigation costs may require evidence in the exclusive possession of the defendants" and "these issues are sufficiently factual to require discovery."

Against this background, the district court's errors here are manifest.

II. THE DECISION BELOW CONSTRUCTS NEW AND IMPROPER RELIABILITY THRESHOLDS

The district court's decision requires undue, unprecedented, and impossible precision from plaintiffs. The plaintiffs alleged a no-AG agreement that falls comfortably within the range of non-cash consideration that courts have readily found subject to antitrust scrutiny.

Plaintiffs alleged that Teva agreed to delay entering the market with a generic version of depression-treating Effexor XR until two years after the expiration of the compound patent. *In re Effexor XR Antitrust Litig.*, 2014 WL 4988410, at *11 (D.N.J. Oct. 6, 2014) ("Opinion") (quoting Direct Purchaser Class Plaintiffs' Second Amended Consolidated Class Action Complaint ("Complaint") ¶ 276). Plaintiffs alleged that Teva delayed entering the market because brand firm

Wyeth promised that it would not introduce an authorized generic version of the drug during Teva's 180-day exclusivity period. *Id.* The no-AG promise was alleged to offer "a substantial financial inducement amounting to over $500 million." Opinion, at *11 (quoting Complaint ¶ 281). As described more fully below, the plaintiffs also offered detail on the effects of authorized generics in general and the effects on a drug with similar sales that lost hundreds of millions of dollars after the introduction of an AG.

Despite these allegations, the court required more from plaintiffs. It did so through its creation of a requirement based on "reliability." Such a concept is nowhere to be found in *Actavis* or the pleading case law. But armed with this new tool, the court invoked it repeatedly:

- Finding that *Actavis* applies to a non-monetary payment but only if it "can be converted to a concrete, tangible or defined amount which yields a reliable estimate of a monetary payment" (Opinion, at *19).
- Allowing analysis "against the *Actavis* factors" but only if the non-monetary payment is "converted to a reliable estimate of its monetary value" (*Id.* at *20).[3]

[3] The court also misapplied the "five sets of considerations to guide its rule of reason analysis." Opinion, at *19. The Supreme Court introduced these considerations not to create a new antitrust framework, but to explain why the previous judicial policy in favor of settlement was not dispositive. *See* Michael A. Carrier, *How Not to Apply Actavis*, 109 Nw. U. L. Rev. Online 113 (2014). In addition, the court should not have analyzed whether a payment was "large" by considering it from the brand's perspective. Opinion, at *23 (requiring "a payment that appears to be large from the perspective of the brand company making the payment"). *Actavis* made clear that it is the *generic* perspective that is crucial in

- Allowing plaintiffs to satisfy the *Twombly* and *Iqbal* standards only if they show that the non-monetary payment has a "reliable foundation showing a reliable cash value" (*Id.* at *20).
- Allowing plaintiffs to "establish the plausibility required by Rule 12(b)(6)," but only if they allege "a reliable foundation supporting" the value of a no-AG agreement (*Id.* at *21).
- Requiring a pleading to "show some reliable foundation for estimating the alleged reverse payment" while quoting a section of an antitrust treatise that addresses a different issue (*Id.* at *20 (quoting IIA Phillip E. Areeda, Herbert Hovenkamp et al., *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 397, at 417 (3d ed. 2007) (analyzing what parties "who are excluded (or foreclosed) from participating in a market" must show to demonstrate economic injury)).
- Injecting, in an article discussing plaintiffs' "valuing [of] consideration," a "contemplat[ion]" that the term "value" is "based on a reliable foundation used within the industry" (*Id.* at *21).
- Stating that it would have considered the value of royalty payments if "general industry guidelines" were alleged "in order to be used as a reliable foundation" (*Id.* at *22).

The district court's frequent use of the "reliability" concept—a newfound concept never adopted before—did not gain persuasiveness through repetition. As we demonstrate next, the district court's scattershot application of a reliability threshold contravenes *Actavis* and well-established pleading law.

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asking whether "the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market." *Actavis*, 133 S. Ct. at 2235.

III. PLAINTIFFS NEED NOT PLEAD EVIDENCE

The district court violated core procedural principles. The court dismissed the complaint because plaintiffs *did not plead evidence*: "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*." Opinion, at *23 (emphasis added).

Of course, the unvarying, longstanding rule is that plaintiffs need not plead the evidence that supports their allegations. *See, e.g.*, *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 325 n.25 (3d Cir. 2010) ("It is not necessary to plead evidence.") (quoting *Bogosian v. Gulf Oil Corp.*, 561 F.2d 434, 446 (3d Cir. 1977)); *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 98 (3d Cir. 2010) (Rule 8(a)(2) "simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element") (internal quotations omitted).[4] A motion to dismiss is designed "merely to assess the legal feasibility of a complaint, not to assay the weight of evidence which might be offered in support

[4] Determining fair market value is a question of fact, not law. *See, e.g.*, *Amerada Hess Corp. v. C. I. R.*, 517 F.2d 75, 82 (3d Cir. 1975) ("[D]etermination of value . . . is a finding of fact . . . based upon the resolution of conflicting evidence . . . .").

thereof." *In re Aggrenox Antitrust Litig.*, 2015 WL 1311352, at *2 (D. Conn. Mar. 23, 2015).

That rule is particularly important here. The manufacturers make these exclusion-payment deals intentionally complex precisely in order to put antitrust regulators and private plaintiffs at an information disadvantage. *See* C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 671 (2009). And the manufacturers have control of all the relevant information. *Id*. These considerations reinforce the rule that plaintiffs need *not* plead evidence. *See, e.g., In re Aggrenox*, 2015 WL 1311352, at *13 ("the very precise and particularized estimates of fair value and anticipated litigation costs may require evidence in the exclusive possession of the defendants, as well as expert analysis"); *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 264 (D. Mass. 2014) (*Actavis* does not "place the initial burden on the Plaintiffs to prove, in their prima facie case, that a transaction was for something other than fair market value"); *In re Cipro Cases I & II,* 348 P.3d 845, 867 (Cal. 2015) (litigation costs and fair value for services "are matters about which the settling parties will necessarily have superior knowledge").[5]

[5] *See* Michael A. Carrier, *Payment After Actavis*, 100 Iowa L. Rev. 7, 24 (2014) ("Given the complexity of these arrangements and their greater access to the information, the defendants should have the burden of showing that the

The district court compounded its fundamental procedural error by picking and choosing among the types of "evidence" it would consider. The court faulted plaintiffs for "not rely[ing] on any knowledge of business practitioners in the pharmaceutical industry." Opinion, at *22. For starters, the "business practitioners" are the ones committing the antitrust violations, so plaintiffs can hardly be faulted for not looking to existing business practices as a yardstick for what the law requires.

Beyond that, however, plaintiffs did rely on the two leading reports on AGs, published by the Federal Trade Commission ("FTC"). The FTC "exercises primary responsibility over federal antitrust enforcement in the pharmaceutical industry" and "has a congressionally-mandated role to conduct studies of industry-wide competition issues," with a "broad authority to compel the production of data and information [that] gives it a unique capacity to conduct 'systematic, institutional study of real-world industries and activities' that 'modern academic research in

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payment is justified."); Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 Minn. L. Rev. 1719, 1730 (2003) (explaining, in the context of determining patent infringement, that "the burdens of production and proof properly rest with the antitrust defendants (or proponents of the settlement) because they typically control the information upon which resolution of the infringement issue will be made"). *Cf.* Aaron Edlin et al., *Activating Actavis*, 28 Antitrust 16, 18 (2013) ("The parties to a payment for delay have ample reason to pack complexities into the deal (such as relatively unimportant services) to conceal its genuine nature.").

industrial organization rarely undertakes.'" FTC Brief as Amicus Curiae, *In re: Effexor XR Antitrust Litig.*, Case 3:11-cv-05479, at 3-4 (D.N.J. filed Aug. 14, 2013).

The FTC published an interim 43-page report in 2009 that presented data showing: price reductions when generics compete with AGs during the 180-day period; 47%-51% revenue reductions for generics facing AG entry during the period; roughly one-quarter of settlements containing provisions relating to AGs; and various types of no-AG provisions in settlements. FTC, *Authorized Generics: An Interim Report*, Ch. 1, at 3; Ch. 2, at 4-10 (2009). Two years later, the FTC followed up with a 153-page report based on an analysis of documents from more than 100 brand and generic drug companies that:

- Examined trends and industry practices in marketing AGs;
- Analyzed "the short-term effects of AGs on . . . prices and on brand and generic revenues based on quantitative analysis of IMS data";
- Described brands' uses of AGs to maintain income streams after generic entry and to reduce incentives to enter the market, and analyzed the brands' "documents and practices" for "consistency with revenue-enhancement and entry deterrence strategies";
- Reviewed generic documents "discussing their concerns with AG competition and the impact of AGs on incentives to challenge brand patents via Paragraph IV certifications";
- Analyzed "quantitative data (i) reflecting long-term effects of AGs on retail and wholesale prices and wholesale expenditures and (ii) indicating how AG competition may affect the break-even point";

- Reviewed generics' challenges to patents and presented data on the relationship between patent challenges and sales levels; and
- Described the roles played by AGs in settlements.

FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* 8-9 (2011). The plaintiffs also relied on 7 articles by (collectively) 17 authors. These authors together have written more than 15 books, 700 articles, and 100 book chapters on health care and the pharmaceutical industry.

Consistent with these sources, the Supreme Court in *Actavis* twice noted that the value to the first-filer generic manufacturer of having the only generic product on the market is "possibly 'worth several hundred million dollars.'" 133 S. Ct. at 2229 (quotation omitted); *see also id.* at 2235 (same); *Lamictal,* 791 F.3d at 404 (same). A No-AG clause that preserves that exclusivity is obviously—without doubt, plausibly—a "large" payment within the meaning of *Actavis*. *See Lamictal*, 791 F.3d at 404.

In short, plaintiffs' complaint is founded on comprehensive FTC studies, a mountain of academic research, and the conclusions reached by the Supreme Court, all of which are of course ultimately founded on what "business practitioners" do in a competitive market, *i.e.*, in a market unblemished by anticompetitive agreements.

The district court also found an "alleged antitrust intent" to be "negated by the fact that the settlement and license agreements were forwarded to the FTC

evidencing the parties' willingness to submit those agreement[s] for review prior to the settlement becoming effective." Opinion, at *24. If the defendants' intent were at all relevant,[6] the district court was nevertheless triply wrong.

First, the defendants did not voluntarily submit the agreement to the federal antitrust agencies – *federal law required them to submit it*. Pub. L. No. 108-173, 117 Stat. 2066, §§1112-1113 (codified as amended in scattered sections of 21, 26, and 42 U.S.C.) ("Medicare Modernization Act" or "MMA") (requiring manufacturers to file settlement agreements concerning the 180-day exclusivity period or production, sale, or marketing of a drug with the FTC and Department of Justice within ten days of the agreement).

Second, the defendants' anticompetitive intent is not negated by their having made the agreement contingent on the agencies' decision to forgo challenging it.[7]

[6] The district court overemphasized the "antitrust intent of the settling parties," claiming that *Actavis* "suggests that a justification can be seen in the intent of the parties in settling." Opinion at *20, *24. While *Actavis* included one line on the parties' "reasons for preferring reverse payment settlements," 133 S. Ct. at 2237, that line most naturally highlighted the anticompetitive effects of exclusion-payment settlements. The Court could not have anticipated that this line would offer a get-out-of-jail-free card allowing parties to escape the consequences of entering into anticompetitive settlements by pointing to a benign intent.

[7] The district court's basic concept here does not make sense. The defendants agreed, in essence, that they would not go forward with the deal if the FTC evinced an intent to challenge it. How does that negate defendants' anticompetitive intent? It is perfectly consistent with an intent to consummate an anticompetitive scheme if defendants could get away with it.

The FTC has very limited resources to deal with the avalanche of exclusion-payment agreements in the pharmaceutical industry. In a recent nine-year period, the FTC identified 194 exclusion-payment agreements.[8] The FTC husbands its resources, strategically picking which few of these cases to litigate on its own, and relying on private plaintiffs to litigate the great majority of the cases in their role as "private attorneys general"—a role that the district court's decision, if left undisturbed, would all but eliminate.[9]

Third, the FTC specifically said that it was *not* evaluating whether the agreement was anticompetitive, noting that its decision "is not to be construed as a determination that the proposed settlement agreement does not violate Section 5 of the FTC Act," and "reserv[ing] the right to take such further action as the public interest may require." Opinion, at *12. And more generally, the MMA's express Savings Clause provides: "Any action taken by the Assistant Attorney General or the Commission, *or any failure of the Assistant Attorney General or the Commission to take action,* under this subtitle *shall not at any time bar any*

[8] *See* FTC, *Overview of Agreements Filed in FY 2013, A Report by the Bureau of Competition* 4 (2014), *available at* https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/141222mmafy13rpt-1.pdf.

[9] *Illinois Brick Co. v. Illinois*, 431 U.S.720, 746 (1977); *Hawaii v. Standard Oil Co*., 405 U.S. 251, 262 (1972).

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 . . . .” Pub. L. No. 108-173, §1117.

The district court also erred in concluding that *Bell Atlantic v. Twombly*, 550 U.S. 544 (2007), somehow required plaintiffs to plead evidence. *Twombly* merely required plaintiffs to provide factual allegations that “raise a right to relief above the speculative level” and offer more than just “a formulaic recitation of the elements of a cause of action.” *Id*. at 555. The Court made clear that plaintiffs did “not need detailed factual allegations,” and it did not “require heightened fact pleading of specifics, but only enough facts to state a claim to relief that is plausible on its face.” *Id.* at 555, 570. The Court did not intend for its “plausibility” requirement to expand into a “probability” hurdle, and it allowed a complaint to proceed “even if it strikes a savvy judge that actual proof of these facts is improbable.” *Id.* at 556. Similarly, the Court in *Ashcroft v. Iqbal* made clear that “[t]he plausibility standard is not akin to a ‘probability requirement,’” and it required a “context-specific” analysis in which “the reviewing court [] draw[s] on its judicial experience and common sense.” *Iqbal*, 556 U.S. 662, 679 (2009).

This Court has made clear that *Twombly* “never said that it intended a drastic change in the law, and indeed strove to convey the opposite impression.” *Phillips*

v. County of Allegheny, 515 F.3d 224, 230 (3d Cir. 2008). The *Twombly* Court "emphasized throughout its opinion that it was neither demanding a heightened pleading of specifics nor imposing a probability requirement." *Id.* at 233; *see also id.* at 234. And this Court has recognized that even after *Twombly*, "Rule 8 requires only a short and plain statement of the claim and its grounds." *Id.* at 232. The same standard applies to antitrust actions. This Court has reversed lower courts that "act as 'gatekeepers'" in "subject[ing] pleadings [in] antitrust and other complex cases" to heightened scrutiny. *West Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 98 (3d Cir. 2010). Such a "gloss on Rule 8 . . . is squarely at odds with Supreme Court precedent," as "it is inappropriate to apply *Twombly*'s plausibility standard with extra bite in antitrust and other complex cases." *Id.*

Consistent with these principles is the understanding that a complaint implicates "[s]tandards of pleading," which "are not the same as standards of proof." *Phillips*, 515 F.3d at 246. This Court connected the *Twombly* language about "whether the complaint alleges 'enough fact[s] to state a claim to relief that is plausible on its face" to introducing "enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of illegal[ity]." *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 319 (3d Cir. 2010).

The difference between the required showings at the pleading stage and trial should be obvious, and this Court already has clarified that plaintiffs need not

prove their case at the pleading stage. It has denied a motion to dismiss even where a complaint "is not as rich with detail as some might prefer" since a plaintiff "need only set forth sufficient facts to support plausible claims." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 211-12 (3d Cir. 2009). In fact, "a complaint may not be dismissed merely because it appears unlikely that the plaintiff can prove those facts or will ultimately prevail on the merits." *Phillips*, 515 F.3d at 231.

In short, the pleading case law in the Supreme Court and this Court makes clear that the plausibility standard sets an attainable bar, that detailed factual allegations are not required, and that only enough facts are required to show the usefulness of discovery.

IV. IN *LAMICTAL*, THIS COURT MADE CLEAR THAT *ACTAVIS* APPLIES TO AGREEMENTS PLED WITH LESS SPECIFICITY THAN THIS COMPLAINT

The decision below also flies in the face of this Court's decision in *Lamictal*. In that case, this Court offered several reasons why "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." 791 F.3d at 403.[10]

[10] *Cf. In re Nexium (Esomeprazole) Antitrust Litig.*, 2015 WL 4720033, at *35 (D. Mass. July 30, 2015) (highlighting the "real-world finding . . . of surpassing importance" that "the jury . . . found as fact that the 'no-AG' clause . . .

This Court explained that "[i]n the *Actavis* Court's view, reverse payments are problematic because of their potential to negatively impact consumer welfare by preventing the risk of competition . . . ." *Id.* at 403-04. And this Court recognized that "no-AG agreements are likely to present the same types of problems as reverse payments of cash." *Id.* at 404. The Supreme Court acknowledged in *Actavis* that the 180–day exclusivity period is "possibly 'worth several hundred million dollars,' and may be where the bulk of the first-filer's profits lie." *Id.* (citation omitted). In the case at issue, there were "plausible indicia that this pattern held true," with "[p]ublic records show[ing] that generic sales of Lamictal in 2008 were . . . 671 million dollars." *Id.* (citation omitted).

Not only was the no-AG promise extremely valuable to generic Teva, but it also entailed a sacrifice on the part of brand GSK. This Court explained that "a brand's commitment not to produce an authorized generic means that it must give up the valuable right to capture profits in the new two-tiered market" as the agreement "transfers the profits the patentee would have made from its authorized generic to the settling generic—plus potentially more, in the form of higher prices, because there will now be a generic monopoly instead of a generic duopoly." *Id.* at 405.

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was a large and unjustified reverse payment with anticompetitive effects outweighing any procompetitive justifications").

This Court did not find a significant distinction between cash and no-AG promises: "The anticompetitive consequences of this pay-for-delay may be as harmful as those resulting from reverse payments of cash." *Id.* "If the brand uses a no-AG agreement to induce the generic to abandon the patent fight, the chance of dissolving a questionable patent vanishes (and along with it, the prospects of a more competitive market)." *Id.* In fact, the agreements are even more anticompetitive: although both settlements delay generic entry, no-AG agreements reduce generic competition after entry. Michael A. Carrier, *Eight Reasons Why "No-Authorized-Generic" Promises Constitute Payment*, 67 Rutgers U. L. Rev. 697, 719-20 (2015).

This Court also found sufficient the *Lamictal* complaint, which offered less detail on a no-AG agreement than the one at issue here. It concluded that "plaintiffs' allegations, and the plausible inferences that can be drawn from them, are sufficient to state a rule-of-reason claim under *Twombly* and *Iqbal* for violation of the Sherman Act on the ground that GSK sought to induce Teva to delay its entry into the . . . market by way of an unjustified no-AG agreement." *Lamictal*, 791 F.3d at 409. According to this Court, plaintiffs there alleged that "GSK agreed not to launch a competing authorized generic during Teva's 180–day exclusivity period"; that such promises can be worth "many millions of dollars of additional revenue"; that "GSK had an incentive to launch its own authorized generic

versions of tablets"; that Teva had a history of launching "at risk"; and that the patent "was likely to be invalidated—as, in fact, its main claim had been." *Id.* at 409-10. This Court thus concluded that "at the pleading stage plaintiffs have sufficiently alleged that any procompetitive aspects of the chewables arrangement were outweighed by the anticompetitive harm from the no-AG agreement." *Id.* at 410.

A side-by-side comparison of the complaint in *Lamictal* and the one here illustrates the sufficiency of the complaint in this case.

	Effexor	***Lamictal***
Delayed generic entry	* "[T]he period of exclusivity granted Teva by Wyeth expired after Teva's 180 day FDA 'exclusivity' expired and up to eleven months after Teva's launch (*i.e.*, June 1, 2011). Complaint ¶ 276.	* GSK agreed "not to launch an [AG] until January 2009 (*i.e.*, 180 days after Teva was on the market with Lamictal Tablets, and over three years after Teva was on the market with Lamictal Chewables)." Consolidated Amended Class Action Complaint ¶ 76.
Effect of AG	* "A 2009 FTC Study found that generics captured between approximately 72% and 85% of sales in the first six months." *Id.* ¶ 56. * A 2006 PhRMA study "found that the presence of an [AG] causes generic prices to be 16% lower than when there is no [AG]." *Id.* ¶ 58. * Three examples show	* "[C]onsumers benefit and the healthcare system saves money during the 180-day exclusivity period when an [AG] enters the market, due to the greater discounting that accompanies the added competition provided by the [AG]." *Id.* ¶ 77.

	AGs "compet[ing] aggressively against independent generics on price" and that "both the authorized and independent generics captured substantial market share from the brand." *Id.* ¶ 60. * The FTC's 2009 study shows that "prices with authorized generic entry are lower during the 180-day exclusivity period." *Id.* ¶ 60. * An AG "can cut a first-filer's generic revenue by more than half during the 180-day exclusivity period, and forces generic prices down." *Id.* ¶ 291. * A PhRMA study "found that an [AG] results in lower generic prices." *Id.* ¶ 291.	
Value of payment	* "Wyeth effectively paid Teva over $500 million . . . in exchange for Teva's promise to delay launching its generic." *Id.* ¶ 292. * Wyeth's no-AG promise transferred "enormous value" to Teva "by ensuring that Teva would (a) garner all of the sales of generic Effexor XR during Teva's generic exclusivity period, instead of dividing those sales with Wyeth's [AG], and (b) charge higher prices than it would	* "Teva received substantial financial inducements that went beyond what Teva could have achieved if it was fully successful in the patent litigation." *Id.* ¶ 20. * "Teva's 180-day market exclusivity period enabled it to generate many millions of dollars of additional revenue." *Id.* ¶ 88.

	have been able to charge if it was competing with Wyeth's [AG]." *Id.* ¶ 282.	
Size of market	* "Effexor XR was a multi-billion [dollar] drug ($2.39 billion in reported sales in 2009) before generic competition," with sales similar to that of blockbuster Paxil, which lost "approximately $400 million" from the presence of an AG and which had similar revenues ("sales of $2.31 billion before generic competition"), and delayed entry nearly twice as long (11, rather than 6, months). *Id.* ¶ 292.	None

If the *Lamictal* complaint satisfied pleading standards, so does the *Effexor* complaint.

V. PLAINTIFFS' COMPLAINT EASILY SATISFIES ORDINARY PLEADING STANDARDS

In determining the sufficiency of a complaint, this Court has articulated a three-part analysis for district courts to apply: "(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); *see also Fowler*, 578 F.3d at 210-11 (offering a similar 2-part test).

Applying the analysis here, first, a plaintiff must show a payment from a brand to a generic and delayed generic entry. The plaintiffs satisfied this with multiple allegations of payment (Complaint ¶¶ 12, 277, 281-83, 285, 292) and delayed entry (*id.* ¶¶ 12-14, 276-77, 279-80, 282, 292). Once the plaintiff makes these showings, the burden shifts to the defendant to show that the payment is justified. But that is not something the plaintiff must allege in its prima facie case. *Actavis* made clear that defendants had the burden of showing "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." *Actavis*, 133 S. Ct. at 2236.

Second, the plaintiffs' allegations relating to payment through a no-AG clause are not conclusory. As discussed above, they rely on the effect of an AG on a drug with similar sales and on comprehensive reports by the FTC and multiple articles. The court below fabricated a threshold based on business practitioners, but even applying such a "test," plaintiffs pass with flying colors.

Third, the plaintiffs alleged the elements of payment and delayed entry:

(1) **Delay**: Wyeth promised that it would not market an AG for at least Teva's 6-month exclusivity period and possibly an additional 5

months, resulting in an 11-month period with no competition from an AG after Teva's launch. Complaint ¶ 276.

(2) **Effect of AGs in general**: FTC reports showed that the introduction of AGs lowers generic prices and that promises not to introduce AGs during the 180-day period reduce first-filing generics' revenues by more than half. *Id.* ¶¶ 58, 60, 291.

(3) **Effect of AG on similar drug**: Effexor (in 2009) gained $2.39 billion in sales, similar to those of blockbuster Paxil ($2.31 billion), for which the introduction of an AG during the *6-month* period reduced revenues by $400 million, supporting a higher figure for Effexor's potential *11-month* period with no AG competition. *Id.* ¶ 292.

(4) **Payment**: Wyeth's no-AG promise transferred "enormous value" to Teva by ensuring that Teva would garner all of the generic Effexor XR sales during the 180-day period and would be able to charge higher prices than if it faced competition from an AG. *Id.* ¶ 282.

In short, plaintiffs showed delayed generic entry and a brand payment to a generic in the form of a promise not to introduce an AG on a blockbuster, billion-dollar drug that most likely was worth hundreds of millions to the generic. This easily satisfies traditional pleading standards of the Supreme Court and this Court. *See generally* Carrier, *Pleading Standards*, at 3-5.

It comes as no surprise that other courts considering no-AG clauses have refused to dismiss complaints pleaded with the same (or less) specificity as the complaint here. The court in *In re Aggrenox Antitrust Litigation* recognized that "plaintiffs have not attempted to assign dollar values with significant precision or very obvious methodological justification to the various provisions of the settlement" that included a no-AG promise and payment for generic services. 2015

WL 1311352, at *13 (D. Conn. Mar. 23, 2015). But the court was not willing to "conclude simply from the absence of precise figures that the pleadings represent formulaic recitations of elements and allegations that fail to rise above the speculative." *Id.*

Similarly, in *In re Nexium (Esomeprazole) Antitrust Litigation*, plaintiffs alleged, without offering backup calculations, that "AstraZeneca agreed to pay over $1,000,000,000 to Ranbaxy and enter into a no-[AG] agreement with it." 968 F. Supp. 2d 367, 391 (D. Mass. 2013). The court found that the no-AG settlement "sufficiently implicate[d] adverse anticompetitive consequences to allow the [plaintiffs'] claims to proceed." *Id.* And the court concluded that the plaintiffs "have pled facts sufficient at the motion-to-dismiss stage to establish" antitrust violations under the Rule of Reason. *Id.* at 393.

In *In re Niaspan Antitrust Litigation*, the court rejected defendants' claims that plaintiffs' allegations regarding payment through a no-AG promise and the provision of generic services were "conclusory assertions" akin to the "formulaic recitation of the elements of a cause of action." 42 F. Supp. 3d 735, 753 (E.D. Pa. 2014). Even if the "plaintiffs' allegations . . . lack the exquisite detail of those in the *Actavis* Complaint, . . . factual allegations . . . do not become impermissible labels and conclusions simply because the additional factual allegations explaining and supporting the articulated factual allegations are not also included." *Id.* The

court understood the appropriate placement of burdens, noting that "[w]hile it [is] possible that defendants will be able to supply evidence to rebut plaintiffs' allegations regarding the true value of the services that Barr agreed to provide, *Twombly* does not require an antitrust plaintiff to plead facts that, if true, definitively rule out all possible innocent explanations." *Id.* The Court thus "conclude[d] that plaintiffs have plausibly alleged the existence of a reverse payment for delayed entry with no legitimate procompetitive justification." *Id.*

Even the district court in *In re Loestrin 24 FE Antitrust Litigation* (which followed the *Lamictal* district court, before it was reversed, in limiting *Actavis* to cash) recognized that it "should come as no surprise" that plaintiffs "struggle to affix a precise dollar value" to the brand's non-cash payment "because pleading facts sufficient to glean the monetary value of non-cash settlements is a tall task, one that would typically require considerable discovery to achieve." 45 F. Supp. 3d 180, 193 (D.R.I. 2014), *appeal docketed, City of Providence, RI v. Warner Chilcott Co.*, No. 15-1250 (1st Cir. filed Feb. 25, 2015); *American Sales Co. v. Warner Chilcott Co.*, No. 14-2071 (1st Cir. filed Oct. 14, 2014).

These courts appropriately applied a flexible analysis that recognizes that defendants have access to the relevant evidence and bear the burden under *Actavis* of justifying the payment.

* * *

The court below erred in requiring plaintiffs, at the motion-to-dismiss stage, to provide evidentiary support typically considered at summary judgment or even trial. Just as concerning, the court required plaintiffs to introduce evidence the Supreme Court expected *defendants* to introduce in justifying payment. These developments fly in the face of *Actavis* and *Lamictal*, and contravene pleading standards articulated in *Twombly*, *Iqbal*, and this Court's rulings.

The Supreme Court's landmark decision in *Actavis* would be undermined if courts were to impose excessive standards at the motion-to-dismiss stage that effectively make it all but impossible for plaintiffs to succeed. This Court's decision in *Lamictal* also would be upended if brands' promises not to introduce authorized generics could be dismissed by requiring the plaintiffs to plead the evidence that will be produced in discovery. And in creating excessive pleading thresholds not supported by *Twombly*, *Iqbal*, or this Court's precedents, the court below misread those decisions, violated the "common sense" required under *Twombly*, and contravened multiple decisions that recognized the realities of exclusion-payment litigation in denying motions to dismiss.

CONCLUSION

For the reasons above, this Court should reverse the decision of the court below granting defendants' motion to dismiss.

Dated: November 17, 2015

Respectfully submitted,

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CERTIFICATE OF BAR MEMBERSHIP

In accordance with Local Rule of Appellate Procedure 28.3(d), I certify that I am a member of the bar of the United States Court of Appeals for the Third Circuit.

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CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE OF APPELLATE PROCEDURE 32(A) AND LOCAL RULE 31.1(C)

1. This brief contains 6,933 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2013 in 14 point Times New Roman font.

3. The text of the electronic pdf version of this brief is identical to the text in the paper copies.

4. Trend Micro OfficeScan Version 10.6.1062 was used to scan the pdf version of this brief and no virus was detected.

Dated: November 17, 2015

/s/ Steve D. Shadowen
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CERTIFICATE OF SERVICE

I, Steve D. Shadowen, certify that counsel for Appellees are Filing Users of the Court's CM/ECF system, and, that this 17th day of November, 2015, this Brief Amici Curiae of 48 Law, Economics, and Business Professors and the American Antitrust Institute in Support of Appellants was served by filing it on the court's CM/ECF system. I further certify that seven hard copies of this Brief were delivered to the Office of the Clerk for the United States Court of Appeals for the Third Circuit. This Brief was also served via e-mail on all counsel by their consent.

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