No. 17-771

In the Supreme Court of the United States

WYETH LLC, WYETH PHARMACEUTICALS, INC., WYETH-WHITEHALL PHARMACEUTICALS LLC, WYETH PHARMACEUTICALS CO., TEVA PHARMACEUTICAL INDUSTRIES LTD., AND TEVA PHARMACEUTICALS USA, INC.,

Petitioners,

v.

RITE AID CORP., RITE AID HDQTRS. CORP., MAXI DRUG INC., ECKERD CORP., JCG (PJC) USA LLC, WALGREEN CO., KROGER CO., SAFEWAY INC., SUPERVALU, INC., HEB GROCERY CO. LP, AMERICAN SALES CO. LLC, GIANT EAGLE, INC., MEIJER, INC., MEIJER DISTRIBUTION, ROCHESTER DRUG CO-OPERATIVE, INC., ET AL., AFL-AGC BUILDING TRADES WELFARE PLAN, ET AL., PAINTERS DISTRICT COUNCIL NO. 30 HEALTH & WELFARE FUND, AND MEDICAL MUTUAL OF OHIO,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

MOTION OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND THE AMERICAN TORT REFORM ASSOCIATION FOR LEAVE TO FILE BRIEF AMICI CURIAE AND BRIEF AMICI CURIAE IN SUPPORT OF PETITIONERS

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Pursuant to Rule 37.2 of the rules of this Court, the Pharmaceutical Research and Manufacturers of America ("PhRMA") and the American Tort Reform Association ("ATRA") (together, "*Amici*") respectfully move

this Court for leave to file the attached brief *amici curiae* in support of the petition for a writ of certiorari to review the judgment of the Court of Appeals for the Third Circuit in *In re Lipitor Antitrust Litig.*, 868 F.3d 231 (3d Cir. 2017). All parties were timely notified of *Amici*'s intent to file the attached brief as required by Rule 37.1. All Petitioners and Respondents Meijer, Inc., Meijer Distribution, and Giant Eagle, Inc. have consented to the filing of this brief. Letters of consent to the filing of this brief are on file with the Clerk of the Court. The remaining Respondents either do not object or take no position.[1]

In this case, the Court of Appeals found that an innovator's grant of a royalty-bearing exclusive license as part of a settlement agreement may trigger antitrust scrutiny. This holding is of fundamental interest to *Amici*, who represent leading pharmaceutical and biotechnology innovators that invest billions of dollars each year in discovering and developing new medicines. *Amici* also represent businesses, corporations, associations, and municipalities that will be negatively impacted by the increase in the number of burdensome lawsuits challenging reverse payments that the Third Circuit's decision will cause, if allowed to stand.

Amici are in a unique position to aid the Court in its considerations of the issues raised by the petition, including the critical importance of patent settlements

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[1] Rochester Drug Co-Operative, Inc., et al., Painters' District Counsel No. 30 Health & Welfare Fund, Medical Mutual of Ohio, and Professional Drug Co., Inc. take no position. AFL-ACG Building Trades Welfare Plan, et al., Walgreen, Co., The Kroger, Co., Safeway, Inc., Supervalu, Inc., HEB Grocery Company LP, American Sales Company, Inc., Rite Aid Corp., Rite Aid Hdqtrs., Corp., JCG (PJC) USA, LLC, Maxi Drug, Inc., Eckerd Corp., and CVS Caremark Corp. do not object.

to continued innovation. *Amici* will also assist the court in understanding the extraordinary investments required for research and development in the pharmaceutical industry and the importance of strong patent rights to incentivize such investment.

Accordingly, *Amici* respectfully request that the Court grant this motion for leave to file a brief *amici curiae*.

Respectfully submitted.

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INTEREST OF AMICI CURIAE[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing leading research-based pharmaceutical and biotechnology companies. PhRMA's members are the primary source of the many new drugs and biologics introduced each year. PhRMA members invest billions of dollars in discovering and developing new medicines, including an estimated $65.5 billion in 2016 alone. *See* PhRMA, *Biopharmaceuticals in Perspective* 35 (2017) (*"2017 Report"*). To continue these extraordinary investments, innovators must be able to maintain strong intellectual property protection and some level of certainty and risk minimization with respect to those rights, including by resolving patent litigation through settlements involving licensing arrangements.

The American Tort Reform Association ("ATRA") is a broad-based coalition of businesses, corporations, municipalities, associations, and professional firms that have pooled their resources to promote reform of the

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[1] No counsel for a party authored this brief in whole or in part, and no person other than amicus and their counsel made any monetary contribution to the preparation or submission of this brief. Pursuant to this Court's Rule 37.2, the parties were timely notified of the intent to file this brief. All Petitioners and Respondents Meijer, Inc., Meijer Distribution, and Giant Eagle, Inc. have consented to the filing of this brief. Letters of consent have been filed with the Clerk. The remaining Respondents either do not object or take no position. Rochester Drug Co-Operative, Inc., et al., Painters' District Counsel No. 30 Health & Welfare Fund, Medical Mutual of Ohio, and Professional Drug Co., Inc. take no position. AFL-ACG Building Trades Welfare Plan, et al., Walgreen, Co., The Kroger, Co., Safeway, Inc., Supervalu, Inc., HEB Grocery Company LP, American Sales Company, Inc., Rite Aid Corp., Rite Aid Hdqtrs., Corp., JCG (PJC) USA, LLC, Maxi Drug, Inc., Eckerd Corp., and CVS Caremark Corp. do not object.

civil justice system with the goal of ensuring fairness, balance, and predictability in civil litigation. For over two decades, ATRA has filed *amicus curiae* briefs in cases before state and federal courts that have addressed important liability issues. ATRA supports strong pleading standards that discourage speculative lawsuits and thus has a significant interest in this litigation.

The Third Circuit's ruling that an innovator's grant of a royalty-bearing exclusive license as part of a settlement agreement may trigger antitrust scrutiny and expose the innovator to the risk of treble-damages liability undermines the ability of innovator pharmaceutical companies to protect and enforce their intellectual property rights. The Third Circuit's toothless interpretation of this Court's pleading standard improperly leaves antitrust defendants subject to lawsuits based on unfounded speculation. PhRMA and ATRA members will be directly disadvantaged if the Third Circuit decision is allowed to stand because it will increase the number of costly and burdensome lawsuits challenging reverse payment settlement agreements.

INTRODUCTION AND SUMMARY OF ARGUMENT

Four years ago, in *FTC* v. *Actavis, Inc.*, 133 S. Ct. 2223 (2013), this Court held that the rule of reason applied in antitrust challenges to "reverse payment" settlements in which the patent holder makes a "large and unexplained" payment to the alleged infringer. The Court left it to the lower courts to further develop the contours of the applicable law in the first instance, but must have recognized that a decision of a court of appeals might require the Court to further develop *Actavis*. That day has come.

The Third Circuit sustained an antitrust complaint in which the only alleged "reverse payment" was an exclusive license provided by the patentee to the generic challenger in exchange for escalating royalties on the generic company's allegedly infringing sales. *Amici* adopt and embrace Petitioners' argument that, under *Actavis*, granting exclusive royalty-bearing licenses to settle Hatch-Waxman patent litigation comes within the rubric of "traditional settlement considerations" insulated from antitrust scrutiny. *See* Pet. 30 -32. Furthermore, the court's holding, which allows an antitrust case to proceed based upon an act expressly authorized by Section 261 of the Patent Act, violates fundamental principles of patent law, and should be reversed on that basis alone.

But the Third Circuit's error went beyond that conflict with core principles of patent law, and fundamentally misapplied the pleading requirements that would apply in reverse payment cases. In particular, the court sustained a complaint that did not plausibly allege that the branded company gave up *anything* of value as part of a Hatch-Waxman settlement. Instead, the court considered the value of the royalty-bearing exclusive license by focusing on the generic manufacturer's perspective. By ignoring whether that exclusive license represented any sacrifice by the branded company, the Third Circuit's holding offends *Actavis'* basic requirement that antitrust scrutiny of settlements should occur only if a plaintiff alleges a payment by the patentee so "large" that it allows the inference, at the pleading stage, that the brand's patent is weaker than the agreed-upon entry date implies. And even when assessing the value of the license from the generic manufacturer's perspective, the Third Circuit compounded its error by reading out of this Court's decision in *Bell*

Atlantic Corp. v. *Twombly*, 550 U.S. 544 (2007), the gatekeeping function the district courts must play on motions to dismiss in antitrust cases. The court somehow found it plausible that the branded company would have launched its own authorized generic product absent settlement (and therefore conferred value on the generic manufacturer by agreeing not to do so), even though the brand lacked any strategy for or experience with authorized generics. But that mere possibility was clearly insufficient under *Twombly*.

BACKGROUND

In 1993, the U.S. Food and Drug Administration ("FDA") approved Wyeth's new drug application ("NDA") to sell Effexor®, a drug for the treatment of depression. *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 246 (3d Cir. 2017).[2] The patent Wyeth held on the compound venlafaxine hydrochloride, the active ingredient in Effexor®, expired on June 13, 2008, but Wyeth later developed an extended-release, once-daily formulation of the drug, called Effexor XR®, which the FDA approved in 1997. *Id.* The U.S. Patent and Trademark Office awarded Wyeth three patents covering the Effexor XR® formulation, each expiring on March 20, 2017. *Id.*

In 2002, Teva filed an abbreviated new drug application ("ANDA") seeking FDA approval to sell a generic version of Effexor XR® before the relevant patents expired. *Lipitor Antitrust Litig.*, 868 F.3d at 247.

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[2] The decision of the court below consolidated two appeals under the caption *In re Lipitor Antitrust Litig.*, one relating to Lipitor® settlements and another relating to Effexor® settlements. *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 239 (3d Cir. 2017). This brief concerns the appeal relating to Effexor® settlements.

It was the first generic applicant to file such an application challenging the patents and, accordingly, was entitled to 180 days of generic marketing exclusivity—meaning the FDA would not approve another ANDA filer for Effexor XR® until Teva's product had been on the market for six months (subject to exceptions not relevant here). *Id.* Upon receiving notice of Teva's challenge to its patents, Wyeth timely sued Teva for infringement in the United States District Court for the District of New Jersey. *Id.* The FDA's approval of generic ANDAs was stayed during the pendency of that case.

In late 2005, Wyeth and Teva settled the infringement suit. *Id.* Under the terms of the settlement, Wyeth granted Teva a license to sell its generic version of Effexor XR® beginning on July 1, 2010, nearly seven years before expiration of the relevant patents. 868 F.3d at 247. Wyeth also agreed that it would not sell its own "authorized generic" version of Effexor XR®—a generically labeled product sold under Wyeth's NDA—during Teva's 180-day period of marketing exclusivity.[3] *Id.* Teva, in return, agreed not to launch its generic product until the license became effective, and to pay Wyeth royalties on Teva's generic sales. *Id.* The royalties escalated—beginning at 15% during the initial six-month exclusivity period, and increasing to 50% for the next six-month period and to 65% thereafter for up to 80 months (depending on whether Wyeth continued not

[3] While the FDA will not approve an ANDA product during the first-filer's generic marketing exclusivity period, products sold under an already-approved NDA are not affected. *See Lipitor Antitrust Litig.*, 868 F.3d at 241; *Mylan Pharm., Inc.* v. *FDA*, 454 F.3d 270, 276-277 (4th Cir. 2006); *Teva Pharm. Indus. Ltd.* v. *Crawford*, 410 F.3d 51, 55 (D.C. Cir. 2005).

to sell an authorized generic and whether any other generic entered the market). *Id.*[4]

In 2011, Respondents brought antitrust claims against Wyeth and Teva under Section 1 of the Sherman Act, 15 U.S.C. § 1, alleging that Wyeth's "no-authorized generic" (or "no-AG") commitment constituted an unlawful "reverse payment" within the meaning of *Actavis*. 868 F.3d at 248. Respondents alleged that the no-AG commitment—which effectively guaranteed Teva six months without competition from another generic—was worth "more than $500 million" to Teva and induced Teva to agree to "delay" its market entry until July 2010. *Id.* at 247.[5] Although an FTC study observed that Wyeth generally "lack[ed] an 'AG Strategy'" and had marketed an authorized generic only once during the period from 2001 to 2008, Respondents alleged that Wyeth "could have" marketed one, and that other innovator companies "typically" do so in similar circumstances. *Id.* at 260. The district court dismissed Respondents' reverse payment claims under Fed. R. Civ. P. 12(b)(6), but the court of appeals reversed, holding that Respondents had plausibly pleaded an unlawful reverse payment under *Actavis*. *Id.* at 258.

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[4] Wyeth also granted Teva a license to sell a generic version of the instant release Effexor (Effexor IR). *Lipitor Antitrust Litig.*, 868 F.3d at 247. There was also an exclusivity provision, and royalties were set at 28% during the first year and 20% the following year (after which the patent expired). *Id.*

[5] Of course, "delay" is a relative term—the settlement permitted Teva to enter nearly *seven years* before patent expiration. *Id.*

ARGUMENT

I. THE PETITION PRESENTS IMPORTANT AND RECURRING QUESTIONS

The decision below threatens to deter common and procompetitive patent settlements, thereby weakening patent rights and undermining important innovation incentives in an industry where such incentives are critical to innovation.

Pharmaceutical innovation has revolutionized healthcare and helped millions live longer, healthier lives. This innovation requires substantial investment. An innovator drug takes an estimated ten to fifteen years and $2.6 billion to develop (when factoring in the great majority of such investments that do not result in marketable products). *See 2017 Report* at 29. Indeed, most compounds studied never reach the clinical trial phase and, of those that do, less than 12% receive FDA approval. *Id.*; Tufts Center for the Study of Drug Development & Tufts University School of Medicine, *Briefing: Cost of Developing a New Drug* 5, 17 (Nov. 18, 2014). And, ultimately, out of every ten new drugs that do reach the market, only two earn revenues to match or exceed research and development costs. Vernon et al., *Drug Development Costs When Financial Risk is Measured Using the Fama-French Three-Factor Model*, 19 Health Econ. 1002, 1004 (2010).

The important medical advances that arise from pharmaceutical research include not only the discovery of new therapeutic compounds, but also improvements to existing medicines, such as improved delivery systems or dosage forms, which are at issue in this case. *See* PhRMA, *2016 Profile*: *Biopharmaceutical Research Industry* 53 (2016). In 2014 alone, PhRMA members spent an estimated $8.8 billion on Phase IV

clinical trials involving research on already-approved products. PhRMA, *2016 PhRMA Annual Membership Survey* 6 (2016). The same requirements for patent protection that apply to new compounds apply equally to such improvements. *See* 35 U.S.C. § 101. The drug at the center of this controversy—Effexor XR®—is one such improvement. New drug formulations, such as Effexor®'s extended-release, once-daily formulation, "may involve changes that appear small but are of significant benefit to consumers or are critical stepping stones to potentially life-saving innovations." Ginsburg et al., *Product Hopping and the Limits of Antitrust: The Danger of Micromanaging Innovation* 3-4, CPI Antitrust Chron. (Dec. 2015).

Strong, reliable patent rights enable pharmaceutical innovators to obtain the returns that make research and development investments and product improvements possible. Burk & Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1616-1617 (2003) ("[I]t is likely that innovation would drop substantially in the pharmaceutical industry in the absence of effective patent protection."). The Federal Trade Commission ("FTC") has acknowledged that "new product development in the pharmaceutical industry is more dependent on patent protection than in many other industries." FTC Bureau of Economics, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change* 180 (Mar. 1999).[6]

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[6] *See also* Cockburn & Long, *The Importance of Patents to Innovation: Updated Cross-Industry Comparisons with Biopharmaceuticals*, Expert Opinion on Therapeutic Patents 739 (2015) ("Compared with other forms of intellectual property protection (such as trade secrets, trademarks, and copyrights) and strategic complementary assets (such as lead time, sales and service, and manufacturing advantages), researchers focused on the US since the 1980s

As one Congressional Budget Office ("CBO") study found, "[p]harmaceutical firms invest as much as five times more in research and development, relative to their sales, than the average U.S. manufacturing firm." CBO, *Research and Development in the Pharmaceutical Industry* 7-9 (2006).

While recognizing the need for strong patent rights to pharmaceutical markets, the Hatch-Waxman Act creates strong incentives for generic drug companies to challenge patents held by innovator companies. First, instead of incurring the cost of extensive clinical trials to demonstrate safety and efficacy, generic applicants are entitled to file ANDAs that rely on the extraordinary clinical trial investment that the innovator funded. *Actavis*, 133 S. Ct. at 2228 (Hatch-Waxman "allow[s] the generic to piggy-back on the pioneer's approval efforts"); *see also* FDA, *Abbreviated New Drug Application (ANDA)*, https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/abbreviatednewdrugapplicationandagenerics/default.htm (last accessed Dec. 22, 2017). Next, Hatch-Waxman allows those generic applicants to litigate the validity, infringement, and enforceability of the innovator's patents without first having to market their own product and thereby risk treble damages for infringement. This enables potential infringers to copy patented inventions and to test those patent rights without exposure to liability if the patent challenge fails. *See* 35 U.S.C. § 271(e)(1); *see also* Sobel, *Consideration of Patent Validity in Antitrust Cases Challenging Hatch-Waxman Act Settlements*, 20 Fed. Cir. B.J. 47, 51 (2010) ("[T]here are ordinarily no dam-

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consistently have found patents to be relatively more important to R&D in pharmaceuticals than in other industries.").

ages claims against the generic because Hatch-Waxman forces the litigation to occur in the period prior to marketing by the generic.").[7] And, finally, as a further incentive to bring those challenges quickly, Hatch-Waxman grants 180 days of generic exclusivity—vis-à-vis other ANDA filers—to the first generic company to challenge an innovator's patents and to obtain FDA approval. 21 U.S.C. § 355(j)(5)(B)(iv).

These provisions in combination make it relatively inexpensive, risk-free, and commonplace to challenge even objectively strong patent protection. One FTC study concluded that for an innovator drug with $130 million in annual sales (roughly the median market size for drugs facing first generic entry during the study period), a patent challenge would be profitable for a generic even if the generic perceived only a 10% chance of success on the merits. FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact*, iii n.7 (2011) ("*FTC Study*"). If, for the same drug, the generic manufacturer did not expect to face competition from the branded company's authorized generic, that same patent challenge would be economically rational based on only a 4% chance of prevailing. For blockbuster drugs with annual revenues of $1 billion or more, challenges are profitable even if the generic's chance of prevailing on the merits is as low as about 2% (and lower if no authorized generic manufacturer is expected). *Id.* at 118.

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[7] By contrast, most patent litigation outside the pharmaceutical context is initiated by patentees after the defendant has made infringing sales. The alleged infringer's exposure in those cases serves as a deterrent to litigating weak patent challenges against strong patents.

Thus, pharmaceutical patents are essential to incentivizing the costly, risky investment necessary in that industry, but are prone to challenge, no matter how strong they appear to be. Challengers have very little to lose. Accordingly, innovators must be able not only to assert and defend their patent rights, but also, where appropriate, to settle patent litigation on reasonable terms. As Chief Justice Roberts has recognized, "patent litigation is particularly complex, and particularly costly." *Actavis*, 133 S. Ct. at 2243 (Roberts, J. dissenting). Settlements reduce the risk and cost of resolving disputes, lessen the burden on judicial resources, and allow companies to focus on research and development rather than litigation. The courts have long recognized the "value" and "desirability" of settlements in patent disputes. *Id.* at 2234, 2237; *see also Flex-Foot, Inc.* v. *CRP Inc.*, 238 F.3d 1362, 1369 (Fed. Cir. 2001) ("[W]hile the federal patent laws favor full and free competition … settlement of litigation is more strongly favored by the law."); *Asahi Glass Co.* v. *Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 991 (N.D. Ill. 2003) (Posner, J.) ("The general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits.").

In pharmaceutical markets, settlements that license generics to launch in advance of patent expiry, and allow first-filers exclusive rights to do so, are a common, pro-competitive means to preserve well-earned patent rights, and the innovation incentives that derive from those rights. These settlements avoid the enormous costs of patent litigation, provide important business certainty, and replace the prospect of no generic competition continuing through patent expiry, with guaranteed, licensed competition in many cases years before the patent is set to expire.

Any legal regime that unduly restricts an innovator's ability to settle patent litigation by granting licenses in exchange for royalties (even exclusive licenses) is undesirable because it chills innovation. Innovators are left with a Hobson's choice of pursuing the legion of patent challenges to a litigated conclusion, or facing massive antitrust litigation with the government and/or private parties, as a consequence of settling in traditional ways. As discussed below, the Third Circuit's framework is such a regime. If the decision stands, innovators will be deterred from granting a commonplace exclusive license with royalty payments as a vehicle for settlement, and the decision's rationale and pleading standard threatens other forms of settlement as well.[8]

II. THE DECISION BELOW CONFLICTS WITH THIS COURT'S DECISIONS IN *TWOMBLY* AND *ACTAVIS*

In the context of motions to dismiss antitrust challenges to alleged reverse payments, *Twombly* and *Actavis* work synergistically. *Twombly* recognized that the courts need to perform a significant gatekeeping function in antitrust cases because of the chilling effect created by such litigation, regardless of the ultimate merits of the claim; *Actavis* recognized that antitrust concerns are not implicated by settlements not involving a "large, unexplained" payment from the patent holder to the alleged infringer. The court of appeals' decision, by giving short shrift to *Twombly* and misap-

[8] A writ is warranted in this case even absent a circuit split because, in light of the antitrust laws' liberal venue provisions, *see* 15 U.S.C. § 22, the Third Circuit has become a principal forum for plaintiffs pursuing reverse payment cases and has decided an important federal question in a manner that conflicts with this Court's settled precedent. Pet. 28-33.

plying *Actavis*, undermines the regime established by this Court and makes it too easy for plaintiffs to proceed with an antitrust claim against a settlement without plausibly alleging its anticompetitive qualities.

A. In *Twombly*, This Court Emphasized The Gatekeeping Function Of District Courts In Antitrust Cases

In *Twombly*, this Court held that an antitrust plaintiff must establish the "plausibility" of its claim to survive a motion to dismiss; "mere possibility" is not enough. *Twombly*, 550 U.S. at 557-559. The Court stressed that district courts must "insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed." *Id.* at 558 (quoting *Associated Gen. Contractors of Cal., Inc.* v. *Carpenters*, 459 U.S. 519, 528 n.17 (1983)); *see also Ashcroft* v. *Iqbal*, 556 U.S. 662, 679 (2009) ("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.").

In the context of allegations of antitrust conspiracy, *Twombly* held that a complaint must contain "enough factual matter (taken as true) to suggest an agreement was made." *Twombly*, 550 U.S. at 556. Importantly, it is insufficient to plead factual allegations "merely consistent with" such an arrangement, and then to add conclusory assertions that an agreement was reached. *Id.* at 556-557.[9] This is because Fed. R. Civ. P. 8(a)(2)

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[9] In *Twombly*, the Court scrutinized the complaint for factual allegations of conspiracy beyond descriptions of parallel conduct, and found none sufficiently specific to plausibly show an "actual agreement." It acknowledged that the complaint contained allega-

requires the plaintiff to include in its complaint "enough heft to 'sho[w] that the pleader is entitled to relief.'" *Id.* at 557 ("An allegation of parallel conduct is thus much like a naked assertion of conspiracy in a § 1 complaint: it gets the complaint close to stating a claim, but without some further factual enhancement it stops short of the line between possibility and plausibility of 'entitle[ment] to relief.'").

The Court's insistence on a sufficient factual basis to establish plausibility is rooted in the expense and expanse of antitrust discovery. As the Court explained, "it is one thing to be cautious before dismissing an antitrust complaint in advance of discovery … but quite another to forget that proceeding to antitrust discovery can be expensive." *Twombly*, 550 U.S. at 558. The Court noted that "the costs of modern federal antitrust litigation and the increasing caseload of the federal courts counsel against sending the parties into discovery when there is no reasonable likelihood that the plaintiffs can construct a claim from the events related in the complaint." *Id.* (quoting *Car Carriers, Inc.* v. *Ford Motor Co.*, 745 F.2d 1101, 1106 (7th Cir. 1984)). As a result, the *Twombly* Court instructed lower courts not to postpone scrutiny of claims to the summary judgment stage because "the threat of discovery expense will push cost-conscious defendants to settle even anemic cases before reaching those proceedings." *Id.* at 559. The Court instead required "enough facts to state a claim to relief that is plausible on its face" and held that antitrust plaintiffs must plead facts that "nudge[] their claims across the line from conceivable to plausible." *Id.* at 570. Put another way, the Court decisively

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tions using that term, but rejected them as "merely legal conclusions resting on the prior allegations [of parallel conduct]. *Twombly*, 550 U.S. at 564.

rejected the prior notion that stating a "mere possibility" of entitlement to relief was enough. *Id.* at 557-558.

B. In *Actavis*, This Court Established A Pleading Requirement Of A Non-Traditional Form Of Settlement[10] Involving A "Large And Unexplained" Payment From The Patentee

In *Actavis*, this Court held that an alleged reverse payment is subject to antitrust scrutiny only if plaintiffs allege and prove, among other things, that there was a "large" and "unexplained" payment from the patent holder. *Actavis*, 133 S. Ct. at 2236-2237. Although the Court did not provide precise definitions of these terms or extensive guidance on how lower courts should apply them, it is clear in context that: (1) the Court did not have in mind simple dictionary definitions of "large" and "unexplained" or an open-ended inquiry; and (2) the Court intended that the "size" of the payment be assessed from the perspective of the patentee, here Wyeth. Indeed, the Court stated that a "large, unexplained" payment could serve as a proxy for the patentee's market power and the patent's relative strength. *Id.* at 2236 ("[T]he 'size of the payment … is itself a strong indicator of power'-namely the power to charge prices higher than the competitive level"); *id.* at 2236-2237 ("[T]he size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness."). Otherwise, a challenger could not show that the settlement was even potentially anticompetitive in the first instance. *Id.*

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[10] For the reasons set forth in the Petition, exclusive licenses are among the "traditional settlement considerations" not subject to scrutiny. *Amici* do not repeat those arguments here, and instead focus on the general *Actavis* pleading requirements.

Especially in the context of a settlement that licenses generic entry before patent expiry, the Court acknowledged the difficulty in assessing the agreement's net impact on consumers. *Actavis*, 135 S. Ct. at 2234 ("We concede that settlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition, again to the consumers' benefit."). Moreover, the Court recognized that a valid patent entitles the patentee to the exclusive use of the patented invention for the life of the patent, as well as the possibility that the patent(s) at issue may be valid and infringed. *Id.* at 2231. Finally, the Court acknowledged the practical difficulties and chilling effect of conducting a trial on the patent merits to assess the legality of a settled claim. *Id.* at 2234.

Weighing these factors against antitrust concerns, the majority in *Actavis* determined that the presence of a large, unexplained payment from the patentee to the challenger warranted a rule of reason inquiry into the competitive merits of the settlement. 133 S. Ct. at 2237 ("In sum, a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects [.]").

Thus, the critical *Actavis* question is whether an unexplained alleged reverse payment was so large that it "suggest[s] that the *patentee* ha[d] serious doubts about the patent's survival." 133 S. Ct. at 2236 (emphasis added). If an unexplained payment is "large" by that standard, then it "may provide strong evidence that the *patentee* seeks to induce the generic challenger to abandon its claim for a share of its monopoly profits that would otherwise be lost." *Id.* at 2235 (emphasis added). On the other hand, if a patentee has not sacrificed much from its perspective, then the payment

(even if attractive to the generic) cannot provide any indication that the patent may be weak (or at least weaker than the agreed-upon entry date implies) or that the patentee's intent was to eliminate the risk of competition. *See King Drug Co. of Florence, Inc.* v. *SmithKline Beecham Corp.*, 791 F.3d 388, 405 (3d Cir. 2015) ("[T]he fact that the brand promises not to launch an authorized generic (thereby *giving up* considerable value to the settling generic) makes the settlement something more than just an agreed-upon early entry." (emphasis added)).

Courts and commentators have noted that for a payment to be large and unexplained, it necessarily must involve a significant sacrifice on the part of the patentee. *See* Edlin et al., *The Actavis Inference: Theory and Practice*, 67 Rutgers U. L. Rev. 585, 595 (2015) ("In any case where the plaintiff asserts that a no-AG provision constitutes all or part of a large and unexplained reverse payment, the plaintiff will need to present evidence allowing the court to reasonably approximate how much money the branded firm sacrificed by agreeing not to introduce or enable an AG version. Evidence regarding the profits the branded firm expected to earn from an AG will be especially relevant for this inquiry."). *See also King Drug*, 791 F.3d at 405 ("'the source of the benefit to the claimed infringer is something costly to the patentee.'" (quoting Edlin et al., *Activating Actavis* 16, 22 n.22, Antitrust (Fall 2011) 16 at 22 n.22))).

C. The Decision Below Conflicts With The Pleading Requirements Set Forth In *Twombly* And *Actavis*

Taken together, *Twombly* and *Actavis* require a district court to dismiss reverse payment claims unless

the plaintiff pleads sufficient facts that, taken as true, plausibly suggest a non-traditional form of settlement in which the patentee made a "large, unexplained" payment to the alleged infringer; that is, a payment that reflects so much brand sacrifice that it allows an inference at the pleading stage that the brand's patent was weaker than the agreed-upon entry date implies. The court below failed to apply these standards to the Respondents' complaint.

As detailed above, the alleged reverse payment in this case was Wyeth's "no-AG" commitment, granting Teva royalty-bearing exclusive licenses (even as to Wyeth) to market generic versions of Effexor XR®. Because the licenses contemplated payment of significant and escalating royalties by Teva to Wyeth, there could not be a "reverse payment" in the first place—much less a "large" one—unless from Wyeth's perspective its expected return on its own authorized generic exceeded the expected royalty stream from Teva. If Wyeth would not have launched an authorized generic even absent settlement, or if Wyeth expected more profits from a license than a launch, then it gave up nothing of value.

Unlike the district court, the court of appeals failed to consider adequately the "large and unexplained" requirement from the brand sacrifice perspective.[11] Ra-

[11] The Third Circuit previously held in *King Drug* that an actionable reverse payment must be one that involves the patentee "giving up considerable value," otherwise it cannot satisfy the rationale of *Actavis* that such payments "may … provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits." *King Drug*, 791 F.3d at 405. The court below, contrary to its own precedent, viewed the payment principally from the perspective of the generic manufacturer instead.

ther, in finding that the payment was sufficiently alleged to be "large," the Third Circuit focused on *Teva's* side of the coin. The court credited Respondents' claim that the no-AG commitment "'amount[ed] to over $500 million in value' given to Teva," but went no further. *Lipitor Antitrust Litig.*, 868 F.3d at 259.[12] Based mostly on this allegation, the court swiftly declared that the complaint sufficiently alleged a "large" payment. *Id.* at 260-261.

The court then compounded its error by misapplying *Twombly*. The Petitioners had argued that Respondents had not plausibly shown that Wyeth gave up *anything* of value, because there were insufficient allegations that it would have launched an authorized generic absent the settlement.[13] Indeed, an FTC study showed that Wyeth "lack[ed] an AG strategy," and had launched a single authorized generic from 2001 to 2008. *Lipitor Antitrust Litig.*, 868 F.3d at 260.[14] Mischaracterizing the Petitioners' argument as a factual one inappropriate at the pleading stage, the Third Circuit found that in the first instance a Wyeth launch was "plausible" based on that single launch, as well as a broad general allegation that branded companies "typically" launch an AG upon generic entry. *Id.* at 260-261.

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[12] That the court of appeals was focused on the value of the no-AG agreement from Teva's point of view is clear from its reliance on the allegation that having no competition from an AG would allow Teva to "maintain a supra-competitive generic price…and to earn substantially higher profits than it otherwise would have earned." *Lipitor Antitrust Litig.*, 868 F.3d at 260.

[13] Here, too, the lower court focused on the wrong party's perspective, considering only whether "the Wyeth no-AG agreement really gave Teva little value." *Id.*

[14] According that same FTC study, in stark contrast to Wyeth, Pfizer (to use one example) launched 19 authorized generics from 2001-2008. *FTC Study* 16.

But these flimsy allegations did not establish "plausibility" any more than the "few stray statements speak[ing] directly of [actual] agreement" established a conspiracy in *Twombly*. *See Twombly*, 550 U.S. at 564. The vague assertion of what branded companies "typically" do said nothing about Wyeth, and could be made in any reverse payment case involving a no-AG agreement. The only "facts" specific to Wyeth were that it had no AG strategy and had launched only one AG in seven years. Indeed, the court of appeals acknowledged the FTC study was "evidence that Wyeth may not have introduced an authorized generic here." *Lipitor Antitrust Litig.*, 868 F.3d at 260. On that record, the court of appeals could not have properly concluded that Wyeth gave up anything of value. At best, it was a "mere possibility" that failed to comport with *Twombly*. And in turn, absent any non-conclusory factual allegations suggesting the plausibility that the payment was "large" from Wyeth's perspective, the court of appeals had no basis to conclude that the threshold requirement of *Actavis* had been met.

The court of appeals also failed properly to assess the import of the royalty payments from Teva to Wyeth in exchange for the no-AG agreement. Again, the court viewed the royalties only in terms of their effect on Teva, acknowledging (but ultimately downplaying) that they might mean that the "no-AG agreement is ultimately worth less [to Teva] than it otherwise would have been." *Lipitor Antitrust Litig.*, 868 F.3d at 261. But the real question is whether the royalties from Teva were worth more to Wyeth than the prospect for revenue from an authorized generic that Wyeth was at best uncertain otherwise to market. The answer is not obvious and could not simply be assumed without factual allegations on point (as the court of appeals did)

given considerations suggesting the opposite result: the royalties were substantial; Wyeth had little experience with AGs and no AG strategy; and if Wyeth had marketed an AG, it would have been competing not only with itself but with one of the leading generic companies. Yet the Third Circuit brushed off the deficiencies of the complaint in this regard, holding that the inquiry "require[d] factual assessment, economic calculations, and expert analysis that are inappropriate at the pleading stage." *Id.* In doing so, the court of appeals again misunderstood *Twombly*'s plausibility requirement and insistence on fact pleading.

In short, while purporting to apply both *Twombly* and *Actavis*, the Third Circuit applied its own analysis that was inconsistent with both precedents. In doing so, the court opens the floodgates of costly antitrust litigation based on no more than unfounded speculation. The result of letting the decision stand will be to deter parties from entering settlements that otherwise could be reached through the traditional means of granting exclusive, royalty-bearing licenses; to force parties to engage in costly and uncertain patent litigation; and ultimately to chill further investment in innovation given the no-win choice between litigating all patent cases to conclusion or facing follow-on antitrust litigation. Thus, not only has the Third Circuit upset the careful balance this Court struck through *Twombly* and *Actavis*, it further weakens patent rights in the industry that depends on those right to discover and improve upon lifesaving therapies.

CONCLUSION

For the foregoing reasons, the petition for a writ of *certiorari* should be granted.

Respectfully submitted.

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