No. 17-752

IN THE SUPREME COURT OF THE UNITED STATES

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT CO., WARNER-LAMBERT CO. LLC, RANBAXY INC., RANBAXY PHARMACEUTICALS, INC., AND RANBAXY LABORATORIES, LTD.,

Petitioners,

v.

RITE AID, ET AL., WALGREEN COMPANY, ET AL., GIANT EAGLE, INC., MEIJER INC., ET AL., ROCHESTER DRUG CO-OPERATIVE, INC., ET AL., AFL-AGC BUILDING TRADES WELFARE PLAN, ET AL.,

Respondents.

On Petition for a Writ of Certiorari to United States Court of Appeals for the Third Circuit

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

Philip S. Goldberg
SHOOK, HARDY & BACON L.L.P.
1155 F Street, N.W., Suite 200
Washington, D.C. 20004
(202) 783-8400
pgoldberg@shb.com

(Additional Counsel Listed on Inside Cover)

Additional Counsel for Amici Curiae

Cary Silverman
Victor E. Schwartz
SHOOK, HARDY & BACON L.L.P.
1155 F Street, N.W., Suite 200
Washington, D.C. 20004
(202) 783-8400

Of Counsel

Melissa B. Kimmel
David E. Korn
PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA
950 F Street, N.W., Suite 300
Washington, D.C. 20004
(202) 835-3400

H. Sherman Joyce
Lauren Sheets Jarrell
AMERICAN TORT REFORM ASSOCIATION
1101 Connecticut Avenue, N.W., Suite 400
Washington, D.C. 20036
(202) 682-1163

Linda E. Kelly
Leland P. Frost
NATIONAL ASSOCIATION OF MANUFACTURERS
733 10th Street, N.W., Suite 700
Washington, D.C. 20001
(202) 637-3000

MOTION FOR LEAVE TO FILE

The Pharmaceutical Research and Manufacturers of America (PhRMA), American Tort Reform Association (ATRA), and the National Association of Manufacturers (NAM), hereby move, pursuant to Supreme Court Rule 37.2, for leave to file a brief as *amici curiae* in support of the petition for a writ of certiorari to the United States Court of Appeals for the Third Circuit. PhRMA, ATRA, and the NAM are filing this motion because not all Respondents provided their consent to the filing of this brief.[1] A copy of the proposed brief is attached to this motion.

As explained more fully in the attached brief under "Interest of *Amici Curiae*," PhRMA represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. ATRA is a broad-based coalition of businesses, corporations, municipalities, associations, and professional firms that have pooled resources to promote fairness, balance, and predictability in civil litigation. The NAM

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[1] Pursuant to Rule 37.2, PhRMA, ATRA, and the NAM provided counsel of record for all parties with notice of their intent to file the proposed brief at least ten days prior to its due date. All Petitioners, along with Respondents Meijer Inc. and Giant Eagle Inc., consented to the filing of this brief. Respondents Walgreen Co., CVS Health Corp., and Rite Aid Corp. do not object to the filing of this *amici* brief. Respondents Burlington Drug Co., Value Drug Co., Rochester Drug Cooperative, Inc., Professional Drug Company, Inc., American Sales Co., Inc., and the End Payor Class Plaintiffs state that they take no position on the request to file this brief.

is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states.

PhRMA, ATRA, and the NAM are concerned that, in the wake of *FTC v. Actavis*, 133 S. Ct. 2223 (2013), branded and generic drug manufacturers that attempt to resolve significant and complex patent disputes are virtually certain to face highly speculative, onerous follow-on antitrust litigation. The proposed brief will aid the Court by explaining that pharmaceutical patent laws facilitate litigation between innovator and generic drug manufacturers, the ability of the parties to settle these disputes is highly beneficial to the public, and speculative antitrust challenges to them will needlessly chill such settlements.

The proposed brief also urges the Court to provide greater guidance on what qualifies as an impermissible reverse payment and what facts plaintiffs must include in a complaint to plausibly allege anticompetitive conduct in order to subject a pharmaceutical patent settlement to antitrust scrutiny. These questions are unanswered, particularly in the context of largely non-monetary global settlements of complex patent disputes. Providing such direction will be helpful to manufacturers so that they can protect their intellectual property rights in ways consistent with the antitrust laws and avoid improper antitrust challenges to their patent settlements.

PhRMA, ATRA, and the NAM, therefore, respectfully request that the Court grant leave to file the attached brief as *amici curiae*.

Respectfully submitted,

Philip S. Goldberg
Counsel of Record
Cary Silverman
Victor E. Schwartz
SHOOK, HARDY & BACON L.L.P.
1155 F Street, N.W., Suite 200
Washington, D.C. 20004
(202) 783-8400
pgoldberg@shb.com
csilverman@shb.com
vschwartz@shb.com

Attorneys for Amici Curiae

Melissa B. Kimmel
David E. Korn
PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA
950 F Street, N.W., Suite 300
Washington, D.C. 20004
(202) 835-3400

H. Sherman Joyce
Lauren Sheets Jarrell
AMERICAN TORT REFORM ASSOCIATION
1101 Connecticut Avenue, N.W.
Suite 400
Washington, D.C. 20036
(202) 682-1163

Linda E. Kelly
Patrick N. Forrest
Leland P. Frost
THE NATIONAL ASSOCIATION OF MANUFACTURERS
733 10th Street, N.W., Suite 700
Washington, D.C. 20001
(202) 637-3000

Of Counsel

Dated: December 22, 2017

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INTEREST OF *AMICI CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for new cures. PhRMA's mission is to conduct effective advocacy for public policies that encourage discovery of important new medicines for patients by pharmaceutical/biotechnology research companies. The ability of innovator and generic pharmaceutical companies to settle patent litigation without unwarranted antitrust liability exposure is vital to PhRMA members.

Founded in 1986, the American Tort Reform Association ("ATRA") is a broad-based coalition of businesses, corporations, municipalities, associations, and professional firms that have pooled resources to promote fairness, balance, and predictability in civil litigation. For more than two decades, ATRA has filed *amicus curiae* briefs in cases before federal and state courts that have addressed important liability

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[1] Pursuant to Rule 37.6, counsel for PhRMA, ATRA, and the NAM certifies this brief was not authored in whole or in part by counsel for any party and that no person or entity, other than the *amici*, their members, or their counsel made a monetary contribution to the preparation or submission of the brief. *Amici* provided counsel of record for all parties with notice of their intent to file the proposed brief at least ten days prior to its due date. As indicated in the accompanying motion for leave to file, all Petitioners and two Respondents granted consent. Other Respondents did not object or took no position on the request to file this brief.

issues. ATRA supports strong pleading standards that discourage speculative lawsuits and avoid expensive, unwarranted discovery costs.

The National Association of Manufacturers (NAM) is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs more than 12 million men and women, contributes $2.17 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for more than three-quarters of all private-sector research and development in the nation. The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

Amici are concerned that, in the wake of *FTC v. Actavis*, 133 S. Ct. 2223 (2013), branded and generic drug manufacturers that attempt to resolve significant and complex patent disputes are virtually certain to face highly speculative, onerous follow-on antitrust litigation. *Amici* urge the Court to provide greater guidance to lower courts on what constitutes a "large" and "unjustified" reverse payment so that manufacturers can protect their intellectual property rights in ways consistent with the antitrust laws.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

This Court recognized in *FTC v. Actavis* that a branded and generic drug manufacturer must be able to settle patent disputes during the transition when generic versions of prescription drugs enter the marketplace, so long as the settlement does not constitute a "large" and "unjustified" reverse payment to the generic firm for "purely" anticompetitive purposes. 133 S. Ct. 2223, 2237 (2013). The reason for allowing antitrust challenges in such limited situations, the Court continued, is to stop a patentee from, in effect, purchasing the exclusive right to sell its product, with the generic firm "walk[ing] away with money simply so it will stay away from the patentee's market." *Id.* at 2233. There must be unlawful antitrust collusion that is "quite different" from legitimate efforts of parties to settle litigation. *See id.*

In *Actavis*, the Court addressed these issues in the context of a government enforcement action involving a relatively straightforward patent settlement. Here, private parties are seeking financial payments by alleging one part of a routine global settlement, which involved sixteen claims and counterclaims, constitutes a "large" and "unjustified" reverse payment for another part of the global settlement. This case, as with other post-*Actavis* private claims, demonstrates the extent to which courts have struggled to distinguish anticompetitive pharmaceutical patent settlements from settlements representing legitimate compromises that should not be subject to protracted burdens and legal exposures of antitrust litigation. *See*, *e.g.*, *In re Aggrenox Antitrust Litig.*,

94 F. Supp. 3d 224, 236 (D. Conn. 2015) (noting district courts are applying *Actavis* inconsistently).

In particular, lower courts have expressed substantial confusion over what constitutes a reverse payment, when such a payment is large, and when a large payment is unjustified. In trying to define such standards, courts have considered many factors, but have been unable to find any common ground or governing principles. *See* Joshua B. Fischman, *The Circular Logic of Actavis*, 66 Am. U. Law. Rev. 91 (2016) (*Actavis* "generated serious confusion in the lower courts."); Melvin F. Jager, *Chapter 5: The U.S. Antitrust Laws,* Licensing Law Handbook § 5:15 (Sept. 2017) (observing the "difficulty" courts have had in applying *Actavis*); Lisa Jose Fales & Paul Feinstein, *Two Years and Counting Since Actavis: Developments in the Law*, 30 Antitrust ABA 31, 31 (2015) ("[L]ower courts have grappled with what the decision means and how to apply it."). There remain no articulated baseline standards for when allegations of a large and unjustified reverse settlement are sufficiently plausible to survive a motion to dismiss.

As a result, branded and generic pharmaceutical manufacturers have no guidance for how to lawfully resolve patent disputes, particularly involving multiple claims and counterclaims, without concern that burdensome antitrust actions will follow. Given the lack of any meaningful plausibility standards in the case at bar, if the Court denies this Petition private plaintiffs will likely target the Third Circuit for filing highly speculative follow-on antitrust claims for pharmaceutical patent settlements. No settlement will be safe from the threat of the treble damages hammer of antitrust litigation.

In *Actavis*, the Chief Justice foreshadowed these concerns, 133 S. Ct. at 2245, and the Court responded that whether a settlement lies "'beyond the limit of patent monopoly' is a conclusion that flows from the analysis and not, as the Chief Justice suggests, its starting point." *Id.* at 2231-32. Here, the Court should grant the Petition to clarify where that starting point lies: what must a plaintiff show to allege a plausible claim that a patent settlement constitutes a large and unjust reverse payment that raises antitrust suspicion? This case provides a proper vehicle for review; it involves many elements in dispute among the lower courts and a type of settlement that has not traditionally raised antitrust scrutiny.

ARGUMENT

I. LEGITIMATE PHARMACEUTICAL PATENT SETTLEMENTS ARE BENEFICIAL AND SHOULD NOT BE ROUTINELY SUBJECT TO FOLLOW-ON ANTITRUST ACTIONS

The threat of treble antitrust damages, when unwarranted, will have a chilling effect on the ability of the nation's medicine manufacturers to settle patent litigation fairly and to the benefit of consumers. Already, high-dollar litigation has become a central component of prescription drug transitions from patent protection to generic availability. Blockbuster drugs, in particular, are subject to intense patent disputes because of the incentive federal drug law gives the first generic manufacturer to file an Abbreviated New Drug Application (ANDA) for that drug. *See Actavis*, 133 S. Ct. at 2234 (noting federal law "facilitat[es] challenges to a patent's validity").

The Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the "Hatch-Waxman Act," allows a generic drug manufacturer to challenge the validity of the innovator's patents and for the innovator, in turn, to allege infringement against the generic drug manufacturer before the generic product is even launched. *See* 21 U.S.C. § 355(j). To do this, a generic manufacturer files a paragraph IV certification alleging its generic will not infringe on the brand-name company's patents, either because the patents are invalid or will not be infringed by the marketing of the generic product. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). "The patent statute treats such a filing as itself an act of infringement, which gives the brand an immediate right to sue." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 407 (2012) (citing 35 U.S.C. § 271(e)(2)(A)). If the patent holder sues within 45 days of receiving notice, "the FDA generally may not approve the ANDA until 30 months pass or the court finds the patent invalid or not infringed." *Caraco*, 566 U.S. at 407 (citing 21 U.S.C. § 355(j)(5)(B)(iii)). When approved, the generic manufacturer, if it was the first to file its ANDA, obtains its own limited monopoly: a 180-day period of exclusivity to sell its competing generic drug. *See* § 355(j)(5)(B)(iv).

For successful pharmaceuticals, such as Lipitor in the case at bar, generic firms vie for this six-month generic monopoly, regardless of the strength of the underlying patents. *See* Henry G. Grabowski, et al., *Evolving Brand-Name and Generic Drug Competition May Warrant a Revision of the Hatch-Waxman Act*, 30 Health Aff. 2157, 2161 (2011) (finding challenges for drugs with sales greater than $100 million

went from 17% in 1995 to 75% in 2008); Kelly Smith & Jonathan Gleklen, *Generic Drugmakers Will Challenge Patents Even When They Have a 97% Chance of Losing: The FTC Report that K-Dur Ignored*, CPI Antitrust Chronicle 6 (Sept. 2012) (observing that "taking a shot at a patent is, if not costless, quite cheap").

One FTC study concluded that for an innovator's 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 it perceived only a ten percent chance of success on the merits. *See* FTC, Authorized Generic Drugs: Short-Term Effects and Long-Term Impact, at iii n.7 (2011). If the generic further did not anticipate competition from an authorized generic during the 180-day period of generic marketing exclusivity, that challenge would be profitable even if the generic had only a four percent chance of prevailing. *See id.* For blockbuster drugs with annual revenues of $1 billion, challenges are profitable even if the generic's chance of prevailing is as low as two percent. *See id.* at 118. Each year from 2009 to 2016, between 250 and 500 Hatch-Waxman patent challenges were filed. Brian C. Howard, *Lex Machina: Hatch-Waxman/ANDA Litigation Report 2017* vii (2017).

Once filed, Hatch-Waxman patent disputes often involve highly complex issues and substantial costs, including discovery costs, time spent by employees "preparing the case, producing documents, working with lawyers on litigation strategy, being deposed, traveling for lawsuit-related events, testifying at trial, and observing legal proceedings." Daniel A. Crane, *Ease Over Accuracy in Assessing Patent Set-*

tlements, 88 Minn. L. Rev. 698, 703-04 (2004). Prolonged patent litigation also creates business uncertainty and, itself, can be anti-competitive. *See* Bret Dickey, Jonathan Orszag & Robert Willig, *A Preliminary Economic Analysis of the Budgetary Effects of Proposed Restrictions on "Reverse Payment" Settlements*, Compass Lexecon (Aug. 2010) (stating Hatch-Waxman patent litigation "can engender significant delays in the possibilities for competition").

In light of these pressures, Hatch-Waxman cases regularly settle, with parties setting a date for when the generic drug manufacturer can enter the market. *See Standard Oil Co. (Indiana) v. United States*, 283 U.S. 163 (1931) (holding the Sherman Act does not preclude such settlements). The public derives significant benefits from these patent settlements, including the types of global settlements at bar where two frequent Hatch-Waxman litigants resolve numerous claims. Generic firms generally enter the market earlier through settlement than when all of the underlying patents expire. Reverse payments can properly facilitate these resolutions. *See* C. Kyle Musgrove & Richard Ripley, *Reverse Payment Settlements: Presumptively Bad or Usually Acceptable*, CPI Antitrust Chronicle (June 2012) (explaining reverse payment settlements can eliminate extensive and costly litigation that has the potential to block the market entry of generic manufacturers).

Often, as here, Hatch-Waxman settlements also involve important so-called "secondary" patents. Technologies covered by secondary patents are valuable because they provide major benefits to consumers. They can improve the efficacy of a medicine, eliminate the need for administration by skilled med-

ical professionals, reduce or eliminate side effects, and reduce frequency of use. *See* Int'l Fed'n of Pharm. Mfrs. & Ass'ns, *Incremental Innovation: Adapting to Patient Needs* 8-14 (2013). Authorizing the patent challenger in these settlements to use secondary patents in the market before they expire is often a key component of settlement, furthering the Court's desire to "bring about competition, again to the consumers benefit." *Actavis*, 133 S. Ct. at 2234.

According to estimates from the generics industry, settlements on ten products alone allowed generic drug manufacturers to launch an aggregate of 83.4 years before patent expiration, resulting in more than $67 billion in savings to consumers. *See* Testimony of Theodore C. Whitehouse of Wilkie, Farr, & Gallagher LLP on behalf of Teva Pharmaceuticals USA, Inc., Hearing on H.R. 1706, "Protecting Consumer Access to Generic Drugs Act of 2009," Before the House Comm. on Energy & Commerce, Subcommittee on Commerce, Trade, and Consumer Protection, at 7, Mar. 31, 2009.

The tension at issue here, as Chief Justice Roberts stated in his *Actavis* dissent, is that Hatch-Waxman patent settlements, by their nature, represent compromises for when allowable monopolies end. *Id.* at 2238 (Roberts, C.J., dissenting) ("The point of patent law is to grant limited monopolies as a way of encouraging innovation."). There is no doubt that patent holders have the constitutional right "to exclude others from profiting by the patented invention." *Dawson Chemical Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980). Therefore, opposition under the antitrust laws must be limited, as this Court recognized in *Actavis*, to only those situa-

tions where the settlement is "purely" a bald attempt to induce the generic firm to "give up the patent fight." *Actavis*, 133 S. Ct. at 2233; *see also United States v. General Elec. Co.*, 272 U.S. 476, 485 (1926) (finding patentee must be "out of the scope of his patent rights" to run afoul of the Sherman Act).

Yet, the Third Circuit's ruling here fails to provide any standards for when a settlement between a branded and generic manufacturer should be subject to antitrust scrutiny, and when it should not. As a result, pharmaceutical companies are virtually certain to face lawsuits in the Third Circuit challenging significant patent settlements. Such follow-on litigation will chill patent settlements, which will undermine patent values and could cause innovators to spend less money developing the next breakthrough drug. *See* FTC Bureau of Economics, The Pharmaceutical Industry: A Discussion of Competitive & Antitrust Issues in an Environment of Change 178 (Mar. 1999) ("[N]ew product development in the pharmaceutical industry is more dependent on patent protection than in many other industries."). The cost of developing and obtaining FDA approval of a new medicine can total well over two billion dollars, making patent protection essential to encouraging that investment. *See* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs,* 47 J. of Health Econ. 20 (2016).

The Court should grant the Petition to ensure that follow-on private antitrust suits, such as the one at bar, do not discourage beneficial pharmaceutical patent settlements. Pharmaceutical companies now have no notice as to how they can enter patent settlements that balance patent rights against legiti-

mate antitrust concerns. They should not have to fight patent disputes to judgment just to avoid speculative follow-on antitrust claims.

II. THE COURT MUST REQUIRE CHALLENGES TO PHARMACEUTICAL PATENT SETTLEMENTS TO MEET A MEANINGFUL PLAUSIBILITY THRESHOLD

The Third Circuit's failure to apply threshold pleading standards in this case also undermines this Court's repeated emphasis on "the importance of clear rules in antitrust law." *Pacific Bell Tel. Co. v. Linkline Comm'ns, Inc.*, 555 U.S. 438, 452 (2009). This Court has observed on multiple occasions that speculative antitrust lawsuits take a considerable toll on the judiciary, waste time and resources, and pressure defendants to settle cases regardless of the merits. *See Kimble v. Marvel Entm't, LLC*, 135 S. Ct. 2401, 2411 (2015) (noting these inquiries produce "notoriously high litigation costs and unpredictable results"); *AT&T Mobility LLC v. Concepcion*, 563 U.S. 333, 350 (2011) (recognizing that with "even a small chance of a devastating loss, defendants will be pressured into settling questionable claims"). Therefore, the Court has required an antitrust complaint to include more than a "bare assertion" of improper conduct or "wholly conclusory" allegations. *Bell Atl. Corp. v. Twombly*, 550 U.S. 554, 556, 561, 560 n.6 (2007). There must be "enough facts to state a claim to relief that is plausible on its face." *Id.* at 570.

Here, the district court followed this guidance, carefully assessing the pleadings and determining, after allowing limited discovery and pleading amendments, that Plaintiffs did not meet this threshold obligation. As the district court poignantly

observed, "this is not a car accident case where plausible facts are easily set forth; it is a non-monetary payment in an antitrust suit which is at the opposite end of the benchmark spectrum." *In re Lipitor Antitrust Litig.*, 46 F. Supp. 523, 550 (D. N.J. 2014). Yet, the Third Circuit reversed this ruling in an opinion devoid of in-depth analysis of how Defendants' global settlement represented a large, unjustified reverse payment. It articulated no meaningful threshold for Plaintiffs to show a reasonable inference that the patent settlement was anticompetitive.

One reason the Court should grant this Petition is that it invokes several important questions for when a court must grant a motion to dismiss under *Actavis*. First, what is a reverse payment? In *Actavis,* the transfer of money was a cash payment. Plaintiffs here allege that non-cash aspects of the global settlement—namely, the compromise of competing damages claims in Accupril patent disputes—can be viewed as a reverse payment for the Lipitor part of the global settlement. Patent settlements regularly include such non-cash terms, such as licensing and joint marketing agreements. In cases soon after *Actavis*, district courts expressed initial confusion over whether any non-cash payment could even be a violation of *Actavis. See, e.g., In re Loestrin, 24 Fe Antitrust Litig.*, 45 F. Supp. 3d 180, 190 (D. R.I. 2014) ("It is more than merely the choice of words describing the consideration, however, that suggests that the majority in *Actavis* intended for it to apply only to cash settlements."). Overall, when non-cash payments are alleged, courts have been unable to distin-

guish traditional settlements, such as compromises over damage claims, from suspect reverse payments.[2]

Second, when is a payment large and unjustified? Plaintiffs claim that the compromise Pfizer provided with respect to the Accupril damages claims in the global settlement was large and unjustified, but provided no foundation to estimate the cash value of that compromise. Courts, at the very least, must require plaintiffs to calculate alleged non-cash payments to a reasonable degree before permitting an antitrust claim to proceed. The amount of the demand in the underlying patent case and perceived strength of the patent may not correlate to the settlement value. Patent litigation is inherently time-consuming, expensive, and risky, particularly when involving counterclaims. *See Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 993 (N.D. Ill. 2003) (Posner, J.) ("No one can be *certain* that he will prevail in a patent suit."). A well-grounded $100 million demand could readily yield a settlement for less than $40 million. Mark G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 Antitrust L.J. 1033, 1046 (2004).

Here, though, the Third Circuit did not require Plaintiffs to support their allegations with any plausible basis that there was a large, unexplained reverse payment. Without at least some way of valuing non-cash aspects of a settlement in pleadings, a

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[2] As the Seventh Circuit observed, "[a] negotiation is more likely to be successful when there are several issues to be resolved . . . because it is easier . . . to strike a deal that will make both parties feel they are getting more from peace than war." *Duffy Tool & Stamping, LLC v. NLRB*, 233 F.3d 995, 998 (7th Cir. 2000) (internal citations omitted).

court cannot determine the size of an alleged reverse payment in assessing the claim's plausibility that it is too large. Courts have also failed to provide consistent guidance on how to assess whether an alleged reverse payment, once calculated, is large and unjustified. *See, e.g., King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 416-18 (E.D. Pa. 2015); *In re Aggrenox*, 94 F. Supp. 3d at 243.

Third, when is an agreed upon date for generic market entry the result of legitimate compromise and when is it a violation of antitrust laws? Here, Pfizer authorized Ranbaxy to enter the market and use its secondary patents for Lipitor well-before the secondary patents expired. Plaintiffs must provide plausible facts showing, at the very least, that the date of generic entry is later than would be anticipated based on the underlying patents. Further, courts have disagreed as to whether the strength of the patents and their likelihood for success had the claims gone to trial are relevant for determining whether competition was ultimately harmed. *Compare In re Aggrenox*, 94 F. Supp. 3d at 240-41 (holding plaintiffs "need not plead (or prove) the weakness of the [relevant patent], because the patent's ultimate validity is not at issue") *with In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 162 (3d Cir. 2017) (assessing whether the alleged reverse payment was tied to the merits of the underlying litigation).

Finally, the Court should address burden shifting. Here, the Third Circuit held that Lipitor defendants had "the burden of justifying" the alleged reverse payment. Again, courts have widely diverged on what plaintiffs must show to make defendants justify patent settlements. *See, e.g.*, *In re*

Asacol Antitrust Litig., 233 F. Supp. 3d 247, 264 (D. Mass. 2017) (shifting the burden after plaintiffs allege a large and unjustified reverse payment to the defendants to show the payment was not anticompetitive); *King Drug Co.*, 88 F. Supp. 3d at 405 (requiring plaintiffs to allege only a large reverse payment before shifting the burden to defendants to prove the payment was justified). The Court must prevent low or nonexistent pleading standards from, in effect, entirely shifting the burden of proof to defendants.

In sum, the Court should grant the Petition so that the right to invoke the judicial system to resolve antitrust allegations is available only to those who allege actual plausible claims. The lower courts have expressed the need for the Supreme Court to grant review in a case such as the one at bar to answer these vital questions from *Actavis*. *See In re Aggrenox,* 94 F. Supp. 3d at 236 ("[Q]uestions like what constitute a reverse 'payment,' and what makes one 'large' and 'unjustified' . . . will surely end up in the Court of Appeals, and perhaps eventually back again at the Supreme Court.").

III. NOT REQUIRING MEANINGFUL PLAUSIBILITY STANDARDS CREATES UNWARRANTED, SPECULATIVE LITIGATION

Finally, the Court should grant the Petition to remind courts that they must earnestly address the lack of plausibility of antitrust claims at the motion to dismiss stage, and not put them off for summary judgment. This is the only way to safeguard defendants and courts from highly speculative claims and needless litigation. *See 16630 Southfield Ltd. P'ship v. Flagstar Bank, F.S.B.*, 727 F.3d 502, 504 (6th Cir.

2013) (needless discovery "imposes costs—not only on defendants but also on courts and society").

Discovery, in particular, "takes too long and costs too much." Am. College of Trial Lawyers Task Force on Discovery & Inst. for the Advancement of the Am. Legal Sys., Final Report, at 2 (Mar. 11, 2009). In high-dollar civil litigation, discovery and the threat of discovery cause businesses to preserve and produce documents far in excess of what is relevant or probative at great cost. Some companies spend more on discovery than paying claims. Discovery costs, though, do not correspond with the litigation value of the documents. In one pharmaceutical patent case, Allergan reported that it collected 1,025,000 documents and produced 391,000, but only 146 ended up as exhibits. Letter from William N. Scarff, Jr., Vice President, Assoc. General Counsel, and Chief Litig. Counsel at Allergan, Inc. & Donald P. Bunnin, Senior Litig. Counsel at Allergan, Inc. to Advisory Committee on Civil Rules, et al. (Jan. 22, 2014).

Experience has shown that these burdens can tilt the scales of justice, sometimes driving litigation outcomes more than the underlying merits. *See* Am. Bar Ass'n Section of Litig. Member Survey on Civil Practice: Full Report, at 2 (Dec. 11, 2009) (reporting 83% of plaintiffs' and defense counsel that responded to the survey believed the litigation costs force parties to settle regardless of a case's merits). Access to justice is an important hallmark of the American civil justice system, including for antitrust cases, but the right to invoke the judicial system to resolve antitrust allegations must be available only to those who plead truly plausible claims.

CONCLUSION

For the foregoing reasons, *amici curiae* respectfully request that this Court grant the Petition for Writ of Certiorari.

Respectfully submitted,

Philip S. Goldberg
Counsel of Record
Cary Silverman
Victor E. Schwartz
SHOOK, HARDY & BACON L.L.P.
1155 F Street, N.W., Suite 200
Washington, D.C. 20004
(202) 783-8400
pgoldberg@shb.com
csilverman@shb.com
vschwartz@shb.com

Attorneys for Amici Curiae

Melissa B. Kimmel
David E. Korn
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
950 F Street, N.W., Suite 300
Washington, D.C. 20004
(202) 835-3400

H. Sherman Joyce
Lauren Sheets Jarrell
AMERICAN TORT REFORM ASSOCIATION
1101 Connecticut Avenue, N.W.
Suite 400

Washington, D.C. 20036
(202) 682-1163

Linda E. Kelly
Patrick N. Forrest
Leland P. Frost
NATIONAL ASSOCIATION OF
MANUFACTURERS
733 10th Street, N.W., Suite 700
Washington, D.C. 20001
(202) 637-3000

Of Counsel

Dated: December 22, 2017