Nos. 14-4202, 14-4203, 14-4204, 14-4205,
14-4206, 14-4602 & 14-4632 (Consolidated)

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

IN RE: LIPITOR ANTITRUST LITIGATION

On Appeal from the United States District Court
for the District of New Jersey,
No. 3:12-CV-02389 et al. (PGS/DEA)

BRIEF OF *AMICI CURIAE* AMERICAN TORT REFORM ASSOCIATION AND PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF DEFENDANTS-APPELLEES AND AFFIRMANCE

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Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and Third Circuit L.A.R. 26.1, *Amici Curiae* make the following disclosure:

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No publicly held corporation that is not a party to the proceeding before this Court has a financial interest in the outcome of this proceeding.

Dated: Mar. 28, 2016

/s/ Philip S. Goldberg
Philip S. Goldberg

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INTEREST OF *AMICI CURIAE*[1]

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 state and federal courts that have addressed important liability issues. ATRA supports strong pleading standards that discourage speculative lawsuits and avoid expensive, unwarranted discovery costs.

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.

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[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 other person or entity—other than *amici* or their counsel—has contributed money that was intended to fund preparing or submitting this brief.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

Speculative antitrust lawsuits take a considerable toll on the judicial system, delaying meritorious cases, wasting the time and money of litigants, and pressuring defendants to settle cases regardless of the merits. Before imposing "sprawling, costly, and hugely time-consuming" discovery, the U.S. Supreme Court requires 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) (addressing antitrust allegations). The complaint must include "enough facts to state a claim to relief that is plausible on its face." *Id*. at 570.

These threshold pleading requirements for antitrust cases are particularly salient here, as this case involves allegations over the collective impact of a multitude of pharmaceutical patent settlements. As the Supreme Court found in *Twombly*, a complaint alleging anticompetitive conduct must offer more than circumstantial allegations when there are obvious lawful, often pro-competitive, explanations for that conduct. *See id*. at 567. It must provide, at the very least, sufficient factual detail to satisfy the elements of anticompetitive conduct. With respect to the case at bar, the Supreme Court articulated the elements that Plaintiffs need to meet in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013). The complexity of the calculations needed for Plaintiffs to establish the plausibility of their allegations cannot serve as a free pass for meeting these obligations.

In assessing the pleadings in this case, the district court concluded, after allowing discovery and amendments to the pleadings, that Plaintiffs did not meet this threshold obligation. Plaintiffs did not provide sufficient facts to allow a reasonable inference that Pfizer violated *Actavis* by paying Ranbaxy a large, unjustified reverse payment. *See id.* at 2237. Rather, the court held, the complaint merely asserted that a settlement of sixteen separate patent-related claims between two pharmaceutical companies was an impermissible reverse payment. Plaintiffs did not show any exchange of cash from the innovator company to the generic manufacturer and provided no means by which the court could determine whether the non-cash aspects of the settlement could plausibly be considered both a reverse payment and a sufficiently excessive one to be anticompetitive. In the wake of *Actavis*, the district court was not allowed to presume illegality by concluding that a patent must be weak simply because the innovator chose to settle. There was no sufficient factual basis upon which the court could plausibly conclude that the Pfizer-Ranbaxy agreement is anything other than two businesses "making peace" by settling significant, expensive litigations.

The district court's decision should be affirmed. Allowing Plaintiffs to proceed despite the absence of factual detail to back up their antitrust assertions would undermine Supreme Court precedent. Further, it would improperly chill the ability of branded and generic pharmaceutical companies to resolve patent

disputes, even when reasonable, pro-competitive, and in the best health care interest of the American public. Future plaintiffs could ensnare them into expensive follow-on antitrust litigation, as here, by merely asserting that those settlements constituted illegal reverse payments afoul of antitrust laws. The end result would not further competition, but harm the public by slowing the development and availability of both innovative and generic medicines.

ARGUMENT

I. PLAINTIFFS' LACK OF PLAUSIBILITY CANNOT HIDE BEHIND THE INTRICACY OF THEIR ANTITRUST ALLEGATIONS

A. Antitrust Cases Require Pleadings to Include Sufficient Facts to Establish a Plausible Foundation for the Allegations

The district court properly recognized that allegations based on reverse payments in Hatch-Waxman settlements must be demonstrated in some fashion before an antitrust case can survive a motion to dismiss. As the 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). Determining whether lawful settlements in sixteen separate patent cases can constitute a reverse payment large enough to run afoul of *Actavis* is an "*intricate proposition.*" *Id.* at 536, 544 (emphasis in original).

Under *Iqbal/Twombly*, in order to survive a motion to dismiss, the complaint must "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570). This standard is met when the complaint includes sufficient factual content for a court "to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. Courts must disregard "[n]aked assertions" and "threadbare recitals of the elements of a cause of action, supported by mere conclusory statements." *Id.* at 678.

In short, the pleadings must have sufficient facts in order to keep the pleading within the realm of plausibility. *See* Victor E. Schwartz & Christopher E. Appel, *Rational Pleading in the Modern World of Civil Litigation: The Lessons and Public Policy Benefits of Twombly and Iqbal*, 33 Harv. J. L. & Pub. Pol'y 1107, 1128 (2010). This is because, as the Supreme Court recognized, antitrust litigation is prone to an "inevitably costly and protracted discovery phase" that is asymmetrically borne by defendants. *Twombly*, 550 U.S. at 558 (quoting *Asahi Glass Co. v. Pentech Pharm., Inc*., 289 F. Supp. 2d 986, 995 (N.D. Ill.2003)). In these cases, mere notice pleading is insufficient. Where, as here, illegality is alleged based on otherwise lawful acts, namely sixteen separate patent settlements, the allegations of wrongdoing must be based on "something more . . . than

suspicion." *See Twombly*, 550 U.S. at 555 (quoting 5 C. Wright & A. Miller, Federal Practice and Procedure § 1216, pp. 235-36 (3d ed. 2004)).

This Court, in implementing *Iqbal/Twombly*, has adhered to this principle in requiring proper factual foundation in order to establish a reliable basis for antitrust allegations. *See Burtch v. Milberg Factors, Inc*., 662 F.3d 212, 227 (3d Cir. 2011) (quoting *Twombly*, 550 U.S. at 557). Otherwise, the claim "stops short of the line between possibility and plausibility." *Id*. If there is an "obvious alternative explanation" for the defendant's conduct, one that is permissible, then the complaint must offer facts that would dispel these alternatives. *In re Ins. Brokerage Antitrust Litig*., 618 F.3d 300, 326 (3d Cir. 2010) (affirming dismissal of most alleged antitrust claims). In that case, the Court found it is just as likely that banks stopped extending credit to a retailer based on unilateral, rational judgments that continuing to finance an ailing business was not a prudent course of action, rather than as part of an illegal agreement. *See id*. at 226-27.

As the court held here, it is not enough for plaintiffs to vaguely allege that defendants engaged in anticompetitive conduct. There must be an agreement to enter an unlawful arrangement and "factual allegations to plausibly suggest as much." *Howard Hess Dental Labs., Inc. v. Dentsply*, 602 F.3d 237, 254-55 (3d Cir. 2010). This Court has called the additional facts needed in antitrust actions the "plus factor," indicating that *Twombly* requires antitrust cases to be plead with

enough facts suggesting the actions were improper. *Burtch*, 662 F.3d at 227-28; *see also* Schwartz & Appel, 33 Harv. J. L. & Pub. Pol'y at 1136-37 (concurring that *Twombly* suggest a "circumstances-plus" threshold for cases involving intent in order for a court to draw a reasonable inference of the alleged misconduct). The district court correctly found the case at bar did not meet this standard.

B. The District Court Properly Applied *Iqbal/Twombly* to the Elements Required in *Actavis*

The district court's opinion demonstrates proper application of the plausibility requirements that the Supreme Court set forth in *Iqbal*/*Twombly* and this Court iterated in the subsequent rulings discussed above. The court took "note of the elements a plaintiff must plead to state a claim," identified conclusory allegations not entitled to an assumption of truth, and determined whether well-pleaded factual allegations, accepted as true, plausibly give rise to an entitlement for relief. *See Santiago v. Warminster Tp.*, 629 F.3d at 130. It also properly applied this plausibility inquiry to the specific claim at issue, which here are governed by *Actavis*, 133 S. Ct. at 2223.

Under *Actavis*, in order for Plaintiffs to plead with plausibility, they must provide sufficient facts to create a reasonable inference that Pfizer provided a large and unexplained "reverse payment" to Ranbaxy. The Supreme Court in *Actavis* held that settlements where consideration flows to generics are not presumptively illegal. *See id.* at 2236. They can be competitively neutral or foster pro-

competitive benefits by mitigating the uncertainty and risk of error associated with patent litigation. Accordingly, there are four elements that must be plausibly shown in order to allow a reasonable inference of anticompetitive activity: (1) there was a transfer of value qualifying as a reverse payment; (2) the payment was large after accounting for traditional settlement considerations; (3) the payment could not otherwise be lawfully justified; and (4) the payment was made in exchange for the alleged infringer's agreement not to enter the market for a period of time. *See Actavis*, 133 S. Ct. at 2236-37; *see also* Barry Harris, et al., *Activating Actavis: A More Complete Story*, 28 Antitrust 83 (2014).

In dismissing the claim, the district court found that Plaintiffs did not come close to meeting these threshold standards, stating that "[t]he lack of any reliable foundation pervades the entire Complaint." *In re Lipitor Antitrust Litig*., 46 F. Supp. at 546. Plaintiffs did not make a plausible showing that the sixteen lawful settlements involving several drugs even constituted a reverse payment with respect to settlement over Lipitor in the U.S. market. Further, and more troubling to the district court, the complaint "lack[ed] any foundation to estimate the cash value" of the other settlements that allegedly constituted this reverse payment. *Id.* Without monetizing these other settlements, the district court held, there was no way for it to determine the size of this alleged reverse payment and, accordingly, whether the reverse payment could have been sufficiently large to satisfy *Actavis*.

The district court's reasoning is fully consistent with what traditionally plaintiff-oriented scholars have observed in these cases: "if the payment takes the form of a settlement payment in unrelated patent litigation that is far off of its reasonable market value, then a plaintiff would have to place a value on the litigation in order to plausibility allege that there was a payment for delay." Aaron Edlin et al., *The Actavis Inference; Theory and Practice*, 67 Rutgers U. L. Rev. 585, 599-600 (2015). The complaint must also include "a sufficient basis for believing the cost to the branded firm exceeds that firm's anticipated litigation costs." *Id*. at 601. Here, the district court explained, it was not asking Plaintiffs to provide a precise amount of the alleged non-monetary payment, but at least some "ballpark" estimate. *Id.* at 550.

The district court's ruling should be upheld. The court properly assessed the legal issues specific to this type of case and found that the complaint relied on the type of labels and conclusory assertions insufficient to meet plausibility standards.

II. REQUIRING THE COMPLAINT HERE TO INCLUDE SUFFICIENT PLAUSIBLE FACTS WILL HELP AVOID HIGHLY SPECULATIVE ANTITRUST LAWSUITS AND UNNECESSARY LITIGATION COSTS

The plausibility standard embraced by the Supreme Court in *Twombly*, and applied by the district court here, recognizes that antitrust litigations can be increasingly expensive. Bald assertions and rote recitation of the elements of an antitrust claim are insufficient to impose the "potentially enormous" cost of

discovery. *Twombly*, 550 U.S. at 559; *see also Kimble v. Marvel Entm't, LLC*, 135 S. Ct. 2401, 2411 (2015) (recognizing that antitrust litigation "produces notoriously high litigation costs and unpredictable results"). If this case were allowed to proceed, the enormous costs of litigating this case could pressure defendants to settle these antitrust claims, even despite the absence of plausible facts supporting the claims. *Cf. AT&T Mobility LLC v. Concepcion*, 131 S. Ct. 1740, 1752 (2011) (observing that with "even a small chance of a devastating loss, defendants will be pressured into settling questionable claims").

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 is available only to those who put forth appropriate claims. The lack of plausibility of antitrust claims must be addressed at the motion to dismiss stage. This is the only way to safeguard these defendants and the courts from excessive discovery and other types of pre-trial litigation abuse, which can distort the ability of courts to administer justice. *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"). As practitioners for all parties have agreed, discovery "takes too long and costs too much." Am. College of Trial Lawyers Task Force on Discovery & Inst. For the Advancement of the Am. Legal Syst., Final Report, at 2 (Mar. 11, 2009).

In the larger civil litigation landscape, discovery and the threat of discovery cause businesses to preserve and produce documents far in excess of what is relevant or probative in their litigations at great cost. For example, some companies spend more on discovery than paying claims. *See* Testimony of Rob Hunter, General Counsel of Altec, Inc., Transcript of Proceedings, In the Matter of: Public Hearing on Proposed Amendments to the Federal Rules of Civil Procedure Judicial Conference Advisory Comm. on Civil Rules at 201 (Jan. 9, 2014) (stating that Altec spent double on discovery than paying claims).

In patent cases generally, average legal costs are $1.6 million just through discovery when $1 million to $25 million is at stake – much more in the types of patent disputes underlying this case. Am. Intellectual Prop. Law Ass'n, 2011 Report of the Economic Survey (2012); *see also Actavis*, 133 S. Ct. at 2243-44 (Roberts, C.J., dissenting) (citing legal costs of $10 million). In personal injury cases, plaintiffs' attorneys have fabricated discovery disputes to disadvantage defendants and generate sanctions. *See* Sherman Joyce, *The Emerging Business Threat of Civil "Death Penalty" Sanctions*, Wash. Legal Found., Sept. 10, 2009.

These adverse impacts of excessive discovery have become magnified in the era of electronic storage, which has dramatically increased the volume of information that must be reviewed to find discoverable information. For example, one analysis found that average business users sent and received more than 100 e-

mail messages a day, which amounts to over 26,000 e-mails per year. *See* Sara Radicati & Quoc Hoang, Email Statistics Report, 2011-2015 (2011), *at* http://www.radicati.com/wp/wp-content/uploads/2011/05/Email-Statistics-Report-2011-2015-Executive-Summary.pdf. Electronic discovery often requires a document-by-document review. These costs, though, do not correspond with the value of the documents. In a 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).

These burdens can be leveraged to tilt the scales of justice, sometimes driving outcomes more than the merits. *See* ABA Section of Litig. Member Survey on Civil Practice: Detailed Report, at 2 (Dec. 11, 2009) (reporting 83% of its members, which include plaintiffs' and defense counsel, believe the cost of litigation forces settlement in cases that should not be settled on the merits). In *Twombly*, "the Supreme Court appeared to toughen the pleading standards [for antitrust cases] expressly because of the burdensome costs that result when vague allegations are allowed to proceed to the discovery stage." Martin H. Redish & Colleen McNamara, *Back to the Future: Discovery Cost Allocation and Modern Procedural Theory*, 79 Geo. Wash. L. Rev. 773, 773 (2011).

In the case at bar, the district court embraced its role to screen the sufficiency of this antitrust complaint and act as a gatekeeper to ensure that the defendant and courts are not forced to spend significant resources on antitrust claims that have yet to be shown to be plausible. Here, justice requires dismissal unless Plaintiffs make a plausible showing of a right to antitrust recovery.

III. SECOND-GUESSING SETTLEMENTS OVER PHARMACEUTICAL PATENTS WITHOUT A PLAUSIBLE FOUNDATION WILL HARM PUBLIC ACCESS TO NEW, HIGH QUALITY, AND AFFORDABLE MEDICINES

In the context of pharmaceutical litigation, when antitrust plaintiffs seek to invalidate patent settlements between manufacturers of branded and generic drugs without sufficient facts to demonstrate that their claims are at least plausible, there can be adverse health care impacts. The unwarranted exposure to antitrust liability can have a chilling effect on the ability of the nation's medicine manufacturers to fairly and appropriately settle patent litigation to the benefit of many consumers.

Today, many blockbuster drugs are subject to intense patent disputes in connection with a generic's first-to-file exclusivity. Lipitor is not unique. When a pharmaceutical is successful, generic firms are highly incentivized to challenge the patent, regardless of its strength. *See* H.G. Grabowski, et al., *Evolving Brand-Name and Generic Drug Competition May Warrant a Revision of the Hatch-Waxman Act*, 30 Health Affairs 2157, 2161 (2011) (noting the probability of challenge for drugs with sales greater than $100 million increased 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 (2012).

Post-settlement antitrust litigation of the type pursued here interferes with the ability for branded and generic drug makers to reach compromise in these actions. *See Actavis*, 133 S. Ct. at 2243-44 (Roberts, C.J., dissenting) ("Simply put, there would be no incentive to settle if, immediately after settling, the parties would have to litigate the same issue—the question of patent validity—as part of a defense against an antitrust suit."). If claims did not have to be plausible to proceed, courts could deprive companies of an important tool for conserving litigation costs and managing risk for no good reason. Pharmaceutical companies would be pressured to fight the underlying patent dispute to judgment, even when it would otherwise make sense for them to settle.

Pharmaceutical patent cases can be highly complex and result in substantial costs to both innovator and generic companies. In addition to the costs of discovery, prolonged litigation creates business uncertainty and can be anti-competitive by causing significant delays in competition. *See Schering-Plough Corp. v. FTC,* 402 F.3d 1056, 1075 (11th Cir. 2005) ("There is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation."). Such costs include 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 Settlements*, 88 Minn. L. Rev. 698, 703-704 (2004).

The structure of Hatch-Waxman patent litigation, in particular, enhances the uncertainty and risk to branded drug manufacturers, which provides important context for allegations in the instant case. Hatch-Waxman facilitates patent challenges by establishing a framework under which the innovator's patent's validity and generic's infringement can be litigated without the generic launching a competing product and incurring any significant damages liability. *See Schering-Plough Corp.*, 402 F.3d at 1056. Thus, regardless of an innovator's own confidence in the strength of a patent, "[n]o one can be *certain* that he will prevail in a patent suit." *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 993 (N.D. Ill. 2003) (Posner, J.). Even a patentee confident in its patent might pay a potential infringer a reverse payment to settle the claims. Such reverse payments "may amount to no more than a rough approximation of the litigation expenses saved through the settlement[,] . . . compensation for other services that the generic has promised to perform[, or] . . . other justifications." *Actavis*, 133 S. Ct. at 2236.

Further, any denigration of "secondary" patents, such as Pfizer's process and formulation patents at issue in the Lipitor settlement, is wholly unwarranted, since

innovation covered by such improvements also yield significant benefits to consumers. Technology covered by secondary patents can provide major benefits to consumers. They can improve the efficacy of a medicine, eliminate the need for administration by a highly skilled medical professional, 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) *at* http://www.ifma.org/resources/publications.html.

These settlements generally result in the generic firms marketing products earlier than the dates of the underlying patents expirations. *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 (observing that according to one generic company's estimate, patent settlements on ten products alone allowed generic launches an aggregate of 83.4 years before patent expiration, resulting in more than $67 billion in savings to consumers). Thus, these settlements promote consumer access to quality, affordable medicines. They should not be challenged or chilled lightly.

Finally, improperly chilling patent settlements could cause innovator companies to spend less money on developing the next medical breakthrough.

"[E]mpirical research indicates 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 & Antitrust Issues in an Environment of Change 178 (March 1999) *at* http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf. The cost of developing and obtaining the FDA's approval of a new medicine can total well over two billion dollars, making patent protection essential to encouraging and potentially recouping that investment. *See* J.A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs; Journal of Health Economics* 2016, 47:20-33. The negative impacts of restricting patent settlements are more significant for small biopharmaceutical companies. They may not have the resources to litigate the underlying claim or risk that their settlements will generate even implausible follow-on antitrust claims.

As the Supreme Court held in *Actavis*, "[w]here a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement." 133 S. Ct. at 2236. If such pharmaceutical patent settlements are to be second-guessed under the heightened penalties of antitrust violations, at the very least the allegations should have to be based on a plausible foundation. Because the claims

at bar do not constitute *per se* antitrust violations, such as price fixing, Plaintiffs here had to demonstrate that their allegations were plausible that the sixteen settlements between Pfizer and Ranbaxy had anticompetitive effects. The district court properly assessed the facts against the required elements of the cause of action and found that such a foundation did not exist. It dismissed the claim.

CONCLUSION

For the reasons above, this Court should affirm the decision below granting Defendants' motion to dismiss.

Respectfully submitted,

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Dated: Mar. 28, 2016

COMBINED CERTIFICATE OF COMPLIANCE

1. This brief contains 4,130 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 2010 in 14 point Times New Roman font for text and footnotes.

3. In accordance with Third Circuit L.A.R. 28.3(d), the undersigned certifies that I am admitted to the bar of the United States Court of Appeals for the Third Circuit.

4. In accordance with Third Circuit L.A.R. 31.1(c), the undersigned certifies that the text of the electronic pdf version of this brief is identical to the text in the paper copies.

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/s/ Phil Goldberg
Phil Goldberg

Dated: Mar. 28, 2016

CERTIFICATE OF SERVICE

I, Phil Goldberg, certify that on this 28th day of March, 2016, ten paper copies of the foregoing Brief of Amici Curiae American Tort Reform Association and Pharmaceutical Research and Manufacturers of America were sent by Fed Ex next business day delivery to the Clerk of the Third Circuit Court of Appeals. I further caused the foregoing brief to be served via electronic notice to all parties, as provided by the CM/ECF system, by consent under Third Circuit L.A.R. 31.1(a).

/s/ Phil Goldberg
Phil Goldberg