Nos. 14-4202, 14-4203, 14-4204, 14-4205, 14-4206, 14-6202, 14-4632

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, Judge Peter G. Sheridan

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

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CORPORATE DISCLOSURE STATEMENT OF AMERICAN ANTITRUST INSTITUTE

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

Dated: December 28, 2015

/s/ Steve D. Shadowen
Steve D. Shadowen

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INTEREST OF AMICI CURIAE

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

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

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

INTRODUCTION AND SUMMARY OF ARGUMENT

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

Exclusion payments today take myriad forms that typically reach beyond the form of naked cash transfers. One of those forms is the forgiveness of millions—if not hundreds of millions—of dollars in separate litigation. Although less obvious upon an initial glance, such a payment has just as much a chance as a naked cash transfer to "induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market." *FTC v. Actavis*, 133 S. Ct. 2223, 2235 (2013).

The court below erred in requiring plaintiffs to produce, at the motion-to-dismiss stage, evidence typically introduced at summary judgment or trial. Just as concerning, the court required plaintiffs to introduce evidence the Supreme Court expected *defendants* to introduce in justifying payment. These requirements are inconsistent with *Actavis*; this Court's ruling in *King Drug Co. of Florence v. Smithkline Beecham Corp. (Lamictal)*, 791 F.3d 388 (3d Cir. 2015); and pleading

standards articulated in *Bell Atlantic v. Twombly*, 550 U.S. 544 (2007), *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), and this Court's precedents.

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

The excessive pleading requirements imposed by the court below are also not consistent with this Court's subsequent ruling in *Lamictal*. In that case, this Court made clear that *Actavis* applies to non-cash payments. Although the issue there arose in the context of a brand's agreement not to introduce its own version of a generic, the reasoning reaches beyond that particular fact pattern to any situation in which a brand conveys consideration to "induce the generic challenger to abandon its claim." *Actavis*, 133 S. Ct. at 2235.

Finally, in manufacturing heightened pleading thresholds, the court below misread *Twombly*, *Iqbal*, and this Court's opinions. It charted a course that violated the "common sense" required under *Twombly* and multiple decisions that recognized the realities of exclusion-payment litigation in denying motions to

dismiss. And it ignored the well-pleaded components of a complaint that alleged: (1) a 20-month delay in generic entry beyond the expiration of the relevant patent; (2) Pfizer's forgiveness of hundreds of millions of dollars in damages for Ranbaxy's token $1 million payment; (3) detailed allegations of the high value of Pfizer's claim for patent damages against Ranbaxy, including allegations of (a) the patent's validity, enforceability, and infringement, (b) Pfizer's preliminary injunction, (c) Pfizer's request for lost profits and enhanced damages, (d) Ranbaxy's entry into the market "at risk," and (e) a "decimated" market that fell from $525 million before Ranbaxy's entry to $71 million after entry; (4) Pfizer's former Chairman and CEO's concession on expected generic entry; and (5) allegations of the right to market generic Lipitor in eleven foreign markets.

ARGUMENT

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

The district court adopted heightened pleading requirements not found in—and in fact directly contrary to—the Supreme Court's landmark *Actavis* decision.[2] In that case, the Supreme Court for the first time considered the antitrust legality of agreements by which brands pay generics to delay entering the market. The Court

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

forcefully held that such agreements could be "unjustified," 133 S. Ct. at 2235-36; have the potential for "significant adverse effects on competition," *id.* at 2234; and "violate the antitrust laws," *id.* at 2227.

In analyzing competitive effects, the Court "le[ft] to the lower courts the structuring of the present rule-of-reason antitrust litigation." *Id.* at 2238. Such a framework was to "consider traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations." *Id.* at 2231. Within the Rule of Reason, the Court anticipated shortcuts. It explained that exclusion payments have the "potential for genuine adverse effects on competition." *Id.* at 2234. And it made clear that the "size of the payment" can serve as "a strong indicator of [market] power." *Id.* at 2236.

A. Plaintiffs Need Not Plead Evidence

Actavis does not alter the general, longstanding rule that plaintiffs need not plead the evidence that supports their allegations. *See, e.g.*, *In re Ins. Brokerage Antitrust Litig.,* 618 F.3d 300, 325 n.25 (3d Cir. 2010) ("It is not necessary to plead evidence.") (quoting *Bogosian v. Gulf Oil Corp.,* 561 F.2d 434, 446 (3d Cir. 1977)*; W. Penn Allegheny Health Sys., Inc. v. UPMC,* 627 F.3d 85, 98 (3d Cir. 2010) (Rule 8(a)(2) "simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element") (internal quotations

omitted).[3] A motion to dismiss is designed "merely to assess the legal feasibility of a complaint, not to assay the weight of evidence which might be offered in support thereof." *In re Aggrenox Antitrust Litig.*, 2015 WL 1311352, at *2 (D. Conn. Mar. 23, 2015).

It is, to say the very least, "plausible" that defendants settled unrelated litigation at above market value when they yoked it to a larger deal in which the generic agreed to delay entering the brand's market. In fact, defendants, who have control of all the relevant information, "have ample reason to pack complexities into the deal . . . to conceal its genuine nature." Aaron Edlin et al., *Activating* Actavis*,* Antitrust, Fall 2013, at 18. These considerations reinforce the rule that plaintiffs need *not* plead evidence. *See, e.g., In re Aggrenox*, 2015 WL 1311352, at *13 ("the very precise and particularized estimates of fair value and anticipated litigation costs may require evidence in the exclusive possession of the defendants, as well as expert analysis"); *In re Cipro Cases I & II,* 61 Cal.4th 116, 153 (Cal. 2015) (litigation costs and fair value for services "are matters about which the settling parties will necessarily have superior knowledge").

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

B. *Twombly* Does Not Require Plaintiffs to Plead Evidence

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

This Court has made clear that *Twombly* "never said that it intended a drastic change in the law, and indeed strove to convey the opposite impression." *Phillips v. County of Allegheny*, 515 F.3d 224, 230 (3d Cir. 2008). The *Twombly* Court "emphasized throughout its opinion that it was neither demanding a heightened pleading of specifics nor imposing a probability requirement." *Id.* at 233; *see also*

id. at 234. And this Court has recognized that even after *Twombly*, "Rule 8 requires only a short and plain statement of the claim and its grounds." *Id.* at 232. The same standard applies to antitrust actions. This Court has reversed lower courts that "act as 'gatekeepers'" in "subject[ing] pleadings [in] antitrust and other complex cases" to heightened scrutiny. *West Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 98 (3d Cir. 2010). Such a "gloss on Rule 8 . . . is squarely at odds with Supreme Court precedent," as "it is inappropriate to apply *Twombly*'s plausibility standard with extra bite in antitrust and other complex cases." *Id.*

Consistent with these principles is the understanding that a complaint implicates "[s]tandards of pleading," which "are not the same as standards of proof." *Phillips*, 515 F.3d at 246. This Court connected the *Twombly* language about "whether the complaint alleges 'enough fact[s] to state a claim to relief that is plausible on its face" to introducing "enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of illegal[ity]." *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 319 (3d Cir. 2010). In fact, at the hearing on the motion to dismiss, the court remarkably stated that "in some cases to show a plausible claim we have expert evidence" and "I didn't see[] any expert evidence." Hearing on Defendants' Motion to Dismiss, *In re Lipitor Antitrust Litig.*, Civ. No. 12-2389 (PGS), at 71 (Mar. 6, 2014); *see also id.* at 72 ("[M]aybe I should do it

like a class certification motion, and that's where we get into the merits of all the claims.").

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

In short, the pleading case law in the Supreme Court and this Court makes clear that the plausibility standard sets an attainable bar, that detailed factual allegations are not required, that only enough facts are required to show the usefulness of discovery, and that a complaint cannot be dismissed even if a plaintiff appears unlikely to prove its facts or prevail at trial.

II. THE DECISION BELOW CONSTRUCTS NEW AND IMPROPER THRESHOLDS

The district court's decision requires undue, unprecedented, and impossible precision from plaintiffs. Under *Actavis* and ordinary pleading standards, plaintiffs' complaint easily states a "pay for delay" claim. *See generally* Carrier, *Pleading Standards*, at 1-3, 6-9.

The court created new hurdles and obstacles blocking plaintiffs that had offered allegations consistent with *Actavis*, as well as *Twombly* and *Iqbal*. It created and repeatedly applied newfound requirements of "reliability." It purported to apply a "plausibility" standard but—despite its frequent invocations of the term—applied a level of scrutiny far more searching. And it constructed an edifice for analyzing payment through damages forgiveness in separate litigation that, through tests with multiple parts and subparts unattainable by plaintiffs on a motion to dismiss, boggles in its complexity. All of this was unnecessary because plaintiffs had shown that Pfizer was likely to obtain significant damages and made a large payment to Ranbaxy by forgiving these damages.

A. Heightened requirements of reliability and plausibility

Ignoring *Actavis* and the pleading case law, the court below created a requirement based on "reliability" and invoked it repeatedly:

- Finding that *Actavis* applies to a non-monetary payment but only if it "can be converted to a concrete, tangible or defined amount which yields a reliable estimate of a monetary payment" (*In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523, 542 (D.N.J. 2014) ("Opinion")).
- Allowing analysis "against the *Actavis* factors" but only if the non-monetary payment is "converted to a reliable estimate of its monetary value" (*Id.* at 543).
- Finding that for non-monetary payments, a pleading "must show some reliable foundation" for estimating the payment (*Id.*).

- Allowing plaintiffs to satisfy the *Twombly* and *Iqbal* standards only if they show that the non-monetary payment has a "reliable foundation showing a reliable cash value" (*Id.* at 543).
- Stating that the standard on a motion to dismiss is not changed from "plausibility to probability" but asserting that plaintiffs must show "a reliable foundation used within the industry to convert the non-monetary payment to a monetary value" (*Id.* at 544).
- Requiring plaintiffs to "plead a reliable foundation upon which to estimate the value of the compromise of [the brand's] damages in [separate] litigation" (*Id.*).
- Rejecting plaintiffs' attempt to show the amount of payment because they "never attempt to value this non-monetary payment to a reliable measure of damages as articulated in the *Panduit* [*v. Stahlin Brothers Fibre*] case" (*Id.* at 545).
- Finding that plaintiffs' payment figures "do not provide a reliable foundation or methodology to estimate the monetary value of Pfizer's claim for infringement damages" (*Id.*).
- Stating that plaintiffs did not "rel[y] on a reliable foundation" (*Id.*).
- Concluding that "[t]he lack of any reliable foundation pervades the entire Complaint" (*Id.* at 546).
- Stating that "[a] reliable foundation need not yield a precise amount of the alleged non-monetary payment, but one that fits within the ballpark like using the loss of profit standard" (*Id.* at 550).

The frequent use of a concept—especially a newfound concept never adopted before—does not gain persuasiveness through repetition. As discussed below, the court's creation and application of a reliability threshold contravenes *Actavis* and well-established pleading law.

The court also imposed unrealistic pleading requirements under the rubric of "plausibility." This term means "possibly true." *Plausible*, Merriam-Webster's Dictionary, http://www.merriam-webster.com/dictionary/plausible (last visited September 21, 2015). The court somehow dismissed as not "plausible" (in other words, not even "possibly true") numerous allegations that, in fact, were more than plausible. The court applied the term to a vast range of allegations it did not credit:

- Stating that figures plaintiffs offered for the value of the brand's damages forgiveness were "not plausible" because "they do not provide a reliable foundation or methodology" (*Id.* at 545).
- Finding allegations in the Amended Complaint (Complaint) "implausible" in "estimat[ing] the cash value of the alleged licenses granted in other countries" (*Id.* at 546).
- Concluding that the Complaint was "implausible" because plaintiffs did not "consider the legal fees aspect" of $4.5 million to $10 million for each of 26 lawsuits settled (*Id.* at 547).
- Finding that it could not determine whether the payment was large because plaintiffs "failed to plausibly allege an estimate of the monetary value of the non-monetary payment, and the amount of legal fees of Ranbaxy [that] should have been subtracted" (*Id.*).
- Finding, for a particularly cogent piece of evidence (in which Pfizer's former Chairman and CEO conceded the date that generic competition was expected), that a smoking-gun quote "does not meet the plausibility standard" or even "support Plaintiffs' argument that the five patents are irrelevant without further plausibility" (*Id.* at 547-48).
- Finding, for similar allegations about Pfizer claiming hundreds of millions of dollars against Ranbaxy, that a statement "sounds more like a demand than a plausible value of the claim" (*Id.* at 548).

- Asserting, in tension with its previous analyses of the allegations, that the statements from leading Pfizer officials were "corroborative evidence," but that "plausibility requires some reasonable foundation to estimate the cash value of the non-monetary reverse payment" (*Id.*).
- Finding plaintiffs' claim "implausible" for "failure to consider the Settlement Agreement as a whole" and to "account [for] a variety of factors" (*Id.* at 548-49).
- Finding that plaintiffs' "selective look at certain provisions of the agreement and bypassing others renders the complaint implausible" (*Id.* at 549).
- Concluding that plaintiffs did not "plead plausible facts" that "includ[e] an estimate [of] the monetary value" of the payment (*Id.* at 550).

Although the court cautioned, in applying pleading standards, not to "chang[e] plausibility to probability," *id.* at 544, it did not apply such a standard in rejecting numerous allegations that easily satisfied the standard of plausibility.

B. Neglect of multiple indicators of significant damages forgiveness

Central to plaintiffs' claim of payment was the forgiveness of damages in separate litigation. The court, however, suggested that plaintiffs could not show payment because the damages forgiven occurred in a lawsuit that was "contingent." *Id.* The "success of Pfizer's full claim for damages in *Accupril II* was dependent upon the court's judgment finding the Accupril patent valid and infringed, *i.e.*, a 'future event that may never happen.'" *Id.* The court worried that "circumstances surrounding the parties often change as a litigation progresses." *Id.*

And "[b]ecause the parties settled before the actual judgment, it is unclear what Ranbaxy's liability would have been if a trial occurred." *Id.*

The court neglected to consider that *all* settlements executed before the ultimate judicial resolution will be contingent. It is never possible to know with certainty the eventual outcome of litigation. But the allegations in this case—especially considering the context of a motion to dismiss—more than plausibly alleged a high likelihood that Pfizer would have won the litigation.

For starters, Pfizer obtained an injunction in a case before the separate Accupril litigation at issue (*Accupril I*) that barred Teva from selling a generic version of Accupril, and the Federal Circuit affirmed the lower court's finding of validity and infringement. *Id.* at 531-32.

In addition, in the litigation in which the damages forgiveness allegedly occurred (*Accupril II*), Teva and Ranbaxy entered into an agreement by which Teva was appointed as the exclusive distributor of Ranbaxy's generic Accupril in return for Teva relinquishing its 180-day exclusivity. *Id.* at 532. Ranbaxy launched at risk in December 2004, and plaintiffs alleged that Pfizer's Accupril sales fell from $525 million in 2004 to $71 million in 2005. *Id.* In January 2005, Pfizer sued Ranbaxy and Teva for infringement, and Ranbaxy "conceded that if the court in *Accupril II* adopted the broader claim construction as Pfizer argued . . . then it 'absolutely' infringed." *Id.* In March 2005, based on the judge adopting Pfizer's

preferred broad claim construction, Pfizer obtained a preliminary injunction, affirmed by the Federal Circuit (on the condition that Pfizer post a $200 million bond), against Ranbaxy and Teva. Teva informed the court that it would not relitigate the validity and enforceability of the Accupril patent, and "Pfizer agreed that Teva had exhausted all of its validity and enforceability defenses and requested that the district court enhance the damages based on a willful infringement theory." *Id.* at 532-33. Ranbaxy initially relied only on a claim of non-infringement, but later sought to present variations of the invalidity theories on which Teva had already lost in *Accupril I*. *Id.* at 533.

In short, based on (1) Pfizer's injunction in *Accupril I*, (2) Pfizer's preliminary injunction (affirmed by the Federal Circuit) in *Accupril II*, (3) Teva's abandonment of challenges to the validity and enforceability of the patent, (4) Ranbaxy's concession that it "absolutely" infringed under the claim construction adopted by the court, and (5) Ranbaxy's at-risk entry on a blockbuster drug that suffered a reduction of more than $450 million in revenues, it was clearly plausible that Ranbaxy would have been liable for significant damages in the *Accupril* litigation.

The court ignored these obvious and clear allegations of significant damages forgiven to create a new, labyrinthine test nowhere imagined in *Actavis* or applied in any case since. Reaching for support to the specific regulatory language from

the False Claims Act, and applying a test never applied in this Circuit and one unique to the setting in which it arose, the court required a plaintiff to "allege facts as if [it were] standing in the shoes of the parties at the time of settlement." Opinion, at 544-45 (citing *U.S. ex rel. Singh v. Bradford Reg'l Med. Ctr.*, 752 F. Supp. 2d 602, 619-20 (W.D. Pa. 2010)).[4] To "value the claim for damages in *Accupril II*," the court asserted that "one must demonstrate the evidence upon which Pfizer would have most likely relied . . . at that time." *Id.* at 545. The claim in *Accupril* "was for an alleged award of profits lost because of diverted sales, price erosion and increased costs, or a royalty fee due to Ranbaxy's infringement." *Id.*

To "prove profits lost," according to the court, "the patent owner must show he would have made some or all of the infringers' sales" and "must show four major elements: (1) demand for the product; (2) absence of noninfringing substitutes; (3) manufacturing and marketing capability; and (4) the amount of profit." *Id.* Sowing even more complexity, "[s]ome of the major elements have subparts," with the fourth element, the amount of profit, having "three components,

[4] *See* 752 F. Supp. 2d at 619-20 (quoting 42 C.F.R. § 411.354(c)(1)(ii) ("Except as provided in paragraph (c)(3)(ii)(C) of this section, a physician is deemed to stand in the shoes of his or her physician organization and have a direct compensation arrangement with an entity furnishing DHS [Designated Health Services] if—(A) "The only intervening entity between the physician and the entity furnishing DHS is his or her physician organization; and (B) The physician has an ownership or investment interest in the physician organization.")).

including the number of sales the patentee would have made, the price change for those sales, and the cost to produce and market same." *Id.*

Perhaps not surprising given the novelty of this creation, the court lamented that the complaint "does not allege any such formulation," and plaintiffs "never attempt[ed] to value this non-monetary payment to a reliable measure of damages as articulated in the *Panduit* case." *Id.* Nor was it surprising that "neither of Plaintiff's figures easily plug into the lost profits criteria," which led the court to conclude that they "are not plausible because they do not provide a reliable foundation or methodology to estimate the monetary value of Pfizer's claim for infringement damages." *Id.*

Erecting yet another layer of inapt obstacles, the court overemphasized intent. It asserted that "the amount of a settlement varies due to the mindset of the parties at the time of the settlement as to the risk of trial." Opinion, at 545. The court cited a case from a different setting to consider factors such as "the risks of establishing liability or damages, the ability of the defendant to withstand a greater judgment and the range of reasonableness in light of the best possible recovery." *Id.* Despite the different context, "the fact remains that some acknowledgement of settlement consideration must be plead." *Id.* The court avowed that "the Complaint does not do so." *Id.*

The district court also erred in placing on *plaintiffs* the burden *Actavis* expressly imposed on *defendants* to justify payment. *Actavis*, 133 S. Ct. at 2236. Then the court exacerbated its legal error with a statistics error. The district court multiplied an average figure of litigation fees of $4.5 million to $10 million by each of 26 settled lawsuits to arrive at the preposterous litigation-costs figures of $117 million to $260 million. Opinion, at 546-47. It is a fundamental tenet of statistics, however, that figures may be multiplied in this manner only when the events they describe are *independent* of one another. *See, e.g.*, *Branion v. Gramly*, 855 F.2d 1256, 1265 (7th Cir. 1988). Simply put, the district court improperly assumed that all 26 cases were entirely independent of one another, *i.e.*, that the cases had no factual or legal overlap and thus Pfizer would have had to continually reinvent the wheel and pay $4.5 million to $10 million to litigate each case. Avoiding such fundamental mistakes is one of the reasons that plaintiffs' plausible allegations are taken as true on a motion to dismiss and these sorts of factual disputes are instead tested in the crucible of summary judgment and trial, where expert witnesses can guide the court and factfinder.

C. Burial of smoking guns

The court inexplicably discredited plaintiffs' allegations involving Pfizer admissions that strongly supported allegations of payment through significant damages forgiveness.

Plaintiffs first offered a statement by Pfizer's former Chairman and CEO that "[t]here are dozens of generic drug manufacturing companies with a red circle around June 28, 2011," which is "the day the patent for our anti-cholesterol medication Lipitor expires." Opinion, at 547. Shortly after that date, the official conceded, "a number of generic alternatives to Lipitor will be introduced and consumers will have a choice of generic tablets." *Id*. The court allowed that the statement constituted an admission under the Federal Rules of Evidence that showed the importance of the date "because it recognizes that the Formulation Patents, the Process Patents, and the '156 patent could not block generics from entering the market." *Id.*

The court nonetheless buried this admission, claiming that it could not "rely upon five lines from a book" without "analyzing the gist of the entire book." *Id.* at 548. The court also asserted that "the quote, on its own, cannot be the sole basis of a cause of action," *id.,* although plaintiffs never suggested it could. The court even went so far as to assert that the admission "does not meet the plausibility standard" or "support Plaintiffs' argument that the five patents are irrelevant without further plausibility." *Id.* It is hard to see how such an admission does not *support* plaintiffs' allegations.

Plaintiffs offered a second statement by Pfizer's CEO to shareholders asserting that "[Pfizer] had very, very substantial damages in the way of lost profits

that we intend to recover from Ranbaxy" in the *Accupril* case. *Id.* (citing Compl. ¶ 170). Rather than viewing such a statement (which, similar to all of plaintiffs' allegations, is supposed to be assumed to be true on a motion to dismiss) as support for plaintiffs' claims that Ranbaxy potentially faced significant damages, the court dismissed it, claiming that "[s]ince the statement does not disclose the monetary value of a non-monetary payment, it is of little impact as to its measurement within the *Actavis* rationale." *Id.* Again, each allegation at the motion-to-dismiss stage need not disclose a monetary value, in particular because it is defendants' burden to adduce justifications. Instead, the assertions are more naturally viewed as building blocks supporting the existence of significant damages liability, clearly above the level of Ranbaxy's $1 million payment, and hence a significant payment.

Third, in a brief submitted to the Federal Circuit in the *Accupril* litigation, a Pfizer attorney wrote that "Pfizer will be claiming hundreds of millions of dollars in damages for the infringing sales that were made prior to the injunction." Opinion, at 540-41 (citation omitted). The court downplayed this obvious support for the significant damages facing Ranbaxy by announcing that it "sounds more like a demand than a plausible value of the claim." *Id.* at 548. A *juror* might (or might not) ultimately credit Pfizer's admission. But the district court was not supposed to be sitting as a juror. Plaintiffs' allegation of the claim's value was

surely plausible because it was directly supported by a Pfizer admission presumably made in good faith to a federal court of appeals.

Finally, the court found the complaint lacking because the settlement agreement at issue "concern[ed] three drugs—Lipitor, Accupril, and Caduet" and it is "not . . . reasonable" that plaintiffs "rely only on certain sections (Accupril) . . . [while] disregard[ing] other sections (Caduet)." *Id.* The "analysis of Caduet and the other terms which resolved other litigation globally" purportedly were "critical in determining the settlement's "monetary value." *Id.* at 549. The court also asserted that the complaint did not consider "the costs of all litigation" and "the agreement to utilize" an active pharmaceutical ingredient from Pfizer in Canada. *Id.* at 548-49. As a result, "the claim is implausible for failure to consider the Settlement Agreement as a whole, and to 'account [for] a variety of factors.'" *Id.* at 549 (citation omitted).

The court's concern was misplaced. To the extent the Caduet settlement affected Pfizer's forgiveness of Ranbaxy's damages, it could only be in the direction of *increasing* damages forgiveness.[5] In addition, insofar as the court viewed the Caduet settlement as a potential procompetitive justification, such a

[5] Moreover, Pfizer's work for Ranbaxy as its exclusive supplier of Lipitor active ingredients increases the value of the payment to the generic. Opinion, at 534. And royalty-free licensing provisions for Lipitor-related patents, again, increase the payment by providing the generic with value from patent rights.

justification is not legally cognizable because it involves alleged procompetitive effects in different drug markets. Competition "cannot be foreclosed with respect to one sector of the economy because certain private citizens or groups believe that such foreclosure might promote greater competition in a more important sector of the economy." *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 610 (1972). A decision to sacrifice competition in one market for alleged benefits in another market "is a decision that must be made by Congress and not by private forces or by the courts." *Id*. at 611; *see also United States v. Philadelphia Nat'l Bank*, 374 U.S. 321, 370-71 (1963).

For that reason, courts routinely hold that "procompetitive justifications for price-fixing must apply to the same market in which the restraint is found, not to some other market." *Law v. NCAA*, 902 F. Supp. 1394, 1406 (D. Kan. 1995), *aff'd*, 134 F.3d 1010 (10th Cir. 1998); *United States v. Am. Exp. Co.*, 88 F. Supp. 3d 143, 229 (E.D.N.Y. 2015); *In re NCAA Student-Athlete Name & Likeness Licensing Litig.*, 37 F. Supp. 3d 1126, 1151 (N.D. Cal. 2014); *In re Elec. Books Antitrust Litig.*, 2014 WL 1282298, at *15 (S.D.N.Y. Mar. 28, 2014).[6] Indeed, *Actavis* carefully noted that payments might be justified when they "reflect compensation

[6] This Court declined to reach this issue in *King Drug*, concluding only that "[i]t may also be" that "procompetitive effects in one market cannot justify anticompetitive effects in a separate market." 791 F.3d at 410 n.34.

for other services that the generic has promised to perform—such as distributing *the patented item* or helping to develop a market *for that item*." 133 S. Ct. at 2236 (emphasis added).

In short, the court below improperly rejected numerous robust allegations showing that Ranbaxy delayed entering the market in return for a payment from Pfizer, most notably in the form of the forgiveness of hundreds of millions of dollars in separate litigation.

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

The decision below also flies in the face of this Court's decision in *Lamictal*. In that case, this Court found a non-cash transfer of consideration to be "an unusual, unexplained reverse transfer of considerable value from the patentee to the alleged infringer" that could "give rise to the inference that it is a payment to eliminate the risk of competition" and that "may be subject to antitrust scrutiny under the rule of reason." 791 F.3d at 403.

This Court did not find a significant distinction between cash and the non-cash transfer at issue in *Lamictal*: "The anticompetitive consequences of this pay-for-delay may be as harmful as those resulting from reverse payments of cash." *Id.* at 405. And this Court stated that the Supreme Court did not "limit its reasoning or holding to cash payments only" and did "not believe the Court intended to draw

such a formal line" between cash and non-cash payments. *Id.* at 405-06. While the no-authorized-generic promise in *Lamictal* threatened significant harm, so do many other conveyances, including those at issue in this case.

Finally, this Court in *Lamictal* accepted a complaint offering less detail on payment and delayed entry than the one at issue here. It concluded that "plaintiffs' allegations, and the plausible inferences that can be drawn from them, are sufficient to state a rule-of-reason claim under *Twombly* and *Iqbal* for violation of the Sherman Act on the ground that [brand] GSK sought to induce [generic] Teva to delay its entry into the . . . market by way of an unjustified no-[authorized generic] agreement." *Id.* at 409. The Court thus concluded that "at the pleading stage plaintiffs have sufficiently alleged that any procompetitive aspects of the chewables arrangement were outweighed by the anticompetitive harm" from the agreement. *Id.* at 410.

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

	Lipitor	**Lamictal**
Delayed generic entry	* "Ranbaxy agreed that it would not compete 'directly or indirectly' with the Pfizer Defendants by selling or authorizing the sale of generic Lipitor in the United States market	* GSK agreed "not to launch an authorized generic until January 2009 (*i.e.*, 180 days after Teva was on the market with Lamictal Tablets, and over three years after Teva was on the market with Lamictal

	until November 30, 2011, more than 20 months after the expiration of the '893 Patent." Complaint ¶ 89. * "Ranbaxy agreed not to sell generic Lipitor in the United States" for "5 months after the '995 Patent was expected to expire if Pfizer succeeded in getting it reiisued." *Id.* ¶ 128.	Chewables)." Consolidated Amended Class Action Complaint ¶ 76.
Value of payment	* Pfizer "gave Ranbaxy substantial financial consideration" through "the settlement and effective forgiveness of Pfizer's claims" against Ranbaxy by allowing Ranbaxy to pay "$1 million to 'settle' a claim by Pfizer that the record in the Accupril litigation shows was likely worth hundreds of millions of dollars." *Id.* ¶ 90. * Plaintiffs supported a high level of expected damages facing Ranbaxy in the Accupril litigation by proffering evidence of the patent's validity, enforceability, and infringement; Pfizer's preliminary injunction; Pfizer's request for lost profits and enhanced damages; Ranbaxy's entry into the market "at	* "Teva received substantial financial inducements that went beyond what Teva could have achieved if it was fully successful in the patent litigation." *Id.* ¶ 20. * "Teva's 180-day market exclusivity period enabled it to generate many millions of dollars of additional revenue." *Id.* ¶ 88.

	risk"; and a "decimated" market that fell from $525 million before Ranbaxy's entry to $71 million after entry. *Id.* ¶¶ 91-96. * Plaintiffs alleged payment from Pfizer's conveyance to Ranbaxy of "the right to market generic Lipitor in eleven foreign markets outside the United States." *Id.* ¶ 98.	

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

IV. PLAINTIFFS' COMPLAINT EASILY SATISFIES ORDINARY PLEADING STANDARDS

In determining the sufficiency of a complaint, this Court has articulated a three-part analysis for district courts to apply: "(1) identifying the elements of the claim, (2) reviewing the complaint to strike conclusory allegations, and then (3) looking at the well-pleaded components of the complaint and evaluating whether all of the elements identified in part one of the inquiry are sufficiently alleged." *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011); *see also Fowler*, 578 F.3d at 210-11 (offering a similar 2-part test).

Applying the analysis here, first, a plaintiff must show a payment from a brand to a generic and delayed generic entry. The plaintiffs satisfied this with

multiple allegations of payment (Complaint ¶¶ 90, 97-98, 129), support for payment through details of the separate litigation (*id.* ¶¶ 91-96, 103-04), and delayed entry (*id.* ¶¶ 89, 99, 101, 128-29). Once the plaintiff makes these showings, the burden shifts to the defendant to show that the payment is justified. But that is not something the plaintiff must allege in its prima facie case. *Actavis* made clear that defendants had the burden of showing "that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason." *Actavis*, 133 S. Ct. at 2236.

Second, the plaintiffs' allegations relating to payment through damages forgiveness are not conclusory. As discussed above, they rely on robust allegations relating to Pfizer's injunctions, the patent's strength, Ranbaxy's at-risk entry into a "decimated" market, and Pfizer officials' concessions on generic entry and significant damages. The only way the court could reject more-than-sufficient evidence was to repeatedly, without explanation, call it "implausible" and construct an array of newfound and unsupported requirements.

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

(1) **Delay**: Ranbaxy delayed entering the market by "agree[ing] that it would not compete 'directly or indirectly' with [Pfizer] by selling or authorizing the sale of generic Lipitor in the United States market until November 30, 2011, more than 20 months after the expiration of the '893 Patent." Complaint ¶ 89; *see also id.* ¶ 128

(also alleging delay of 5 months after expected expiration (if reissued) of '995 Patent).

(2) **Payment**: Pfizer "gave Ranbaxy substantial financial consideration" through "the settlement and effective forgiveness of Pfizer's claims" against Ranbaxy by allowing Ranbaxy to pay "$1 million to 'settle' a claim by Pfizer that the record in the Accupril litigation shows was likely worth hundreds of millions of dollars." *Id.* ¶ 90; *see also id.* ¶¶ 87, 97.

(3) **Support for payment**: Plaintiffs supported a high level of expected damages facing Ranbaxy in the Accupril litigation by proffering evidence of the patent's validity, enforceability, and infringement; Pfizer's preliminary injunction; Pfizer's request for lost profits and enhanced damages; Ranbaxy's entry into the market "at risk"; and a "decimated" market that fell from $525 million before generic entry to $71 million after entry. *Id.* ¶¶ 91-96.

(4) **Smoking guns**: Plaintiffs offered various statements of leading Pfizer officials about expected generic entry and the weakness of certain patents. *Id.* ¶¶ 103, 104

(5) **Additional payments**: Plaintiffs alleged payment from Pfizer's conveyance to Ranbaxy of "the right to market generic Lipitor in eleven foreign markets outside the United States." *Id.* ¶ 98.

In short, plaintiffs showed delayed generic entry and a brand payment to a generic in the form of the forgiveness of hundreds of millions of dollars in damages and the right to enter in multiple foreign markets. This easily satisfies traditional pleading standards.[7]

[7] *See also In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 391 (D. Mass. 2013) (denying motion to dismiss because "AstraZeneca's forgiveness of Teva's and Dr. Reddy's contingent liabilities related to the infringement of non-Nexium-related patents sufficiently implicate[d] adverse anticompetitive consequences to allow the [plaintiffs'] claims to proceed."); *In re Aggrenox Antitrust Litig.*, 2015 WL 1311352, at *13 (D. Conn. Mar. 23, 2015); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 753 (E.D. Pa. 2014).

* * *

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

The Supreme Court's landmark decision in *Actavis* would be undermined if courts were to impose newfound excessive standards at the motion-to-dismiss stage that effectively make it all but impossible for plaintiffs to succeed. This Court's decision in *Lamictal* also would be upended if brands' conveyances to generics of significant value could be dismissed by requiring plaintiffs to plead the evidence that will be produced in discovery. And in creating excessive pleading thresholds not supported by *Twombly*, *Iqbal*, and this Court's rulings, the court below misread those decisions and violated the "common sense" required under *Twombly*.

CONCLUSION

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

Dated: December 28, 2015

Respectfully submitted,

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CERTIFICATE OF BAR MEMBERSHIP

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

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

1. This brief contains 6,941 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

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

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

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

Dated: December 28, 2015

/s/ Steve D. Shadowen
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CERTIFICATE OF SERVICE

I, Steve D. Shadowen, certify that counsel for Appellees are Filing Users of the Court's CM/ECF system, and, that this 28th day of December, 2015, this Brief Amici Curiae of 48 Law, Economics, and Business Professors and the American Antitrust Institute in Support of Appellants was served by filing it on the court's CM/ECF system. I further certify that seven hard copies of this Brief were delivered to the Office of the Clerk for the United States Court of Appeals for the Third Circuit. This Brief was also served via e-mail on all counsel by their consent.

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