

PLEADING STANDARDS: THE HIDDEN THREAT TO *ACTAVIS*

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INTRODUCTION

In *FTC v. Actavis*,¹ the Supreme Court issued one of the most important antitrust decisions in the modern era. It held that a brand drug company's payment to a generic firm to settle patent litigation and delay entering the market could violate the antitrust laws.

Since the decision, courts have analyzed several issues, including causation, the role of the patent merits, and whether "payment" is limited to cash. But one issue—the pleading requirements imposed on plaintiffs—has slipped under the radar. This issue has the potential to undercut antitrust law, particularly because settlements with payment and delayed entry today typically do not take the form of cash. The complexity of non-cash conveyances increases the importance of the pleading stage.

For that reason, it is concerning that several courts have imposed unprecedented hurdles. For example, the district court in *In re Effexor XR Antitrust Litigation* failed to credit allegations that a generic delayed entering the market because a brand promised not to introduce its own "authorized generic" that would have dramatically reduced the true generic's revenues.² The same judge, in *In re Lipitor Antitrust Litigation*, dismissed a complaint despite allegations that the generic delayed entry in return for the brand's forgiveness of hundreds of millions of dollars in potential damages in separate litigation.³

This Essay first introduces the Supreme Court's *Actavis* decision. It then discusses the pleading standards articulated by the Court in *Bell Atlantic v. Twombly*⁴ and *Ashcroft v. Iqbal*.⁵ Turning to the cases that applied excessively high pleading requirements, it next focuses on the *Effexor* and *Lipitor* cases. Finally, it analyzes the settlement cases that applied a more justifiable analysis.

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¹ 133 S. Ct. 2223 (2013).

² No. 11-5479, 2014 WL 4988410, at *23 (D.N.J. Oct. 6, 2014).

³ 46 F. Supp. 3d 523, 548–50 (D.N.J. 2014).

⁴ 550 U.S. 544 (2007).

⁵ 556 U.S. 662 (2009).

I

ROBUST ANTITRUST ANALYSIS UNDER *ACTAVIS*

In its landmark *Actavis* decision, the Supreme Court for the first time considered the antitrust legality of agreements by which brands pay generics to delay entering the market. The Court forcefully held that such agreements could be “unjustified,” have the potential for “significant adverse effects on competition,” and “violate the antitrust laws.”⁶

The Court emphasized the significant antitrust harms that result when a brand pays a generic to stay out of the market. The payment “in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product.”⁷ In fact, payment can “provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market.”⁸

In analyzing competitive effects, the Court “[le]ft to the lower courts the structuring of the present rule-of-reason antitrust litigation.”⁹ Such a framework was to “consider[] traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations.”¹⁰ Within that framework, the Court anticipated that defendants would bear the burden of demonstrating a payment’s justifications.¹¹

II

ATTAINABLE PLEADING STANDARDS UNDER *TWOMBLY/IQBAL*

Just like *Actavis* anticipated that a plaintiff “should have . . . the opportunity to prove its antitrust claim,”¹² pleading case law also gives plaintiffs leeway to clear the motion-to-dismiss stage without offering evidence or satisfying probability-based tests.

In *Bell Atlantic v. Twombly*, the Supreme Court required plaintiffs to provide factual allegations that “raise a right to relief above the speculative

⁶ *Actavis*, 133 S. Ct. at 2227, 2231, 2235–36.

⁷ *Id.* at 2234.

⁸ *Id.* at 2235.

⁹ *Id.* at 2238.

¹⁰ *Id.* at 2231.

¹¹ See *id.* at 2236 (“An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.”).

¹² See *id.* at 2234–37 (reviewing “five sets of considerations” leading the court to conclude that the lower court erred in finding that the parties’ settlement was immune from antitrust review).

level” and offer more than just “a formulaic recitation of the elements of a cause of action.”¹³ The Court, however, made clear that plaintiffs did not need “detailed factual allegations,” but only “enough facts to state a claim to relief that is plausible on its face.”¹⁴ The Court did not intend for its “plausibility” requirement to expand into a “probability” hurdle.¹⁵ And it allowed a complaint to proceed “even if it strikes a savvy judge that actual proof of these facts is improbable.”¹⁶

Similarly, the Court in *Ashcroft v. Iqbal* required plaintiffs to offer more than “[t]hreadbare recitals of the elements of a cause of action.”¹⁷ But again, it made clear that “[t]he plausibility standard is not akin to a ‘probability requirement’” and that “[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.”¹⁸ These determinations require a “context-specific” analysis in which “the reviewing court . . . draw[s] on its judicial experience and common sense.”¹⁹

Courts have understood that *Twombly* “never said that it intended a drastic change in the law, and indeed strove to convey the opposite impression.”²⁰ In fact, a complaint “may not be dismissed merely because it appears unlikely that the plaintiff can prove [the alleged] facts or will ultimately prevail on the merits.”²¹

The same standard applies to antitrust actions. Courts cannot “act as ‘gatekeepers’” in “subject[ing] pleadings” in “antitrust and other complex cases” to heightened scrutiny.²² 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.”²³

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

¹³ 550 U.S. 544, 555 (2007).

¹⁴ *Id.* at 555, 570.

¹⁵ *Id.* at 556.

¹⁶ *Id.*

¹⁷ 556 U.S. 662, 678 (2009).

¹⁸ *Id.*

¹⁹ *Id.* at 679.

²⁰ *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 230 (3d Cir. 2008).

²¹ *Id.* at 231.

²² *West Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 98 (3d Cir. 2010).

²³ *Id.*

III

NO-AUTHORIZED-GENERIC PROMISES AND RELIABILITY REQUIREMENTS IN
EFFEXOR

*In re Effexor XR Antitrust Litigation*²⁴ provides the first example of a court imposing an excessively high bar. In that case, the plaintiffs alleged that Teva agreed to delay entering the market with a generic version of depression-treating Effexor XR until two years after the expiration of the compound patent.²⁵ Such delay allegedly resulted from brand Wyeth's promise not to introduce an authorized generic (AG) during the 180-day period reserved for Teva, the first generic to challenge Wyeth's patent.²⁶

Consistent with *Actavis* and the pleading case law, the plaintiffs alleged the required elements of payment and delayed entry:

- 1) **Delay:** Wyeth promised that it would not market an AG for at least Teva's 6-month exclusivity period and possibly an additional 5 months, resulting in an 11-month period with no competition after Teva's launch.²⁷
- 2) **Effect of AGs in general:** Reports of the Federal Trade Commission (FTC) showed that the introduction of AGs lowers generic prices and that promises not to introduce AGs during the 180-day period reduce first-filing generics' revenues "by more than half."²⁸
- 3) **Effect of AG on similar drug:** Effexor (in 2009) gained \$2.39 billion in sales, similar to those of blockbuster Paxil (\$2.31 billion), for which the introduction of an AG during the 6-month period reduced revenues by \$400 million, supporting a higher figure for Effexor's potential 11-month period with no AG competition.²⁹
- 4) **Payment:** Wyeth's no-AG assurance transferred "enormous value" to Teva by ensuring that Teva would garner all of the generic Effexor XR sales during the 180-day period and would be able to charge higher prices than if it faced competition from an AG.³⁰

Bypassing these allegations of payment for delayed entry, the *Effexor* court required more from plaintiffs. For starters, the court created pleading

²⁴ No. 11-5479, 2014 WL 4988410 (D.N.J. Oct. 6, 2014).

²⁵ *Id.* at *11.

²⁶ *Id.*

²⁷ Direct Purchaser Class Plaintiffs' Second Amended Consolidated Class Action Complaint and Jury Demand at ¶ 276, *In re Effexor XR Antitrust Litig.*, No. 3:11-cv-05479 (D.N.J. Oct. 23, 2013), 2013 WL 5940018 [hereinafter *Effexor Complaint*].

²⁸ *Id.* ¶¶ 58, 60, 291.

²⁹ *Id.* ¶ 292.

³⁰ *Id.* ¶ 282.

requirements based on the concept of reliability. Though such a concept does not appear in *Actavis* or the pleading case law, the court applied it across an array of issues. It required non-monetary payments to be “something of value . . . which yields a *reliable* estimate of a monetary payment.”³¹ It called for any “foundation” for “estimating the alleged reverse payment” to be “reliable.”³² It applied the concept to pleading standards, asserting that plaintiffs satisfy *Twombly* and *Iqbal* only if they show that the non-monetary payment has a “reliable foundation showing a reliable cash value.”³³ And it required payments to follow “general industry guidelines” offered as “a reliable foundation.”³⁴ In fact, the court invoked the concept *15 times* in raising the bar confronting plaintiffs.

Relatedly, the court picked and chose among the types of evidence it would consider. Plaintiffs included the two leading reports on AGs, published by the FTC, the entity that “exercises primary responsibility over federal antitrust enforcement in the pharmaceutical industry” and that “has a congressionally-mandated role to conduct studies of industry-wide competition issues.”³⁵

The FTC published a 43-page empirical report in 2009 showing price reductions when generics compete with AGs during the 180-day period and 47%–51% revenue reductions for generics facing AG entry during the period.³⁶ The FTC followed up two years later with a 153-page analysis of materials from more than 100 brand and generic drug companies that examined trends and industry practices in marketing AGs, analyzed brands’ “documents and practices” regarding their use of AGs to maintain revenue after generic entry, and analyzed data on the effects of AGs on price.³⁷ In

³¹ *In re Effexor XR Antitrust Litig.*, No. 11-5479, 2014 WL 4988410, at *19 (D.N.J. Oct. 6, 2014) (emphasis added); *see also id.* at *20 (arguing that the estimate of the payment’s monetary value must be “reliable” so that it may be analyzed against the “*Actavis* factors”).

³² *Id.* at *20.

³³ *Id.* at *20. *See also id.* at *21 (requiring “a showing of a reliable foundation used within the industry to convert the non-monetary payment to a monetary value”). Other courts have imported the requirement that there be a “reliable foundation” for facts pled by the plaintiffs. *See, e.g., In re Actos End Payor Antitrust Litig.*, No. 13-CV-9244, 2015 WL 5610752, at *19 (S.D.N.Y. Sept. 22, 2015) (citing the “reliable foundation” language in *Effexor* and concluding that the “bare allegations” in the complaint were “insufficient for the [c]ourt to make a reasonable estimate of the settlements’ value” and evaluate whether they met the standards delineated in *Actavis*).

³⁴ *Effexor*, 2014 WL 4988410, at *22. The court also switched between “reliable foundation” and “reasonable foundation,” two phrases that have different meanings as is apparent from reasonable foundations that do not satisfy a higher threshold of reliability. *Id.*

³⁵ FTC Brief as Amicus Curiae at 3, *In re Effexor XR Antitrust Litig.*, No. 3:11-cv-05479 (D.N.J. Aug. 14, 2013), 2013 WL 5183029.

³⁶ FED. TRADE COMM’N, AUTHORIZED GENERICS: AN INTERIM REPORT, Ch. 1, at 3 (2009), <https://www.ftc.gov/sites/default/files/documents/reports/authorized-generics-interim-report-federal-trade-commission/p062105authorizedgenericsreport.pdf>.

³⁷ FED. TRADE COMM’N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-

addition to not crediting these comprehensive reports, the court did not consider Supreme Court authority³⁸ or multiple articles on the effects of AGs cited in plaintiffs' complaint.³⁹ None of these sources counted in the court's conclusion that plaintiffs did "not rely on any knowledge of business practitioners in the pharmaceutical industry."⁴⁰

Just as concerning, and ignoring the procedural setting, the court punished plaintiffs for not offering "evidence" in their complaint. It asserted that "[s]ince the . . . [p]laintiffs fail to provide appropriate evidence for the Court to determine the value of the payment, the allegations in the Complaint do not reach the plausibility standard established in *Iqbal* and *Twombly*."⁴¹ Even under a plausibility standard, however, plaintiffs do not need to present evidence in a complaint. That is the point of discovery. And evidence related to the justifications for a payment typically lie in defendants' possession.⁴²

Finally, the court overemphasized the "antitrust intent of the settling parties," claiming that *Actavis* "suggests that a justification can be seen in the intent of the parties in settling."⁴³ While *Actavis* included one line on the parties' "reasons to prefer settlements that include reverse payments,"⁴⁴ that line most naturally highlighted anticompetitive effects. The Court could not have anticipated that this line would allow parties to escape the consequences of entering into anticompetitive settlements by pointing to a benign intent.

Nor, even if intent were a factor, was the "evidence" the court unearthed useful. The court found an "alleged antitrust intent" to be "negated by the fact that the settlement and license agreements were forwarded to the FTC evidencing the parties' willingness to submit those

TERM IMPACT 8–9 (2011), <https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf>.

³⁸ In particular, the court ignored *Fed. Trade Comm'n v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

³⁹ See *Effexor Complaint*, *supra* note 27, ¶¶ 49–61 & nn.4–10 (citing the FTC's 2009 report and scholarship on the effect of authorized generics).

⁴⁰ *Effexor*, 2014 WL 4988410, at *22.

⁴¹ *Id.* at *23.

⁴² *E.g.*, *In re Opana ER Antitrust Litig.*, MDL Docket No. 2580, Case No. 14 C 10150, 2016 WL 521005, at *7 (N.D. Ill. Feb. 10, 2016); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 245 (D. Conn. 2015); *In re Cipro Cases I & II*, 348 P.3d 845, 866–67 (Cal. 2015) (citing *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 104 (2d Cir. 2010)).

⁴³ *Effexor*, 2014 WL 4988410, at *20, *24.

⁴⁴ *Fed. Trade Comm'n v. Actavis, Inc.*, 133 S. Ct. 2223, 2237 (2013). The Court explained that "[i]f the basic reason [to agree to a particular settlement] is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement." *Id.*

agreement[s] for review prior to the settlement becoming effective.”⁴⁵ Far from any such consequence, the parties’ filing of the agreements was required under federal law. Pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, brand and generic companies are required to file settlement agreements concerning the 180-day exclusivity period or production, sale, or marketing of a drug with the FTC and Department of Justice within ten days of the agreement.⁴⁶

IV

IMPOSING NEW TESTS AND DISREGARDING SMOKING GUNS IN *LIPITOR*

The same judge that dismissed the *Effexor* complaint dismissed a similarly robust complaint in *In re Lipitor Antitrust Litigation*.⁴⁷ In that case, the plaintiffs alleged that Pfizer paid Ranbaxy to delay entering the market with a generic version of blockbuster cholesterol drug Lipitor.⁴⁸ Such a payment allegedly took the form of the forgiveness of significant damages facing Ranbaxy in separate litigation involving the blood-pressure drug Accupril.⁴⁹

Consistent with *Actavis* and the pleading case law, 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.”⁵⁰
- 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 . . . was likely worth hundreds of millions of dollars.”⁵¹
- 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

⁴⁵ *Effexor*, 2014 WL 4988410, at *24.

⁴⁶ Pub. L. 108-173, §§ 1112–1113, 117 Stat. 2066, 2461–2463 (codified as amended at 21 U.S.C. § 355 (2012)).

⁴⁷ 46 F. Supp. 3d 523 (D.N.J. 2014).

⁴⁸ Amended Complaint & Demand for Jury Trial at ¶¶ 89, 129, *In re Lipitor Antitrust Litigation*, 46 F. Supp. 3d 523 (D.N.J. filed Oct. 23, 2013) [hereinafter *Lipitor Complaint*].

⁴⁹ *Id.* ¶¶ 90, 97.

⁵⁰ *Id.* ¶ 89.

⁵¹ *Id.* ¶ 90.

entry into the market “at risk”; and a “decimated” market that fell from \$525 million before Ranbaxy’s entry to \$71 million after entry.⁵²

- 4) **“Smoking guns”:** Plaintiffs offered various statements by leading Pfizer officials about expected generic entry and the weakness of certain patents.⁵³
- 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.”⁵⁴

In ignoring these allegations of payment for delayed entry, the court raised pleading standards to unprecedented levels. For starters (and similar to *Effexor*), it created a requirement based on reliability and applied it across an array of antitrust issues, including non-monetary payments,⁵⁵ pleading standards,⁵⁶ forgiven damages,⁵⁷ and the complaint as a whole.⁵⁸

The court also imposed unrealistic expectations under the guise of “plausibility.” Even though this term means “possibly true,”⁵⁹ the court dismissed as not “plausible” a vast range of allegations it did not wish to credit on damages forgiveness,⁶⁰ the value of payment,⁶¹ the size of payment,⁶² the complaint itself,⁶³ and smoking-gun quotes about Pfizer’s strong claim for damages.⁶⁴ Two of the most egregious of these errors—failing to accept as plausible damages forgiveness claims and smoking-gun quotes—are discussed more extensively below.

A. *Neglect of indicators of significant damages forgiveness*

Central to plaintiffs’ claim of payment was the forgiveness of damages in separate litigation. The court lamented that plaintiffs could not show payment because the damages forgiven occurred in a lawsuit that was “contingent” and because “it is unclear what Ranbaxy’s liability would

⁵² *Id.* ¶¶ 91–96.

⁵³ *Id.* ¶¶ 103–104.

⁵⁴ *Id.* ¶ 98.

⁵⁵ *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523, 543 (D.N.J. 2014).

⁵⁶ *Id.* at 543–44.

⁵⁷ *Id.* at 544–45.

⁵⁸ *Id.* at 546.

⁵⁹ *Plausible*, MERRIAM-WEBSTER’S DICTIONARY, <http://www.merriam-webster.com/dictionary/plausible> (last visited Sept. 21, 2015).

⁶⁰ *Lipitor*, 46 F. Supp. 3d at 545.

⁶¹ *Id.* at 546, 548, 550.

⁶² *Id.* at 547.

⁶³ *Id.* at 548–49.

⁶⁴ *Id.* at 547–48.

have been if a trial occurred.”⁶⁵ The court, however, neglected to consider that all settlements executed before the ultimate judicial resolution will be contingent, as it is never possible to know with certainty the eventual outcome of litigation.

In the litigation in which the damages forgiveness allegedly occurred, Pfizer obtained a preliminary injunction (affirmed by the Federal Circuit) and requested enhanced damages based on willful infringement.⁶⁶ The damages promised to be substantial given Ranbaxy’s at-risk launch, after which Pfizer’s Accupril sales allegedly fell from \$525 million to \$71 million.⁶⁷

The court ignored these obvious allegations of significant damages forgiven to create a new, labyrinthine test. Reaching for support to the specific regulatory language of the False Claims Act, and applying a test 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.”⁶⁸

To prove Pfizer’s anticipated lost profits, the court required Ranbaxy, standing in the patentee’s shoes, to “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.”⁶⁹ Some of these have subparts, with the fourth element—the amount of profit—having “three components, including the number of sales the patentee would have made, the price change for those sales, and the cost to produce and market same.”⁷⁰

Perhaps not surprising given the novelty of this creation, the court lamented that the complaint “does not allege any such formulation” and “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.”⁷¹

B. Burial of smoking guns

The court also offered multiple rejections of plaintiffs’ “smoking guns” that proffered robust allegations of payment through significant damages forgiveness.

⁶⁵ *Id.* at 544.

⁶⁶ *Id.* at 532–33.

⁶⁷ *Id.* at 532.

⁶⁸ *Id.* at 544 (internal citation omitted).

⁶⁹ *Id.* at 545.

⁷⁰ *Id.*

⁷¹ *Id.*

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."⁷² Shortly after that date, "a number of generic alternatives to Lipitor will be introduced and consumers will have a choice of generic tablets."⁷³ The court confessed that the statement "may constitute" 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."⁷⁴

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."⁷⁵ The court also asserted that "the quote, on its own, cannot be the sole basis of a cause of action."⁷⁶ The court even went so far as to assert that the smoking gun "does not meet the plausibility standard" or "support Plaintiffs' argument that the five patents are irrelevant without further plausibility."⁷⁷ 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.⁷⁸ Rather than viewing such a statement 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."⁷⁹

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."⁸⁰ The court downplayed this obvious support for significant damages facing Ranbaxy by avowing that the statement "sounds more like a demand than a plausible value of the claim."⁸¹

In short, under well-established pleading standards and given Pfizer's acceptance of \$1 million to resolve litigation worth hundreds of millions of

⁷² *Id.* at 547.

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.* at 548.

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.*

dollars, plaintiffs alleged payment in the form of significant damages forgiveness.⁸²

V

MORE JUSTIFIABLE PLEADING DECISIONS

In contrast to the *Effexor* and *Lipitor* rulings, other courts have more justifiably refused to dismiss complaints challenging settlements pleaded with the same (or less) specificity. The court in *In re Aggrenox Antitrust Litigation* recognized that “plaintiffs have not attempted to assign dollar values with significant precision or very obvious methodological justification to the various provisions of the settlement” that included a no-AG promise and payment for generic services.⁸³ But the court was not willing to “conclude simply from the absence of precise figures that the pleadings represent formulaic recitations of elements and allegations that fail to rise above the speculative.”⁸⁴

Similarly, in *In re Nexium (Esomeprazole) Antitrust Litigation*, plaintiffs alleged, without offering backup calculations, that “AstraZeneca agreed to pay over \$1,000,000,000 to Ranbaxy and enter into a no-[AG] agreement with it.”⁸⁵ The court found that the settlement “sufficiently implicate[d] adverse anticompetitive consequences to allow the [plaintiffs’] claims to proceed.”⁸⁶ And the court concluded that the plaintiffs “have pled facts sufficient at the motion-to-dismiss stage to establish” antitrust violations under the rule of reason.⁸⁷

Finally, in *In re Niaspan Antitrust Litigation*, the court rejected defendants’ claims that plaintiffs’ allegations regarding payment through a no-AG promise and the provision of generic services were “conclusory assertions” akin to the “formulaic recitation of the elements of a cause of action.”⁸⁸ The court understood the appropriate placement of burdens,

⁸² For other courts applying heightened thresholds to allegations involving non-cash consideration, see *In re Actos End Payor Antitrust Litig.*, No. 13-CV-9244, 2015 WL 5610752, at *13 (S.D.N.Y. Sept. 22, 2015) (“[I]n order for the Court to find an unlawful reverse payment, it must be able to estimate the value of the term, at least to the extent of determining whether it is ‘large’ and ‘unjustified.’”); *Fed. Trade Comm’n v. AbbVie Inc.*, 107 F. Supp. 3d 428, 436 (E.D. Pa. 2015) (concluding that the FTC failed to allege “a reverse payment under *Actavis*”).

⁸³ *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 244–45 (D. Conn. 2015).

⁸⁴ *Id.* Other courts also recognize the difficulty of assigning firm dollar values to non-monetary payments. *Cf. In re Opana ER Antitrust Litig.*, MDL Docket No. 2580, Case No. 14 C 10150 (N.D. Ill. Feb. 10, 2016), 2016 WL 521005, at *8 (“While sharing the concerns expressed by [courts that require a reliable foundation for payment value estimates], the [c]ourt is also aware that a precise valuation may require discovery, as it will likely depend on evidence in [d]efendants’ exclusive possession and on expert analysis.”).

⁸⁵ 968 F. Supp. 2d 367, 391 (D. Mass. 2013).

⁸⁶ *Id.*

⁸⁷ *Id.* at 393.

⁸⁸ 42 F. Supp. 3d 735, 753 (E.D. Pa. 2014) (internal citations omitted).

noting that “[w]hile it [is] possible that defendants will be able to supply evidence to rebut plaintiffs’ allegations regarding the true value of the services that [the generic] agreed to provide, *Twombly* does not require an antitrust plaintiff to plead facts that, if true, definitively rule out all possible innocent explanations.”⁸⁹

In short, the *Aggrenox*, *Nexium*, and *Niaspan* courts applied a more appropriate pleading standard than the unprecedented *Effexor* and *Lipitor* decisions.

* * * * *

Drug patent settlements have received significant attention since *Actavis*. In this context, pleading rules have avoided sustained scrutiny. But the imposition of excessive standards, as was done by the *Effexor* and *Lipitor* courts, threatens to overturn established pleading standards and undercut the landmark *Actavis* decision. Such a result would significantly weaken the antitrust analysis of potentially anticompetitive settlements.

⁸⁹ *Id.*