No. 15-1055

IN THE

Supreme Court of the United States

SMITHKLINE BEECHAM CORPORATION, D/B/A GLAXOSMITHKLINE; TEVA PHARMACEUTICAL INDUSTRIES LTD.; TEVA PHARMACEUTICALS, USA,
Petitioners,

v.

KING DRUG COMPANY OF FLORENCE, INC.; LOUISIANA WHOLESALE DRUG CO., INC., ON BEHALF OF ITSELF AND ALL OTHERS SIMILARLY SITUATED,
Respondents.

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

BRIEF OF NATIONAL ASSOCIATION OF MANUFACTURERS AS AMICUS CURIAE IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE*

The National Association of Manufacturers ("NAM") is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs over 12 million men and women, contributes roughly $2.17 trillion to the U.S. economy annually, has the largest economic impact of any major sector and accounts for three-quarters of private sector research and development. The NAM's mission is to enhance the competitiveness of manufacturers and improve American living standards by shaping a legislative and regulatory environment conducive to U.S. economic growth.[1]

The NAM's membership includes innovators, patent holders, and patent challengers, as well as purchasers and users of patented technologies. The NAM favors legal rules that enable parties to understand their rights and obligations, resolve disputes efficiently, and focus on the development and commercialization of new technologies to support American manufacturing.

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[1] Pursuant to Sup. Ct. R. 37.6, *amicus curiae* the NAM states that this brief was not authored in whole or in part by counsel for any party other than the NAM and that no person or entity other than the NAM or its counsel made a monetary contribution intended to fund the preparation or submission of this brief. All parties have consented to the filing of this Brief: letters of consent have been filed with the Clerk of Court.

SUMMARY OF ARGUMENT

This case turns on the allegation that GlaxoSmithKline LLC ("GSK")—the holder of a patent on an active ingredient named lamotrigine and certain methods of using it—settled a challenge to that patent by: (1) granting the challenger, Teva,[2] the right to market and sell generic lamotrigine drugs before the end of GSK's term of exclusivity; and (2) agreeing not to introduce its own "authorized generic" in addition to the branded drug during Teva's license period. *See* Petition for Writ of Certiorari ("Pet.") 8–9. The question at the heart of this case is whether such an allegation states a plausible antitrust claim after *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

Respondents and the Court of Appeals label this arrangement a "no-AG agreement." *See, e.g.*, Pet. Appendix ("App.") 7a, 10a. But it is just an exclusive license, substituting one generic supplier (here, Teva) in place of another (here, GSK). Such agreements are not inherently anticompetitive, are common in every industry, and in fact are routinely procompetitive.

The Court of Appeals below failed to recognize that, if agreements like this one are given an automatic pass to antitrust discovery, the result will be much more litigation, and, in this context, much more *patent litigation* in particular—one of the most costly, burdensome, and unpredictable forms of

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[2] This brief will refer to Teva Pharmaceuticals, USA, and Teva Pharmaceutical Industries Ltd. as "Teva."

litigation. As such, the policy imperatives in favor of encouraging settlement are particularly compelling in this context. Parties must not be forced to choose between lengthy and expensive patent litigation if they do not settle a patent challenge and lengthy and expensive antitrust litigation if they do.

The holding below threatens to eviscerate *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007), in one of the contexts where it is most needed. Specifically, the Third Circuit misreads this Court's holding in *Actavis* as support for the notion that an antitrust plaintiff can trigger the avalanche of antitrust discovery simply by alleging the existence of an exclusive license in a patent settlement. *See* Pet. App. 31a–45a. But that was not the holding in *Actavis*, and it cannot be the law. Speculative antitrust challenges alleging only commonplace settlement terms like the exclusive license here should be dismissed under Fed R. Civ. P. 12(b)(6), consistent with *Twombly*, not waved through into discovery.

The holding below perpetuates widespread confusion in the lower courts about the scope and meaning of the *Actavis* decision, and threatens to turn a commonplace commercial tool in a wide range of industries—including the many industrial sectors reflected in the NAM's membership—into guarantees that antitrust litigation will follow wherever patent litigation has been avoided. This Court should intervene to avoid that outcome. For these reasons, as explained in further detail below, this Court should grant the petition for certiorari.

BACKGROUND

I. Patent Litigation

This Court has recognized that "patent litigation is particularly complex, and particularly costly."[3] A chorus of federal courts has agreed, with one noting that "patent litigation is the slowest and most expensive litigation in the United States."[4] Very simply, "the costs of patent litigation are enormous with an average patent case costing upwards of $3 million for each side."[5]

In 2015, the American Intellectual Property Law Association ("AIPLA") quantified the median costs for patent infringement litigation of all varieties as follows:

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[3] *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223, 2243 (2013). *See also, e.g., Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 334 (1971) ("[P]atent litigation is a very costly process.").

[4] *DeLaventura v. Columbia Acorn Trust*, 417 F. Supp. 2d 147, 153 n.7 (D. Mass. 2006). *See also, e.g., Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011) ("[P]atent infringement ... is already notorious for its complexity and high cost.") (quoting *amicus* brief of the American Bar Association) (internal quotation marks omitted); *Schering-Plough Corp. v. F.T.C.* 402 F.3d 1056, 1075 (11th Cir. 2005) ("Patent litigation breeds a litany of direct and indirect costs[.]"); *United States v. FMC Corp.*, 717 F.2d 775, 787 (3d Cir. 1983) ("Patent litigation is very expensive.").

[5] *Ohio Willow Wood Co. v. Thermo-Ply, Inc.*, 629 F.3d 1374, 1376-77 (Fed. Cir. 2011) (Moore, J., concurring).

Figure 1: Median Patent Litigation Costs

Amount in controversy	Costs through end of discovery	All costs
< $1,000,000	$400,000	$600,000
$1,000,000 – $10,000,000	$950,000	$2,000,000
$10,000,000 – $25,000,000	$1,900,000	$3,100,000
> $25,000,000	$3,000,000	$5,000,000

Source: AIPLA, 2015 *Report of the Economic Survey*, 37.[6]

Moreover, Abbreviated New Drug Application ("ANDA") litigation—the type of patent litigation that led to the settlement at issue here—is unusually expensive: one study cited in *Actavis* noted that "litigation expenses can raise the expense of an ANDA to around $10 million."[7]

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[6] The costs included by AIPLA include outside legal and paralegal services, local counsel, associates, paralegals, travel and living expenses, fees and costs for court reporters, photocopies, courier services, exhibit preparation, analytical testing, expert witnesses, translators, surveys, jury advisors, and similar expenses. They exclude costs relating to settlements and damages. AIPLA, 2015 *Report of the Economic Survey*, 3.

[7] Michael R. Herman, *The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation*, 111 COLUM. L. REV. 1788, 1795 n.41 (2011). *See also, e.g.*, H. Keeto Sabharwal, et al., *Managing an ANDA Litigation, in ANDA Litigation: Strategies And Tactics For Pharmaceutical Patent Litigators* 540 (2012).

Patent cases are also "among the longest, most time-consuming types of civil actions."[8] A 2015 PricewaterhouseCoopers report ("PwC Report") estimated that the average patent litigation takes about 2.4 years to get from filing to trial.[9]

Despite the arduous and costly nature of patent litigation, the process remains "inherently uncertain."[10] In part, this is a function of the dense, technical nature of patent litigation, which forces a generalist judge or lay jury to "venture out into a jungle of technology, conflicting expert testimony, technical evidence, and technical arguments."[11] In cases involving juries in particular—which decided 67% of non-ANDA patent infringement litigation from 2010 to 2015,[12] and which "almost always" try high-stakes patent cases[13]—the problem can be very serious. One court has suggested that "patent cases may well be the most difficult for [juries] to

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[8] *Ohio Willow Wood Co.*, 629 F.3d at 1376 (Moore, J., concurring) (noting that "[a]s of 2009, 384 patent cases had been pending in the district courts for three years or more") (citation omitted).

[9] PricewaterhouseCoopers, *2015 Patent Litigation Study* 14 (May, 2015), http://www.pwc.com/us/en/forensic-services/publications/patent-litigation-study.jhtml.

[10] *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 208 (E.D.N.Y. 2003).

[11] Morgan Chu & Joseph M. Lipner, *Adopting A Case Theme, in Patent Litigation Strategies Handbook* 41 (Barry L. Grossman & Gary M. Hoffman, eds. 2000).

[12] PwC Report 6.

[13] *Id.* 7.

understand both as to the evidence and the law."[14] Moreover, "[m]ock jury deliberations show that jurors often confuse one patent with another and will sometimes confuse which party is the plaintiff and which is the defendant."[15] Before the 10 federal judges deciding the greatest number of patent litigations between 1995 and 2014, overall success rates varied between 9 percent and 73 percent.[16] And more than half of appealed cases are modified in some way on appeal.[17]

Uncertainties are most costly when the stakes at issue are high, and the stakes in patent litigation are very high. While this case arises in the context of Paragraph IV litigation triggered by an ANDA certification (*see* Pet. 7) and therefore lacks a damages component, a great many patent cases involve enormous damages claims, and often enormous damages *awards*. The median damages award in patent litigation in 2014 was $2.0 million.[18] Three of the largest jury awards of all time in patent litigation date from the last few years: *Monsanto v. DuPont* ($1 billion), *Apple v. Samsung* ($1.05 billion), and *Carnegie Mellon University v. Marvell* ($1.17

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[14] *Cooper Indus., Inc. v. Juno Lighting, Inc.*, No. 85 C 7243, 1987 WL 15086, at *6 (N.D. Ill. Jan. 28, 1987), *aff'd* 826 F.2d 1073 (Fed. Cir. 1987).

[15] Chu & Lipner, *Adopting A Case Theme*, at 43.

[16] PwC Report 18.

[17] *Id.* 19.

[18] *Id.* 4.

billion).[19] 2014 saw a $467 million award in *Masimo Corp. v. Phillips Electronics*,[20] and a settlement between Medtronic and Edwards Lifesciences for around $1.15 billion.[21]

II. Patent Settlements

This Court has stated that "public policy wisely encourages settlements."[22] Settlement agreements allow parties "to avoid litigation costs, to reduce uncertainty, and to maintain ongoing commercial relationships. . . ."[23] This is particularly important in the patent context, in light of the burdens and costs described above. Thus, "the Federal Circuit has repeatedly expressed the view that there is a

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[19] *See Monsanto Co. v. E.I. DuPont de Nemours & Co.*, Case No. 4:09-CV-00686, 2012 WL 5397601, at *2 (E.D. Mo. Nov. 2, 2012); *Apple Inc. v. Samsung Elecs. Co.*, Case No. 11-CV-01846, 2012 WL 4078433 (N.D. Cal. Aug. 24, 2012), *judgment modified*, Jury Verdict, ECF No. 2822 (Nov. 21, 2013); *Carnegie Mellon Univ. v. Marvell Tech. Grp.*, Case No. 2:09-cv-00290, 2012 WL 7991311 (W.D. Pa. Dec. 26, 2012), *judgment modified*, 807 F.3d 1283 (Fed. Cir. 2015) (subsequent settlement reached, *see Marvell Carnegie Mellon Reach $750M Deal To End Patent War*, Law 360 (Feb. 17, 2016)). The damages figures given in the text are initial jury verdicts only, and do not reflect subsequent *vacatur*, modification, appeals, settlements, etc.

[20] Andrew Khouri, *Court upholds Masimo's victory in patent suit against Philips units*, L.A. TIMES (May 19, 2015), http://www.latimes.com/business/la-fi-masimo-award-20150520-story.html.

[21] PwC Report 5.

[22] *McDermott, Inc. v. AmClyde*, 511 U.S. 202, 215 (1994).

[23] *Id.*

strong public interest in settlement of patent litigation."[24]

For some entities—including non-profits, small businesses, universities, and others—settlement agreements can provide not just an attractive and efficient alternative to litigation, but the *only* realistic mechanism through which their rights can be asserted and accommodated. As Justice Powell once observed, litigation costs can bar the courtroom door: a party may simply be unable to litigate to the bitter end.[25] And when litigation costs are abnormally high—as in the patent context—settlement agreements may offer the only alternative to the all-or-nothing proposition of litigating to verdict.

Of course, these considerations are not unique to patent cases. The litigation process is both

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[24] *Foster v. Hallco Mfg. Co., Inc.*, 947 F.2d 469, 477 (Fed. Cir. 1991). *See also, e.g., Rates Tech. Inc. v. Speakeasy, Inc.*, 685 F.3d 163, 172 (2d Cir. 2012) (recognizing the "strong judicial policy favoring the settlement of litigation, including patent litigation"); *Fidelity & Guar. Ins. Co. v. Star Equip. Corp.*, 541 F.3d 1, 5 (1st Cir. 2008) ("Settlement agreements enjoy great favor with the courts as a preferred alternative to costly, time-consuming litigation.") (citation and internal quotation marks omitted).

[25] *Delta Air Lines, Inc. v. August*, 450 U.S. 346, 363 n.1 (1981) ("Unfortunately, the cost of litigation in this country—furthered by discovery procedures susceptible to gross abuse—has reached the point where many persons and entities simply cannot afford to litigate even the most meritorious claim or defense.") (Powell, J., concurring).

expensive and wasteful,[26] and as one appellate judge has observed, e-discovery excesses "have made the formal trial process less attractive than almost any alternative."[27] But the magnitude of the patent litigation burden makes the policy imperatives in favor of settlement particularly strong.

It is therefore unsurprising that parties settle patent cases *much* more often than they litigate to judgment. One author has calculated that, between 1991 and 2011, "parties settled about 95% of patent actions [filed in federal district court]. For every action litigated to conclusion, the parties settled 19 actions. And this is merely the tip of the iceberg. For every dispute that resulted in litigation, many others were resolved without filing a complaint."[28]

III. The Importance of Flexibility in Settlement

In general, settlements are possible when parties can find a solution that offers value to each party, compared to the alternatives of litigating to verdict or conceding. Crucially, the likelihood of settlement varies in proportion with the breadth of alternatives at the parties' disposal: the wider the choice among

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[26] *See generally* Lawyers for Civil Justice et al., *Statement on Litigation Cost Survey of Major Companies* (2010), http://www.uscourts.gov/file/document/litigation-cost-survey-major-companies.

[27] Patrick Higginbotham, *The Disappearing Trial and Why We Should Care*, RAND REVIEW 3 (Summer 2004).

[28] John W. Schlicher, *Settlement of Patent Litigation and Disputes: Improving Decisions and Agreements to Settle and License* 5 (ABA 2011).

structures and models for negotiation and agreement, the easier it is to create gains from trade or Pareto improvements that are rational for *all* parties.[29] Conversely, limiting the forms that a settlement can take makes settlement more difficult, and litigation harder to avoid.

In particular, negotiating parties find it harder to reach an agreement when only a single variable is at issue. In such a situation the parties are locked in a zero-sum game in which a marginal gain for one party (*e.g.*, one dollar more or less in a settlement payment) means a marginal loss for the other. One more apple for me is one fewer apple for you, even if we value apples differently. This creates an economic and psychological barrier to agreement.

By contrast, as more variables are added to the negotiation, the opportunity to reach an agreement improves. If we are negotiating over oranges as well as apples, and if we value them differently, we may be able to exchange an apple for an orange, leaving us *both* better off. Thus, the prospects for a successful negotiation can turn on whether the parties can find trades of this kind that exploit their divergent valuations of different variables. As Judge Posner put it:

> A negotiation is *more likely to be successful when there are several issues to be resolved ("integrative bargaining")*

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[29] *See generally, e.g.*, Robert S. Pindyck & Daniel L. Rubinfeld, *Microeconomics*, 590–91 (2009); Howard Raiffa, et al., *Negotiation Analysis: The Science and Art of Collaborative Decision Making* 402 (2002).

> *rather than just one*, because it is easier in the former case to strike a deal that will make both parties feel they are getting more from peace than from war.[30]

Thus, the extent to which parties will be able to settle complex disputes depends, in crucial part, on flexibility. The greater the freedom that parties are afforded to structure a settlement, the more likely it becomes that a settlement can be reached and litigation avoided. Conversely, whenever a settlement term or provision is converted into a trigger for antitrust litigation—and particularly for antitrust discovery under the rule of reason—settlement becomes harder to reach, and litigation becomes more likely. The result: patent holders, patent challengers, and consumers *all* lose.

IV. The Importance of Exclusive Licensing

One common feature of settlement agreements, cooperative relationships, and commercial arrangements of all kinds is the *exclusive license*, which is specifically contemplated by the Patent Act. 35 U.S.C. § 261 ("The . . . patentee . . . may . . . grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States."). Such licenses are ubiquitous across the economy: one 2011 study found that exclusive licenses represent 66% of all patent

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[30] *Duffy Tool & Stamping, L.L.C. v. N.L.R.B.*, 233 F.3d 995, 998 (7th Cir. 2000) (emphasis added) (citing Howard Raiffa, *The Art and Science of Negotiation*, 97–103, 131–32) (1982).

licenses issued by commercial licensors; 84 percent of all patent licenses in the life sciences sector; and 94 percent of all patent licenses issued by universities.[31]

Moreover, exclusive licenses frequently promote competition and enhance output. The economic effect of an exclusive license is to replace one competitor (the licensor) with another (the licensee). This, of course, is competitively neutral in the abstract. But exclusive licenses can often be *procompetitive*, particularly when the licensee has a greater ability or incentive to compete with the patent (or commercialize it) than the licensor. In fact, it is for this very reason that parties often find it efficient to create an exclusive license.

More generally, in many contexts exclusive licenses provide an attractive way to efficiently align the incentives of licensor and licensee—for example, by protecting against free-riding—and it is therefore unsurprising that they are routinely associated with collaboration and investment. The 2011 study mentioned above found that exclusive licenses are more than twice as likely as non-exclusive licenses to be accompanied by a grant of equity interest in the licensee.[32] Lower courts have recognized the economic benefits of exclusive licenses.[33]

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[31] Thomas R. Varner, *An Economic Perspective on Patent Licensing Structure and Provisions*, 46 BUS. ECON. 229, 237 (2011).

[32] *Id. See also, e.g.*, Thomas C. Meyers, *Field-of-Use Restrictions as Precompetitive Elements in Patent and Know-How Licensing Agreements in the United States and the European Communities*, 12 NW. J. INT'L L. & BUS. 364, 373-

(continued ...)

In sum, exclusive licenses are specifically contemplated by the Patent Act, they are commonplace, and they are often procompetitive. Far from being aberrant or suspicious, they are a central part of the toolkit used by businesses of all kinds across the economy to structure commercial cooperation and—just as here—to settle disputes.

ARGUMENT

I. The "No-AG Agreement" Is an Exclusive License.

The central factual allegation in this case is that Teva's challenge to GSK's patent was settled by granting Teva the exclusive right to market and sell generic lamotrigine drugs before the expiration of GSK's exclusive rights. Specifically, Teva was licensed to market and sell generic lamotrigine

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74 (1991) ("Exclusive dealing arrangements between licensors and licensees can . . . alleviate the risks of sunk costs to investors in patented technology."); Patrick W. Schmitz, *Exclusive Versus Non-Exclusive Licensing Strategies and Moral Hazard*, 97 ECON. LETTERS 208, 212 (2007) ("[W]hen . . . effort costs are small it is optimal to provide an exclusive license and implement high effort[.]").

[33] *See, e.g., Am. Needle, Inc. v. New Orleans La. Saints*, Case No. 04-cv-7806, 2014 WL 1364022, at *1 (N.D. Ill. Apr. 7, 2014) ("[D]efendants contend that the exclusive license arrangement encouraged additional licensee commitment and had numerous procompetitive effects, including improvements in product design, quality, distribution, and coordination of styles with other apparel items. These contentions are sufficiently supported by evidence and expert opinion to be facially plausible."). *See also, e.g., Ralph C. Wilson Indus., Inc. v. Am. Broad. Cos., Inc.*, 598 F. Supp. 694, 706 (N.D. Cal. 1984).

chewables roughly 43 months, and generic lamotrigine chewables roughly 6 months, before the termination of GSK's exclusive rights. Pet. 8–9. Under the terms of the agreement, GSK agreed not to introduce an "authorized generic" of its own during Teva's license period, but GSK would retain its right to market and sell the branded lamotrigine drug Lamictal. *Id.*

The Third Circuit labeled this arrangement a "no-AG agreement." *See, e.g.*, Pet. App. 7a, 17a. But this Court should appreciate that the "no-AG agreement" is just an exclusive license—a type of agreement that is ubiquitous, not just in the pharmaceutical industry but in every sector—and that the ruling here will have consequences for exclusive licenses across the economy.[34] Absent the licensing agreement, GSK would have been the exclusive supplier of the branded drug (Lamictal) and also the exclusive supplier of the generic lamotrigine drugs. Under the agreement, GSK remained the exclusive supplier of the branded drug, and Teva rather than GSK became the exclusive supplier of the generic lamotrigine drugs during its license term. Pet. 8–9. The result: one supplier was replaced with another. This is an exclusive licensing arrangement like countless others in every industrial sector.[35]

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[34] The Court of Appeals below indicated, without holding, that it disagreed with the characterization of the agreement as an exclusive license, but gave no reasons for this disagreement and expressly reserved the question. *See* Pet. App. 36a n.27.

[35] Indeed, the licensing agreement here was even *better* for competition than it may appear from the face of the Third Circuit's opinion, because GSK's branded drug and Teva's

(continued ...)

II. Alleging an Exclusive License in a Patent Settlement Does Not State a Plausible Antitrust Claim.

The Court of Appeals below held that respondents here stated a plausible antitrust claim, and in so doing relied centrally on the "no-AG agreement." Pet. App. 42a–47a. Specifically, the court relied heavily on allegations that: (1) the parties had settled by reaching a no-AG agreement, when otherwise GSK would have launched an authorized generic; (2) the no-AG agreement was valuable; and (3) the lamotrigine patent was likely to be invalidated. *See id.* 43a–45a.

As a threshold matter, antitrust plaintiffs will *routinely* allege that a patent challenger would have succeeded in invalidating a patent if litigation had continued. But the Patent Act expressly provides that patents and patent claims must be presumed valid, *even if one claim has been invalidated.* 35 U.S.C. § 282(a) ("A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity."). So it is far from clear that such boilerplate allegations in the face of a

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generic in fact competed vigorously on price in the marketplace. *See* Pet. 12 n.3.

presumption of validity add much, if anything, to the plausibility of an antitrust complaint.

That aside, the central question in this case is whether it is enough for an antitrust plaintiff to allege a "no-AG agreement"—that is, an exclusive license—in a patent settlement to survive a motion to dismiss. The Third Circuit indicated that this is enough, even if plaintiffs cannot allege that a more procompetitive settlement was even *possible* (let alone likely). Pet. App. 44a–45a.

The theory seems to be that there was a chance that Teva would have prevailed in the patent litigation, invalidating GSK's patent, and GSK was forbidden by the antitrust laws from eliminating that chance by settling the case. But there *cannot* be an antitrust duty to litigate every patent case to the bitter end just because patent litigation is uncertain and the challenger might prevail. Indeed, the Third Circuit's approach ignores the reality that virtually *every* settlement of a challenge to the validity of a patent involves the loss of some chance of greater competition, because patent litigation is virtually *always* uncertain (*see supra* pp. 6–8) and there is always some risk that the challenger will succeed in invalidating the patent. But turning these settlements into ready-made antitrust complaints waiting to be filed would push companies to litigate patent cases to verdict in virtually every case, harming businesses and consumers alike.

This Court should reject that outcome. Plaintiffs should not be permitted to avoid their obligation to allege a plausible antitrust claim by simply pointing to an exclusive license instead. Doing so would

needlessly turn a crucial and commonplace commercial tool, relied on by countless businesses in every sector, into an antitrust time-bomb.

A. Patent Settlements Should Be Analyzed Under *Twombly*'s Plausibility Standard, Not an "*Actavis* Exception."

The Third Circuit appeared to read *Actavis* as lowering the bar set by Rule 12(b)(6) for antitrust complaints. *See* Pet. App. 44a ("[W]e do not read *Actavis* to require allegations that defendants could in fact have reached another, more competitive settlement."). But this Court's decision in *Actavis* did nothing of the kind. *Twombly,* along with the decision in *Ashcroft v. Iqbal*, 556 U.S. 662 (2009), still governs a motion to dismiss in this context, and under that standard only a "plausible" claim for relief will survive dismissal under Rule 12. *Twombly*, 550 U.S. at 556–57. *Actavis* did not create a "short cut" or exception for challenges to patent settlements.

The robustness of *Twombly*'s standard is critical to courts and businesses alike: not least because antitrust discovery in rule of reason cases is acutely expensive. The Court explored these burdens in detail in *Twombly* itself, 550 U.S. at 557–60, and recently noted that the antitrust rule of reason produces "notoriously high litigation costs." *Kimble v. Marvel Entertainment, LCC,* 135 S. Ct. 2401, 2411 (2015) (citation omitted).

B. An Exclusive License Is Not Enough To State a "Plausible" Claim.

The question is therefore whether alleging a no-AG agreement is enough to satisfy the "plausibility" standard articulated in *Twombly* and *Iqbal*. But the answer to that question must be "no."

A bare allegation that a patent holder and patent challenger have concluded an exclusive license (whether or not this is labeled a "no-AG agreement") does not constitute a "plausible" allegation that the antitrust laws have been violated. Exclusive licenses are—as explained above—commonplace, and are routinely procompetitive or competitively neutral. *See supra* pp. 12–14. An antitrust claim built on the allegation that one company (the patent holder) has simply been replaced by another (the patent challenger) as a supplier of generics does not clear Rule 12(b)(6).

The Third Circuit also seems to have been influenced by the allegation that the license represented a transfer of *value* from GSK to Teva, because the right to market and sell generics was profitable to Teva and would have been profitable to GSK if it had retained it. *See* Pet. App. 43a. But that is also irrelevant. Because of the unique configuration of Paragraph IV litigation, the respective incentives of the parties will routinely favor a transfer of "value" from the patentee to the generic infringer. The patent holder in such a case faces much greater risk and has much more to lose. Given the expense, length, and uncertainty of patent litigation, as well as the reality that discovery and litigation costs in an invalidity challenge will often

bear more heavily on the patent holder than on the generic challenger, a patent holder facing even a weak claim of invalidity may rationally be willing to transfer a great deal of value to fend off the challenge and protect its expected period of exclusivity.[36]

Conversely, the patent challenger holds what amounts to a lottery ticket offering the prospect of a huge windfall, and is in a strong position to demand an aggressive sum in settlement. It likely has much less to lose from litigation. And because a Paragraph IV filing triggers infringement litigation *before* the patent challenger has entered with a generic drug, the patent holder virtually never has a damages claim as countervailing leverage.

The obvious result of these incentives is that *the patent holder will rationally transfer value to the patent challenger* to settle Paragraph IV litigation. Such a payment is not an aberration giving grounds for concern: it is a natural consequence of the system that Congress has established.

In summary, the Third Circuit's analysis conjures a "plausible" antitrust claim from an allegation which could (and if left uncorrected, *will*) just as easily be made about countless benign agreements throughout the economy, and which contains no

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[36] For example, if a generic infringer has even a 15% or 20% chance of prevailing on an invalidity claim against a billion-dollar patent—quite possible in view of the uncertainty of patent litigation, *see* above pp. 6-8—a patentee might very rationally choose to pay *hundreds of millions* of dollars to settle without ever doubting the validity of its patent.

indication that any more competitive agreement was likely or even possible. This must be corrected. The fact that patent litigation is uncertain cannot create an antitrust obligation to refrain from settling it; and the fact that an exclusive license is valuable does not make it harmful to competition.

III. The Third Circuit's Holding Would Promote Uncertainty and Deter Settlement.

For manufacturers across America—including patent holders, patent licensees, and purchasers and users of patented articles and processes—the Third Circuit's holding promotes uncertainty and creates a dilemmatic choice between lengthy, expensive patent litigation and lengthy, expensive antitrust litigation.

The Petition correctly notes that lower courts have encountered a great deal of confusion in the interpretation of *Actavis*. *See* Pet. 15–20. The opacity of terms like "payment," "large," "unjustified," and so on have left businesses of all kinds—and parties on both sides of patent disputes—uncertain of the boundaries of antitrust safe conduct when settling patent litigation. *Actavis* must be clarified if lower courts are to understand the analytical framework that it ordains.[37] And some

[37] Indeed, by contrast with the Third Circuit's condemnation of a "no-AG agreement," the First Circuit recently made a point of *declining* to opine on the adequacy under *Twombly* of a "no-AG agreement" in the abstract, instead appropriately "proceed[ing] one step at a time" by remanding to the district court below for specific analysis of that issue. *In re Loestrin 24 FE Antitrust Litig.*, Case Nos. 14-2071, 15-1250, 2016 WL 698077, at *12 (1st Cir. Feb. 22, 2016).

form of "safe zone" must be articulated for companies struggling to understand how they can conform their conduct to the law.

The current confusion is profoundly undesirable for companies and consumers alike. The burdens, expenses, and uncertainty of patent litigation are proverbial. *See supra* pp. 4–8. The importance of reasonable freedom and flexibility when negotiating and structuring settlements cannot be overstated: every time businesses are denied the use of a particular settlement tool by the threat of antitrust litigation (and antitrust discovery in particular), more patent cases are pushed into litigation. *See supra* pp. 10–12. When businesses are forced to litigate every patent controversy to verdict, no one wins, but the American economy—and ultimately the American consumer—loses.

The Third Circuit's decision here will deter rational, efficient settlements. For the reasons explained above (*supra* pp. 19–20), a patent holder has every incentive to pay a patent challenger to resolve Paragraph IV litigation, even when confident of the validity of its patent, and a patent challenger has every incentive to demand payment, even when its challenge is highly speculative. There is *nothing* surprising or suspicious about a "reverse" transfer of value in the context of Paragraph IV patent litigation, regardless of the form that value takes.

Moreover, the use of an exclusive license is particularly benign. It allows the parties to resolve litigation in a way that offers value to both parties

and is routinely positive or neutral for competition.[38] Settlement is desirable for patent holders, patent challengers, the courts, and society as a whole: particularly compared to interminable patent litigation costing millions of dollars. *See supra* pp. 4–14. But the holding below turns a routine settlement agreement into a sure-thing ticket into antitrust litigation and antitrust discovery: the very same burdensome prospect that this Court lamented at length in *Twombly*, 550 U.S. at 557–60, and shaped the Rule 12 standard to avoid.

This development is doubly unwelcome because of its national breadth and cross-industry implications. As the Petition correctly points out, the Sherman Act's venue provision throws open the doors of the Third Circuit to antitrust plaintiffs across the country, with the result that parties to patent litigation will settle their cases "only at their own peril, if at all." Pet. 32. Moreover, the Court of Appeals' holding lays out a path for antitrust plaintiffs—beyond the framework of Paragraph IV, beyond the pharmaceutical industry, and even outside the patent context altogether—to transmute bare allegations of an exclusive license into a "plausible" antitrust complaint in case after case.

So the holding below should not stand. The Court should grant the petition for a writ of certiorari: to ensure the proper application of Rule 12(b)(6); to resolve the growing confusion surrounding *Actavis*; and to ensure that the exclusive license—a common,

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[38] Such a license may even promote competition, as it did in this case. *See supra* note 35.

frequently procompetitive tool of commercial activity for businesses in all industries—is not needlessly denied to parties attempting to avoid the burdens and costs of patent litigation.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari to the United States Court of Appeals for the Third Circuit should be granted.

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