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., 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 ALLERGAN PLC AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

Whether the Third Circuit's sweeping holding that a patentee's grant of an exclusive license must undergo antitrust scrutiny by courts and juries—even though such a license is specifically permitted under the patent laws—is inconsistent with this Court's decision in *Actavis* and decades of this Court's earlier precedents.

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IDENTITY AND INTEREST OF AMICUS CURIAE

Allergan plc ("Allergan") is a pharmaceutical company offering both branded and generic products. Allergan is the successor in interest to Actavis, Inc. Allergan must frequently settle patent litigation brought under the Hatch-Waxman Act, and has a substantial interest in maintaining the ability to settle such litigation in mutually-beneficial, procompetitive ways, which it cannot do if traditional forms of settlement such as exclusive licenses are routinely subject to billion-dollar antitrust litigation.

SUMMARY OF ARGUMENT[1]

Allergan agrees that *certiorari* is necessary for all the reasons discussed in the Petition, including that exclusive licenses are authorized by the Patent Act and not suspect under *United States v. General Electric Co.* ("*GE*"), 272 U.S. 476 (1926). As Petitioners make clear, applying *Actavis* scrutiny to exclusive licenses would create significant conflicts between the antitrust and patent laws, which this Court did not intend to create.

Allergan writes separately to reiterate the importance of settlement, and to address how this Court's ruling in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), avoids applying antitrust scrutiny to exclusive licenses and other "traditional" forms of

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[1] Pursuant to Supreme Court Rule 37.6, Allergan states that it and its counsel are the sole monetary contributors to and authors of this *amicus curiae* brief. Counsel for Allergan informed counsel of record for all parties of their intention to file an *amicus curiae* brief at least 10 days prior to the due date for the *amicus curiae* brief, and consent was granted.

settlement this Court did not intend to discourage. In addition to the reasons discussed in the Petition, *certiorari* is appropriate because (a) the availability and legality of traditional settlement forms is an important federal question affecting numerous ongoing cases and billions of dollars in alleged liability, and (b) the Third Circuit's holding below conflicts with this Court's decision in *Actavis* in at least three ways:

First, exclusive licenses are not suspect under *Actavis*'s rationale. Courts must consider the five-part rationale set forth in *Actavis* before extending its holding to what this Court termed "traditional" forms of agreement—such as exclusive licenses. This Court's rationale in *Actavis* does not apply to all forms of agreement—for example, the *Actavis* rationale does not apply to compromised damages claims or entry-date-only settlements, neither of which are reverse payments under *Actavis*. Nor would it apply to exclusive licenses, as such licenses are normal, ubiquitous, and authorized by the Patent Act and thus (1) do not suggest anticompetitive harm and (2) require no justification. Nor would an exclusive license (3) allow an inference of market power or (4) suggest the patent weakness necessary to this Court's analysis in *Actavis*, as exclusively licensing a patent hardly suggests that the licensor has market power or that the patent is thereby weak. Finally, given their ubiquity and the challenges associated with judicially second-guessing such agreements, exclusive licenses cannot (5) be subjected to antitrust scrutiny without harming the settlement process. The Third Circuit thus erred in extending *Actavis* scrutiny to exclusive licenses.

Second, even if an exclusive license could in some cases be treated as a reverse payment (as shown above, it cannot), courts in all events must nonetheless require plausible allegations that the license at issue involved a potentially-unlawful payment rather than "fair value" or mutual benefit. Settling parties in complex disputes often seek to "expand the pie" to create fair value for both parties, and thus overcome gaps between their respective views of the litigation merits. Such mutually-beneficial arrangements are often procompetitive and not normally understood as suspect, and this Court's holding in *Actavis* should not be read to change that understanding. Rather, *Actavis* addressed only the situation in which a patentee initially sacrifices something of value from its perspective in order to pay the generic, and then allegedly recoups its sacrifice from delay in generic entry. At the pleadings stage, courts must distinguish between such initial sacrifices and mutually-beneficial compromises, so as to avoid deterring normal, fair value settlement agreements this Court did not seek to discourage. The Third Circuit erred by failing to require plausible allegations of patentee sacrifice.

Finally, even if exclusive licenses could sometimes be payments under *Actavis* (they cannot), and then even if a given exclusive license is plausibly alleged to represent such a payment, courts still cannot simply assume that all—or even most—exclusive licenses are therefore "large" payments. Rather, an FTC study found that the average patentee benefit from launching an authorized generic rather than granting an exclusive license is

"not statistically significant." A plaintiff thus must plausibly allege that the decision to grant a particular exclusive license contained a large payment—that is, a sacrifice by the patentee of something of sufficient value to the patentee as to allow a meaningful inference that the patentee is purchasing delay in generic entry. By instead simply assuming that all exclusive licenses are large payments, the Third Circuit further erred.

Certiorari should therefore be granted.

FACTUAL BACKGROUND

The Third Circuit assumed that introducing an authorized generic ("AG") would have been more profitable for the brand pharmaceutical defendant than granting an exclusive license. App. 33a ("launching an [AG] would seem to be economically rational for the brand"). An FTC study refutes this assumption, however, finding that because AGs "cannibalize" substantial branded product sales, they are far from universally profitable for brand firms. *See* Authorized Generic Drugs: Short-term Effects and Long-Term Impact ("FTC Study") at 73.[2]

Because of this cannibalization effect, in 2005 members of Congress asked the FTC to study whether *launching* AGs represents an anticompetitive profit sacrifice by brands. *See id.* at iv (AGs might involve "sacrifice" of brand revenues to "discourage future patent challenges"); *id.* at A-1

[2] Available at https://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission.

("'authorized' generic drugs may produce anti-competitive results"). The resulting 2011 FTC Study noted industry skepticism regarding the profitability of AGs, quoting brand companies as believing that "[f]inancially speaking, [AGs are] not a particularly attractive proposition," *id.* at 71, and generic companies as arguing that "no brand name company launches an authorized generic during the 180-day exclusivity for the comparatively negligible profits associated with such licensing." *Id.* at 65. The FTC further quoted the Generic Pharmaceutical Association as arguing that "[t]here are … no legitimate business reasons for [AGs] launched during the generic exclusivity period." *Id.* at 65.

The FTC did not find that AGs represent a uniform profit sacrifice by brand companies, as some had argued. Nor did it find that AGs were uniformly profitable, as the Third Circuit assumes. Rather, the FTC found that whether to launch or not launch an AG was a product-by-product, market-by-market, and firm-by-firm strategic decision. Although an AG may provide the brand firm with additional revenue from low-margin generic sales, it does so at the expense of high-margin branded sales "cannibaliz[ed]" by the additional generic competition. *See id.* at 60 (noting that "introducing an AG into a market with only an ANDA-generic competitor decreases the revenues of the brand-name product by about 27%, compared to what it would have earned if no AG had been marketed" and that the impact can be as high as 49%); *id.* at 59 ("A potential cost of AG introduction is the cannibalization of brand-name product sales by the AG"); *id.* at 68 ("The brand-name firms' keen interest

in the revenues arising from AGs and their intense concern with any impact of the AG on branded sales are reflected in their extensive forecasting and sales analysis documents.").

The FTC ultimately concluded that while companies that chose to launch an AG "tended to make greater revenues" by doing so, "this result was not statistically significant." *Id.* at 118; *see also id.* at 62 ("[a]lthough not all of our specifications allow us to conclude that brand-name firms earn more revenues in markets with an AG than in markets without an AG, none of the estimates provides evidence that brand-name firms lose revenues as a result of introducing an AG"); *id.* at 62 n.53 (neither of the FTC's models "can reject the hypothesis that introducing an AG has no effect on brand-name firm revenues").[3]

ARGUMENT

I. EXCLUSIVE LICENSES DO NOT FIT THE RATIONALE OF *ACTAVIS*

The Third Circuit erred by failing to ask whether exclusive licenses—a traditional form of settlement—are consistent with this Court's rationale for applying antitrust scrutiny in *Actavis.* In fact, exclusive licenses do not fit that rationale

[3] Though not at issue in this case, where the generic is willing to pay the brand royalties for exclusivity, the profitability of an exclusive license can increase even further. *See, e.g.*, *In re Effexor XR Antitrust Litig.*, No. 11-5479 (PGS)(LHG), 2014 WL 4988410 (D.N.J. Oct. 6, 2014) (dismissing exclusive license claim in light of royalties).

and thus should not be subject to the scrutiny *Actavis* prescribes.

Prior to *Actavis*, courts worried that exposing "payments" to antitrust scrutiny could condemn all settlements involving the exchange of *any* value, on the theory that there is no meaningful difference between agreeing to a fair value side deal or compromise of damages, on the one hand, and paying for delay, on the other. The 2003 district court decision in *In re Ciprofloxacin Hydrochloride Antitrust Litigation* explained this problem, which led it to adopt the scope-of-the-patent test:

> [E]ven in the traditional context, implicit consideration flows from the patent holder to the alleged infringer. For instance, suppose a case is ready for trial and the patent holder can prove damages (infringing sales) of $100 million. The parties settle before trial with the alleged infringer paying the patent holder $40 million and agreeing to cease sales of its product. In addition to the $40 million payment to the patent holder, there is an implicit $60 million payment to the alleged infringer to cease its sales.... Under plaintiffs' analysis, a settlement such as this, where the patent holder forgoes collecting all damages due, would be a *per se* violation. Such a rule would discourage any rational party from settling a patent case because it would be an invitation to antitrust litigation.

261 F. Supp. 2d 188, 252 (E.D.N.Y. 2003); *see also* Marc G. Schildkraut, *Patent-Splitting Settlements and the Reverse Payment Fallacy*, 71 Antitrust L.J. 1033, 1046-48 (2004) (explaining *Cipro* court's concern and noting danger that courts could begin to find "an implicit 'reverse payment' running from the patent holder to the infringer" in "virtually all traditional patent settlements," whether under Hatch-Waxman or otherwise).

This Court answered that concern in *Actavis*, offering the same example as the *Cipro* district court but holding that it was possible to distinguish between (a) "traditional" and "commonplace" compromises that provide value to the generic but are nonetheless lawful, such as a compromised damages claim or early-entry license, and (b) "unusual" "payments" that are subject to antitrust scrutiny. *Actavis*, 133 S. Ct. at 2233-34. To explain this distinction, the Court provided a five-part rationale that can sometimes, but not always, be extended to other settlement forms. *See id.* at 2234-37. Exclusive licenses are a poor fit for this rationale, and thus for *Actavis* antitrust scrutiny.

a. Exclusive Licenses Do Not Suggest a Potential for Harm to Competition

In *Actavis* the Court held that "unusual," "large," "unexplained" payments of money to the generic could sometimes suggest that the settling parties are seeking to delay competition. *Id.* at 2234-35. Exclusive licenses, by contrast, are routine—even authorized by Congress's enactment of the Patent Act—and hardly suggest either a sacrifice by the patentee or the expectation of generic delay in

return. *See* 35 U.S.C. § 261. Indeed, exclusive licenses are granted in virtually every industry. *Compare Actavis*, 133 S. Ct. at 2235 (reverse payments, by contrast, may appear primarily in Hatch-Waxman context). Nor do exclusive licenses suggest a profit sacrifice—they do not, as the Court put it in *Actavis*, suggest that the parties maintained "supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market." *Id.* at 2236.

Accordingly, when asked about exclusive licenses at oral argument in *Actavis*, counsel for the United States answered that (1) "an exclusive license is expressly authorized by the Patent Act," and (2) "an exclusive license doesn't give the … infringement defendant anything that it couldn't hope to achieve by prevailing in the lawsuit." Transcript of Oral Argument at 4, *FTC v. Actavis,* 133 S. Ct. 2223 (2013) (No. 12-416) (Malcolm L. Stewart, Deputy Solicitor General). Exclusive licenses therefore do not fit the first part of *Actavis*'s rationale.

b. Exclusive Licenses Do Not Require Any Justification

Nor do exclusive licenses fit the second part of *Actavis*'s rationale, which assumes that a large payment suggesting anticompetitive effect already has been established. *See Actavis*, 133 S. Ct. at 2235-36. Like other traditional, commonplace settlement terms, there is no need to "justify" the entry into an exclusive license between one licensor and one licensee.

Exclusive licenses are specifically authorized by the Patent Act and fall within this Court's ruling in *GE*, in which this Court held (and reiterated in *Actavis*) that a license between a single licensor and a single licensee was not subject to antitrust second-guessing, even though the licenses included resale price-fixing provisions, at the time a *per se* antitrust offense. *See id.* at 2232 (citing *GE*, 272 U.S. at 489). Although the government argued that the Patent Act could not authorize a license linked with resale price-fixing, the Court found that the Patent Act controlled. *GE*, 272 U.S. at 489; *see also Kimble v. Marvel Entm't, LLC*, 135 S. Ct. 2401, 2413 (2015) ("[T]he patent term—unlike the 'restraint of trade' standard—provides an all-encompassing bright-line rule, rather than calling for practice-specific analysis."). Like the government in *GE*, the Third Circuit here held that the Patent Act did not authorize a patent license coupled with a future date for generic entry (which it assumed represented "delay," although the entry date was before expiration of the relevant patent). App. 37a-38a. But even accepting that there is something anticompetitive about a future entry date, an agreed pre-expiry entry date is certainly no more "anticompetitive" than the vertical price-fixing at issue in *GE*, and such licenses require no justification.

c. Exclusive Licenses Do Not Allow an Inference of Market Power

This Court's third consideration again assumes that one has established the existence of a "large" reverse payment, and notes that a large

payment was "a strong indicator of [market] power," as "a firm without" the "power to charge prices higher than the competitive level" is not "likely to pay 'large sums' to induce others to stay out of its market." *Actavis*, 133 S. Ct. at 2236. By contrast, a patentee's decision to grant an exclusive license provides no information about its market position—and thus cannot be the basis of an inference of market power. *Cf. Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006) (mere possession of patent not enough, without more, to suggest market power). The smallest and least successful player in a segment as to which, say, eight different branded products treat the same or similar ailment may decide that introducing an authorized generic is not worthwhile—if there are now to be nine competing products, why introduce a tenth?—and it may thus decide that an exclusive license offers greater returns. To infer market power from this decision would be incongruous, and exclusive licenses thus also fail to satisfy the third rationale of *Actavis*.

d. Exclusive Licenses Do Not Allow an Inference of Patent Weakness

Nor do exclusive licenses satisfy the fourth rationale. In *Actavis* this Court reasoned that a "large" payment by the branded firm may suggest that the brand did not have confidence in its patent and thus used a payment to prop up an otherwise-vulnerable patent—that an "unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival." *Actavis*, 133 S. Ct. at 2236. Where this proxy for patent weakness is unavailable, *Actavis*

refrains from applying antitrust scrutiny. *See id.* at 2233, 2236.

Exclusive licenses do not allow this inference of patent weakness. Such licenses are granted in countless industries and circumstances, and hardly because the licensed patent or other intellectual property is weak. For example, a fast food franchisor may grant an exclusive license to its intellectual property in a given territory not because it believes that the intellectual property is weak, but rather because it believes that exclusive licensees in each territory will maximize its profits. *Cf. Cont'l T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 58-59 (1977) (antitrust law "based upon demonstrable economic effect rather than … upon formalistic line drawing"). Courts therefore cannot simply assume that the grant of an exclusive license suggests a weak patent.

e. Subjecting Exclusive Licenses to Antitrust Scrutiny Threatens the Ability to Settle

Finally, *Actavis* held that subjecting cash reverse payments to antitrust scrutiny would "not prevent litigating parties from settling their lawsuit." *Actavis*, 133 S. Ct. at 2236-37. Applying antitrust scrutiny to exclusive licenses, however, would substantially deter such settlements and thus fails the fifth *Actavis* rationale. Whether to grant an exclusive or non-exclusive license is a business decision—as the court in *Actos* noted, no patentee "manufacturer is obligated as a matter of law to license an authorized generic." *See In re Actos End Payor Antitrust Litig.*, No. 13-cv-9244, 2015 WL 5610752, at *18 (S.D.N.Y. Sept. 22, 2015). As the

FTC Study shows, this decision is made on a product-by-product basis. *See supra* at 5. But under a rule subjecting exclusive licenses to antitrust scrutiny, a patentee would be required to choose not its own preferred business option, but rather the option it thinks a court or jury will later prefer. Moreover, it would be difficult not to apply hindsight if the firm's business decision turned out to be a poor one—as many do. *See* Gregory J. Werden (Senior Economic Counsel for the DOJ's Antitrust Division), *The "No Economic Sense" Test for Exclusionary Conduct*, 31 J. Corp. L. 293, 304 (2006) ("Many business decisions ultimately prove unprofitable because of misfortune or ineptitude, and the antitrust laws do not add insult to injury by deeming as exclusionary all unprofitable conduct."); *United Artists Theatre Co. v. Walton*, 315 F.3d 217, 231 (3d Cir. 2003) ("The art of governing [a company] (it is emphatically not a science) is replete with judgment calls and 'bet the company' decisions that in retrospect may seem visionary or deranged, depending on the outcome."). No party would settle with an exclusive license under such a test.

Exclusive licenses therefore do not fit the *Actavis* rationale, and the Third Circuit erred in applying antitrust scrutiny to such licenses.

II. THE THIRD CIRCUIT FAILED TO REQUIRE A PLAUSIBLE ALLEGATION OF A SUSPECT PAYMENT, RATHER THAN A FAIR VALUE COMPROMISE

Even if exclusive licenses could in some cases be treated as suspect payments under this Court's holding in *Actavis* (and they cannot), courts must

nonetheless require plausible allegations that a given exclusive license constitutes such a payment, rather than a fair value compromise.

Actavis recognizes a "general legal policy favoring the settlement of disputes." 133 S. Ct. at 2234; *see also Wygant v. Jackson Bd. of Educ.*, 476 U.S. 267, 305 (1986) ("general policy in favor of settlements"). But even solidly procompetitive, fair value settlements will not occur if they are likely to result in burdensome antitrust litigation. *Actavis*, 133 S. Ct. at 2243 ("Simply put, there would be no incentive to settle if, immediately after settling, the parties would have to litigate the same issue.") (Roberts, C.J., dissenting).

To protect such settlements, this Court in *Actavis* recognized a stark distinction, even at the pleadings stage, between (1) "large and unjustified" "payments," i.e., patentee sacrifices that transfer value to the generic, and (2) fair value compromises. *Id.* at 2236-37. The Third Circuit failed to draw this distinction, instead simply assuming that launching an AG instead of granting an exclusive license would have been in the patentee's "economic interest" and was therefore a "payment." *See* App. 43a.

a. A Payment Requires a Patentee Sacrifice, Rather than Mutual Benefit

In a reverse payment, as described in *Actavis*, a patentee (1) initially "pays" the generic, allegedly "sharing" a portion of its anticipated monopoly profits, and then (2) allegedly recoups its sacrifice through eventual delay in generic entry. 133 S. Ct. at 2233, 2235-36. An initial patentee sacrifice is

thus required to raise any specter of anticompetitive conduct. Indeed, two of the five considerations that supported *Actavis*'s holding—the assumption that a patentee would not make a large and unjustified payment unless it (1) had enough market power to recoup its investment through delayed generic entry, and unless it (2) viewed the patent as weak—depend on the assumption that the patentee is initially "out-of-pocket" in some way. *See id.*; *see also Effexor*, 2014 WL 4988410, at *23 ("must be a payment that appears to be large from the perspective of the brand company making the payment"); Aaron Edlin, Scott Hemphill, Herbert Hovenkamp, & Carl Shapiro, *Activating Actavis*, 28 Antitrust 16, 18 (2013) ("consideration should be valued from the perspective of the patentee"). Where the patentee instead suffers no loss, there can be no such payment—as this Court's holding regarding saved litigation costs demonstrates. *See Actavis*, 133 S. Ct. at 2236 (no reverse payment where patentee pays generic what it would otherwise have paid to continue litigating and thus suffers no loss).

Nor would any contrary approach make sense. Nothing in *Actavis* suggests that a settling party must choose a less-profitable settlement option simply to prevent the other side from profiting. *See, e.g.*, Kent Bernard, *Hatch-Waxman Patent Case Settlements—The Supreme Court Churns the Swamp*, 15 Minn. J. L. Sci. & Tech. 123, 132 (2014) ("[I]f you condemn a legitimate side deal simply because it can generate legitimate business profits for the generic, there is no stopping point, and all settlements that are anything other than partial surrender by the patentee are illegal."). Given the

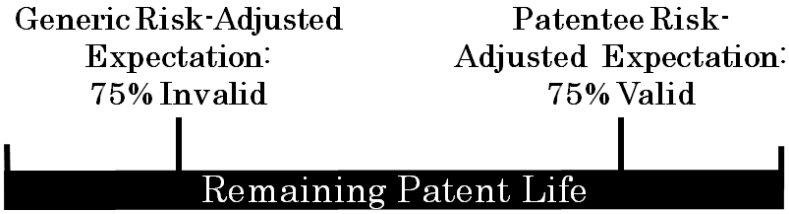
dynamics of the research and sale of pharmaceuticals, patentees and generics are frequently dealing with one another on multiple litigations and multiple issues. A rule that prohibits the parties from creating synergies or mutual benefits would be one that bars settlement entirely. *Id.* ("The alternative would be to hold that once patent litigation is filed, the two parties cannot do ordinary business together, which would be ludicrous."). Instead, patentees remain free to enter ordinary settlements that make both parties better off, without those settlements being treated as potentially-unlawful reverse payments—it is only when the patentee sacrifices and thus pays the generic that suspicion is appropriate under this Court's ruling. *See Actavis*, 133 S. Ct. at 2231 (focusing on "unusual" agreements).

b. Focusing on Patentee Sacrifice Avoids Deterring Fair Value Compromises

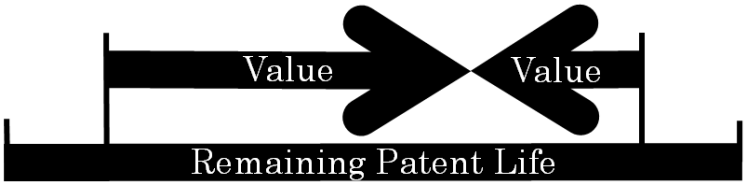
Further underlying the need to distinguish between fair value compromises and potentially-unlawful "payments" is an insight about bargaining, particularly in complex disputes. Agreement is accomplished either through (1) distributive bargaining, in which parties negotiate to distribute a fixed "pie," or (2) integrative bargaining that integrates the parties' interests to create value and facilitate agreement—i.e., agreement that "expands the pie." *See, e.g.*, Michael Watkins & Susan Rosegrant, Breakthrough International Negotiation 29-31 (2001) (defining distributive versus integrative bargaining). These two options are not created equal, as leading negotiation scholars have long

made clear. *See, e.g.*, Roger Fisher, William Ury, Bruce Patton, Getting to Yes 59-61 (3d ed. Penguin Books 2011) (rejecting "assumption of a fixed pie: the less for you, the more for me," as negotiators should "Invent Options for Mutual Gain"); John Burwell Garvey & Charles B. Craver, Skills & Values: Alternative Dispute Resolution 35 (2013) (avoid "zero sum game" by "expand[ing] the overall pie and enhanc[ing] the benefits to both sides"). Because litigation adversaries often have deeply-held, differing views on the respective strength of their patent cases, there is often a "gap" between their respective litigation expectations that, without more, may make settlement on a purely distributive, "fixed pie" basis impossible. *See Actavis*, 133 S. Ct. at 2233-34 (reiterating importance of compromise); Fisher, *supra*, at 155-56 ("In most negotiations there will be no one 'right' or 'fairest' answer; people will advance different standards by which to judge what is fair.... Differences in values, culture, experience, and perceptions may well lead parties to disagree about the relative merits of different standards.").

Even when each side adjusts its position to reflect the risk of loss, this gap may make agreement impossible—one negotiator noted that if each side was asked its likelihood of success in litigation, the sum of the two sides' risk-adjusted expectations would often exceed 150 percent. Dwight Golann, Mediating Legal Disputes 243 (1996).



The textbook way to bridge such gaps is through integrative bargaining—creating and exchanging value outside of the parties' dispute in order to make settlement more attractive than the alternative of litigation.



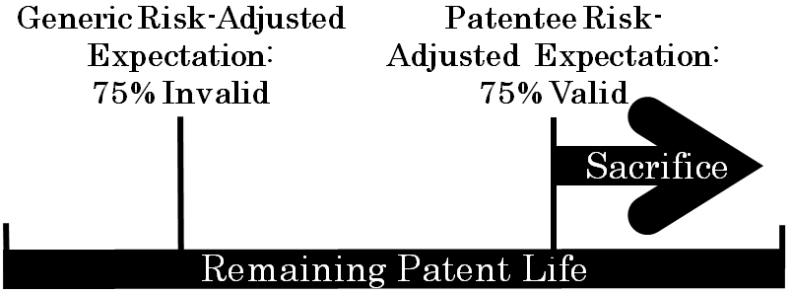
See, e.g., G. Richard Shell, Bargaining for Advantage: Negotiation Strategies for Reasonable People 12 (2d ed. 2006) (integrative bargaining the "ideal" way to reach agreement in complex situations); Fisher, *supra*, at 81 ("In a complex situation, creative inventing is an absolute necessity. In any negotiation it may open doors and produce a range of potential agreements satisfactory to each side."); *id.* at 58 ("One lawyer we know attributes his success directly to the ability to invent solutions advantageous to both his client and the other side. He expands the pie before dividing it."); Golann, *supra* at 243 ("[M]ediators can assist the parties and advance settlements by *creating value*, that is, arranging for one or more of the disputants to receive benefits that are different from, and more valuable than, the remedies a court would award.");

Alex J. Hurder, *The Lawyer's Dilemma: To Be or Not to Be a Problem-Solving Negotiator*, 14 Clinical L. Rev. 253, 255 (2007) ("Negotiation theory assumes that the possibility of creating value greater than the sum of the parts is the motivation for the parties to negotiate an agreement."); *id.* at 266 (problem solving approach of negotiation "bases the search for solutions on the needs, interests, and values of the client and other parties to the negotiation, and thus the scope of the negotiation might expand beyond the initial scope of the case").

This Court in *Actavis* did not prohibit these textbook "win-win," fair value exchanges. 133 S. Ct. at 2237. In fact, this Court made clear that it did not intend to subject traditional settlements to antitrust scrutiny. *Id.* at 2233. Nor should it, as most such "win-win" agreements "bridge the gap," and thereby allow generic entry as early as or earlier than the patentee's risk-adjusted litigation expectations. *See supra* at 18. Such entry is inherently procompetitive. *See Actavis*, 133 S. Ct. 2236 (assessing competitive effect relative to patentee's risk-adjusted litigation expectations); Transcript of Oral Argument at 20, *FTC v. Actavis,* 133 S. Ct. 2223 (2013) (No. 12-416) (Malcolm L. Stewart, Deputy Solicitor General) (arguing for liability for agreements that might lead to generic entry dates "later than the one the brand name would otherwise find acceptable"). And barring such settlements would risk harming competition, as many Hatch-Waxman settlements have been followed by patentee victories with respect to the very same patent, such that the settling generic entered years before a valid patent expired. *See, e.g.*, *Pozen, Inc. v. Par Pharm.,*

Inc., 696 F.3d 1151 (Fed. Cir. 2012); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006).

There is one form of integrative bargaining, however, that suggests the possibility that the parties created value only by delaying generic entry, and it was only this form that the Court held in *Actavis* might sometimes raise antitrust suspicion. In a potentially-unlawful reverse payment, the patentee initially sacrifices and thus transfers value to the generic. *Actavis*, 133 S.Ct. at 2233. This Court held that such a sacrifice might in some cases, where large and unexplained, suggest the possibility that the patentee expected to recoup its sacrifice through delay in generic entry relative to the patentee's risk-adjusted litigation expectations.



See id. at 2236 (paying to avoid risk of patent invalidation the relevant antitrust harm); Schildkraut, *supra* at 1064-66 (illustrating settlement in similar terms). The Court thus held that such a sacrifice *might* ultimately prove anticompetitive. *See Actavis*, 133 S. Ct. at 2227 (question presented whether "reverse payments" can "sometimes" raise antitrust concerns). Of course,

that there appears to be such a sacrifice is hardly the end of the inquiry but only the beginning—the agreement may not include a sacrifice at all, the sacrifice may be unrelated to any delay in generic entry, it may not be "large" (as discussed below), the agreement may be procompetitive, there may not be causation, etc.—and the plaintiff asserting such a claim would be required to "prove its case as in other rule-of-reason cases." *Actavis*, 133 S. Ct. at 2237.

c. Courts Must Require Plausible Allegations of a Patentee Sacrifice, as a Settlement that Guarantees Further Litigation Is No Settlement at All

The possibility that one form of integrative bargaining might in some cases create value only from delay does not mean that *all* forms of integrative bargaining are suspect—in subjecting certain reverse payments to antitrust scrutiny this Court did not throw the procompetitive baby out with the antitrust bathwater by also condemning fair value compromises. Instead, courts must distinguish upfront between potentially-unlawful reverse payment settlements involving a patentee sacrifice, which can be an appropriate subject for antitrust inquiry, and fair value compromises, which cannot. This requires alleging more than the mere *possibility* that the patentee sacrificed value. *See, e.g.*, *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (demanding "more than a sheer possibility that a defendant has acted unlawfully").

Nor is the failure to apply such pleading standards harmless, as exposing procompetitive settlements to antitrust litigation effectively outlaws

such settlements—and in many cases would thus bar all settlement. Although, as Professor Hovenkamp has noted, "[s]aying that a practice is subject to the antitrust laws … is not to conclude that it violates them," Herbert Hovenkamp, *Antitrust and the Patent System: A Reexamination*, 76 Ohio St. L.J. 467, 516 (2015), as a practical matter parties will not enter even procompetitive agreements that carry with them the risk of antitrust litigation. *See Actavis*, 133 S. Ct. at 2243 ("Simply put, there would be no incentive to settle if, immediately after settling, the parties would have to litigate the same issue.") (Roberts, C.J., dissenting).

The danger of failing to meaningfully distinguish between fair value compromises and payments can be seen in the courts that have allowed otherwise-unremarkable settlements to be transformed into multi-billion dollar antitrust cases. *See, e.g.*, *United Food & Commer. Workers Local 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052 (N.D. Cal. 2014) (though licensee paid substantial royalties, court treated exclusive license as payment by *licensor*); *In re Opana ER Antitrust Litig.*, No. 14-C-10150, 2016 WL 521005 (N.D. Ill. Feb. 10, 2016) (mere possibility that generic benefited sufficient to state claim); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 243 (D. Conn. 2015) (dismissal denied although payment potentially "illusory"); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 752 (E.D. Pa. 2014) (relying on generic benefit for reverse payment); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-md-2503-DJC, 2015 WL 5458570 (D. Mass. Sept. 16, 2015) (allowing claim to

proceed based on "payment" equivalent to 0.04% of patentee's annual profits); *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 419 (E.D. Pa. 2015) ("While evidence that these payments exceed fair value for goods and services would certainly be helpful for Plaintiffs in rebutting Defendants' justifications, I do not find that it is a necessary element of Plaintiffs' claims.").

For example, at least one plaintiff has alleged that a royalty paid to the patentee was a "reverse" payment because an even higher royalty rate might have permitted earlier generic entry—the "payment" was the difference between the royalty rate the generic paid and the royalty rate a class action plaintiffs' lawyer later decided the generic should have paid. *See* Omnibus Mem. of Law at 13, *Barba v. Shire U.S., Inc.*, 13-cv-21158-JAL (S.D. Fla. Dec. 10, 2015), ECF 367 (arguing that "whether [allegedly 'too-low'] royalties can constitute reverse payments is an open question"). And although *Actavis* assumed reverse payments would arise only in Hatch-Waxman litigation, plaintiffs have sought to apply it well outside the pharmaceuticals industry. *See* Order at 12, *United Tactical Sys., LLC v. Real Action Paintball, Inc.*, No. 14-cv-04050-MEJ (N.D. Cal. Feb. 10, 2016), ECF 211 (refusing to dismiss *Actavis* claim in irritant projectiles market).

Settlement under the Third Circuit's standard is thus a fool's errand—why settle a patent case when doing so merely means re-labeling the litigation boxes to read "antitrust" rather than "patent?" Indeed, as this Court recently noted in *Kimble*, the application of the rule of reason is a

strong deterrent, because "whatever its merits may be for deciding antitrust claims, that 'elaborate inquiry' produces notoriously high litigation costs and unpredictable results." 135 S. Ct. at 2411. The parties are deterred from settling if the settlement itself would merely result in such a costly and unpredictable inquiry. To avoid this result, settling parties could settle only if they happened to agree on an entry date through distributive bargaining—if there was no "gap" between their risk-adjusted positions. *Actavis* demanded no such absurd, anticompetitive result, and *certiorari* should be granted to allow this Court to clarify that *Actavis* was not intended to deter fair value settlements and thus that courts must require plausible allegations that a settlement involved a payment rather than mutually-beneficial fair value.

III. COURTS MUST REQUIRE PLAUSIBLE ALLEGATIONS OF "LARGENESS"

Finally, even if exclusive licenses were appropriate for antitrust scrutiny under *Actavis* (they are not), and even if a potentially-unlawful "payment" were properly alleged, courts must require plausible allegations that the payment was "large" within the meaning of *Actavis*.

This Court in *Actavis* used the presence of a large payment as a "surrogate" from which it could infer patent weakness. 133 S. Ct. at 2236-37. This surrogate requires more than just a mere payment, however—a single dollar would hardly offer a meaningful proxy for patent weakness. Rather *Actavis* requires a "large" payment that provides meaningful insight into the patentee's view of the

patent's strength or weakness. 133 S. Ct. at 2236-37 ("the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed explanation of the validity of the patent itself"); *id.* at 2235 ("The rationale behind a payment of this size cannot in every case be supported by traditional settlement considerations" and might instead be to avoid patent risk); Herbert Hovenkamp, *Anticompetitive Patent Settlements*, 15 Minn. J. L. Sci. & Tech. 3, 10 (2013) (size of payment "signals the degree of doubt about the underlying patent dispute").

Even if exclusive licenses were "payments" under *Actavis* (they are not), courts would not be able to simply assume that all such licenses are therefore automatically "large" payments under this Court's definition, as the Third Circuit did here. As noted, the FTC found that the difference in expected profits from launching an authorized generic versus granting an exclusive license was "not statistically significant." *Supra* at 5-6; FTC Study at 118. Whatever "large" may mean under *Actavis*, it surely must be large enough to show statistical significance. Particularly in the face of this finding, courts must require plausible factual allegations supporting the claim that any particular exclusive license contained a large patentee sacrifice—not merely assume that all do. Because the Third Circuit failed to apply such a requirement, *certiorari* should be granted.

CONCLUSION

The Court should grant *certiorari* to review the Third Circuit's decision, and ultimately reverse.

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