No. 15-1055

In the Supreme Court of the United States

SMITHKLINE BEECHAM CORPORATION, DBA GLAXOSMITHKLINE, ET AL.,
Petitioners,

v.

KING DRUG COMPANY OF FLORENCE, INC., ET AL.,
Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE GENERIC PHARMACEUTICAL ASSOCIATION AS AMICUS CURIAE IN SUPPORT OF PETITIONERS

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INTERESTS OF AMICUS CURIAE[1]

The Generic Pharmaceutical Association (GPhA) is a nonprofit, voluntary association representing nearly 100 manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. GPhA's members provide American consumers with generic drugs that are just as safe and effective as their brand-name counterparts, but substantially less expensive. GPhA members' products account for roughly 80% of all prescriptions dispensed in the United States but only 27% of the money spent on prescriptions. In this way, the products sold by GPhA members save consumers nearly $200 billion each year. GPhA's core mission is to improve the lives of consumers by providing timely access to affordable pharmaceuticals.

GPhA often files amicus briefs in cases pending before this Court, taking legal positions that are adopted by GPhA's Board of Directors and reflect the position of GPhA as an organization. *See*, *e.g.*, *FTC v. Actavis, Inc.*, No. 12-416 (2013); *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, No. 10-844 (2012). GPhA also advocates for regulations and legislation that further the objectives of the Hatch-Waxman Act

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[1] The parties have consented to the filing of this amicus brief. Counsel of record for all parties received timely notice of the intention to file this brief. No counsel for a party authored this brief in whole or in part; and no such counsel or any party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity, other than amicus and its counsel, made a monetary contribution intended to fund its preparation or submission.

(formally, the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585), which Congress enacted in 1984 to accelerate the introduction of less costly generic drugs. In particular, GPhA has opposed efforts by brand-name drug manufacturers to undermine the Hatch-Waxman Act's carefully designed incentive structure by introducing authorized generic products during a true generic drug's 180-day exclusivity period.

INTRODUCTION AND SUMMARY OF ARGUMENT

The question presented in this case is of tremendous importance to the generic pharmaceutical industry and to the consumers who benefit from the cost-saving measures embodied in the Hatch-Waxman Act. For Hatch-Waxman to function as envisioned, generic pharmaceutical manufacturers need an incentive to challenge drug patents and open the market to generic competition. If successful, these efforts benefit the public by bringing lower-priced drugs to market sooner. But lawsuits are expensive, and litigating a patent case to judgment is a particularly costly and risky endeavor. At least two things help mitigate that expense and, in turn, encourage companies to file the necessary patent challenges, thereby enhancing the prospects for competition.

First, Congress created a 180-day exclusivity period for the first successful challenger to a pharmaceutical patent. 21 U.S.C. §§ 355(j)(2)(A)(vii)(IV), (5)(B)(iv). This exclusivity is a pro-consumer measure that incentivizes generics to challenge weak patents that suppress competition. Second, as in other litigation, there always remains the

prospect of a settlement on mutually agreeable terms, *i.e.*, resolution of the patent dispute without the need for a lengthy and costly trial. The possibility of settlement is a critical part of the generic's calculus when deciding whether to expend the effort and expense of mounting a patent challenge.

The Third Circuit's decision misapprehends the purpose and scope of the 180-day exclusivity period and severely limits the options for settling Hatch-Waxman patent litigation. And the court's approach may decrease competition and raise the cost of drugs for the very consumers that Congress intended to benefit. The Third Circuit held that a patent settlement that brings a generic drug to market before patent expiration (*i.e.*, permits "early entry"), and provides for 180-day exclusivity (*i.e.*, by precluding the brand manufacturer from introducing its own "generic" during that period), can be a "large" and "unexplained" payment subject to "rule-of-reason" antitrust scrutiny. The court of appeals reached that result by misconstruing this Court's decision in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

The Third Circuit is not alone. In the wake of *Actavis*, courts are struggling to figure out whether or how to apply rule-of-reason scrutiny to noncash settlements. *See* Pet. 15-20. *Actavis* has prompted a rash of antitrust lawsuits—including private class actions and multidistrict litigation (MDL)—challenging patent settlements under Hatch-Waxman as anticompetitive. And the prospect of a circuit split in the near future is less likely than in the ordinary case because antitrust plaintiffs are statutorily entitled to nationwide venue and the Third Circuit "is home to a large percentage of the nation's pharmaceutical

companies," Pet. 32. Fearing the profound expense and risk of follow-on antitrust investigations and lawsuits, drug companies will be forced to negotiate settlements in the shadow of the Third Circuit decision: which effectively means that the only possible way to settle is to confine any agreement to an early entry date.

Actavis did not purport to tie the parties' hands in that manner, and this case presents an ideal vehicle to forestall further expansion beyond the Court's reasoning. There is no question that an early entry date, standing alone, cannot give rise to a viable antitrust claim. The only question is whether an agreement to adhere to the 180-day exclusivity period (what the Third Circuit referred to as the "no AG" provision) itself can constitute a "large" and "unexplained" payment under *Actavis*. Answering that question will provide courts much needed guidance on how to faithfully apply *Actavis* to noncash settlement terms.

ARGUMENT

Actavis involved a cash payment from a brand manufacturer to a generic company that the Court described as "large" and "unexplained." 133 S. Ct. 2223 (2013). But in many Hatch-Waxman settlements, cash does not change hands. Courts are struggling with how to apply *Actavis* to noncash settlements at the pleading stage and, by and large, courts are letting antitrust challenges survive a motion to dismiss—despite the clear indication of the *Actavis* Court that rule-of-reason scrutiny and all of the costs and burdens associated with that standard are not appropriate for all patent settlements. The real-world consequence of this growing trend is less competition, in contravention of the scheme Congress enacted and to the detriment

of consumers. The Third Circuit's decision exemplifies the problem, further percolation will only breed more confusion, and this case presents a clean vehicle for the Court's review.

I. COURTS ARE CONFUSED ABOUT HOW TO APPLY *ACTAVIS* TO NONCASH SETTLEMENTS

1. This Court's decision in *Actavis* makes two things clear. First, the terms on which drug companies settle patent disputes under the Hatch-Waxman Act are not categorically immune from antitrust scrutiny in all cases. More specifically, when there are well-pleaded allegations of a "large" and "unexplained" cash payment from the brand manufacturer (the plaintiff in the patent case) to the generic manufacturer (the defendant in the patent case), the risk of anticompetitive effect is sufficient to allow an antitrust challenge to proceed under the "rule of reason." 133 S. Ct. at 2234-38.

Second, and equally important, *Actavis* held that some patent settlements do not give rise to a viable antitrust claim. For example, in *Actavis*, the Court explained that parties could settle patent disputes "by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." *Id.* at 2237. That sort of settlement, where the "patent challenger" is permitted "to enter the market before the patent expires," actually fosters "competition" and inures to "the consumer's benefit." *Id.* at 2234. Accordingly, such early entry settlements do not risk "antitrust liability." *Id.* at 2233-34.

The FTC has consistently agreed. In *Actavis*, the FTC told the Court that "the parties may settle with an earlier entry date and no reverse payment, which would benefit consumers by lengthening the period during which price competition could occur." FTC Br. 40, *FTC v. Actavis, Inc.*, No. 12-416 (2013) ("FTC *Actavis* Br."). At argument, the FTC again explained that "a logical subject of compromise would be to agree upon an entry date in between" immediate entry and the expiration of the patent, and described this sort of settlement as a "legitimate" one that it did not have a "problem with." Transcript of Oral Argument at 5-6, 10, *Actavis*, 133 S. Ct. 2223 (No. 12-416) ("*Actavis* Tr."). And, in its Third Circuit amicus brief, the FTC reiterated that "if the parties agree to a date on which generic entry will be permitted and go no further, the agreement is generally unproblematic." FTC Br. 10-11, *King Drug Co. of Florence, Inc. v. Smthkline Beecham Corp.*, No. 14-1243 (3d Cir.) ("FTC *King Drug* Br.").

What remains much less clear is how *Actavis* should apply to a follow-on antitrust lawsuit that includes one or more additional, noncash settlement terms beyond early entry. Applying *Actavis* to noncash settlements has proven to be a difficult task for the lower courts. One reason for the confusion is that courts do not know how to determine when a noncash settlement crosses the line and becomes so "large" and "unexplained" that the risk of anticompetitive effects justifies full rule-of-reason scrutiny. Another cause for confusion is that this Court used the size of the cash payment as a proxy for the relative strength of the underlying patent and, in turn, a proxy for the potential anticompetitive effect. Because a "valid patent excludes all except its owner

from the use of the protected process or product," *Actavis*, 133 S. Ct. at 2231, the Court used the presence of "[a]n unexplained large reverse payment" to "suggest that the patentee has serious doubts about the patent's survival." *Id.* at 2236. That simplified approach becomes considerably more complex when the exchange between the parties has different terms.

2. One cannot merely assume that a settlement runs the risk of being anticompetitive, and thus subject to rule-of-reason scrutiny, simply because the parties agree to terms that involve something other than an early entry date. The Court recognized as much in *Actavis* when it commented that even cash settlements may be justified if they "reflect compensation for other services that the generic has promised to perform." *Id.* at 2236. Yet, plaintiffs are routinely challenging all such settlements and, by and large, courts are allowing these claims to proceed to discovery.

Courts have now allowed claims to move past a motion to dismiss and into discovery based on settlements that involved agreements to purchase products, *see In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-md-2503, 2015 U.S. Dist. LEXIS 125999, at *38-39 (D. Mass. Aug. 16, 2015), agreements to jointly develop products with corresponding royalty payments, *id.* at *40; *In re Opana ER Antitrust Litig.*, No. 14 C 10150, 2016 U.S. Dist. LEXIS 16700, at *13-15 (N.D. Ill. Feb. 10, 2016), agreements to co-promote or license separate products or processes, *Am. Sales Co. v. Warner Chilcott Co. (In re Loestrin 24 Fe Antitrust Litig.)*, Nos. 14-2071, 15-1250, 2016 U.S. App. LEXIS 3049, at *15-19 (1st Cir. Feb. 22, 2016); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 744 (E.D. Pa. 2014), agreements to

exclusively license the product at issue in the suit, *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d at 744; Pet. App. 16a-17a; *In re Opana ER Antitrust Litig.*, 2016 U.S. Dist. LEXIS 16700, at *14-15, and agreements to distribute the brand's drug, *United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1063 (N.D. Cal. 2014).

Actavis provides no support for this approach and, what is more, such a lax pleading standard runs contrary to this Court's decision in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). It is easy to label a settlement "large," "unexplained," and "anticompetitive." But mere labeling does not (and cannot) answer the "the basic question" identified by this Court: whether there is "the presence of significant unjustified anticompetitive consequences." *Actavis*, 133 S. Ct. at 2238. If virtually any settlement (perhaps short of pure early entry) can be labeled a large, unexplained payment, then nothing about this bare allegation makes an antitrust claim plausible. This cannot be squared with the Court's case law.

3. This growing trend threatens to have the perverse effect of discouraging procompetitive conduct in a way that Congress could not have intended and this Court could not have envisioned.

If every (or virtually every) patent settlement under the Hatch-Waxman Act is subject to a follow-on antitrust suit that will survive the pleading stage and burden the parties with years of voluminous discovery, there will be fewer patent challenges under the Act. Litigating a patent challenge to judgment is a risky and expensive proposition, and the calculus undoubtedly changes when the prospects of settlement on mutually agreeable terms diminish. Parties, in turn, will be

increasingly wary of entering into a settlement resolving the patent dispute only to open themselves up to a follow-on antitrust lawsuit with the threat of treble damages. Indeed, as this Court has recognized, merely "proceeding to antitrust discovery can be expensive." *Twombly*, 550 U.S. at 558.

And such follow-on lawsuits have become a near certainty. Settling parties cannot rely on prosecutorial discretion. Even if the FTC declines to investigate or challenge patent infringement settlements, the class action bar can and, as this case demonstrates, they will file suit. *See* Pet. 9 (noting that neither the FTC nor the DOJ objected to the settlement after it was proposed). Indeed, such claims are now routinely filed based on nothing more than media reports that there has been a Hatch-Waxman settlement.

In *Actavis*, the Court "recognize[d] the value of settlements and the patent litigation problem," 133 S. Ct. at 2234, but insisted that its decision "does not prevent litigating parties from settling their lawsuit," *id.* at 2237. Unless the Court intervenes, that may no longer be true. As noted above (*supra* at 7-8), the list of settlement provisions that courts have characterized as an "unexplained large reverse payment" continues to grow. Parties are thus left to litigate patent validity with a shrinking window of settlement options. This Court identified an early-entry settlement as an "example" of one "way[]" parties could settle patent litigation without facing antitrust scrutiny. As it stands now, it may be the only way.

This creates a zero sum game with little room for compromise when the parties take differing views of the strength of the patent. *See Duffy Tool & Stamping, L.L.C. v. NLRB*, 233 F.3d 995, 998 (7th Cir.

2000) (Posner, J.) ("A negotiation is more likely to be successful when there are several issues to be resolved . . . 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."). That is particularly true with respect to patent litigation under the Hatch-Waxman Act. Brand and generic manufacturers typically have different expected values for litigation, both because the brand manufacturer has more to lose from generic entry (especially if the entry entails invalidating a patent) than the generic company stands to gain, and because they may have different predictions about the generic's likelihood of success. *See* Barry C. Harris et al., *Activating* Actavis*: A More Complete Story*, 28 Antitrust 83, 84, 86-87 (2014), http://www.crai.com/sites/default/files/publications/Activating-Actavis-A-More-Complete-Story.pdf.

The absence of viable settlement options will have one of two consequences: either protracted litigation or an informed decision not to bring the patent challenge in the first place. Either way, consumers lose. A world with fewer generic patent challenges, less generic competition, and higher drug prices undermines the objectives of both the Hatch-Waxman Act and the antitrust laws. *Actavis* does not support (let alone compel) that perverse result.

II. THIS CASE IS AN IDEAL VEHICLE TO PROVIDE MUCH NEEDED GUIDANCE TO THE LOWER COURTS

This case presents an ideal vehicle for the Court to provide much needed guidance to the lower courts about how to apply *Actavis* to noncash settlements. The settlement at issue is similar in kind to the types of

settlements that this Court (and the FTC) have blessed as procompetitive or otherwise not subject to antitrust scrutiny. And the so-called "no AG" agreement is a common settlement term. While it remains possible that other courts of appeals will (correctly) disagree with the Third Circuit at some point, the prospect of a circuit split is less likely than in the ordinary case and the harm that will arise in the ensuing years warrants earlier intervention.

1. The settlement at issue has two relevant components: (i) the generic drug will enter the market before the patent expires, and (ii) the brand manufacturer will not introduce its own generic during the 180-day exclusivity period. The first term is procompetitive and, standing alone, indisputably could not support an antitrust challenge. *See supra* at 5-6. Properly understood, the second term (*i.e.*, the "no AG" agreement) also fosters competition and, importantly, furthers the policies and purposes underlying the Hatch-Waxman Act. More than that, it is an exclusive license expressly authorized by the Patent Act. 35 U.S.C. § 261. For both reasons, the Third Circuit erred in allowing this follow-on antitrust suit to proceed.

a. The Hatch-Waxman Act was intended to "jumpstart generic competition with name brand pharmaceuticals." *See In re K-Dur Antitrust Litig.*, 686 F.3d 197, 203 (3d Cir. 2012), *vacated sub nom. Upsher-Smith Labs., Inc. v. La. Wholesale Drug Co. and Merck & Co. v. La. Wholesale Drug Co.*, 133 S. Ct. 2849 (2013). But Congress recognized that generic drug manufacturers needed incentives to undertake the FDA approval process and to risk patent suits from brand manufacturers. Hatch-Waxman accordingly "provides a special incentive for a generic to be the

first to file an Abbreviated New Drug Application" that challenges a brand's patent. *Actavis*, 133 S. Ct. at 2228-29. Specifically, these first filers receive 180 days of exclusivity before other generics can enter the market. 21 U.S.C. § 355(j)(5)(B). That congressionally mandated exclusivity period is a "pro-consumer device" specifically designed to promote competition. *See Teva Pharm. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1318 (D.C. Cir. 2010).

The incentives created by the Hatch-Waxman Act have worked extremely well. Generic drugs' share of the pharmaceutical market has expanded dramatically since 1984, to the overwhelming benefit of consumers. In the first 12 years under the Act, the share of generic drugs in the prescription-drug market more than doubled, leading to many billions of dollars of savings. Congressional Budget Office, *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* 27, 31 (July 1998), https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf. Over time, generic market share has continued to grow. In 2011, nearly 80 percent of the prescriptions written in the United States were filled with generics. GPhA, *Generic Drug Savings in the U.S.* 1 (5th ed. 2013).

Here, the brand manufacturer promised the generic precisely the sort of "pro-consumer" exclusivity provided by Congress. The Third Circuit thought otherwise because the terms of the settlement meant that the brand manufacturer also would not introduce its own generic drug (a so-called "authorized generic") during that period. But that does not, in any meaningful way, grant the generic drug company anything beyond what Congress intended. And it does

not transform a pro-consumer device into a potential antitrust violation. In holding to the contrary, the Third Circuit fundamentally misunderstood the congressional scheme.

Authorized generics were essentially unheard of at the time of the Hatch-Waxman Act, *see* Federal Trade Commission, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* at 11-12 (2011),[2] and therefore were not expected to be a source of competition during the exclusivity period. In other words, Congress expected that the 180-day exclusivity period would involve competition only between the brand and the generic. And when authorized generics began to proliferate, Representative Waxman recognized that these products reduce the benefits for generic entrants and "raise[] the serious possibility that generic drug manufacturers may stop challenging patents." Statement of Rep. Henry Waxman, GPhA First Annual Policy Conference, Sept. 20, 2005 (Exhibit A to GPhA Amicus Br., No. 14-1243 (3d Cir. June 3, 2014)); *accord* 157 Cong. Rec. S797 (daily ed. Feb. 16, 2011) (statement of Sen. Rockefeller) ("[A]uthorized generics only serve to reduce generic competition, extend brand monopolies, and lead to higher health care costs for consumers over the long-term."). Congress thus made the judgment that granting a short period of *true* generic exclusivity, free from competition other than with the brand, would lead to the most generic competition (and resulting reduction

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[2] 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.

in drug prices) in the long run. There is no basis for projecting later market developments backward to attribute to Congress an intent to limit the benefit of this exclusivity.

Moreover, unlike the cash payment in *Actavis*, this specific restraint does not have the "potential for genuine adverse effects on competition." 133 S. Ct. at 2234 (citation omitted). An early entry settlement, even one that specifies exclusion of the licensor, creates competition between the generic and the brand. The court below complained that such agreements are anticompetitive because they permit the generic company to charge higher prices in "a generic monopoly instead of a generic duopoly." Pet. App. 33a. But antitrust law does not guarantee a perfectly competitive market or the most pro-consumer result; it guarantees a competitive result. *See Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415-16 (2004) (noting that even though the Sherman Act is the "Magna Carta of free enterprise," it "does not give judges *carte blanche* to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition" (citation omitted)).

In the end, the settlement here is more akin to the early entry settlement that this Court and the FTC made clear does not raise any antitrust concerns, than the "large" and "unexplained" cash settlement at issue in *Actavis*. If *Actavis* should not be read to preclude "litigating parties from settling their lawsuit[s]," 133 S. Ct. at 2237, and if a pure early entry settlement is only one "example" of such a permissible settlement, then it is hard to see how the Third Circuit's decision can withstand scrutiny.

b. The settlement at issue should also have been unobjectionable for another reason: it is an exclusive license expressly permitted by the Patent Act. *See* 35 U.S.C. § 261. The "no-AG" agreement simply grants the generic manufacturer an exclusive license, against all others, for the duration of the 180-day period. At oral argument in *Actavis*, the government identified two important differences between an exclusive license and a cash payment, the "first" being "that an exclusive license is expressly authorized by the Patent Act." *Actavis* Tr. 4. In its amicus brief before the Third Circuit, however, the FTC retreated from that position. It acknowledged that "[m]ost exclusive licenses raise no antitrust concerns because they promote competition," but then argued that, "[m]ore generally, exclusive licensing agreements are not immune from antitrust scrutiny." FTC *King Drug* Br. 27, 28 n.21. The government was right then and is wrong now.

As an initial matter, exclusive licenses are generally procompetitive. They "give a licensee an incentive to invest in the commercialization and distribution of products embodying the licensed intellectual property," and thus "allow[] the licensor to exploit its property as efficiently and effectively as possible." Federal Trade Commission & U.S. Dep't of Justice, *Antitrust Guidelines for the Licensing of Intellectual Property* at 5 (Apr. 6, 1995), https://www.justice.gov/sites/default/files/atr/legacy/2006/04/27/0558.pdf. Contrary to the FTC's current view, a patentee or licensee is not required to defend the wisdom behind the exclusive license on a case-by-case basis by arguing to a judge or jury that its particular exclusive license is procompetitive and thus survives

rule-of-reason review. Rather, because "the Patent Act expressly authorizes [the] specific practice" of exclusive licensing, "that practice standing alone cannot violate the more general antitrust laws." Herbert Hovenkamp, *Anticompetitive Patent Settlements and the Supreme Court's* Actavis *Decision*, 15 Minn. J. L. Sci. & Tech. 3, 17 (2014).

Indeed, this is precisely the sort of conflict that the Court sought to avoid in *Actavis*. This Court asked "whether the patent statute specifically gives a right to restrain competition in the manner challenged." *Actavis*, 133 S. Ct. at 2231 (citation and internal quotation marks omitted). The answer, the Court explained, should guide how to "determin[e] the scope of the patent monopoly—and consequently antitrust law immunity—that is conferred by a patent." *Id.* at 2231 (internal quotation marks omitted). Applying this reasoning, the Court concluded that settlements alleged to involve "large, unjustified reverse payment[s]" may give rise to antitrust liability because, among other reasons, no patent statute "whether expressly or by fair implication" gives the patent holder a right to make such payments. *Id.* at 2223, 2237. By contrast, the Patent Act *does* "specifically give[]" patent holders the right to grant exclusive licenses. *See id.* at 2231 (citation omitted).

The Third Circuit was far too quick to dismiss the resulting conflict. Indeed, this Court's cases makes clear that the antitrust laws must yield to conflicting federal statutes and regulatory schemes in certain instances. *See, e.g.*, *Credit Suisse Sec. (USA) LLC v. Billing*, 551 U.S. 264, 275 (2007) (holding that where there is a "clear repugnancy," or the two are "clearly incompatible," the antitrust laws must yield); *Trinko*,

540 U.S. at 406 ("[A] detailed regulatory scheme . . . ordinarily raises the question whether the regulated entities are not shielded from antitrust scrutiny altogether by the doctrine of implied immunity."); *see also Town of Concord v. Boston Edison Co.*, 915 F.2d 17, 22 (1st Cir. 1990) (Breyer, C.J.) ("An antitrust rule that seeks to promote competition but nonetheless interferes with regulatory controls could undercut the very objectives the antitrust laws are designed to serve."), *cert. denied*, 499 U.S. 931 (1991). To the extent antitrust scrutiny would otherwise be warranted, the direct conflict between the antitrust laws and the Patent Act should lead to the conclusion that prosecution under the former is impliedly precluded. *See Credit Suisse*, 551 U.S. at 271. By failing to engage in the relevant inquiry, the Third Circuit decision stretches *Actavis* beyond its breaking point.

2. This case presents a clean vehicle for the Court's review. The settlement permitted generic entry before the expiration of the patent and did not involve any exchange of money. Unlike some of the other patent settlement cases where patent claims are settled for product A in exchange for an agreement to also purchase product B or develop and co-promote product C, the settlement at issue provided one thing of significant value: an exclusive license ensuring that the congressionally enacted 180-day exclusivity period was truly exclusive.

Exclusive licenses (*i.e.*, those with "no-AG" commitments) are becoming an increasingly common term in patent infringement settlements. Since this Court's decision in *Actavis*, at least eight courts have

considered patent settlements containing such terms.[3] Deciding whether (or how) *Actavis* should be applied to noncash settlements in this context will accordingly provide much needed guidance.

3. To be sure, the Third Circuit is the first appellate court to decide this question. But the First Circuit recently considered the same issue. *In re Loestrin*, 2016 U.S. App. LEXIS 3049, at *6, *33 (reversing grant of motion to dismiss, holding that *Actavis* applies to noncash settlements, and declining to decide whether "plaintiffs adequately pled that the provisions at issue in the . . . settlement agreements are unlawful reverse payments under *Actavis*"). And there is reason to believe that a circuit split is less likely to develop here than in the ordinary case, particularly in the short term.

First, as petitioners explain (Pet. 32), the Clayton Act allows for nationwide service of process and nationwide venue. 15 U.S.C. § 22. Going forward, prudent plaintiffs will simply file suit in the Third Circuit to benefit from the favorable case law. Second, more than half of the follow-on antitrust MDLs already on file, and the only ones pending on appeal, are in the First or Third Circuits.[4]

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[3] *See In re Opana*, 2016 U.S. Dist. LEXIS 16700; *In re Loestrin*, 2016 U.S. App. LEXIS 3049; *In re Niaspan*, 42 F. Supp. 3d 735; Pet. App. 2a; *United Food*, 74 F. Supp. 3d 1052; *In re Nexium (Esomeprazole) Antitrust Litig.*, 309 F.R.D. 107 (D. Mass. 2015); *In re Wellbutrin XL Antitrust Litig.*, Nos. 08-2431, 08-2433, 2015 U.S. Dist. LEXIS 127373 (E.D. Pa. Sept. 23, 2015); *In re Effexor XR Antitrust Litig.*, No. 11-5479, 2014 U.S. Dist. LEXIS 142206 (D.N.J. Oct. 6, 2014).

[4] *See In re Opana ER Antitrust Litig.*, MDL No. 2580 (N.D. Ill.); *United Food & Commercial Workers Local 1776 v. Teikoku*

Third, many of the pending district court cases will not see an appeal for many months, or years, if ever. That is because courts are denying most motions to dismiss antitrust challenges. *See supra* at 7-8. At best then, these cases will proceed through discovery, summary judgment, and (perhaps) trial before seeing an appellate courtroom. At worst, the risks and costs inherent in this sort of litigation will cause defendants to settle, leaving the appellate courts without any judgment to review. As this Court has recognized time and time again, "[f]aced with even a small chance of a devastating loss, defendants will be pressured into settling [even] questionable claims." *AT&T Mobility LLC v. Concepcion*, 563 U.S. 333, 350 (2011); *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 163 (2008) ("[E]xtensive discovery and the potential for uncertainty and disruption in a lawsuit allow plaintiffs with weak claims to extort settlements from innocent companies."); *Coopers & Lybrand v. Livesay*, 437 U.S. 463, 476 (1978) ("Certification of a large class may so increase the defendant's potential damages liability and litigation costs that he may find it economically prudent to settle and to abandon a meritorious defense.").

Pharma USA, No. 14-md-2521 (N.D. Cal.); *In re Aggrenox Antitrust Litig.*, No. 14-md-2516 (D. Conn.); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-md-2503 (D. Mass.); *In re Loestrin 24 Fe Antitrust Litig.*, No. 13-2472 (D.R.I.); *In re Niaspan Antitrust Litig.*, No. 13-md-2460 (E.D. Pa.); *In re Nexium (Esomeprazole) Antitrust Litig.*, No. 12-2409 (D. Mass.); *In re Skelaxin (Metaxalone) Antitrust Litig.*, No. 12-md-2343 (E.D. Tenn.); *In re Lipitor Antitrust Litig.*, No. 12-2389 (MDL No. 2332) (D.N.J.); *In re AndroGel Antitrust Litig.*, 09-ml-2084 (N.D. Ga.); *In re K-Dur Antitrust Litig.*, MDL No. 1419 (D.N.J.).

In the end, this Court may not have another opportunity to review this important issue in the near term and, in the interim, the confusion will only continue to grow. Further review is warranted now.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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