No. 21-406

In the
Supreme Court of the United States

IMPAX LABORATORIES, INCORPORATED,

Petitioner,

v.

FEDERAL TRADE COMMISSION,

Respondent.

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

REPLY BRIEF FOR PETITIONER

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REPLY BRIEF

This Court held in *FTC v. Actavis, Inc.*, 570 U.S. 136, 158-59 (2013), that "quick look" antitrust review, under which anticompetitive effects are presumed, is inappropriate for so-called "reverse payment" patent settlements because not all such agreements have anticompetitive effects. Yet, under the decision below, all reverse-payment settlements will be deemed to have anticompetitive effects, regardless of any case-specific "convincing justification[s]" to the contrary. *See id.* at 159. The Fifth Circuit held that, to establish anticompetitive effects, all the FTC must show is that a restraint "replace[s] the 'possibility of competition with the certainty of none.'" App.17-18. But not even the FTC can deny that all patent settlements do just that. Making matters worse, the Fifth Circuit then went on to hold that evidence of a settlement's *actual effects on competition* is irrelevant as a matter of law, because such evidence by definition did not exist at the time of settlement. That is the opposite of what this Court's cases demand. This Court's cases "require[] courts to conduct a fact-specific assessment" of a challenged restraint's "'actual effect' on competition." *Ohio v. Am. Express*, 138 S.Ct. 2274, 2284 (2018) (quoting *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 768 (1984)). Nor is there support for the Fifth Circuit's ultimate holding that, because a generic manufacturer can "always"—in theory, at least—agree to the same early-entry date but no payment, there will be a less restrictive alternative to a reverse-payment settlement in every case.

The decision below means that reverse-payment settlements are presumptively anticompetitive at the

threshold and conclusively so in the final analysis. That cannot be squared with *Actavis*, other decisions correctly applying it, or this Court's antitrust cases more generally. Nor can it be allowed to persist pending further percolation. If the decision below stands, fewer generics will challenge the patents protecting brand-name drugs, and prescription drug prices will rise. The Court should grant the petition.

I. The Decision Below Conflicts With *Actavis* And Other Decisions Correctly Applying It.

1. This Court held in *Actavis* that antitrust challenges to so-called reverse-payment settlements may proceed only under the rule of reason—not under "quick look." 570 U.S. at 158-59. The difference between those two standards boils down to the need to prove anticompetitive effects. Under quick look, anticompetitive effects are presumed; under the rule of reason, the plaintiff bears the burden to prove them. *Id.* at 159. The decision below reinstates quick look for challenges to reverse-payment settlements in all but name, in direct violation of *Actavis*. Pet.18-22.

The FTC points out that the Fifth Circuit did not declare that it was effectively authorizing quick look, and instead "repeated the standard set forth in *Actavis*" and proceeded to "appl[y] that standard to this case." BIO.14; *see also* BIO.20. But that is a vice, not a virtue. The FTC does not deny that, under the Fifth Circuit's decision, the mere fact that a settlement "replace[s] the 'possibility of competition with the certainty of none'" is sufficient to establish anticompetitive effects. App.17-18. Nor could it. "Impax argue[d] that the Commission needed to do more at this first stage of the rule of reason" than

merely "conclude that the reverse payments" eliminated the prospect of generic competition during the patent term, but the court explicitly "disagreed." App.17-18. So while the Fifth Circuit did recount some additional features of the settlement in deciding anticompetitive effects, *see* BIO.14; App.14-17, none of those features made a difference in the court's ultimate analysis.

Therein lay the problem. *All* reverse-payment settlements "replace the 'possibility of competition with the certainty of none'" for at least some period of time between the settlement's entry and the patent's (or patents') expiration. Pet.22. The FTC does not argue otherwise. What that means is that, under the decision below, every antitrust challenge to a reverse-payment settlement will proceed to the second step regardless of whether the court admitted it—which is exactly what it means to apply quick look. The decision below thus directly conflicts with *Actavis*.

The FTC nonetheless contends that "[t]his Court's cases" support the Fifth Circuit's approach. BIO.11. That is wrong thrice over. First, the rule of reason requires "a fact-specific assessment," BIO.11 (quoting *NCAA v. Alston*, 141 S.Ct. 2141, 2151 (2021)), and a rule under which all challenges to a class of settlements bypass the first step is not "fact-specific." Second, and as noted, the decision below blesses exactly what *Actavis* explicitly rejected. Third, the net effect of the Fifth Circuit's approach will be to increase the risks to generic manufacturers in challenging brand-name patents—which, in turn, will mean higher prescription drug prices across the board.

"That is precisely the *opposite* result that *Actavis* and the antitrust laws mean to encourage." AAM.6.

The FTC asserts that *Actavis* "determined that an 'unexplained reverse payment' is likely to reflect an effort to eliminate potential competition." BIO.11. True enough—but the simple fact that a settlement eliminates some forms of potential future competition *does not* make the settlement "anticompetitive" "by definition."[1] If it did, then *Actavis* would have agreed with the FTC and adopted quick look in this context. Instead, *Actavis* did just the opposite, explaining that "the likelihood of a reverse payment bringing about anticompetitive effects" *at all* "depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." 570 U.S. at 159.

2. The decision below also contradicts *Actavis*, lower court decisions correctly applying it, and basic antitrust principles in failing to consider real-world evidence of the strength of the patents at issue. The FTC stresses that *Actavis* "observed that 'it is normally not necessary to litigate patent validity to answer the antitrust question.'" BIO.15 (quoting 570 U.S. at 157). That is a red herring. Impax agrees that courts "normally" should not need "to litigate patent validity to" decide an antitrust case. Impax's position is much more modest: When (as here) there is evidence of patent strength—such as judicial opinions

[1] Of course, *some* such settlements have anticompetitive effects. But when (as here) there would have been less competition without it, an agreement is not anticompetitive under *any* definition, and certainly not under "[t]his Court's cases." BIO.11.

ruling exclusively for the brand in Paragraph IV cases challenging follow-on patents—ignoring that evidence and instead looking only to "surrogate[s]" of patent strength, *see* BIO.15-17, turns *Actavis* upside-down.

Actavis rejected quick look in this context in part because whether a reverse-payment settlement has "anticompetitive effects" depends on whether the agreed-to "restraint" "lies 'beyond the limits of the patent monopoly,'" which in turn depends on the strength of the patents at issue. 570 U.S. at 147-49, 156-58. *Actavis* made clear, in other words, that reverse-payment settlements allowing pre-expiry generic entry at a date that is justifiable given the strength of the patents ordinarily will not have "anticompetitive effects." So while "surrogate" evidence of patent strength "normally" may be all a court has to go on, it is inconsistent with *Actavis* (and antitrust law more generally) to treat surrogate evidence as superior to the real thing when, as here, *actual* evidence exists. Yet the FTC does not deny that that is just what the Fifth Circuit did here. Pet.22-25.

In declining to consider real-world evidence of patent strength, the decision below conflicts with the Third Circuit's decision *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388 (2015). The Third Circuit there concluded that a patent settlement may be deemed to have anticompetitive effects only upon a showing that it "delay[ed] competition for longer than the patent's strength would otherwise permit." *Id.* at 409. That obviously requires some inquiry into the "patent's strength." *Id.* Other lower courts have been even more explicit about the relevance of evidence of patent strength. *See, e.g.*,

FTC v. Cephalon, Inc., 36 F.Supp.3d 527, 531 (E.D. Pa. 2014); *cf. In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 63 (1st Cir. 2016) (concluding that district court did not err by requiring plaintiffs to put forth "evidence of the patents' invalidity or noninfringement before allowing the plaintiffs to pursue an at-risk launch theory"). And while the Third Circuit noted in *King Drug* and subsequent decisions that antitrust courts ordinarily need not "conduct a detailed exploration of the validity of the patent" in order to decide rule-of-reason cases, *King Drug*, 791 F.3d at 403; BIO.16-17, that court has never endorsed what the Fifth Circuit did here: "refusing to consider [real-world evidence of] the strength of Endo's patents as part of its analysis" when there is every indication that the surrogate evidence is off the mark. BIO.15.

The FTC responds by saying that what happens after parties enter an agreement is irrelevant to assessing the agreement's impact on competition. BIO.17-19. The FTC cites no Supreme Court decisions in support of this supposed categorical rule, and there are none. In fact, the FTC's categorical rule breaks with this Court's many decisions "requir[ing]" antitrust courts "to conduct a fact-specific assessment of … 'the [restraint]'s *actual effect' on competition*." *Am. Express*, 138 S.Ct. at 2284 (emphasis added); *see also, e.g.*, *NCAA*, 141 S.Ct. at 2160 (rule of reason requires courts to "weigh[] *all of the circumstances of a case*" (emphasis added)). A settlement's "actual effect" on competition is quite often different from the effects forecasted before the settlement takes effect, and this Court's cases do not permit lower courts to ignore evidence of a challenged restraint's actual

competitive effects when, as here, that evidence is validly presented to them.[2]

3. Moving past anticompetitive effects, the court below held that (a) procompetitive benefits, no matter how significant, can be assumed away, App.24, (b) a settlement without a payment is less restrictive than a settlement with one, App.25 n.8, and (c) it is always possible for a generic manufacturer to agree to the same early-entry date without a payment, App.28-29. Taken together, these holdings—which the FTC does not meaningfully address—make it all but impossible to defend reverse-payment settlements.

To be sure, the Fifth Circuit styled its analysis as "case-specific," App.28 n.10, and it declined to disturb the Commission's factual findings about the viability of a settlement "with an earlier entry date" in this case, *see* BIO.19 (emphasis omitted) (quoting App.25).[3] But that does not erase the separate, non-case-specific holding that "settling without a reverse payment" is a less restrictive alternative by definition. App.22. The Fifth Circuit was clear that "[e]ven if Impax's entry date were the same in a no-payment settlement, the arrangement would be less anticompetitive than the actual agreement because it would not include Endo's 'payment.'" App.25 n.8. That "reasoning extends to pharmaceutical patent

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[2] The FTC asserts that the evidence is not as strong as Impax claims because the post-settlement Paragraph IV cases involved follow-on patents, not the patents at issue here. But the follow-on patents would have blocked Impax's generic *even if Impax had won its case*. That makes the evidence stronger, not weaker.

[3] Notably, however, the ALJ—the factfinder closest to the evidence—reached the opposite conclusion. App.370; Pet.14.

settlements across the board." AAM.Br.12. And it is "a recipe for disaster," for it means that many "legitimate business arrangements" will be "condemn[ed]" as unlawful, which will "chill the very' procompetitive conduct 'the antitrust laws are designed to protect.'" *NCAA*, 141 S.Ct. at 2161 (quoting *Verizon Commc'ns Inc. v. L. Offs. of Curtis V. Trinko, LLP*, 540 U.S. 398, 414 (2004)); Pet.33-34.

This case proves the point. The FTC's own expert admitted that "consumers are better off today because Impax is selling oxymorphone ER." App.269 ¶599. And as the ALJ explained, that is a direct result of the settlement Impax reached with Endo. App.362-70; Pet.13-15. The FTC now claims that the fact that any version of Opana—Impax's generic—is currently on the market at all is a consequence "of developments that occurred years after the settlement," not of the Impax-Endo settlement. BIO.18-19. That is simply false. Had Impax not settled its litigation with Endo, the very same "developments"—i.e., Endo securing follow-on patents for Opana and prevailing in every Paragraph IV suit challenging them—would have barred Impax from launching its generic for another decade. Pet.25. This is true even assuming Impax "fully litigated" "[t]he patents at issue here" and won, and regardless of whether Endo executed its "product-hop strategy," BIO.18-19. Pet.11-12, 25-26.

Under the decision below, real-world evidence of procompetitive benefits made no difference, and real-world evidence of patent strength did not either. All that mattered was that the settlement has a reverse payment. The net result is quick look on steroids: reverse-payment settlements are presumed to have

anticompetitive effects; their procompetitive benefits can be assumed away; and the presence of a payment suffices to prove the possibility of a less restrictive alternative, at least absent some iron-clad evidence that the brand drew a clear red line. Pet.28-30. That sweeping holding cannot be squared with *Actavis*, this Court's rule-of-reason cases more generally, or with lower court decisions correctly applying them. The FTC should not be permitted to obtain a streamlined standard that this Court explicitly declined to give it in *Actavis*, especially since what the Court *did* endorse in *Actavis* itself went too far for multiple Justices.

II. The Questions Presented Are Exceptionally Important And Warrant Immediate Review.

The decision below gives the FTC everything it asked for, and this Court declined to give, in *Actavis*—and then some. That is reason enough to grant the petition. But it is far from the only reason. Making it easier for the FTC (and private plaintiffs' lawyers) to win antitrust challenges to patent settlements does not just affect antitrust law or drug companies' bottom lines. It affects prescription drugs prices nationwide.

"Entry of a single competitive generic product can lower prices by thirty to forty percent." Philip E. Alford, PhD, *Rethinking FDA Regulation of Complex Products*, 21 Minn. J.L. Sci. & Tech. 477, 517 (2020). That explains why generic alternatives to brand-name drugs saved Americans over $2 trillion over the past decade, and over $300 billion in 2019 alone. Ass'n for Accessible Meds., *Securing Our Access & Savings: 2020 Generic Drug & Biosimilars Access & Savings in the U.S. Report* 4, 18 (2020), https://bit.ly/3kNZTsr.

But a generic cannot simply enter the market, and help bring prices down, when it obtains FDA approval. In most cases, a brand-name drug is on the market and presumptively protected by a patent that a generic version may well infringe. And if a generic launches "at risk" during the brand's patent term(s), it risks potentially ruinous liability. *See* 35 U.S.C. §§271(e)(4)(C), 284. There are thus only two viable ways generics can enter the market before the expiration of blocking patents' terms: (1) winning a Paragraph IV action; or (2) settling with the brand.

The former is fraught with peril and considerable expense. "Even if the brand's patent estate turns out to be meritless, manufacturers of generics and biosimilars still face years of cripplingly expensive litigation to prove invalidity in court." AAM.Br.19; *see* Pet.31. The prospect of needing to win multiple multimillion-dollar infringement suits against each separate patent protecting a brand-name drug—which may number in the triple-digits—explains why nearly a third of FDA-approved biosimilars remain off the market, and why prices for many aging drugs remain so high. Pet.5-6; AAM.Br.17-18.

It also explains why settlements are so important in this context. In recent years, the number of generic and biosimilar medicines that came onto market pre-expiry because of a Paragraph IV litigation win pales in comparison to the number that came onto market pre-expiry as a result of a patent settlement. That is not because generic manufacturers are rent-seeking. It is because patent law, including Hatch-Waxman, deliberately pushes parties toward settlement.

The decision below threatens to take that option off the table. Under its approach, "manufacturers of generic medicines risk liability anytime an early-entry settlement can be characterized as including a 'payment,' no matter how procompetitive [it] is as a whole." AAM.Br.5-6 (alteration in original). The inevitable result will be fewer generics and biosimilars trying to launch pre-expiry, will will mean less competition and higher prices—to the detriment of all Americans who rely on prescription drugs.

The FTC's only response is to say that most pharmaceutical patent cases in this context can settle without a reverse payment. BIO.20-21. That misses the point. Generic manufacturers know they cannot afford to litigate every patent blocking their lower-priced products' entry; if antitrust liability likely awaits them any time they settle a patent case on terms that could be construed as containing a payment, then they will stop filing Paragraph IV certifications altogether, and instead will take the far less-risky option of filing under Paragraph III and waiting to launch until every patent blocking their products' entry has expired. That is simple economics. But it is not something the government should be content simply to wave away as collateral damage. Nor is the problem solved by looking only to the patent cases that have been filed. Even if 80% of recent cases settled without a reverse payment, that still means that a sizable minority of them did not. Yet brands win Paragraph IV cases that go to judgment *twice as often as generics*, Pet.5-6, and when they do, they are often able to extend their exclusivity even further.

The FTC does not meaningfully respond to any of this. Instead, it asserts that it "is no concern" "[t]hat some settlements might no longer be possible." BIO.21 (alteration in original). The price of prescription drugs is a concern to Americans, and it was a motivating factor behind Hatch-Waxman.

Yet without this Court's intervention, the decision below will become the de facto national standard. The Sherman Act's venue provision, 15 U.S.C. §22, allows plaintiffs to sue in any district court nationwide. And no reasonable lawyer will forego a forum in which victory is all but a fait accompli.

CONCLUSION

The Court should grant the petition for certiorari.

Respectfully submitted,

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