No. _____

In the
Supreme Court of the United States

IMPAX LABORATORIES, INCORPORATED,
a corporation,

Petitioner,

v.

FEDERAL TRADE COMMISSION,

Respondent.

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

PETITION FOR WRIT OF CERTIORARI

MATTHEW D. ROWEN
KIRKLAND & ELLIS LLP
1301 Pennsylvania Ave., NW
Washington, DC 20004
(202) 389-5000

JAY P. LEFKOWITZ, P.C.
Counsel of Record
DEVORA W. ALLON, P.C.
KIRKLAND & ELLIS LLP
601 Lexington Ave.
New York, NY 10022
(212) 446-4800
lefkowitz@kirkland.com

Counsel for Petitioner

September 10, 2021

QUESTIONS PRESENTED

Because settlement agreements that permit a "generic manufacturer to enter [a] patentee's market prior to the patent's expiration" increase competition, lower prices, and redound "to the consumer's benefit," this Court in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013), explicitly "decline[d]" "to hold that reverse payment settlement agreements are presumptively unlawful"; instead, "the FTC must prove its case as in other rule-of-reason cases," and courts must ensure that the inquiry is not "too abbreviated to permit proper analysis" into what matters most: a settlement's actual effects on competition. *Id.* at 158-60. Despite these clear instructions, the Fifth Circuit here adopted an abbreviated form of review under which patent settlements effectively are conclusively unlawful anytime they convey "valuable consideration" from the brand to the generic—which is just another way of saying they contain a large reverse payment—and "replace[] the 'possibility of competition [during the patent term] with the certainty of none'"—which is true of *all patent settlements*. App.17-18. Even more, and creating a textbook split with the Third Circuit, the Fifth Circuit held that the strength of the patents at issue is categorically irrelevant to the inquiry even when (as here) the patents have been deemed valid and infringed in separate litigation.

The questions presented are:

1. Whether the presence of a "reverse payment" that exceeds a patentee's saved litigation costs and the value of any services provided by a patent challenger suffices to render a patent settlement unlawful, despite this Court's holding to the contrary in *Actavis*.

2. Whether courts reviewing antitrust challenges to patent settlements can disregard evidence of the strength of the patents at issue, as the Fifth Circuit held here, or instead whether they must consider what "the patent's strength would otherwise permit," as the Third Circuit held in *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 409 (3d Cir. 2015).

PARTIES TO THE PROCEEDING

Petitioner is Impax Laboratories, LLC (formerly Impax Laboratories, Inc.).

Respondent is the Federal Trade Commission.

CORPORATE DISCLOSURE STATEMENT

Petitioner Impax Laboratories, LLC is a wholly-owned subsidiary of Amneal Pharmaceuticals LLC. Amneal Pharmaceuticals, Inc., a publicly traded company, owns a greater-than-10% interest in Amneal Pharmaceuticals LLC. Tushar Patel, an individual, owns approximately 18% of Amneal Pharmaceuticals, Inc.'s total common stock. Gautam Patel, also an individual, owns approximately 10% of Amneal Pharmaceuticals, Inc.'s total common stock. Fosun International Limited, which is traded on the Hong Kong Stock Exchange and holds shares through one or more affiliates, owns 17% of Amneal Pharmaceuticals, Inc.'s Class A stock. T. Rowe Price Associates, Inc. owns 14% of Amneal Pharmaceuticals, Inc.'s Class A stock. Funds associated with TPG Global, LLC own 12% of Amneal Pharmaceuticals, Inc.'s Class A stock.

STATEMENT OF RELATED PROCEEDINGS

Impax Laboratories, Inc. v. FTC, No. 19-60394 (5th Cir.) (opinion issued Apr. 13, 2021), is related within the meaning of this Court's Rule 14(b)(iii).

TABLE OF CONTENTS

APPENDIX

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

PETITION FOR WRIT OF CERTIORARI

The settlement that gave rise to this antitrust suit is singularly responsible for consumers' current ability to buy an in-demand pharmaceutical product, and at lower prices. Under any reasonable mode of analysis, such results should be celebrated. Below, however, the responsible settlement was condemned. No rule of reason could produce such an unreasonable result. So it should come as no surprise that, although the Fifth Circuit paid lip service to the rule of reason in its decision below, its actual analysis not only defies what this Court's cases require, but squarely conflicts with this Court's decision in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013), and lower court decisions correctly applying it. The need for this Court's review is clear.

After years of protracted litigation concerning the patents for a prescription drug called Opana ER, patent holder Endo Pharmaceuticals Inc. and generic drug manufacturer Impax Laboratories, LLC, settled. Endo agreed to give Impax a license to sell a generic version of the drug (called oxymorphone ER) beginning on January 1, 2013, well before Endo's existing patents were set to expire. Endo also agreed not to sue Impax all over again in the event that it acquired additional patents for the drug—which Endo did not long thereafter, and which it has successfully used to bar other generic manufacturers from selling oxymorphone ER *until 2023*. Without this settlement, there would not be a generic version of the drug on the market. In fact, *no* version of the drug would be on the market, because Endo stopped selling Opana ER altogether in 2017. The settlement has thus been a boon for consumers—a fact that the FTC's own ALJ

recognized in ruling that the Impax-Endo settlement was procompetitive and lawful.

Yet none of that mattered to the full Commission, which reversed its ALJ and held that the settlement violated the antitrust laws. Nor did it matter to the Fifth Circuit, which affirmed the Commission. All that mattered instead was that, in addition to the license to market its generic version prior to patent expiry and unencumbered by future patent litigation, Impax *also* received separate consideration—a so-called "reverse payment"—under the settlement.

That is not an overstatement. The Fifth Circuit first held that the FTC satisfied its "initial burden … to show anticompetitive effects" simply because the settlement provided "valuable consideration" to Impax that exceeded Endo's saved litigation costs and the value of any services Impax agreed to provide (*i.e.*, it contained a "large," "unexplained" reverse payment) and "replaced the 'possibility of competition [during the patent term] with the certainty of none'" (which is true of *literally all patent settlements*). App.17-18. And, after assuming that the parties' settlement had procompetitive benefits and thus bypassing the second "step" of the rule of reason, the Fifth Circuit further held that the FTC satisfied its ultimate burden to show a less restrictive alternative simply because the settlement has a reverse payment; for, according to the court of appeals, a settlement *without* a reverse payment but the same license terms is not just less restrictive by definition, but always on the table, even if no one would ever accept such a deal. App.25 n.8.

None of that can be reconciled with *Actavis*. In *Actavis*, this Court explicitly "decline[d]" the FTC's

invitation "to hold that reverse payment settlement agreements are presumptively unlawful," and held instead that "the FTC must prove its case as in other rule-of-reason cases" even when it challenges patent settlements with "large" and "unjustified" reverse payments. 570 U.S. at 158-60. Yet under the decision below, such settlements are not just presumptively unlawful, *but conclusively so*. It is difficult to imagine a clearer conflict with this Court's caselaw.

The decision below also creates a circuit split. Because valid patents grant the right to keep all competitors off the market during the patent term, this Court made clear in *Actavis* that whether a settlement has "anticompetitive effects" necessarily depends on whether the "particular restraint" at issue "lies 'beyond the limits of the patent monopoly.'" *Id.* at 147-49. In line with that holding, the Third Circuit "read[s] *Actavis* to hold 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." *King Drug Co. of Florence v. Smithkline Beecham Corp.*, 791 F.3d 388, 409 (3d Cir. 2015). In the decision below, however, the Fifth Circuit held that anticompetitive effects may be inferred without considering patent strength at all, and even though the patents here *have been deemed valid and infringed*, whenever a patent settlement contains a large reverse payment.

The decision below contradicts this Court's precedent, creates a circuit split, and is poised to frustrate rather than facilitate timely market entry of low-priced generic drugs. Certiorari is warranted.

OPINIONS BELOW

The Fifth Circuit's opinion, 994 F.3d 484, is reproduced at App.1-30. The Commission's opinion, 2019 WL 1552939, is reproduced at App.31-128. The ALJ's opinion is reproduced at App.129-394.

JURISDICTION

The Fifth Circuit opinion issued on April 13, 2021. App.1. Impax's petition is timely under this Court's Orders of March 19, 2020, and July 19, 2021. This Court has jurisdiction under 28 U.S.C. §1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The relevant provisions are reproduced at App.395-533.

STATEMENT OF THE CASE

A. Legal Background

Under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585 (codified in various sections of titles 21, 35 & 42 U.S.C.), generic versions of previously approved brand-name drugs may obtain FDA approval through what are known as abbreviated new drug applications ("ANDAs"). An ANDA "shows that the generic drug has the same active ingredients as, and is biologically equivalent to, [a] brand-name drug" that the FDA has already approved. *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012); *see* 21 U.S.C. §355(b)(1). This streamlined process allows manufacturers to "obtain approval" for generics without having to undertake "the 'costly and time-consuming studies' needed to obtain approval 'for a pioneer drug.'" *Actavis*, 570 U.S. at 142 (quoting *Eli*

Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676 (1990)). "In this way," the Hatch-Waxman Act helps "'speed the introduction of low-cost generic drugs to market,'" "thereby furthering drug competition" and lowering prices. *Id.* (quoting *Caraco*, 566 U.S. at 405).

But there's a catch. "Because the FDA cannot authorize a generic drug that would infringe a patent," "a company filing an ANDA must assure the FDA that its proposed generic drug will not infringe the brand's patents." *Caraco*, 566 U.S. at 405-06. One common option "is to file a so-called paragraph IV certification, which states that a listed patent 'is invalid or will not be infringed by the manufacture, use, or sale of the generic drug.'" *Id.* at 407 (quoting 21 U.S.C. §355(j)(2)(A)(vii)(IV)). But because the Patent Act "treats such a filing as itself an act of infringement" that gives the brand manufacturer the right to sue, *id.*; *see* 35 U.S.C. §271(e)(2)(A), "[f]iling a paragraph IV certification means provoking litigation," *Caraco*, 566 U.S. at 407. Patent-infringement litigation is thus engineered by federal law as a stepping stone on the pathway generics must travel to enter the market.

Unfortunately, "the cost of litigation in this specific context," *i.e.*, "a generic challenging a brand name pharmaceutical patent," is staggering. *Actavis*, 570 U.S. at 170 (Roberts, C.J., dissenting). The cost "was about $10 million per suit" as of a decade ago, *id.*, and it has sharply increased since then, *see* Malathi Nayak, *Costs Soar for Trade Secrets, Pharma Patent Suits, Survey Finds*, Bloomberg Law (Sept. 10, 2019), https://bit.ly/2ki106U (cost rose 67% 2015-2019). Such suits are also notoriously difficult for generics to win: When infringement cases are litigated to judgment,

generic manufacturers lose twice as often as they win. *See* Lex Machina, *Pharmaceutical Patent Litigation Increases Nearly 30 Percent in 2017: Lex Machina Releases Fourth Hatch-Waxman/ANDA Litigation Report* (May 3, 2018), https://bit.ly/2JnHSxo (generics lost ~70% of cases that reached judgment in 2016-17).

Patent settlements, which can resolve claims on all patents protecting a brand-name drug, are thus often indispensable in enabling timely generic entry. Indeed, if generic manufacturers needed to litigate every patent blocking their products' entry all the way to final judgment, then few generic medicines would come onto the market prior to patent expiry—and not just because there would be fewer successful litigation outcomes, but because the expected cost, delay, and risk of failure in litigation would deter generic manufacturers from filing paragraph IV ANDAs in the first place, knowing that they almost invariably "provok[e] litigation." *Caraco*, 566 U.S. at 407.

In light of this reality, and the fact that settlement agreements that permit a "generic manufacturer to enter [a] patentee's market prior to the patent's expiration" typically redound "to the consumer's benefit" via increased competition and lower prices, this Court in *Actavis* explicitly "decline[d]" the FTC's invitation "to hold that reverse payment settlement agreements"—*i.e.*, settlements in which the brand-name manufacturer agrees to compensate the generic challenger—"are presumptively unlawful and that courts reviewing such agreements should proceed via a 'quick look' approach.'" 570 U.S. at 154, 158-59. The Court held instead that only patent settlements with "unjustified" and "large" "reverse payments" are

subject to antitrust scrutiny at all, and even then, only under the rule of reason, which requires a fulsome, fact-intensive evaluation into a challenged restraint's *actual* effects of on competition. *Id.* at 152, 158-59.

B. Factual Background

1. Impax files a Paragraph IV ANDA challenging three Endo patents; Endo responds by suing Impax.

In June 2006, Endo obtained FDA approval to sell a brand drug called Opana ER. App.149 ¶46. The drug is an extended-release version of oxymorphone (hence the "ER"), an opioid that the FDA approved "for the relief of moderate to severe" chronic pain. *Id.*

Impax developed a generic version of Opana ER ("oxymorphone ER"). In June 2007, Impax filed an ANDA seeking approval to sell the drug. App.151 ¶55. At the time, Endo had just one patent listed in the Orange Book. App.150 ¶¶49-50. Because that patent was set to expire in 2008, Impax informed the FDA that it would wait until the patent term ended before launching, rather than risk litigation. App.151-52 ¶¶56-57.

But things changed when, in October 2007, Endo listed three additional patents covering Opana ER, including two that were not set to expire until September 2013. App.150 ¶¶51-53. Impax responded by amending its ANDA to include a paragraph IV certification, which claimed that the three new patents were "invalid, unenforceable, or [would] not be infringed by" Impax's generic. App.151-52 ¶58.

That certification did two things: First, it set Impax on a path toward near-certain litigation with

Endo over the patents. Second, because Impax was the first generic manufacturer to file a paragraph IV certification with respect to Opana ER, it triggered the Hatch-Waxman Act provision under which, if Impax won or settled the litigation, it would have 180 days as the exclusive generic manufacturer of oxymorphone ER once it began selling the product. *See* 21 U.S.C. §355(j)(5)(B)(iv). During that "period of exclusivity," *Actavis*, 570 U.S. at 143-44, the FDA would be barred from approving ANDAs for oxymorphone ER filed by other generics, so Impax could face competition only if Endo launched its own generic version, which is known as an "authorized generic[]." *See* App.145 ¶24.

On January 25, 2008, Endo filed suit, alleging that Impax's ANDA infringed the patents set to expire in September 2013. App.152 ¶61. Endo's decision to sue triggered the Hatch-Waxman Act's automatic 30-month stay, which meant that the FDA could not approve Impax's ANDA until June 14, 2010, at the earliest. App.153 ¶¶62-63.

In the meantime, the parties got to litigating. The first significant milestone in the case was a claim-construction hearing scheduled for December 2009. App.154 ¶70. In advance of that hearing, representatives from Impax and Endo conducted a round of settlement negotiations. App.164 ¶112. Impax proposed settling the case in exchange for a license allowing it to begin selling oxymorphone ER in mid-to-late 2011. App.165 ¶116. Impax's rationale for that date was that it approximated the mid-point between expiration of the Hatch-Waxman 30-month stay (in June 2010) and expiration of the patents at issue (in September 2013). *Id.* Endo rejected the

proposal, arguing that Impax was using the wrong benchmark: A settlement, it asserted, should allow Impax to begin selling oxymorphone ER at the mid-point between the expected end of the litigation and expiration of the longest-running patent, which would lead to a later entry date. *Id.* Unable to bridge the divide, the parties cut off discussions. App.165 ¶118.

2. Impax and Endo eventually settle.

Impax and Endo returned to the negotiating table in May 2010. App.165 ¶119. This time, the talks proved fruitful, resulting in two agreements: a Settlement and License Agreement ("SLA") ending the patent litigation, and a Development and Co-Promote Agreement ("DCA") outlining future cooperation on a potential treatment for Parkinson's disease.

The SLA began taking shape when Endo sent Impax a term sheet in late May 2010. Endo proposed that, in exchange for agreeing to end the patent lawsuit, Impax would receive a license allowing it to sell oxymorphone ER beginning on March 10, 2013, which was consistent with Endo's prior insistence on an entry date between the expected end of litigation and the expiration of the patents at issue. App.169 ¶¶131-32. Endo also proposed that it would agree not to launch an authorized generic during Impax's 180-day exclusivity period, so long as Impax paid a royalty—a covenant known in the industry as a no-authorized-generic, or "no-AG," agreement. *Id.*

Impax pressed Endo on its willingness to accept an earlier entry date. In particular, Impax counter-offered with an agreement framework that maintained the no-AG and allowed Impax to begin selling the generic on January 1, 2013. App.170 ¶137.

Impax also proposed "[a]n acceleration provision" that would allow it to launch oxymorphone ER earlier if Opana ER sales fell, which would be likely to happen if, say, Endo launched a crush-resistant formulation of Opana ER that would draw patients away from a generic version of the original. App.170-71 ¶¶138-39.

Holding firm to its position that launch dates before 2013 were unacceptable, Endo expressed comfort with Impax's proposed entry date of January 1, 2013, but flatly rejected the proposed acceleration clause. App.172 ¶147. Instead, Endo proposed a term called the "Endo Credit," whereby Endo would agree that, if Opana ER sales fell by a certain amount before Impax launched its generic version of oxymorphone ER, then Endo would pay Impax based on the extent of those lost sales. App.168 ¶129.

Impax's lead negotiators were initially comfortable with Endo's proposal and, on June 3, 2010, the parties reached an agreement in principle. App.174 ¶154. Impax's management, however, decided to keep negotiating. On June 4, 2010, management appointed new lead negotiators and directed them to propose a simpler settlement, without the no-AG provision or the Endo Credit. App.174-75 ¶155. Following those instructions, Impax's new team went back to Endo and offered to end the patent lawsuit if Endo would allow Impax to begin selling oxymorphone ER on July 15, 2011. *Id.* That date was consistent with what Impax had proposed during the first round of settlement negotiations. *Id.* Endo rejected the proposal, reiterating that the proposed entry date was too early

and demanding a return to the deal the parties had been discussing. App.175 ¶156.

In light of Endo's response, Impax went back to the previous deal, this time with a new request. During negotiations, Impax had discovered that Endo had applied for additional patents on Opana ER, and that Endo could potentially acquire new patents from other companies. App.178-79 ¶167. Impax thus proposed that the license it would receive in a settlement would cover not only the patents at issue in the parties' patent litigation, but any other, related patents that Endo might obtain in the future. App.179 ¶169.

On June 7, 2010, Endo accepted Impax's request, and the parties signed the SLA. Under the final settlement agreement, Endo gave Impax a license allowing Impax to begin selling oxymorphone ER on January 1, 2013, without having to worry about the threat of future Endo patents. Endo also agreed to refrain from launching an authorized generic (in exchange for a royalty), and to pay the Endo Credit if Opana ER sales dropped. That same day, the parties also executed the DCA, in which they agreed to cooperate on the development and marketing of a potential treatment for Parkinson's disease. App.197-99 ¶¶244-53.

3. Impax becomes the sole supplier of oxymorphone ER.

Impax's decision to obtain a license covering Endo's future patents proved prescient. In March 2012, Endo acquired a patent on Opana ER from another company. App.264 ¶¶573-74. And later that year, the Patent and Trademark Office issued Endo

three additional patents on the drug. Endo wasted no time using those new patents in lawsuits against other generic manufacturers that (like Impax) had developed generic versions of Opana ER and filed paragraph IV certifications. Its efforts were successful: Endo won injunctions barring the other manufacturers from selling oxymorphone ER until 2023 at the earliest. App.265-67 ¶¶575-87.

Impax would have fallen victim to these injunctions, too, were it not for the broad license it received in the settlement. But because of the settlement, Impax began selling oxymorphone ER as scheduled on January 1, 2013, and has continued to sell it without interruption. App.268 ¶¶596-98.

What is more, not only is Impax's oxymorphone ER the sole *generic* version of Opana ER on the market, *it is the only version of the drug available, period*. App.268 ¶598. Endo stopped distributing its original formulation of Opana ER in 2012 and launched a crush-resistant version of the drug. App.163 ¶110. Five years later, in June 2017, the FDA asked Endo to withdraw this new type from the market, and Endo complied. App.163-64 ¶111. So, without this settlement, there would not be any extended-release oxymorphone on the market at all.

C. Procedural Background

1. The FTC initiates antitrust enforcement proceedings.

In January 2017, attorneys at the FTC ("complaint counsel") issued an administrative complaint alleging that the Impax-Endo Settlement violated section 5 of the Federal Trade Commission Act. According to the administrative complaint, the

Impax-Endo settlement is unlawful because it included a "large, unjustified 'reverse payment' from Endo" (the patent holder) to Impax (the paragraph IV filer). App.130. Endo settled with the FTC; Impax chose to proceed to trial before the FTC's sole ALJ. *Id.*

2. ALJ Chappell finds that the Impax-Endo Settlement is procompetitive.

ALJ Chappell ruled that the settlement "provided real and substantial procompetitive benefits to consumers that outweigh any anticompetitive effect," and accordingly ruled in favor of Impax. App.139.

First, ALJ Chappell found that complaint counsel made out a *prima facie* case of anticompetitive harm. He reasoned that (1) by ensuring Impax 180 days as the sole generic on the market, the no-AG agreement increased Endo's expected revenues by over $20 million, and (2) the Endo Credit "was designed to 'back-up' the value of the no-AG provision" by paying Impax if the market for oxymorphone ER shrank before it could begin selling the generic. App.187. These terms together acted "as compensation to Impax for giving up its patent challenge," App.327, which sufficed to satisfy complaint counsel's initial burden to show anticompetitive effects, *see* App.327-59.

Next, ALJ Chappell found that the settlement generated significant procompetitive benefits. App.362-70. This was not even a close call, as even complaint counsel's expert admitted that "consumers are better off today because Impax is selling oxymorphone ER." App.269 ¶599. Had Impax continued litigating, it might have lost the patent litigation, in which case its lower-priced generic version would have been kept off the market all the

way until the expiration of Endo's later-acquired patents. The settlement eliminated that risk, guaranteeing Impax the ability to launch in January 2013 and ensuring that, regardless of any subsequent patents, it could continue selling its lower-priced generic. And because Endo proved successful in its other suits against generics challenging the Opana patents, the "real-world effect" of the settlement was that oxymorphone ER is "available to consumers [and] would not be there" otherwise. App.269 ¶600.

Third, relying on extensive evidence surrounding the agreement's formation, ALJ Chappell concluded that complaint counsel had failed to show that these procompetitive benefits "could have been achieved with a less restrictive settlement agreement." App.370.

Finally, ALJ Chappell balanced the effects and found the settlement to be decisively procompetitive. He explained that any anticompetitive harm was "largely theoretical" because there was little chance of Impax selling oxymorphone ER before January 2013, even absent a settlement. App.385. Impax, he found, "would not have launched [the generic] at risk" because it rarely did at-risk launches, would have faced substantial damages, and was not prepared for such a launch. App.375. Continued litigation, ALJ Chappell added, also was unlikely to lead to earlier entry because, even if Impax won, it was unlikely to prevail until "close to January 2013" and would subsequently have faced litigation related to Endo's newly acquired patents. App.385. By contrast, the settlement guaranteed entry in January 2013 without the risk of potentially losing the patent lawsuit, and it

ensured that Impax would be able continuously to provide patients with access to the generic regardless of any new patents. On balance, then, the evidence could not show the settlement "constituted an unreasonable restraint of trade." App.388.

3. The full Commission reverses, and rules for the Commission.

FTC complaint counsel appealed to the full Commission, which reversed. The Commission agreed that the no-AG provision and Endo Credit constituted large, unexplained payments that "induce[d] … Impax [to] giv[e] up its patent challenge and commit[] to not launch [oxymorphone ER] until January 2013." App.358. The threshold question was thus whether complaint counsel had made out a *prima facie* case of anticompetitive harm. Unlike ALJ Chappell, the Commission concluded that complaint counsel did not need to prove that Impax would have begun selling oxymorphone ER earlier absent the payment it received under the settlement. Rather, because (it said) "the relevant anticompetitive harm" in such cases is "prevent[ion of] the risk of competition," the Commission concluded that it need only find that "the generic drug manufacturer might plausibly have entered the marketplace prior to the agreed entry date," even if that entry was unlikely. App.80. That condition satisfied was here because, even though it was not actually likely that Impax would have done so, "there was a real threat" in the Commission's view that Impax might launch oxymorphone ER at risk. *Id.*

Next, breaking sharply with ALJ Chappell, the Commission concluded that Impax had failed to show sufficient procompetitive benefits. According to the

Commission, the relevant "restraint of trade" was Impax's "commitment not to" launch its generic version of oxymorphone until January 2013. App.100. And because Impax "could have accepted the license" allowing it to launch during Endo's patent term "without also accepting a payment" (*i.e.*, it could have left money on the table), the Commission ruled that there was no "link between the reverse payment and the purported procompetitive benefits." App.107, 109.

For the same reason, the Commission concluded that there was a "less restrictive alternative" for achieving the same procompetitive benefits: In the Commission's view, nothing prevented Impax and Endo from reaching the same settlement with the same entry date, just "without a reverse payment." App.114. The Commission thus brushed aside evidence (which the ALJ found credible and dispositive) that Impax tried, *but failed*, to convince Endo to settle with only an entry date. In sum, the Commission condemned the Impax-Endo Settlement as an unreasonable restraint of trade, and accordingly issued a cease-and-desist order.

D. The Decision Below

Impax timely filed a petition for review in the Fifth Circuit, which held oral argument in June 2020. The Fifth Circuit denied Impax's petition for review, effectively affirming the Commission's decision.

At the outset, the court held that the settlement contained a large and unjustified reverse payment and so was subject to antitrust scrutiny under *Actavis*. Because "of the valuable consideration" (in the form of the no-AG agreement and Endo Credit) that "Impax received in exchange for delaying entry," there was no

dispute that the settlement contained a large payment from the brand to the generic. App.15. And because the value of those terms exceeded the "$3 million in litigation expenses" Endo saved by settling, the court concluded that the payment was "unjustified." App.16-17.

The court then turned to the rule-of-reason analysis. First, it held that the "large and unjustified payment generated anticompetitive effects," because it induced a settlement that "replaced the 'possibility of competition with the certainty of none.'" App.17-18. That is true of all patent settlements, however, which is why Impax argued that "this first stage of the rule of reason" requires an evaluation of "the patent's strength, which is the expected likelihood of the brand manufacturer winning the litigation." App.18. The court disagreed. In the Fifth Circuit's view, nothing in *Actavis* "requires the Commission to assess the likely outcome of the patent case in order to find anticompetitive effects." *Id.* Rather, the mere "fact that generic competition was possible, and that Endo was willing to pay a large amount to prevent that risk, is enough to infer anticompetitive effect" and shift the burden to Impax. *Id.* In reaching that conclusion, the court held that it was irrelevant that "the settlement does not look anticompetitive in hindsight" (because, as a result of Endo's subsequent successes in litigating infringement cases against other generics and its product hop, "Impax's generic is now the only version of Opana ER on the market"). App.20. In the court's view, all that matters are the facts that "existed when the parties adopted the settlement"; what happens in the real world as a direct result of a settlement makes no difference. App.21.

"The next rule-of-reason question is whether Impax can show procompetitive benefits," *id.*, but the court assumed that Impax met its showing and skipped directly to the third rule-of-reason step. At the third step, the court affirmed the Commission's ruling that "Impax could have obtained the proffered benefits by settling without a reverse payment for delayed entry—which is a practical, less restrictive alternative." App.22 (quoting App.114). The court did not deny that Impax had tried, but failed, to secure an earlier entry date; it just held that that made no difference, because Impax could have accepted the same entry date without the no-AG or Endo Credit, or it could have accepted a sooner date. App.25-26 & n.8. As a result, the court denied Impax's petition for review, effectively affirming the decision that the settlement—without which there would be no version of Opana ER on the market—is unlawful.

REASONS FOR GRANTING THE PETITION

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

1. The starting point here is *Actavis*. As with this case, *Actavis* arose out of Hatch-Waxman litigation. A pharmaceutical manufacturer (Solvay) developed and held the patent for an FDA-approved product called AndroGel. 570 U.S. at 144. A generic manufacturer (Actavis) filed a paragraph IV ANDA challenging Solvay's patent; another generic manufacturer (Paddock) did the same not long after; and Solvay responded by "initiat[ing] paragraph IV patent litigation against [both]." *Id.* at 144-45. The parties ultimately settled, after which the FTC sued them, claiming their agreement violated the antitrust laws.

Id. at 145. When the case ultimately got to this Court, the FTC "urge[d the Court] to hold that reverse payment settlements are presumptively unlawful and that courts reviewing such agreements should proceed via a 'quick look' approach, rather than applying a 'rule of reason,'" but this Court *explicitly "decline*[*d*] *to do so*." *Id.* at 158-59 (emphasis added).

This Court rejected the FTC's position for two main reasons. First, presuming that reverse-payment settlements are anticompetitive would deter a great deal of procompetitive activity. Settlements that "allow[] the generic manufacturer to enter the patentee's market prior to the patent's expiration" generally "bring about competition" and lower prices, which redounds "to the consumer's benefit." *Id.* at 154, 158; *see* Philip E. Alford, PhD, *Rethinking FDA Regulation of Complex Products*, 21 Minn. J.L. Sci. & Tech. 477, 517 (2020) ("Entry of a single competitive generic product can lower prices by thirty to forty percent …"). Presuming anticompetitiveness makes it easier for antitrust plaintiffs to prove a violation, and thus much costlier to enter into such an agreement—which in this context would harm competition. *Actavis*, 570 U.S. at 154, 158-59.

Second, a presumption of anticompetitiveness is a mismatch for reverse-payment patent settlements for the simple reason that they involve *patents*. Outside of the patent context, a settlement that divvies up the market temporally between would-be competitors would be an obvious antitrust violation. But that is not true when it comes to patents. Patentees have "absolute freedom in the use or sale of rights under the patent laws of the United States," *E. Bement & Sons*

v. Nat'l Harlow Co., 186 U.S. 70, 91 (1902), including the rights to prevent competitors from practicing the patented invention, *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980), and to allow competitors to enter the market during the patent term if they so choose, *Gen. Talking Pictures Corp. v. W. Elec. Co.*, 305 U.S. 124, 127 (1938). The ordinarily-unlawful competitive harm that comes from an agreement to "delay" entry of a competing product is thus *not unlawful* when a valid patent is involved, provided the "delay" is within the lawful bounds of the patent monopoly. So, when it comes to patent settlements, the only cognizable anticompetitive harm is the loss of competition beyond what is *justified by the strength of the patent*. *Actavis*, 570 U.S. at 156-58.

The same reasoning explains why the *Actavis* Court also rejected the position at the other pole, *i.e.*, the argument that any patent settlement that permits generic entry prior to the expiration of the patent term is immune from antitrust attack. As the Court explained, not every patent is valid; a patent "may or may not be valid, and may or may not be infringed." *Id.* at 147. And if the patent protecting a brand-name drug is *not* valid, then a settlement that permits generic entry before the end of the patent term, but post-litigation, may well be a "restraint [that] lies 'beyond the limits of the patent monopoly,'" because the patent monopoly is legally worthless. *Id.* at 149.

The lesson of *Actavis*, then, is that the only way to figure out whether a patent settlement is *unduly* anticompetitive, as opposed to anticompetitive in the short term but within the lawful bounds of the patent monopoly, is to figure out the strength of the patents

at issue. To be sure, it is clear "that the Commission need [not] litigate the patent's validity" all the way to judgment or "present every possible supporting fact or refute every possible pro-defense theory." *Id.* at 159. But it is equally clear that the only way to answer "the basic question—that of the presence of significant *unjustified* anticompetitive consequences"—is to determine what would be justified by the strength of the patents. *Id.* (emphasis added). And that, in turn, will depend on the actual facts of each case, not on presumptions or heuristics—which is why the Court explicitly held that "the FTC must prove its case as in other rule-of-reason cases," and that lower courts likewise must ensure that the rule-of-reason inquiry for patent settlements is not "too abbreviated to permit proper analysis" into what matters: the settlements' actual effect on competition. *Id.* at 159-60.

2. The decision below cannot be reconciled with that clear holding. In rule-of-reason cases, the first thing the FTC must do to prove its case is show that the challenged restraint has an actual anticompetitive effect.[1] *Ohio v. Am. Express Co.*, 138 S.Ct. 2274, 2284 (2018); *see, e.g.*, *In re Cipro Cases I & II*, 348 P.3d 845, 863-64 (Cal. 2015) (measuring anticompetitive effects by looking to "the average level of competition that would have obtained absent settlement"); *In re Cal. Dental Ass'n*, 121 F.T.C. 190, 311-12 (1996) (same).

[1] That is because one cannot determine whether a restraint has an anticompetitive effect without knowing what competition would have looked like absent the restraint. Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. of Econ. 391, 396 (2003).

Indeed, requiring the FTC to show the baseline level of competition that would have obtained but for the challenged restraint is a key part of what separates rule-of-reason review from quick look, which jumps directly to requiring the defendant to "show empirical evidence of procompetitive effects." *Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 775 n.12 (1999).

Yet the Fifth Circuit held that the mere fact that the Impax-Endo settlement "replaced the 'possibility of competition with the certainty of none'" sufficed to satisfy the FTC's initial burden. App.17-18. And because *all* settlements replace the "possibility of competition with the certainty of none" for some amount of time between the settlement date and the end of the patent term, that means that the FTC will *always* satisfy its initial burden (to prove anticompetitive effects) under the Fifth Circuit's approach when it challenges a reverse-payment payment under the antitrust laws. The decision below thus effectively allows the FTC to bypass its initial burden under the rule of reason—in direct conflict with *Actavis*.

3. In the course of allowing the FTC to bypass its initial burden, the Fifth Circuit also lost sight of what is critical when it comes to reverse-payment patent settlements: the fact that they *involve patents*. "Of course, there is restraint in a patent," since it confers "the right to exclude others from the use of the invention, absolutely or on the terms the patentee chooses to impose." *United States v. United Shoe Mach. Co.*, 247 U.S. 32, 57 (1918). But that "is the compensation which the law grants for the exercise of invention." *Id.* So, whereas providers of non-patented

services have no legal right to preclude others from offering the same service or to agree with a would-be competitor that the latter cannot enter the market until some future date, *patentees do*. Indeed, a legal right to keep competitors off the market for a period of time *is exactly* what a patent monopoly confers, along with the concomitant right to allow competitors to enter the market during the patent term on agreed-upon terms. *Gen. Talking Pictures*, 305 U.S. at 127.

That means that, when it comes to determining what the marketplace would have looked like without a patent settlement (and thus whether the settlement has actual anticompetitive effects), it is necessary to inquire into the strength of the patents at issue. This Court explicitly recognized as much in *Actavis*. As the Court made clear, whether a patent settlement has "anticompetitive effects" depends on whether the "particular restraint" at issue "lies 'beyond the limits of the patent monopoly,'" 570 U.S. at 147-49, which in turn depends on the strength of the patent at issue, *id.* at 156-58. In stark contrast, the Fifth Circuit held that a court need not consider patent strength *at all*, let alone "assess the likely outcome of the patent case[,] in order to find anticompetitive effects" in reverse-payment patent-settlement cases. App.18.

To be sure, *Actavis* noted in dicta that "it is normally not necessary to litigate patent validity to answer the antitrust question." 570 U.S. at 157. But it also made clear that the cognizable anticompetitive harm flowing from a patent settlement that allows pre-expiry generic entry is the elimination of the risk of competition *beyond what is justified by the strength of the patent*. *See id.* at 146-48. That is why *Actavis*

recognized that the antitrust analysis in patent settlement cases must focus on whether an alleged reverse payment is a "surrogate for a patent's weakness" or instead evidence of something else. *Id.* at 158. The Fifth Circuit's conclusion that patent validity or invalidity is categorically irrelevant to the antitrust inquiry cannot be reconciled with *Actavis*.[2]

It also creates a textbook circuit split. In *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, the Third Circuit (correctly) "read *Actavis* to hold that antitrust law may prohibit settlements that are anticompetitive because … they delay competition *for longer than the patent's strength would otherwise permit*." 791 F.3d at 409 (emphasis added); *see also Cephalon*, 36 F.Supp.3d at 531 (declining to endorse the FTC's view of "*Actavis* … that a patent's strength or weakness is irrelevant to the antitrust analysis of a

---

[2] To be clear, antitrust courts need not *conclusively* determine patent validity or infringement in analyzing anticompetitive effects in reverse-payment cases. But because a valid and infringed patent suffices to keep all generics off the market during the patent term, they cannot ignore patent strength, either. Rather, it often will "be necessary to establish how likely it is that the patent is valid to determine the reasonableness of any settlement." Michael F. Werno, *More Questions than Answers? The Uncertainties Surrounding Reverse Payment Settlements in the Post-*Actavis *World*, 21 B.U. J. Sci. & Tech. L. 200, 215 (2015). When there is reason to believe the payment is *not* "a workable surrogate" for patent strength—such as when the patent has been determined valid and infringed in subsequent actions, as is the case here, *see* pp.11-12, *supra*—an evaluation of patent strength must be part of the analysis. *See, e.g.*, *FTC v. Cephalon, Inc.*, 36 F.Supp.3d 527, 531-32 (E.D. Pa. 2014) (discussing "situations where the validity of the patent should be litigated within a reverse payment antitrust trial").

reverse payment settlement"). In stark contrast, the Fifth Circuit (incorrectly) endorsed the FTC's position and (incorrectly) read *Actavis* to hold that patent strength is irrelevant to the antitrust inquiry. Only this Court can resolve the circuit conflict.

4. Furthermore, in analyzing whether the FTC established anticompetitive effects, the Fifth Circuit not only disregarded *Actavis*'s clear holding, but held to consider the settlement's real-world consequences. That error, too, warrants plenary review.

In March 2012, Endo obtained additional patents on Opana ER, which it quickly used to sue the other generic manufacturers that had developed their own generic versions of the drug and filed ANDAs with paragraph IV certifications against Endo's original patents. App.264-65 ¶¶573-78. This second round of Hatch-Waxman litigation ended with Endo winning injunctions barring the other generic manufacturers from selling their versions of oxymorphone ER until 2023 at the earliest. App.265-67 ¶¶579-87. Impax may well have found itself in the same place—*i.e.*, off the market altogether—had it not received a broad license from Endo in the settlement. *See* pp.11-12, *supra*. Instead, its drug has been on the market since January 2013.

It is difficult to imagine something more relevant to the question of whether an alleged restraint has anticompetitive effects than the fact that, as a result of the challenged restraint (and *only* as a result of the challenged restraint), consumers have access to an in-demand product. That is all the more true given that Endo stopped distributing its original formulation in 2012 (when it hopped to a crush-resistant product),

and later withdrew the crush-resistant product, App.163-64 ¶¶110-11, which means that Impax's generic version is now the only version of the drug on the market—and the settlement is singularly responsible. That explains why the ALJ had no trouble finding that "consumers are better off" because of the settlement. App.269 ¶599; *see also* App.369 ("The real-world effect of the [settlement] is that there is a product on the market and available to consumers today that would not be there had Impax not had the foresight to negotiate licenses to future patents."). Yet the court of appeals—which agreed that "the settlement does not look anticompetitive in hindsight," App.20—deemed the marketplace reality under the settlement *irrelevant to the analysis*. For, according to the court of appeals, the only "facts" that matter in determining anticompetitive effects at the first rule-of-reason step are facts that "existed when the parties adopted the settlement." App.21.

That approach is antithetical to the rule of reason and this Court's caselaw. "The whole point of the rule of reason is to furnish 'an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint' to ensure that it unduly harms competition before a court declares it unlawful." *NCAA v. Alston*, 141 S.Ct. 2141, 2160 (2021) (quoting *Cal. Dental Ass'n*, 526 U.S. at 781). Consistent with this emphasis on the real-world circumstances of each case, "[t]he rule of reason requires courts to conduct a fact-specific assessment of … 'the [restraint]'s *actual effect*' on competition." *Am. Express*, 138 S.Ct. at 2284 (emphasis added) (quoting *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 768 (1984)). To do so, a court is supposed to "weigh[] *all of the circumstances of a*

case." *NCAA*, 141 S.Ct. at 2160 (emphasis added). Yet the court of appeals here held anticompetitive as a matter of law a settlement that even the court itself agreed was *not* anticompetitive as a matter of fact. Nothing in law or logic requires courts reviewing antitrust claims to blind themselves to reality. That explains why the Fifth Circuit did not cite a single precedent of this Court in support of its position that evidence of a settlement's *actual* effects on competition could not be considered in evaluating "the impact of [the] agreement" because the evidence (obviously) did not yet exist when the agreement was signed. App.20.

The Fifth Circuit's approach is also internally inconsistent. The court determined the value of the reverse payment (the Endo Credit) *not* by reference to its inchoate value at the time the settlement was entered, but rather based on facts that happened years after the fact. But, here, the value of the Endo Credit at the time of the settlement could have been *negative* (*i.e.*, not a reverse payment at all): If sales of Endo's original formulation of Opana had increased (because its planned product hop was unsuccessful), then Impax would have had to pay Endo, not the other way around. The notion that a settlement's effects on competition must be measured at the time of settlement (when they have not yet come to pass), but the value of any reverse payment must be measured only once it materialized, is tailor-made to force liability onto settling parties in patent cases, and fundamentally antithetical to the rule of reason.

In short, under a proper application of the rule of reason—which *Actavis* explicitly requires, *see* 570 U.S. at 159 ("conclud[ing] that the FTC must prove its case

as in other rule-of-reason cases")—the settlement here would have been upheld as a boon to consumers, just as the ALJ found, and just as common sense dictates. Yet, under the decision below, it was condemned.

5. Finally, the Fifth Circuit held that the FTC met its burden at the third step to show a less restrictive alternative *again* simply because the settlement contains a reverse payment—which means that, under the decision below, *all* reverse-payment patent settlements will be *conclusively* unlawful.

According to the Fifth Circuit, a patent settlement without a payment from the brand to the generic is, by definition, less restrictive than a settlement with one. *See* App.25 n.8. That is illogical; if the entry date is the same, then the effect on competition is the same regardless the existence or size of a payment. In any event, even accepting the Fifth Circuit's illogic, it does not follow that a no-payment settlement with the same entry date will invariably be feasible, which is what the rule of reason demands. This case proves the point: It is undisputed that not only "Impax had unsuccessfully sought entry dates during 2011 and even January 2012," but also that Endo steadfastly refused to accept any entry date before 2013. App.28.

In the court's view, that undisputed reality made no difference. Even though complaint counsel did not prove that pre-2013 entry was feasible,[3] the court found it "fairly obvious" that it was just because

[3] That is unsurprising. Allowing pre-2013 generic entry would have made Endo's goal of a successful product hop more difficult (if not impossible) to achieve. Endo's resistance to a pre-2013 entry was not a negotiating tactic; it was the whole ballgame.

"industry practice" (the fact that parties sometimes settle without a reverse payment) and "economics" (the truism that "everything has a price") "support" the intuition "that Endo would have entered into a settlement with an earlier entry date if it could have could have kept the [amount] it ended up paying Impax" under the settlement. App.28-29.

That is a remarkable, and untenable, conclusion. Although the court tried to make its holding appear "case-specific," App.28 n.10, the only "case-specific" evidence it cited was the *absence* of evidence, namely the fact that Endo never told Impax *in haec verba* "that it would 'not settle the litigation' with an entry date before 2013" and the purported "failure [by Impax] to consider other possible 2012 entry dates." App.28. As should be obvious, though, those points are not "case-specific" at all. Few serious negotiators are going to communicate a true red line; and if a party's failure to raise potential earlier dates is enough at the third step, then no settlement will pass muster unless the parties make a separate settlement proposal for every single calendar day between the date of negotiation and the date of expiry. That cannot be the law. Yet it is the logical consequence of the decision.

To top it all off, the Fifth Circuit concluded by holding that the presence of a payment means not just that a "less restrictive alternative way to achieve the procompetitive benefits" was feasible (and so the third step is satisfied), but that that conclusion ends the inquiry, thereby erasing any need for balancing or consideration of procompetitive benefits *at all*. App.12. Taken together, then, the Fifth Circuit (1) held that the mere existence of a reverse payment

was enough for the FTC to move past the first step; (2) assumed that the settlement had procompetitive benefits at the second step; and (3) held at the third step that those procompetitive benefits made no difference to the analysis because Impax could have gotten the same license (and thus accomplished the same procompetitive benefits) without accepting any additional consideration, which will be true in 100% of reverse-payment settlements. So, even though the Fifth Circuit couched its opinion in the language of the rule of reason, its analysis ultimately means that patent settlements *will always be unlawful* whenever they contain a reverse payment and regardless of their procompetitive benefits. That sweeping holding cannot be squared with *Actavis*, which went out of its way to reject the FTC's request to "hold that reverse payment settlement agreements are presumptively unlawful," 570 U.S. at 158-59, or with this Court's antitrust and patent cases more generally.

II. The Questions Presented Are Exceptionally Important.

The questions presented in this case are obviously of great importance to pharmaceutical patent holders and generic drug companies that, as a direct result of Congress's design in the Hatch-Waxman Act, often find themselves facing off in costly patent litigation. They are of equal (if not greater) importance to the millions of Americans who depend on pharmaceutical products day in, day out. It is no secret that brand-name prescription drugs are expensive. A solution to that reality is to increase access to generic medicines. Indeed, generic alternatives to brand-name drugs saved Americans over $2 trillion over the past decade.

Much of these savings, however, would not have been possible without patent settlements. That is a result of congressional design and economic reality. As noted, *see* pp.4-6, *supra*, filing a paragraph IV ANDA is often the first step to potential generic entry prior to expiration of the patents for a brand-name drug. If a patent holder exercises its right to bring an infringement action against the generic manufacturer that filed a paragraph IV ANDA—which it usually will, *see Caraco*, 566 U.S. at 407—the FDA will be legally unable to approve *any* ANDAs covering the patent until 30 months pass or a court resolves the infringement action in favor of the generic. 21 U.S.C. §355(j)(5)(B)(iii). The very thing needed to obtain approval for generic entry thus itself delays generic entry for two-and-a-half years by operation of law.

Economic reality typically pushes generic launch even further. To be sure, if 30 months go by without a final decision, then the generic manufacturer can obtain FDA approval and launch its product "at risk." But, in practice, at-risk launches are rare because (as the name suggests) they involve significant risk: If the generic manufacturer loses the infringement suit after launch, it will be on the hook for potentially ruinous damages. *See* 35 U.S.C. §271(e)(4)(C), §284; *see also, e.g.*, *Sanofi-Synthelabo v. Apotex Inc.*, 492 F.Supp.2d 353, 357-58 (S.D.N.Y. 2007) ($442 million in damages following a mere 23-day at-risk launch).

Even when the brand-name drug is protected by only one patent, the risks of litigating to judgment will often outweigh the expected value for the generic manufacturer. After all, generic manufacturers typically operate on thin margins (since low prices are

the whole point), and patent lawsuits cost millions of dollars. Yet it is increasingly rare for a brand-name drug to be protected by just one patent. Brand-name drug companies often file what are known as "follow-on" patent applications, which, if granted, extend their exclusivity period for many more years—and, accordingly, multiply the cost of patent litigation many times over. Armed with a portfolio of follow-on patents, brand-name companies can increase the cost of bringing a new generic drug to market through the expedited pathway federal law provides. The only ways generic manufacturers can obtain certainty that they may lawfully begin selling their (lower-priced) products are thus either to litigate infringement cases all the way to judgment and appeal, or to settle. And for all of the FTC's handwringing about the purported evils of "reverse payments," the fact of the matter is that consideration to the generic is often a necessary ingredient of getting both sides of a patent dispute to settle—which, again, is often a necessary ingredient of timely generic entry. *See, e.g.*, Robert Willig & John Bigelow, *Antitrust Policy Toward Agreements that Settle Patent Litigation*, 49 Antitrust Bull. 655, 676 (2004); Bret Dickey et al., *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Annals Health L. 367, 391 (2010).

This case proves the point. Impax proposed various settlements without any reverse payment, but those settlements always sought earlier entry dates, which Endo rejected as unacceptable. The parties were able to bridge the gap *only* by adding a payment term to the mix. *See* pp.8-11, *supra*. With Endo unwilling to accept an earlier entry date, taking payment off the table would have meant no

settlement. And without the settlement, consumers likely would have *no access* to *any* version of a sought-after, effective product. After it agreed to Impax's terms, Endo secured follow-on patents, which have been upheld as valid and deemed infringed by other, identical generic versions, and which Endo has thus been able to use to enjoin all other generics from entering the market until 2023.

The only response the Fifth Circuit could muster was to say the settlement's procompetitive benefits did not make a difference, because, according to the court, Impax could have agreed to the same license without accepting any other consideration. App.25-26 & n.8. To be sure, a seller always *can* accept less money than buyers are willing to pay. But that does not make it unlawful to accept the market rate; "antitrust law does not require businesses to use anything like the least restrictive means of achieving legitimate business purposes." *NCAA*, 141 S.Ct. at 2161; *see also Judkins v. HT Window Fashion Corp.*, 529 F.3d 1334, 1340 (Fed. Cir. 2008) ("[T]he fact that both [sides of an agreement] took from the settlement something of value points to a constructive, mutually beneficial resolution to a legitimate dispute."). So too here: Even putting aside that an agreement with the same entry date is no less anticompetitive than one with a reverse payment (its effect on competition is the same), a settlement is not unlawful just because the parties could have reached a more procompetitive deal.

The Fifth Circuit's contrary conclusion is "a recipe for disaster, for" (as this case makes clear) "a 'skilled lawyer' will 'have little difficulty imagining possible less restrictive alternatives to most joint

arrangements.'" *NCAA*, 141 S.Ct. at 2161 (quoting 11 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶1913b, p.398 (3d ed. 2018)). Worse, its approach will likely "prove counter-productive, undercutting the very economic ends [antitrust] seek[s] to serve." *Id.* (quoting *Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227, 234 (1st Cir. 1983) (Breyer, J.)). "After all, even 'under the best of circumstances,' applying the antitrust laws 'can be difficult'—and mistaken condemnations of legitimate business arrangements 'are especially costly, because they chill the very' procompetitive conduct 'the antitrust laws are designed to protect.'" *Id.* (quoting *Verizon Commc'ns Inc. v. L. Offs. of Curtis V. Trinko, LLP*, 540 U.S. 398, 414 (2004)).

The Fifth Circuit's approach would be insupportable in any context, but particularly so here. As noted, settlements are often indispensable in enabling timely market entry of generic medicines. A *de facto* quick look or *per se* regime like the one adopted below will thus make settling more difficult for generic manufacturers, which in turn will mean that fewer paragraph IV ANDAs will be filed, as a result, that fewer generic medicines will come onto the market in a timely manner. The net result will be less competition and higher prescription-drug prices—exactly the opposite of what both antitrust law and the Hatch-Waxman Act are designed to achieve.

CONCLUSION

For the foregoing reasons, this Court should grant the petition for certiorari.

Respectfully submitted,

MATTHEW D. ROWEN
KIRKLAND & ELLIS LLP
1301 Pennsylvania Ave., NW
Washington, DC 20004
(202) 389-5000

JAY P. LEFKOWITZ, P.C.
Counsel of Record
DEVORA W. ALLON, P.C.
KIRKLAND & ELLIS LLP
601 Lexington Ave.
New York, NY 10022
(212) 446-4800
lefkowitz@kirkland.com

Counsel for Petitioner

September 10, 2021