No. 21-406

In the Supreme Court of the United States

IMPAX LABORATORIES, INC., PETITIONER

v.

FEDERAL TRADE COMMISSION

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

BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

In *FTC* v. *Actavis, Inc.*, 570 U.S. 136 (2013), this Court held that a "reverse-payment" agreement, in which a holder of a drug patent pays a rival to drop a challenge to the patent and to stay off the market, can have anticompetitive effects and is subject to antitrust scrutiny under the rule of reason. *Id.* at 159. The question presented is as follows:

Whether the court of appeals correctly sustained the Federal Trade Commission's determination that petitioner's reverse-payment agreement violated the antitrust laws under the rule of reason.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases:

Cases—Continued: Page

Statutes and rule:

Miscellaneous:

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-30) is reported at 994 F.3d 484. The opinion of the Federal Trade Commission (Pet. App. 31-128) is available at 2019 WL 1552939. The decision of the administrative law judge (Pet. App. 129-394) is reported at 165 F.T.C. 988.

JURISDICTION

The judgment of the court of appeals was entered on April 13, 2021. The petition for a writ of certiorari was filed on September 10, 2021. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

The Federal Trade Commission (FTC or Commission) determined that petitioner, a manufacturer of generic drugs, had violated Section 5 of the Federal Trade

Commission Act (FTC Act), 15 U.S.C. 45, by entering into an anticompetitive "reverse-payment" agreement. The court of appeals denied the petition for review. Pet. App. 1-30.

1. The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585, regulates the marketing of pharmaceutical drugs. The statute requires the manufacturer of a new brand-name drug to undergo a comprehensive testing process before receiving marketing approval from the Food and Drug Administration (FDA). *FTC* v. *Actavis, Inc.*, 570 U.S. 136, 142 (2013). If the FDA approves the brand-name drug, manufacturers of generic versions of that drug may obtain marketing approval through an abbreviated process. *Ibid.*

The Hatch-Waxman Act establishes procedures to protect the brand-name manufacturer's patent rights. *Actavis*, 570 U.S. at 143. A generic manufacturer that seeks to market its drug before the brand-name manufacturer's patent expires generally must certify that the patent is invalid or that the generic drug will not infringe the patent. *Ibid.* When such a certification is filed, the brand-name manufacturer may sue the generic manufacturer to seek judicial resolution of the patent dispute. *Ibid.* If the brand-name manufacturer brings such a suit within 45 days, the FDA must withhold approval for the generic drug for up to 30 months or until the patent suit is resolved, whichever is sooner. *Ibid.* If the suit remains pending after 30 months, the generic manufacturer may launch its product "at risk," taking the chance that a court will later find the patent valid and infringed. Pet. App. 7 n.2.

To encourage the speedy entry of generic drugs into the market, the Hatch-Waxman Act grants a 180-day

period of exclusivity to whichever generic manufacturer is the first to file an application through the statute's abbreviated process. *Actavis*, 570 U.S. at 143. During this period, no other generic manufacturer may compete with the first-to-file company. *Id.* at 143-144. Generic manufacturers generally earn more revenue during the 180-day exclusivity period than during the product's remaining time on the market. *Id.* at 144. During the exclusivity period, however, a brand manufacturer may offer its own competing generic product, known as an "authorized generic," which can substantially reduce the profitability of the exclusivity period. Pet. App. 40.

Although the Hatch-Waxman Act was meant to promote competition, it has also created incentives for brand-name and generic manufacturers to collude with each other. *Actavis*, 570 U.S. at 156. Because brand-name drugs carry far higher prices than generic drugs, the brand-name manufacturer's potential loss from generic competition frequently exceeds the generic rival's potential revenue. *Id.* at 154. Often the brand-name and generic manufacturers will both be better off if the parties settle any patent dispute, with the generic manufacturer agreeing to defer launching its product in return for a share of the brand-name manufacturer's monopoly profits. *Ibid.* Such a settlement, in which the brand-name manufacturer (the plaintiff in the infringement suit) pays the generic manufacturer and the generic manufacturer agrees not to enter the market for a period of time, is known as a "reverse payment" agreement. *Id.* at 141. That term reflects the fact that payments made to settle patent-infringement suits more typically flow in the opposite direction, *i.e.*, from the defendant (who would potentially be liable for damages if

it received an adverse decision) to the plaintiff. See *id.* at 140-141.

A reverse-payment agreement can subvert competition. The agreement can eliminate the generic manufacturer's incentive to maintain a challenge to any unwarranted patents granted to the brand-name manufacturer. *Actavis*, 570 U.S. at 151. By preventing the generic manufacturer's launch of its product for a time, the agreement also temporarily eliminates one of the brand-name company's potential competitors from the market. *Ibid.* And the agreement can have spillover effects on other potential competitors: By deferring the entry of the first generic manufacturer, the agreement also defers the start of the 180-day exclusivity period, thus "prolong[ing] the 'bottleneck' that delays entry of other generic competitors." Pet. App. 14 (citation omitted). In such a settlement, the brand-name and generic manufacturers both gain, but "the consumer loses." *Actavis*, 570 U.S. at 154.

This Court has held that reverse-payment agreements are subject to antitrust scrutiny under the rule of reason. *Actavis*, 570 U.S. at 159. Under the rule of reason, "the plaintiff has the initial burden to prove that the challenged restraint has a substantial anticompetitive effect that harms consumers in the relevant market." *Ohio* v. *American Express Co.*, 138 S. Ct. 2274, 2284 (2018). If the plaintiff satisfies that requirement, "the burden shifts to the defendant to show a procompetitive rationale for the restraint." *Ibid.* "If the defendant makes this showing, then the burden shifts back to the plaintiff to demonstrate that the procompetitive efficiencies could be reasonably achieved through less anticompetitive means." *Ibid.*

2. Beginning in 2006, brand-name manufacturer Endo Pharmaceuticals sold an opioid pain reliever under the brand name Opana ER. Pet. App. 5. In 2007, petitioner filed the first application for approval to market a generic version of Opana ER. *Ibid.* Petitioner certified that Endo's patents, which would expire in 2013, were invalid or would not be infringed. *Id.* at 43. In January 2008, Endo sued petitioner for patent infringement. *Id.* at 5.

Endo's patent-infringement suit had the effect of delaying FDA approval of petitioner's generic drug for 30 months (unless the litigation ended sooner). Pet. App. 6. At the end of the 30 months, however, petitioner would have been free to launch its product at risk. *Id.* at 7 & n.2. Endo's projections showed that petitioner's entry into the market "would cut Opana ER sales by 85 percent within three months and cost it $100 million in revenue within six months." *Id.* at 6.

To avoid that result, Endo deployed a strategy known as a "product hop." Pet. App. 7. It planned to withdraw Opana ER from the market, to replace it with a reformulated version of the same drug, and to obtain new patents to protect that reformulated drug. *Id.* at 6. When petitioner's generic drug eventually reached the market, "it would not be therapeutically equivalent to Endo's new branded drug and thus pharmacists would not be able to automatically substitute the generic when filling prescriptions." *Ibid.* "[I]f Endo succeeded in switching consumers to its reformulated drug, which would be just different enough from the original formulation to preclude substitution, the market for [petitioner's] generic would shrink dramatically, preserving Endo's monopoly profits." *Ibid.*

Endo's strategy could work only if petitioner's entry into the market was delayed until after Endo had executed the product hop. Pet. App. 7. But in May 2010, the FDA tentatively approved petitioner's drug, and trial in the patent-infringement suit was set to begin. *Id.* at 7-8, 44.

The parties settled the patent-infringement suit the next month. Pet. App. 8. Petitioner agreed not to launch its generic drug until January 2013—"two and a half years after [petitioner] otherwise could have entered 'at risk.'" *Ibid.* In return, Endo provided petitioner various forms of compensation. *Ibid.* As relevant here, Endo agreed to refrain from marketing its own generic version of Opana ER during petitioner's 180-day exclusivity period, a benefit projected to be worth $24.5 million. *Id.* at 8, 15. Endo also agreed to insure petitioner against the prospect that the planned product hop would extinguish the generic market before the launch of petitioner's generic drug. *Id.* at 8. Endo ultimately executed the product hop and paid petitioner $102 million under the insurance provision. *Id.* at 8-9. Endo's commitment not to market its drug, along with the payment under the insurance provision, together constituted the reverse payment at issue in this case. *Id.* at 70-72. Endo also gave petitioner "a broad license to Endo's existing and future patents." *Id.* at 8.

3. The Commission issued administrative complaints against petitioner and Endo, alleging that the reverse-payment settlement constituted an unfair method of competition under Section 5(a) of the FTC Act, 15 U.S.C. 45(a). Pet. App. 9. Endo settled the charge against it. *Ibid.*

a. An administrative law judge (ALJ) dismissed the complaint against petitioner. Pet. App. 129-394. The

ALJ found that the reverse-payment agreement was anticompetitive. *Id.* at 139-140, 358-359. Specifically, he found that the agreement had the "purpose and effect" of "induc[ing] [petitioner] to give up its patent challenge," *id.* at 139; that the reverse payment was large and was not justified by avoided litigation costs or by any services that petitioner had agreed to provide, *id.* at 323, 326 n.28, 328-330; and that Endo possessed market power in the relevant product market consisting of brand and generic Opana ER, *id.* at 359-362. The ALJ concluded, however, that the procompetitive benefits of licensing Endo's patents outweighed these anticompetitive effects. *Id.* at 385-388.

b. The FTC unanimously reversed the ALJ's decision and found that petitioner had engaged in unfair methods of competition. Pet. App. 31-128.

The Commission first determined that petitioner's settlement with Endo had substantial anticompetitive effects. Pet. App. 60-96. It noted the ALJ's finding that petitioner had received a "large and unjustified payment" as part of its settlement with Endo, and it observed that petitioner "d[id] not challenge that finding before the Commission." *Id.* at 63. It reaffirmed the ALJ's determination that the payment to Endo far exceeded any saved litigation costs, did not reflect any services that petitioner had promised to provide, and could not be explained as anything other than compensation for preventing petitioner's entry into the market until 2013. *Id.* at 69-72. The FTC thus concluded that the payment had enabled Endo to avoid a "real" "risk of competition"—"a cognizable harm under the antitrust laws." *Id.* at 63.

The FTC also concluded that the challenged restraint had not generated any procompetitive benefits.

Pet. App. 96-114. The Commission explained that petitioner had not shown "that it needed to accept these payments in order to enjoy the procompetitive benefits of the patent license." *Id.* at 97; see *id.* at 108-110.

As an alternative ground for its unfair-competition finding, the FTC further determined that, even assuming that the challenged restraint had generated procompetitive benefits, petitioner could have realized those benefits through a substantially less restrictive means, *i.e.*, by settling the case with no reverse payment and with an earlier entry date. Pet. App. 114-120. Although petitioner asserted that it had secured the earliest entry date that Endo was willing to offer, the Commission found that the testimony of petitioner's witness on that point was not credible and that the testimony contradicted other parts of the record. *Id.* at 117 n.43. The Commission instead found that the "only impediment" to that less restrictive alternative was "the parties' desire to preserve and split * * * monopoly profits," which is the essence of a violation under *Actavis*. *Id.* at 119.

The FTC entered a cease-and-desist order prohibiting petitioner from entering into future agreements likely to raise similar antitrust concerns. Pet. App. 121-127. The order does not invalidate any of petitioner's existing agreements.

4. The court of appeals denied the petition for review. Pet. App. 1-30.

The court of appeals sustained the Commission's finding that petitioner's reverse-payment settlement had harmed competition. Pet. App. 12-21. The court noted this Court's conclusion in *Actavis* that a "large and unjustified" reverse payment suggests a likelihood of "significant anticompetitive effects." *Id.* at 14

(quoting 570 U.S. at 158). The court of appeals observed that, in this case, petitioner had conceded that the payment was not justified as saved litigation costs but served instead as "valuable consideration * * * for delaying entry." *Id.* at 15.

Petitioner contended that the FTC was required to "assess the likely outcome of the patent case in order to find anticompetitive effects." Pet. App. 18. The court of appeals rejected that argument, relying on the *Actavis* Court's determination that "[t]he size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." *Ibid.* (quoting 570 U.S. at 158).

Petitioner also observed that, in the years since the settlement, "Endo has obtained more patents for Opana ER and proven their validity in court," and that "the product hop ended up failing once Endo had to take reformulated Opana ER off the market due to safety concerns." Pet. App. 20. Petitioner argued that, given these developments, "the settlement does not look anticompetitive in hindsight." *Ibid.* The court of appeals rejected that argument as well, citing the "basic antitrust principle that the impact of an agreement on competition is assessed as of 'the time [the agreement] was adopted.'" *Ibid.* (citation omitted).

The court of appeals found it unnecessary to decide whether, as the FTC had concluded, the reverse-payment agreement had "generated no procompetitive benefits." Pet. App. 22. The court instead sustained the Commission's "alternative ruling" that petitioner could have obtained the alleged procompetitive benefits through the "less restrictive alternative" of "settling without a reverse payment for delayed entry." *Ibid.* The court

observed that this FTC finding rested on "industry practice, economic analysis, expert testimony, and adverse credibility findings discounting the testimony of [petitioner's] lead settlement negotiator." *Id.* at 24-25. The court stated that, while petitioner surely "would have preferred the settlement that paid it over $100 million" to a settlement with no payment and with earlier competition, the "'desire to share in monopoly rents' cannot undermine the Commission's finding that a less restrictive settlement was viable." *Id.* at 29 (citation omitted).

ARGUMENT

The court of appeals correctly sustained the Commission's determinations that petitioner's reverse-payment agreement harmed competition and that the parties could have obtained any procompetitive benefits by settling without making such a payment. Petitioner's challenges (Pet. 18-34) to those determinations lack merit, and the court's decision does not conflict with any decision of this Court or another court of appeals. The petition for a writ of certiorari should be denied.

1. This Court has set forth a burden-shifting framework for determining whether a restraint violates the rule of reason. See *Ohio* v. *American Express Co.*, 138 S. Ct. 2274, 2284 (2018). The plaintiff must first show that the challenged restraint has "a substantial anticompetitive effect." *Ibid.* One way of doing so is by showing "[i]ndirect evidence" of anticompetitive effects through "proof of market power plus some evidence that the challenged restraint harms competition." *Ibid.* If the plaintiff makes that showing, the defendant must establish "a procompetitive rationale for the restraint." *Ibid.* If the defendant satisfies that requirement, the plaintiff must show that "the procompetitive efficiencies

could be reasonably achieved through less anticompetitive means." *Ibid.*

That standard involves "a fact-specific assessment." *NCAA* v. *Alston*, 141 S. Ct. 2141, 2151 (2021) (citation omitted). The factfinder must consider "'all of the circumstances,'" including "'specific information about the relevant business,'" "'the restraint's history, nature, and effect,'" and "[w]hether the businesses involved have market power." *Leegin Creative Leather Products, Inc.* v. *PSKS, Inc.*, 551 U.S. 877, 885-886 (2007) (citations omitted). In reviewing the FTC's application of the rule of reason, a court must treat the Commission's findings of fact as "conclusive" if those findings are "supported by evidence." 15 U.S.C. 45(c); see *FTC* v. *Indiana Federation of Dentists*, 476 U.S. 447, 454 (1986).

The court of appeals correctly sustained the Commission's finding that the reverse-payment agreement had a substantial anticompetitive effect. This Court's cases establish that "[e]liminating potential competition is, by definition, anticompetitive." Pet. App. 13; see, *e.g.*, *United States* v. *Falstaff Brewing Corp.*, 410 U.S. 526, 532-533 (1973). And in *FTC* v. *Actavis, Inc.*, 570 U.S. 136 (2013), the Court determined that an "unexplained reverse payment" is likely to reflect an effort to eliminate potential competition. *Id.* at 158. The Court explained that, if a reverse payment cannot be justified by some other objective, such as saving litigation costs or compensating the generic manufacturer for services provided, the factfinder can infer that the payment instead seeks "to maintain supracompetitive prices to be shared among the patentee and the patent challenger rather than face what might have been a competitive market." *Id.* at 157.

In this case, petitioner conceded that it had received a large reverse payment, that this payment was not justified by saved litigation costs or by the value of services provided, and that the payment could only be explained as compensation for preventing petitioner's entry into the market until 2013. Pet. App. 15-17. It follows directly from *Actavis* that, by helping Endo eliminate a "real threat of competition," this payment caused anticompetitive harm. *Id.* at 80.

The court of appeals also correctly sustained the Commission's finding that, even if the settlement generated procompetitive benefits, those benefits could reasonably have been achieved using a substantially less restrictive alternative. "The existence of a viable less restrictive alternative is ordinarily a question of fact." Pet. App. 25 (quoting 11 Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 1913b at 398 (4th ed. 2013-2018)) (brackets omitted). In *Actavis*, this Court identified a less restrictive alternative to a reverse payment: the parties to drug-patent litigation may settle the case "by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without * * * paying the challenger to stay out prior to that point." 570 U.S. at 158.

The FTC made a factual finding that this alternative was feasible here. Pet. App. 114-120. As the court of appeals explained, that finding rested on "[t]hree evidentiary legs." *Id.* at 29. First, expert testimony and studies showed that, after *Actavis*, drug companies had routinely settled patent disputes without reverse payments. *Id.* at 26. Second, economic analysis supported the factual finding that "Endo would have entered into a settlement with an earlier entry date if it could have

* * * kept the more than $100 million it ended up paying [petitioner]." *Id.* at 28. Finally, although petitioner's chief negotiator had testified that Endo would not settle with an entry date before 2013, that witness had previously admitted that he "could not remember" whether petitioner had ever "tried to get a date earlier than January 2013" or whether Endo had refused to settle with such a date. *Id.* at 27. As the court noted, this inconsistency not only supported the FTC's finding that the chief negotiator's testimony was not credible, but also allowed the Commission to infer that petitioner had engaged in wrongdoing. *Id.* at 28; see *Reeves* v. *Sanderson Plumbing Products, Inc.*, 530 U.S. 133, 147 (2000) (discussing "the general principle of evidence law that the factfinder is entitled to consider a party's dishonesty about a material fact as 'affirmative evidence of guilt'") (citation omitted).

2. Petitioner identifies (Pet. 21-30) four purported errors in the court of appeals' analysis. For the reasons discussed below, the court's analysis is correct and petitioner's contrary arguments lack merit. In any event, those arguments do not warrant this Court's review. At bottom, the arguments involve fact-bound objections to the court's application of the rule of reason to the circumstances of this case. But "[a] petition for a writ of certiorari is rarely granted when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law." Sup. Ct. R. 10; see *United States* v. *Johnston*, 268 U.S. 220, 227 (1925) ("We do not grant a certiorari to review evidence and discuss specific facts.").

a. Petitioner contends (Pet. 22) that the court of appeals erroneously allowed the Commission to "bypass its initial burden under the rule of reason" to prove that

the reverse-payment agreement here had anticompetitive effects, and that this aspect of the decision below conflicts with this Court's decision in *Actavis*. That argument is mistaken.

In *Actavis*, this Court rejected the contention that reverse payments should be viewed as "presumptively unlawful." 570 U.S. at 158. The Court concluded that the likelihood that a given reverse payment produces anticompetitive effects depends on the circumstances of the case. See *id.* at 159. Relevant circumstances include "[the payment's] 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." *Ibid.*

Contrary to petitioner's contention, the court of appeals did not presume, in violation of *Actavis*, that "all" reverse payments "always" cause anticompetitive effects. Pet. 22 (emphases omitted). The court instead repeated the standard set forth in *Actavis*: "The likelihood of a reverse payment bringing about anticompetitive effects 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." Pet. App. 14-15 (brackets and citation omitted). The court then applied that standard to this case. The court emphasized that "[t]he size" of the payment here ($24 million for Endo's promise not to market an authorized generic, plus another "$102 million" for the market insurance policy) makes this case "comparable to other cases where courts have inferred anticompetitive effect"; that this amount dwarfs the "$3 million in litigation expenses" that petitioner was estimated to

have saved; and that the agreement did not involve "any services * * * that could otherwise justify the large payment." *Id.* at 16-17; see *id.* at 8, 15. The court also noted that "the FTC required [a] showing of market power to show potential anticompetitive effect" and that petitioner did not dispute the existence of market power. *Id.* at 13 n.4. After considering those factors, the court concluded that "*[t]his* large and unjustified payment generated anticompetitive effects." *Id.* at 17 (emphasis added). Far from allowing the FTC to bypass its initial burden, the court followed *Actavis* in finding that the Commission had met that burden.

b. Petitioner contends (Pet. 22-25) that the court of appeals erred by refusing to consider the strength of Endo's patents as part of its analysis, and that this aspect of the court's decision conflicts with *Actavis* and with the Third Circuit's decision in *King Drug Co. of Florence, Inc.* v. *Smithkline Beecham Corp.*, 791 F.3d 388 (2015), cert. denied, 137 S. Ct. 446 (2016). That argument lacks merit.

In *Actavis*, this Court observed that "it is normally not necessary to litigate patent validity to answer the antitrust question." 570 U.S. at 157. The Court explained that "[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival." *Ibid.* The Court therefore concluded that "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." *Id.* at 158; see *ibid.* ("[A] court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the

patent."); *id.* at 159 ("To say this is not to require the courts to insist * * * that the Commission need litigate the patent's validity.").

The decision below is consistent with that approach. The court of appeals quoted this Court's statement that "[t]he size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." Pet. App. 18 (quoting *Actavis*, 570 U.S. at 158). The court then applied that principle to "this settlement." *Id.* at 19. The court observed that, "[i]f the parties thought Endo was highly likely to win the infringement suit, then [petitioner] would have been happy with a deal giving it nothing more than entry months in advance of the likely-valid patent's expiration." *Ibid.* In that context, the very fact that Endo felt the "need to add [a] substantial enticement," "potentially worth nine figures," suggests that the parties regarded the patent as weak. *Ibid.* The court properly concluded that, in these circumstances, it was unnecessary to inquire directly into "the likely outcome of the patent case." *Id.* at 18.

The Third Circuit's decision in *King Drug* is likewise consistent with that approach. Petitioner relies on the Third Circuit's statement that "antitrust law may prohibit settlements that are anticompetitive because," without justification, "they delay competition *for longer than the patent's strength would otherwise permit*." Pet. 24 (quoting *King Drug*, 791 F.3d at 409). But the italicized language does not mean, as petitioner suggests, that the Third Circuit required a direct inquiry into patent strength as part of the antitrust case. To the contrary, the Third Circuit recognized that, under *Actavis*, "the size of the unexplained reverse payment

can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." *King Drug*, 791 F.3d at 403 (quoting *Actavis*, 570 U.S. at 158). Applying that principle, the court concluded that the plaintiffs in that case had sufficiently pleaded an antitrust violation, because their allegations indicated that the settlement involved "an unusual, unexplained transfer of value from the patent holder to the alleged infringer." *Id.* at 409. Other Third Circuit decisions reflect the same understanding. See *FTC* v. *AbbVie Inc.*, 976 F.3d 327, 348 (2020) (explaining that "reverse-payment antitrust claims do not present a question of patent law" because "[t]he size of an unexplained reverse payment can provide a workable surrogate for a patent's weakness"), cert. denied, 141 S. Ct. 2838 (2021); *In re Lipitor Antitrust Litigation*, 868 F.3d 231, 251 (2017) ("A patent holder may be concerned about the validity of its patent, and so the size of the payment may very well correspond with the magnitude of that concern."), cert. denied, 138 S. Ct. 983, and 138 S. Ct. 984 (2018).

c. Petitioner argues (Pet. 25) that the court of appeals failed to consider "the settlement's real-world consequences" when assessing its anticompetitive effects. Specifically, petitioner asserts that the court should have asked whether, "in hindsight," the reverse payment turned out to harm competition. Pet. 26 (citation omitted). That contention is mistaken.

"[I]t is a basic antitrust principle that the impact of an agreement on competition is assessed as of 'the time it was adopted.'" Pet. App. 20 (quoting *Polk Bros.* v. *Forest City Enterprises, Inc.*, 776 F.2d 185, 189 (7th Cir. 1985) (Easterbrook, J.)). That principle applies with particular force in the context of reverse

payments, which can harm consumers by "prevent[ing] *the risk* of competition." *Actavis*, 570 U.S. at 157 (emphasis added). Determining whether a given payment had that effect necessarily requires an assessment of the risk that existed at the time of the settlement. See, *e.g.*, *Valley Drug Co.* v. *Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294, 1306 (11th Cir. 2003) (focusing on the facts "at the time the [reverse-payment] agreements [we]re entered into"), cert. denied, 543 U.S. 939 (2004).

In any event, petitioner's arguments from hindsight fail on their own terms. Petitioner asserts that the court of appeals "agreed that 'the settlement does not look anticompetitive in hindsight.'" Pet. 26 (quoting Pet. App. 20). But the court actually stated: "*Impax also argues* that the settlement does not look anticompetitive in hindsight." Pet. App. 20 (emphasis added). The italicized language, omitted from petitioner's quotation, shows that the court was describing petitioner's argument, not stating its own view.

In arguing that post-settlement events have shown the agreement not to be anticompetitive, petitioner asserts (Pet. i) that "the patents have been deemed valid and infringed in separate litigation." But that separate litigation involved patents different from the ones at issue here. See Pet. App. 20. The patents at issue here expired in 2013 without ever being fully litigated by anyone, much less found valid or infringed. See *id.* at 5.

Petitioner also observes (Pet. 26) that its "generic version is now the only version of the drug on the market." That is so, however, because of developments that occurred years after the settlement: Endo obtained additional patents that were successfully enforced, Pet. App. 20; Endo's product-hop strategy "ended up failing once Endo withdrew reformulated Opana ER from the

market due to safety concerns," *ibid.*; and Endo and petitioner struck an additional agreement that effectively keeps Endo from reentering the market for original Opana ER, in exchange for compensation from petitioner, *id.* at 127-128, 267. An otherwise unlawful conspiracy to restrict competition does not become lawful merely because the intended effects of the conspiracy do not come to pass for independent reasons.

d. Petitioner criticizes (Pet. 28-30) the court of appeals' analysis of the purported procompetitive effects of the settlement agreement. Those fact-bound arguments lack merit.

Petitioner asserts (Pet. 28) that the court of appeals "illogical[ly]" treated a settlement without a reverse payment as less restrictive than a settlement with such a payment "if the entry date is the same." But the court explained that the Commission's "ultimate ruling relied on an agreement with *an earlier entry date* as a less restrictive alternative." Pet. App. 25 (emphasis added). The court observed that petitioner "does not dispute that an agreement with an earlier entry date would be less restrictive." *Id.* at 26.

Petitioner also asserts (Pet. 28) that a less restrictive settlement would not have been "feasible." The *Actavis* Court recognized, however, that it will often be feasible "to settle patent disputes without the use of reverse payments." 570 U.S. at 158. The FTC found that alternative to be feasible in the circumstances of this case, Pet. App. 114-120, and the court of appeals sustained that finding, *id.* at 29-30. Petitioner asserts (Pet. 28) that a settlement with an earlier entry date would not have been feasible because "Endo steadfastly refused to accept any entry date before 2013." But the Commission made, and the court sustained, "adverse credibility

findings discounting the testimony of [petitioner's] lead settlement negotiator" on that point. Pet. App. 24-25.

3. Petitioner argues (Pet. 30-34) that the practical consequences of the decision below warrant this Court's intervention. But petitioner's account of those consequences rests on the erroneous premise (Pet. i) that the FTC and the court of appeals treated all reverse payments as "conclusively unlawful." Neither the FTC nor the court made any such determination. To the contrary, "[t]he Commission *rejected* the argument that just showing a large payment was enough to establish anticompetitive harm." Pet. App. 16 (emphasis added); see *id.* at 66. Indeed, although petitioner received multiple forms of payment under its settlement with Endo, the Commission concluded that only some of those payments were anticompetitive. See *id.* at 70-77 (finding some payments from Endo to petitioner to be anticompetitive, but declining to rely on other payments that may have been justified). The court's and the FTC's nuanced analyses belie petitioner's fears that, under the decision below, "patent settlements will always be unlawful whenever they contain a reverse payment and regardless of their procompetitive benefits." Pet. 30 (emphasis omitted).

Petitioner also suggests (Pet. 32) that large reverse payments are "often a necessary ingredient of getting both sides of a patent dispute to settle," and that the court of appeals' decision will deter such settlements. But "over 80 percent of brand-generic settlements reached within the year following *Actavis* did not include a reverse payment." Pet. App. 26. And in 2017, the most recent year for which data are available, only three of 226 brand-generic settlements included explicit compensation exceeding avoided litigation costs. See

Bureau of Competition, FTC, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Overview of Agreements Filed in FY 2017*, at 1-2, 6 (Dec. 3, 2020). In any event, "[t]hat some settlements might no longer be possible absent a payment in excess of litigation costs is no concern if the ones now barred would have simply facilitated the sharing of monopoly profits." *In re Cipro Cases I & II*, 348 P.3d 845, 869 (Cal. 2015).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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