Nos. 19-60394

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

IMPAX LABORATORIES, INCORPORATED,

Petitioner,

v.

FEDERAL TRADE COMMISSION

Respondent.

Petition for Review on an Order of the
Federal Trade Commission
(FTC Docket No. 9373)

BRIEF FOR THE AMERICAN ANTITRUST INSTITUTE, PUBLIC KNOWLEDGE, AND PATIENTS FOR AFFORDABLE DRUGS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

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CERTIFICATE OF INTERESTED PERSONS

The undersigned counsel of record for the American Antitrust Institute, Public Knowledge, and Patients for Affordable Drugs (*amici curiae* supporting Respondent) certifies that all interested persons described in the fourth sentence of Rule 28.2.1 who have an interest in the outcome of this case are listed in the Certificate of Interested Persons in Petitioner's brief and the briefs of *amici curiae* supporting Petitioner. These representations are made in order that the judges of this Court may evaluate possible disqualification. In addition, *amici curiae* supporting Respondent and their counsel are identified below:

The American Antitrust Institute is a non-profit corporation and, as such, no entity has any ownership interest in it.

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Dated: December 16, 2019

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INTEREST OF *AMICI CURIAE*[1]

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[1] All parties consent to the filing of this *amicus* brief. No counsel for a party has authored this brief in whole or in part, and no party, party's counsel, or any other person—other than *amici* or their counsel—has contributed money that was intended to fund preparing or submitting this brief.

[2] Individual views of members of the American Antitrust Institute's Board of Directors or its Advisory Board may differ from its positions.

Patients For Affordable Drugs is the only national not-for-profit patient organization focused exclusively on policies to lower the prices of prescription drugs. It does not accept funding from any organizations that profit from the development or distribution of prescription drugs.

INTRODUCTION AND BACKGROUND

The FTC's unanimous decision elaborating and applying the rule of reason to reverse-payment settlements was entirely consistent with *Fed. Trade Comm'n v. Actavis, Inc.*, 570 U.S. 136 (2013), and unremarkable. Rather than adopting an automatic presumption of illegality, as Impax claims, the Commission adopted strict requirements for establishing a prima facie case. It required Complaint Counsel to show not only that the brand drug manufacturer made a large reverse payment to its generic challenger, but also that the payment was unjustified, notwithstanding *Actavis*'s instruction that it is up to the "antitrust *defendant* [to] show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason." *Id.* at 156 (emphasis added).[3] And, having found that the reverse payment was large and unjustified, the Commission required Complaint Counsel additionally to show that "there was a risk of competition to eliminate." Op. 24. Moreover, the Commission required a showing of market power, and undertook a

[3] Complaint Counsel had sought a less demanding standard. *See* Op. 17.

full-blown analysis of the issue, notwithstanding its recognition that *Actavis* permits the inference of market power from a large and unjustified payment alone. *Id.* at 26-31.

Impax, in contrast, seeks a radical rewrite of *Actavis*. Although it concedes the existence of a large, unjustified reverse payment intended to delay generic entry (and that the brand manufacturer had market power), Impax would require the FTC to show that but for the reverse payment, generic entry would likely have occurred earlier. But such a causation requirement, which *private* plaintiffs may have to satisfy in order to show injury or damages, is inconsistent with *Actavis*'s directive that the relevant antitrust harm for establishing a violation of the Sherman Act (for the government or private plaintiffs) is preventing the "risk of competition." 570 U.S. at 157. Moreover, Impax would resurrect the "scope of the patent" test that *Actavis* rejected, by having courts treat as a procompetitive benefit the fact that a settlement allows generic entry before patent expiration—which is a widespread feature of Hatch-Waxman patent settlements with or without reverse payments. Impax would also open a huge loophole in *Actavis* by conjuring a procompetitive benefit out of another term that is ubiquitous in settlements without reverse payments—a broad patent license guaranteeing the generic firm "freedom to operate" in the event the brand manufacturer acquires additional patents. And

Impax would further upend *Actavis* by having courts view the procompetitive benefit of a broad patent license in hindsight, based on unanticipated and fortuitous events occurring after the settlement, rather than evaluating the competitive effects of a reverse-payment settlement at the time of the settlement, as the logic of *Actavis* and the rule of reason dictate. This Court should affirm to ensure that consumers, health insurers, employers, municipalities, states, and the federal government continue to enjoy the benefits of lower drug prices that *Actavis*'s restriction on anticompetitive reverse payments has enabled.

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In 2006, Endo Pharmaceuticals, Inc. (Endo), launched Opana ER, the brand name for an extended-release formulation of the opioid pain medication, oxymorphone hydrochloride. Op. 7. In 2007, Impax Laboratories, Inc. (Impax) filed an Abbreviated New Drug Application (ANDA) to market a generic version of Opana ER. *Id.* Impax was the first generic to file such an ANDA covering the five most popular dosage strengths of Opana ER, entitling it to a 180-day period of generic exclusivity. *Id.* In January 2008, Endo filed a patent infringement action against Impax alleging that Impax's generic products would infringe two patents expiring in September 2013. *Id.* The suit triggered Hatch Waxman's 30-month automatic stay, which meant that Impax could not launch before June 14, 2010. *Id.*

Endo estimated that each month of delayed generic entry was worth more than $20 million in net sales. Op. 7. To protect its Opana ER monopoly and blunt the impact of generic entry, Endo intended to (and did) engage in a "product hop"—that is, shift patients from Opana ER to a reformulated, crush-resistant version of the drug—which would destroy the market for original Opana ER before Impax could bring its generic to market. *Id.* at 7-8, 20.[4] Endo estimated that if its reformulated Opana ER beat generics to the market, its peak-year sales would exceed $199 million by 2016, but that if generics launched before Endo could transition the market, its peak-year sales would be only $10 million. *Id*. at 8.

In early June 2010, shortly after Impax received tentative FDA approval and just before expiration of the automatic stay, Endo and Impax settled their patent litigation with Impax agreeing not to launch its generic version of Opana ER for 30 months, until January 1, 2013–only nine months before the expiration of Endo's patents at issue. Op. 7-8. In return, Endo agreed that it would not launch an "authorized generic" (AG) during Impax's 180-day exclusivity period (the "No-AG Commitment") and would pay Impax a substantial sum if, as Impax feared, Endo

[4] "Product hopping" itself can be unlawful, especially when the original drug is pulled from the market. *See New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015). Product hopping thwarts generic entry because under state drug-substitution laws, the generic for the original drug is not identical to—and therefore not substitutable at the pharmacy for—the high-priced reformulated version, and "competition through state drug substitution laws is the only cost-efficient means of competing available to generic manufacturers." *Id.* at 655-56.

engaged in a product hop and substantially reduced its sales of original Opana ER before Impax's launch date (the "Endo Credit"). *Id.* at 9.[5] Endo provided a license to Impax that covered not only the patents at issue, but also any patents covering original Opana ER that Endo might subsequently acquire in the future. *Id.*

That broad license turned out to be valuable to Impax because Endo subsequently did acquire additional patents and successfully asserted them against other generic firms that sought to offer generic Opana ER and its reformulated version. Op. 10. Moreover, in 2017, Endo acceded to the FDA's request to remove its reformulated version from the market because of its increased risk of abuse. And because Endo had already removed its original Opana ER as part of its product hop, Impax was left as the only seller of an extended-release oxymorphone hydrochloride product, a monopoly status that it bolstered by obtaining Endo's agreement not to re-enter the market. *Id.* at 11, 46.

[5] "The Endo Credit was designed to 'back-up' the value of the No-AG Commitment and provide Impax with the profits it would have earned [during its 180-day exclusivity period, with no AG] had Endo not shifted the market away from original Opana ER." Op. 9; ALJ Initial Decision (ALJ) 34-35. In March 2012, Endo introduced its reformulated Opana ER and removed original Opana ER from the market. Op. 10. "Because these actions effectively eliminated the market for the branded original Opana ER, Endo was required to pay Impax $102 million under the Endo Credit." *Id.*

SUMMARY OF ARGUMENT

1. By discouraging "pay-for-delay" settlements that subvert the Hatch-Waxman Act, *Actavis* has saved patients and taxpayers billions of dollars per year and promoted innovation. Impax's radical rewrite of *Actavis* would undermine those gains.

2. Impax's challenge to the FTC's prima facie case rests entirely on its claim that although it agreed to delayed entry in exchange for a large, unjustified reverse payment, the FTC failed to show that it was likely that it would have entered the market earlier if the litigation continued. But *Actavis* imposes no such requirement; on the contrary, it identifies the relevant antitrust harm as eliminating a "risk of competition," which Impax does not contest occurred here. Impax claims that the FTC failed to show the elimination of more risk than the strength of Endo's patents warranted, but the large and unjustified reverse payment establishes precisely that. That is *Actavis*'s core holding.

3. The FTC correctly rejected Impax's purported procompetitive justifications. The fact that Impax was able to enter the market before patent expiration is not a cognizable procompetitive justification under *Actavis*. And the fact that Impax received a broad patent license that protected it from patents that Endo might subsequently acquire is also not a cognizable procompetitive justification for three independently sufficient reasons:

a. *First*, the broad license does not explain or justify the reverse payment nor offset any part of the restraint's anticompetitive effects. A large and unjustified reverse payment shows that the settlement with the broad patent license, as with an "early" entry license, is harmful to consumers compared to a settlement without such a payment or to the expected litigation outcome.

b. *Second*, there was no causal link between the broad patent license and the reverse payment. Impax failed to show that a reverse payment and delayed entry were reasonably necessary to reach a settlement that included a broad license. It invoked "asymmetric expectations or information" as precluding settlement but failed to show that such factors were at work here. And while Endo rejected a no-payment settlement offer with an earlier entry date, that does not mean that such a settlement was practically unavailable to parties seeking to comply with the law. At the same time, the FTC showed, based on its own experience, studies, and expert testimony, that settlements without a reverse payment are very viable, as *Actavis* suggested and post-*Actavis* empirical data confirms. And the vast majority of such settlements include the kind of broad patent license at issue here.

c. *Third*, any procompetitive benefit of the broad patent license was speculative and likely *de minimis*. Impax claims that the broad patent license turned out to be a boon for consumers, but it is improper to evaluate the competitive effects in hindsight. Rather, reverse-payment settlements must be evaluated *ex ante*, at the

time of the settlement, as the *Actavis* framework, the rule of reason, and pragmatic considerations dictate. At the time of the settlement, the value of the broad patent license was contingent on the uncertainties of whether Endo would acquire additional patents and could successfully enforce them against Impax. Moreover, if Endo's product hop destroyed the market for original Opana ER, as Endo intended and Impax feared, then the value of the broad license would have been slight in any event. That Endo and Impax considered the broad patent license to be inconsequential is confirmed by the negotiation history of the settlement.

ARGUMENT

I. THE *ACTAVIS* FRAMEWORK FOR SCRUTINIZING REVERSE-PAYMENT SETTLEMENTS BENEFITS CONSUMERS AND INNOVATION

As the Association for Accessible Medicines (AAM) points out, generic drugs provide "extraordinary savings [to] American patients and taxpayers [of] approximately $5 billion per week." AAM Br. 4. The Hatch-Waxman Act has helped drive those savings. And by discouraging "pay-for-delay" settlements that subvert the Hatch-Waxman Act, *Actavis* saves patients and taxpayers billions of dollars per year. *See* FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (2010), https://www.ftc.gov/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff; Michael Kades, *Competitive Edge: Underestimating the Cost of Underenforcing U.S. Antitrust*

Laws (Dec. 13, 2019), https://equitablegrowth.org/competitive-edge-underestimating-the-cost-of-underenforcing-u-s-antitrust-laws/ (calculating cost of reverse-payment settlements prior to *Actavis* to be over $60 billion). It also promotes innovation by encouraging brand-name drug manufacturers to invest more in developing new drug compounds or active ingredients protected by strong patents and less on making tweaks in formulations and changes in methods of use protected by weak secondary patents and reverse payments. *See* C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 Science 1386, 1387 (2013) (finding that most reverse-payment settlements involved challenges to secondary patents which generics were likely to win). At the same time, by restricting reverse payments, *Actavis* did not deter generics from pursuing paragraph IV challenges and the reward of 180 days of generic exclusivity to first filers, contrary to the predictions made by the generic drug industry in *Actavis* and here. *See* AAM Br. 5; Lex Machina Patent Litigation Report 5 (Feb. 2019) (showing significant increase in ANDA case filings since 2013). Accordingly, this Court should be wary of accepting Impax's invitation to undermine *Actavis.*

II. THE COMMISSION PROPERLY CONCLUDED THAT ENDO'S LARGE AND UNJUSTIFIED PAYMENT TO DELAY IMPAX'S ENTRY WAS PRIMA FACIE ANTICOMPETITIVE

The FTC found that Complaint Counsel made out a prima facie case of an anticompetitive reverse-payment agreement under *Actavis* by demonstrating that

Endo's No-AG Commitment (backed up by the Endo Credit) constituted a large and unjustified payment made in exchange for Impax agreeing to defer entry into the market, and that Endo had market power. Op. 16. As the Commission points out, Impax did not challenge the ALJ's finding that "the No-AG Commitment and Endo Credit had the 'purpose and effect' of 'inducing Impax to give up its patent challenge and agree not launch a generic Opana ER until January 2013.'" Op. 31 (quoting ALJ 6-7, alteration omitted). Nor does Impax appeal the FTC's market-power finding.

Impax argues that the FTC erred because evidence purportedly showed that actual anticompetitive harm was unlikely.[6] According to Impax, absent the settlement it was unlikely that Impax would have entered the market before the January 2013 agreed-upon entry date because the patent litigation was unlikely to finish before then, and Impax was unlikely to enter "at risk," i.e., before the litigation finished. Impax Br. 13, 36. Impax argues, therefore, that the "settlement allowed Impax to begin selling oxymorphone ER *earlier* than it would lawfully have been able to had litigation continued. Even if Endo had *no* chance of winning the patent

[6] While the ALJ found that Complaint Counsel *had* established a prima facie case, the ALJ considered the likelihood of anticompetitive harm in connection with the third step of the rule of reason, weighing pro-competitive benefits against the anti-competitive harm. Op. 13.

litigation . . . the settlement did not harm competition." *Id.* at 36 (emphasis in original).

A. The Relevant Antitrust Harm Under *Actavis* Is Preventing the Risk of Earlier Entry

The FTC properly rejected Impax's argument that a *prima facie* case requires showing that the entry date would likely have been earlier if the litigation continued. *See* Impax Br. 2, 17, 27, 28. If a plaintiff were required to show that earlier entry through litigation was more likely than not, then reverse-payment settlements involving strong patents would be *per se* legal because such patents are more likely than not to be found valid and infringed. But that is not the law because "the relevant anticompetitive harm" in a reverse-payment case is "prevent[ing] the *risk* of competition." *Actavis*, 570 U.S. at 157 (emphasis added); *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 404 (3d Cir. 2015) (*Actavis* "reasoned that 'even a small risk of invalidity' may not justify a 'large payment'" (quoting *Actavis*, 570 U.S. at 157)). Given a large and unjustified reverse payment, the FTC reasonably held that it was sufficient that "the generic drug manufacturer might plausibly have entered the marketplace prior to the

agreed entry date." Op. 24.[7] Beyond that threshold, the likelihood of earlier generic entry had the litigation hypothetically continued is irrelevant to whether a reverse-payment agreement violates the antitrust laws.[8]

B. A Large and Unjustified Payment Shows that Entry is Later than Warranted by the Strength of the Patent

Impax maintains that the FTC misconstrued *Actavis*'s holding that preventing the risk of competition is the relevant antitrust harm. Br. 32. Impax argues that the "relevant anticompetitive harm is eliminating the risk of competition by delaying generic entry *relative to what is justified by the strength of the patent*." *Id.* at 33 (emphasis added). Impax is correct about the legal principle. *See King Drug*, 791 F.3d at 404 (issue is the elimination of risk by delaying entry "for longer than the patent's strength would otherwise allow"); *In re Cipro Cases I & II*, 348 P.3d 845, 865 (Cal. 2015). But it is wrong that the FTC ignored it. On the contrary, the FTC concluded that Endo's large, unjustified reverse payment resulted in an agreed-upon entry date that presumably *was* later than what was warranted by

[7] Impax does not contest the FTC's conclusion that "ample evidence supports the proposition that there was a real threat of competition from Impax" entering before the agreed upon entry date. Op. 24. Obviously, Endo would not have paid it tens of millions of dollars to delay its entry until January 2013 if there was no real risk of Impax entering before then.

[8] In contrast, in order to show antitrust injury, a private plaintiff may have to show that but for the unlawful reverse payment, generic entry would likely have occurred before it actually did. *See In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 60 (1st Cir. 2016).

the strength of its patents, exactly as a "wealth of economic scholarship and analysis" predicts. *Cipro*, 348 P.3d at 867; *see, e.g.*, Aaron Edlin et al., *Activating* Actavis, 28 Antitrust 16, Fall 2013, at 17.

"Holding everything else equal, Impax's acceptance of payment would normally be expected to result in a later entry date than what Impax would have accepted based on the strength of the patents alone." Op. 42; *see also King Drug*, 791 F.3d at 405 & n.23; *Cipro*, 348 P.3d at 865. Indeed, as the FTC points out in its brief, Impax has *conceded* that the entry date it agreed to was later than its expected result in litigation based on the strength of the patents. *See* Impax Br. 45, 48, 53. And Endo would not have made a large, unjustified reverse payment if it did not believe that the agreed entry date was later than its expected result in litigation. Op. 24 ("A large payment would be an 'irrational act' unless the patentee believed such a payment would preserve its profits." (quoting Herbert Hovenkamp, *Anticompetitive Patent Settlements and the Supreme Court's* Actavis *Decision*, 15 Minn. J. L. Sci. & Tech. 3, 25 (2014))); *see Cipro*, 348 P.3d at 867 (large, unjustified payment indicates that "exclusion [is] beyond the point that would have resulted, on average, from simply litigating the case to its conclusion" because "[o]therwise, the brand would have had little incentive to settle at such a high price"). Indeed, Impax also recognizes this point. Br. 32 ("[T]he generic manufacturer in a reverse-payment settlement . . . will invariably accept at least a somewhat

later entry date than it might have been able to achieve had it continued litigating. *Otherwise, the brand manufacturer would refuse to settle*.") (emphasis added); *see also* ALJ 61(¶ 446) ("large reverse payment can imply that the market entry date in the settlement agreement is later than the date that the patent holder expected the alleged infringer would enter").

Thus, the FTC does *not* "define[] . . . the baseline level of competition as the earliest date that Impax might have entered the market, without regard for the possible validity of Endo's patents." Impax Br. 35. Rather, as is clear from its analysis, the relevant baseline is the entry date that the parties would have agreed to in the absence of a reverse payment, or the "the average period of competition that would have obtained in the absence of settlement." *Cipro*, 348 P.3d at 870; *id.* at 865 ("In the absence of payment, one would expect rational parties that settle to select a market entry point roughly corresponding to their joint expectation as to when entry would have occurred, on average, if the patent's validity and infringement had been fully litigated."); *see also King Drug*, 791 F.3d at 405. And, contrary to Impax's suggestion (Br. 36, 53), the FTC was not required to determine that baseline entry date. Departure from the baseline (towards delay) is established by the large, unjustified payment itself. *See Actavis*, 570 U.S. at 158 ("[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.").

So it is Impax, not the FTC, that distorts *Actavis*'s characterization of the relevant antitrust harm as preventing the risk of competition. Indeed, the FTC applied the risk-of-competition consideration in a manner favorable to *defendants* because it required Complaint Counsel to show that "there was a risk of competition to eliminate," notwithstanding the presence of a large, unjustified reverse payment. Op. 24. That was unnecessary. The recognition that a patentee would not make a large, unjustified payment *unless* the settlement provided for an entry date later than its expected result in litigation should be sufficient to establish that there was a risk of competition to eliminate.[9]

III. THE COMMISSION PROPERLY CONCLUDED THAT THE REVERSE PAYMENT HAD NO COGNIZABLE PRO-COMPETITIVE BENEFITS

Having found that Endo's large and unexplained reverse payment was prima facie anticompetitive—that it had the "purpose and effect" of delaying Impax's entry until January 2013 (Op. 31)—the FTC properly rejected Impax's purported pro-competitive justifications, namely that the settlement enabled Impax to enter before

[9] The FTC suggested that "a clear impediment to generic launch, such as a finding that the FDA had disapproved the generic firm's ANDA, would mean that no risk of competition was lost and therefore that no liability should lie." Op. 23-24. But a patentee would not make a large, unjustified reverse payment in those circumstances.

patent expiration and to do so with a broad license that protected it against Endo's later-acquired patents. According to Impax, the settlement "was a boon for patients" because Endo used those later-acquired patents to obtain injunctions against other generic firms that sought to sell original or reformulated Opana ER. Br. 1. "Impax might have fallen victim to the injunctions, too, were it not for the broad license." *Id.* at 11; *see also* ALJ 157 (purported "real world" procompetitive benefits of settlement "enabled a generic Opana ER to enter the market eight months before Endo's original Opana ER patents expired, and sixteen years before Endo's after-acquired patents expired"). But neither a license to enter before patent expiration nor a broad license to practice after-acquired patents—terms that are common to most Hatch-Waxman settlements with or without reverse payments—constitutes a legitimate procompetitive justification for the large reverse payment here.

A. Allowing Entry Before Patent Expiration is Not a Cognizable Procompetitive Benefit

The FTC properly rejected the argument that generic entry prior to expiration of the patent term is a cognizable pro-competitive justification for a reverse payment. This conclusion follows from the fact that a large and unjustified payment shows that the agreed upon "early" entry date is actually *later* than it would have been under a settlement with no payment or relative to the expected outcome

of litigation. *See* Op. 33 (noting that *Actavis* recognized that "patent licenses 'permitting the patent challenger to enter the market before the patent expires' bring about competition," but it also "stressed that competitive harm arises when the patentee makes a reverse payment to preclude the risk of *even earlier* competition" (quoting *Actavis*, 570 U.S. at 154) (emphasis in original)). Allowing such a justification would resurrect the "scope of the patent" test that *Actavis* rejected. *See Actavis*, 570 U.S. at 145 (settlement allowed entry 65 months before patent expiration); *King Drug*, 791 F.3d at 407 (reverse payment is "not immunized, of course, simply because of . . . early-entry 'license'"); *Cipro*, 348 P.3d at 870 ("antitrust defendant cannot argue a settlement is procompetitive simply because it allows competition earlier than would have occurred if the brand had won the patent action").

B. The Broad Patent License is Not a Cognizable Procompetitive Benefit

The broad patent license also is not a cognizable procompetitive benefit for three independently sufficient reasons. *First*, Impax failed to meet its burden "to show a procompetitive rationale *for the restraint*." *Ohio v. Am. Express, Inc.*, 138 S. Ct. 2274, 2284 (2018) (emphasis added). Impax emphasizes that the broad license enabled "early and sustained generic competition," Br. 41, but it ignores that the reverse payment was designed to do the opposite. As the FTC and ALJ found, the reverse payment was intended to induce Impax to delay its entry in the market

and thereby protect Endo's Opana ER franchise. *See Actavis*, 570 U.S. at 158 ("If the basic reason [for a settlement with a reverse payment] is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement."). Impax adduced no evidence to suggest that any of the benefits it attributes to the broad license were an intended consequence of the reverse payment or did anything to offset any part of the anticompetitive effects of concern (i.e., delayed generic entry). The FTC thus correctly held that the broad license did not "explain and justify the payment itself," as *Actavis* requires, or show that "the reverse payment leads to more competition than would have resulted without the payment." Op. 33, 36. As with an "early" entry license, a large unjustified reverse payment shows that the settlement with the broad patent license is harmful to consumers compared to a settlement without such a payment or relative to the expected outcome of litigation.[10]

[10] As explained *infra* at 24, the procompetitive benefits, like the anticompetitive effects, must be assessed at the time of settlement. A settlement with just an entry date and a broad license would not be problematic, even if the generic traded a somewhat later entry date for the broad license (which is not the case here, *see infra* at 26). But adding a large, unjustified payment to the mix only makes the entry date later. It is of no moment that Impax could not have obtained the broad license to the after-acquired patents by succeeding in the paragraph IV lawsuit. What counts is that in deciding whether to settle and provide a broad patent license, Endo would have taken into account any procompetitive "risks" of such a license. And it would not have made a large unjustified payment unless it believed the result in litigation (taking into account potential after-acquired patents) would be appreciably

Second, Impax failed to establish a sufficient (or any) causal link between the broad patent license and the reverse payment. *See N. Tex. Specialty Physicians v. FTC*, 528 F.3d 346, 369 (5th Cir. 2008) (procompetitive benefits not cognizable because petitioner "has no theory as to how its proffered procompetitive effects . . . result from or are in any way connected to" the anticompetitive restraints); *cf. Gen. Leaseways, Inc. v. Nat'l Truck Leasing Assoc.*, 744 F.2d 588, 595 (7th Cir. 1984) (Posner, J.) (restraint not ancillary where "the organic connection between the restraint and the cooperative needs of the enterprise . . . is missing"). Specifically, Impax failed to show that it could not obtain the benefits of a broad patent license without the harms of delayed generic entry.

Impax argues that the reverse payment "helped [the parties] bridge an otherwise insurmountable difference in positions," Br. 46, but the argument is factually and legally deficient. It fails on the facts because Impax never showed the kind of asymmetric expectations or information that some experts argue may preclude a brand manufacturer and a generic firm from reaching a settlement based on the strength of the patent alone.[11] Impax points out that Endo rejected Impax's offer of

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worse (more procompetitive from consumers' perspective) than under the settlement. Moreover, Impax has conceded that the result it expected in litigation (taking into account the possibility of Endo acquiring other patents and asserting them) was better (more procompetitive) than under the settlement. Br. 48.

[11] Impax cites Willig & Bigelow and Dickey et al. in support, Br. 46-47, but the circumstances in which asymmetric information may preclude an entry-only settle-

an earlier entry date without a reverse payment. *Id.* at 48. But this does not mean that an earlier entry date was practically unavailable.[12] As the FTC suggests, it means only that Endo *preferred* a date that extended its monopoly, and Impax was willing to agree to that date solely because Endo agreed to share its monopoly profits. Op. 41; *see* Kevin B. Soter, *Causation in Reverse Payment Antitrust Claims*, 70 Stan. L. Rev. 1295, 1336 (2018) (cautioning against "a rule [that] tells defendants that all they need to do to avoid liability is to insist in settlement talks that the only agreement they would make is an illegal one").

Impax's argument also fails on the law because *Actavis* rejected the facilitation-of-settlement justification for a large reverse payment. The Court emphasized that the absence of a payment "does not prevent litigating parties from settling their lawsuit. They may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's

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ment are not common. *See* Einer Elhauge & Alex Krueger, *Solving the Patent Settlement Puzzle*, 91 Tex. L. Rev. 283, 291 (2012). Significantly, the articles cited by Impax were also cited extensively in the briefs of the drug company respondents and their *amici* in *Actavis*. *See, e.g.*, Actavis Br. at 25, 2013 WL 662705; Solvay Br. at 57-58, 2013 WL 648743; Generic Mfgs. Br. at 18-22, 2013 WL 769339; Antitrust Economists Br. at 19-21, 31, 2013 WL 836946. But the Court nonetheless concluded that settlements without reverse payments were eminently feasible.

[12] The FTC rejected, as unsupported by the record, Impax's assertion that Impax received the earliest date that Endo was willing to offer. Op. 41 n.43. Notably, Endo had provided an earlier entry date to another generic firm that introduced generic Opana ER for two low-sales dosages. *Id.* at 30; ALJ 17(¶ 87).

expiration, without the patentee paying the challenger to stay out prior to that point." 570 U.S. at 158; *see also Cipro*, 348 P.3d at 868 (no-payment settlements are "ordinarily" available).[13] The FTC also pointed to expert testimony in the case and its own studies which together show that "'settlements are very viable without reverse payments'" and that "branded and generic pharmaceutical companies routinely—and far more often than not—settle patent litigation disputes without reverse payments, consistent with the Supreme Court's statements in *Actavis*." Op. 40 (quoting expert). Moreover, although it was not necessary for the FTC to show that a settlement with no payment and earlier entry *would* have been reached, *see* FTC Br. 54, courts routinely accept such an alternative-settlement scenario as a basis for showing private plaintiffs were injured. *See, e.g.*, *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2018 WL 563144, at *21-23 (D. Mass. Jan. 25, 2018); *United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA*, 296 F. Supp. 3d 1142, 1162-64 (N.D. Cal. 2017); *In re Androgel Antitrust Litig. (No. II)*, 2018 WL 2984873, at *15-*17 (N.D. Ga. June 14, 2018).

[13] *Cipro* also points out that bridge-the-gap settlements ordinarily are bridges to anticompetitive results. *See Cipro*, 348 P.3d at 869 n.17 ("Money may be needed to bridge the gap between the parties' expectations, but a rational brand asked to pay more than its litigation costs to persuade a generic with different perceptions would, in the ordinary case, presumably just litigate."). The same is true here. *See supra* n.10.

Notably, there is nothing unusual about no-payment Hatch-Waxman settlements that give the generic firm a broad patent license. On the contrary, the FTC's most recent report on final settlements of Hatch-Waxman cases found that in 82 percent of settlements, the generic company received rights not only to the patents at issue in the litigation, but also to licenses or covenants not to sue for *all* brand patents that might cover the generic product at any time after the settlement. *See* FTC Br. 43 n.9 (citation for report). And the report showed that few of the reported settlements involved any obvious reverse-payment concerns.

Accordingly, to the extent that the FTC adopted a presumption that parties can settle Hatch-Waxman patent suits without reverse payments, such a presumption is fully justified, and Impax failed to show that such a settlement was not practically available here.

Third, the broad patent license is not a cognizable procompetitive benefit for the additional reason that its *ex ante* value was speculative and *de minimis*. To be sure, it *turned out* to be valuable to Impax, especially after a monopoly landed in its lap.[14] And the ALJ found the benefits to be "substantial." Op. 14. But it is error to evaluate the competitive effects of the broad license in hindsight.

[14] Even in retrospect, the benefits to competition that Impax's generic original Opana ER may have provided while reformulated Opana ER was on the market were limited not only by the product hop, but by the royalties Impax was required to pay Endo. *See* Op. 10; CCFF ¶1419 (Endo sought royalty of 85% of Impax's gross profits). Moreover, it would be a mistake to assume that there would be no

It is well settled that the competitive effects of a reverse-payment settlement are evaluated *ex ante*, at the time of the settlement. *See Cipro*, 348 P.3d at 870 ("[a]greements must be assessed as of the time they are made"); *Valley Drug Co. v. Geneva Pharms, Inc.*, 344 F.3d 1294, 1306 (11th Cir. 2003) ("the reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into"); *Apotex, Inc. v. Cephalon, Inc.*, 255 F. Supp. 3d 604, 611 (E.D. Pa. 2017) ("rule of reason analysis is conducted on an ex ante basis"); *In re Lo-estrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 337 (D. R.I. 2017) ("deal must be valued at the time the parties entered the deal"); *see generally* Herbert Hovenkamp, *Antitrust and the Patent System: A Reexamination*, 76 Ohio St. L.J. 467, 523 (2015) ("settlements as well as other licensing agreements must be analyzed ex ante, based on the parties' reasonable expectations, rather than ex post"); *see also* Economists Br. 12-13 (it is "important for the settlement terms to be evaluated on an ex ante basis").

The *ex ante* approach is inherent in *Actavis*'s framework and consistent with the rule of reason generally. *See, e.g.*, *Polk Bros., Inc. v. Forest City Enters.*, 776 F.2d 185, 189 (7th Cir. 1985); FTC & U.S. DOJ, *Antitrust Guidelines for Collaborations Among Competitors* §2.4 (2000). An *ex post* approach would also be unfair

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Opana ER on the market today but for the broad license, as Endo would have had a strong incentive to at least license original Opana ER after it had to pull the reformulated version from the market. CCFF ¶1435.

and impractical, making it difficult or impossible for settling parties to conform their behavior to the law.

Under *Actavis*'s *ex ante* approach, a reverse-payment settlement that allows entry before patent expiration is not made lawful because a court ultimately finds the patent to be valid and infringed by the generic product. *See Cipro*, 348 P.3d at 870. Nor is a settlement that defers generic entry automatically anticompetitive because the patent turns out to be invalid or not infringed by the generic product. *Id.*; *see Valley Drug*, 344 F.3d at 1306-07. So too here, the analysis of the reverse payment's competitive effects would not change if Endo's two original patents at issue were later found to be valid or infringed. And it is just as irrelevant to the analysis of competitive effects that Endo's after-acquired patents were found to be valid and infringed as it would be if the after-acquired patents were found to be *invalid* or *not* infringed.

At the time of the settlement, the benefit of the broad patent license was highly uncertain at best. The value of the broad license would have depended in part on the expected likelihood that Endo would acquire additional patents and that they would be found valid and infringed by Impax's generic Opana ER. But, as Endo's attorney stated, "nobody knew whether those patents were going to issue." *See* FTC Br. 39. The value also would have depended on the expected size of the market for the original version of Opana ER from which Impax might otherwise

have been excluded. But if Endo's product hop was successful, the market for the original Opana ER would be "destroyed," and the value to Impax of the broad patent license (or the cost to Endo of giving up the right to exclude) would be slight, regardless of the likelihood of additional patent rights maturing. And destruction of the market is exactly what Endo expected and Impax feared. Op. 7-9. That Endo considered the broad license to be inconsequential is confirmed by the negotiation history of the settlement, which shows that Impax proposed the broad license, and Endo quickly acceded to it, after the parties had reached agreement in principle on the entry date, reverse payment, and other terms. ALJ 29(¶¶169-170).

Accordingly, the purported procompetitive benefits of the broad patent license should be rejected as speculative and *de minimis*. *See Competitor Collaboration Guidelines* § 3.36(a) (speculative efficiency claims not considered). Measured from Endo's perspective, the procompetitive "cost" of the broad patent license was negligible. *Cf.* Economists Br. 12 (arguing that a reverse payment should be valued *ex ante* "from the patentee's perspective"). Likewise, from Impax's perspective, the expected value was apparently slight. In all events, contrary to Impax's claim, Br. 1, 13, the unanticipated and largely accidental "real world" (i.e., *ex post*) benefits of the broad license are not the proper measure of its procompetitive benefits.

CONCLUSION

The Court should follow *Actavis* and affirm the FTC's decision.

Respectfully submitted,

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Dated: December 16, 2019

CERTIFICATE OF SERVICE

I certify that on December 16, 2019, I served the foregoing brief on counsel of record using the Court's electronic case filing system. All counsel of record are registered ECF filers.

s/ Richard M. Brunell

Dated: December 16, 2019

CERTIFICATE OF COMPLIANCE

I certify that the foregoing brief complies with the volume limitations of Fed. R. App. P. 32(a)(7)(B) because it contains 6497 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii), and that it complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it was prepared using Microsoft Word in 14 point Times New Roman type.

s/ Richard M. Brunell

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