No. 19-60394

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

IMPAX LABORATORIES, INCORPORATED,
a corporation,
Petitioner,

v.

FEDERAL TRADE COMMISSION,
Respondent.

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

BRIEF OF THE FEDERAL TRADE COMMISSION [REDACTED PUBLIC COPY]

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REQUEST FOR ORAL ARGUMENT

The FTC requests oral argument. This case will be the Court's first opportunity to apply *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013), which held that "reverse-payment" settlements can violate the antitrust laws.

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INTRODUCTION

Generic drug competition saves consumers billions of dollars each year—but those savings cannot be realized if generic manufacturers collude with their brand-name counterparts to share the brand's monopoly profits rather than compete. In this antitrust case, a generic manufacturer agreed not to compete with a patented brand-name drug for two-and-a-half years in exchange for a large, unjustified payment. The deal settled a lawsuit challenging the drug patents and allowed the brand-name company, Endo Pharmaceuticals, to avert the risk that its patents would be declared invalid or not infringed and that it would face generic competition. Endo shared its now-secured monopoly profits with its would-be competitor, petitioner Impax Laboratories, in return for Impax's agreement to stay out of the market. Impax acknowledges that without this payment, it would have rejected Endo's proposal to defer generic competition. Br.45, 48, 53. Impax and Endo benefitted, while consumers lost.

In *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013), the Supreme Court explained how such collusive patent settlements can harm competition. The payment allows the brand company to eliminate the "risk of competition" and "induce[s] the generic challenger to abandon" its patent challenge in return for "a share of [the brand's] monopoly profits that would otherwise be lost in the competitive market." 570 U.S. at 154, 157. These "anticompetitive consequences" guarantee that drug

prices remain at monopoly levels. *Id.* 156. Since Impax *admits* taking a payment in return for staying out of the market and provides no other justification for the payment, the teachings of *Actavis* fit this case like a glove.

Applying the antitrust rule of reason to the Impax-Endo agreement, as called for in *Actavis*, the Federal Trade Commission found the deal unlawful. First, the Commission determined that the agreement harmed competition in light of Endo's market power and the payment's effect of eliminating Impax's threat to Endo's monopoly. It then held that Impax had failed to proffer any plausible procompetitive justifications for the payment to stay off the market. Finally, the Commission ruled that even if Impax's purported justifications were credited, settling without the payment would have been a viable, less-restrictive alternative.

As shown below, the Commission's ruling was correct and should be affirmed. The Supreme Court rejected Impax's argument that the payment's anticompetitive harm can be offset by the benefits of a license allowing generic entry before patent expiration. *Actavis*, 570 U.S. at 154. And while Impax claims that unforeseeable events occurring years after the settlement render it procompetitive, antitrust law requires examining an agreement's effects "at the time it was adopted." *Polk Bros, Inc. v. Forest City Enters.*, 776 F.2d 185, 189 (7th Cir. 1985).

JURISDICTION

The Commission's Final Order was entered on March 28, 2019 and served on Impax on April 8, 2019. Impax timely petitioned for review on June 6, 2019. The Court has jurisdiction under 15 U.S.C. §45(c).

QUESTIONS PRESENTED

1. Whether Impax's acceptance of a large and unjustified payment to stay off the market harmed competition by eliminating the threat to Endo's monopoly.

2. Whether Impax demonstrated that the payment to stay off the market had any procompetitive rationale.

3. Whether Impax and Endo could have achieved the purported procompetitive objectives without a payment to stay off the market.

STATEMENT OF THE CASE

A. Legal Framework For Generic Drug Competition

Generic drug competition lowers prices for consumers. When the first generic enters the market, it is typically priced 10 to 25 percent lower than the brand-name drug. IDF31 (R17).[1] Subsequent generic entry ultimately leads to prices 50 to 80 percent below the original price. *Id.* All 50 states, the District of

[1] "Op." means the Commission's opinion, "ID" means the ALJ's Initial Decision, and "IDF" means the ALJ's numbered findings of fact.

Columbia, and health insurance plans encourage pharmacists to automatically substitute cheaper generics for branded drugs. IDF29-30, 32 (R17).

Congress encourages generic competition by facilitating their approval and establishing incentives to market them. The Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act, governs the process. Hatch-Waxman creates a streamlined method for regulatory approval of generics. A company seeking to market a new branded drug must submit a New Drug Application to the FDA showing that the drug is safe and effective. 21 U.S.C. §355(a), (b)(1). A generic company need only file an Abbreviated New Drug Application showing that its product is "bioequivalent" to the brand-name drug. 21 U.S.C. §355(j).

Brand-name drugs are often covered by patents, although many pharmaceutical patents do not withstand judicial scrutiny. Hatch-Waxman provides a timely way to resolve patent disputes between brand and generic companies. When the generic company files its application, it may provide a "Paragraph IV" certification declaring that its product will not infringe any patents identified by the brand company or that such patents are invalid. 21 U.S.C. §355(b)(2)(A)(iv), (j)(2)(A)(vii)(IV). The certification is deemed to infringe, thus permitting the patentee (typically the brand company) to sue immediately. 35 U.S.C. §271(e)(2).

A Paragraph IV infringement lawsuit blocks the FDA from approving the generic application for 30 months, unless the case is resolved earlier. 21 U.S.C. §355(c)(3)(C), (j)(5)(B)(iii). If the suit is still pending after 30 months, the generic manufacturer may launch its product "at risk," the risk being monetary liability should the court later find the patents valid and infringed. *See In re Lipitor Antitrust Litig.*, 868 F.3d 231, 241 (3d Cir. 2017).

Hatch-Waxman creates an incentive for generic manufacturers to challenge a brand company's patents under Paragraph IV by awarding the first-filer a 180-day exclusivity period. This exclusivity blocks the FDA from approving any subsequent generics until 180 days after the first-filer enters the market. 21 U.S.C. §355(j)(5)(B)(iv). This freedom from competition has considerable value: generic revenues earned during the exclusivity period often dwarf revenues from the product's remaining time on the market. *See Actavis*, 570 U.S. at 144. Nevertheless, a brand manufacturer may introduce its own "authorized generic," or "AG," during the first-filer's 180-day window, which can compete with the first-filer's product and significantly reduce the profitability of the exclusivity period. *See King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 396 (3d Cir. 2015).

Although Hatch-Waxman was meant to promote competition, it also creates "special incentives" for brand and generic manufacturers to conspire to thwart

competition. *Actavis*, 570 U.S. at 156. Because branded drugs are usually priced much higher than generics, the brand manufacturer stands to lose far more revenue from generic competition than the generic rival stands to gain. *Id.* 154. Almost always, brand and generic manufacturers both will be better off if the generic agrees to defer entry in return for "a share of [the brand's] monopoly profits." *Id.* Such settlements subvert competition by removing the generic's incentives to challenge "unwarranted patent grants," *id.* 151, and to launch its product as early as possible. Deferred entry also creates a "bottleneck" preventing entry by other generic sellers, who cannot compete until the close of the 180-day exclusivity period. *In re Nexium Antitrust Litig.*, 842 F.3d 34, 41 (1st Cir. 2016). In such collusive settlements, "[t]he patentee and the challenger gain; the consumer loses." *Actavis*, 570 U.S. at 154.

A Paragraph IV litigation settlement where the brand pays the generic is known as a "reverse payment" agreement. *Id.* 141. In *Actavis*, the Supreme Court found these settlements to be "unusual," since the generic, "a party with no claim for damages[,] walks away with money simply so it will stay away from the patentee's market." *Id.* 147, 152. The antitrust legality of these settlements depends on whether the payment can be justified by "traditional settlement considerations, such as avoided litigation costs or fair value for services" the generic has agreed to provide. *Id.* 156. A reverse-payment settlement may harm

competition even if it allows generic entry before the patents expire, since those patents may be invalid or not infringed. *Id.* 147-48, 154.

Brand and generic rivals may structure reverse payments in forms other than cash. They may, for instance, enter into "no-AG" agreements, in which the payment takes the form of the brand's pledge not to launch an authorized generic during the 180-day exclusivity period. IDF185 (R37). That is tantamount to a cash payment because it allows the generic first-filer to earn more sales at higher prices. IDF177, 180 (R36). No-AG agreements can serve as anticompetitive reverse payments under *Actavis*. *Smithkline Beecham*, 791 F.3d at 403-09; *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 549-52 (1st Cir. 2016).

B. Opana ER And Potential Generic Competition

The drug products at issue here are the extended-release opioid Opana ER and its generic equivalent, oxymorphone ER. IDF41-43, 55 (R18-20). The FDA approved Opana ER in 2006. IDF46 (R19). In 2007, Impax filed an abbreviated application for a generic equivalent with a Paragraph IV certification asserting that three of Endo's patents were invalid or not infringed by its product. IDF55-60 (R20). As the first generic filer to challenge Endo's patents, Impax was eligible for 180 days of exclusivity once it entered the market. IDF174 (R36). Endo promptly sued Impax for infringement of two patents set to expire in September 2013. IDF53, 61, 68 (R19, 21). Endo's suit triggered the 30-month Hatch-

Waxman stay, which barred the FDA from approving Impax's generic until June 2010. IDF62-63 (R21).

The parties briefly discussed settlement in 2009. Impax proposed entry dates in 2011, but Endo rejected them. IDF112-18 (R27). Negotiations resumed on May 17, 2010, when Endo learned that the FDA planned to approve Impax's drug when the 30-month stay ended in June. IDF119-22, 283 (R28, 49). The patent trial was also set to begin in early June. IDF73 (R22). Endo recognized that Impax could introduce its generic at-risk in June or July 2010, or after the infringement trial and appeals as early as mid-2011. A185-86, 188, 228.

Before the settlement, Impax was preparing to launch its generic product at-risk. Its executives had informed the board of directors that "Oxymorphone was a good candidate for an at-risk launch." IDF493-97 (R72-73); *see also* A126-27, 136-37, 164-65, 198-99, 201-02. The company had obtained DEA approvals, manufactured over $1 million worth of product (which it destroyed after the settlement), obtained letters of intent from purchasers, and taken other steps. IDF537-40 (R77-78); A142-60, 166-70, 213-15. Internal documents prepared just two weeks before the settlement forecasted only two possible launch dates: June 2010 ("upside") or July 2011 ("base"). A207, 210.

For its part, Endo had a massive financial incentive to prevent or delay generic competition for Opana ER. It projected a loss of 85 percent of sales within

three months of generic launch and $100 million lost revenue within six months. IDF133 (R30); A174. Facing the demise of its market, Endo developed a plan to extend its monopoly. Endo would remove original Opana ER from the market and replace it with a reformulated version. IDF96-98, 102 (R24-25). Once patients had switched to the reformulation, pharmacists could not automatically substitute generic oxymorphone ER (since the products are not bioequivalent), thereby degrading the market for the generic. IDF199-204 (R39). This strategy is known as a "product hop." But Endo's plan depended on having enough time to switch patients to the reformulated version of Opana ER *before* Impax launched its generic version of the original product. IDF99-107 (R25-26).

When the parties resumed settlement negotiations in 2010, Endo knew that an Impax at-risk launch—or even a launch following appeal in late 2011—would foil its plan to extend its Opana ER brand monopoly. IDF107 (R26). Indeed, by that time Endo had not even sought FDA approval for the reformulated product, which could take up to ten months. IDF105 (R26). Switching over patients would take another six to nine months. IDF106 (R26). Endo therefore decided that if Impax's generic reached the market first, Endo would launch an authorized generic to compete with Impax. IDF108-09, 192 (R26, 38). To prevent that outcome, Endo's principal goal in settlement was to defer Impax's market entry until after the product hop. *See* IDF99-101, 147, 154, 156, 158 (R25, 31-33).

Beating Impax to the market and successfully product hopping would mean hundreds of millions in additional monopoly profits. Endo estimated that introduction of reformulated Opana ER before Impax's entry would yield annual sales of $199 million by 2016. If Impax launched first, however, that figure would be reduced to $10 million. IDF99 (R25); A191.

Impax was concerned that Endo might product hop and that any delay in entry would allow Endo to destroy the market for Impax's generic. IDF204-05 (R39-40). Impax had an eye on a profitable settlement, since a no-AG promise "would be a great outcome," A225, resulting in at least $23 million in additional sales in the first six months. IDF190-91 (R38). But Impax also considered it "super, super important" that Endo offer "downside" protection in the form of a cash "true-up payment" should Endo wipe out the generic marketplace before Impax's launch. IDF206-11 (R40).

C. The Endo-Impax Settlement

The parties executed a Settlement and License Agreement (SLA) on June 7, 2010. IDF73-74 (R22). Impax agreed not to launch its generic for two-and-a-half years, until January 1, 2013. IDF124 (R28); A38-39, 46 (SLA §§1.1, 4.1(a)). As Endo explained to its investors, the breathing room granted by the settlement gave the company a "clear path … to establish … demand" for the reformulated product. A316. Under the agreement, Endo promised to:

1. Refrain from selling its own authorized generic during Impax's 180-day exclusivity period (which would start at the 2013 launch). IDF127, 130 (R29); A47-48 (SLA §4.1(c)).

2. Give Impax what amounted to an insurance policy against market damage from the product hop. The so-called "Endo Credit" required Endo to pay Impax cash if Endo's sales for original Opana ER fell by more than 50% between their quarterly peak and the fourth quarter of 2012 (right before Impax's launch date). IDF129, 195 (R29, 38); *see* A40, 43, 49 (SLA §§1.1, 4.4). The payment was designed to approximate what Impax's revenues from the exclusivity period would have been had Endo not shifted the market. IDF212-14 (R40-41).

3. Provide Impax with a license to its current patents and others that it might later acquire covering original Opana ER. Endo also promised not to sue Impax for infringing those patents. IDF125-26, 567-68, 570 (R28-29, 81); A46-47 (SLA §4.1(a)-(b)).[2]

[2] Endo and Impax also executed a Development and Co-Promotion Agreement regarding a potential Parkinson's disease treatment. IDF244-46 (R44-45). Endo made an upfront cash payment and promised additional milestone payments in exchange for a share of future profits. IDF247-50 (R45). The ALJ found that the Parkinson's drug side deal was justified by the value Endo received, ID132, 138 (R138, 144), and while the Commission expressed skepticism about that conclusion, it declined to resolve the issue. Op.21-22 (R189-90).

D. Events After The Settlement

Six days after the settlement, the FDA granted final approval to Impax's generic. IDF66 (R21). But for its agreement to stay off the market until 2013, Impax would have been able to launch at risk on June 14, 2010. *Id.* No other generic manufacturers could enter the market until six months after Impax's 2013 launch. IDF449 (R67).

In March 2012, Endo introduced reformulated Opana ER and stopped selling the original product. IDF110, 229-31 (R26, 43). To eliminate demand for the original version, Endo publicly declared it unsafe and asked the FDA to withdraw approval of Impax's generic. IDF233 (R43). (The FDA disagreed and found that Endo had *not* withdrawn the product for safety reasons. IDF235 (R43)). Having decimated the market for original Opana ER, Endo paid Impax $102 million under the Endo Credit insurance policy. IDF236-37 (R44).

More than two years later, the Patent and Trademark Office issued additional patents to Endo related to Opana ER. IDF575-77, 579-84 (R82-83). Based on those patents, Endo won court rulings enjoining manufacturers (other than Impax) from selling generic versions of the original drug until at least 2023. IDF578, 586-87 (R82-83).

Impax has sold generic oxymorphone ER since January 2013 and is the only generic on the market. IDF596-97 (R84-85). In 2017, Endo agreed not to compete

with Impax under the terms of a new settlement agreement resolving a royalties dispute. IDF590 (R84). [redacted] Op.45-46 (R213-14). Impax is "now in the role of a monopolist" paying Endo "to stay out of the market." *Id*. 46 (R214).

Finally, although Endo's product hop was initially successful, the FDA determined in 2017 that Endo's reformulated Opana ER was unsafe, and Endo withdrew it from the market. IDF111 (R27); A313-15. Impax's generic is the only extended-release oxymorphone product available to consumers. IDF598 (R85).

E. The FTC's Complaint And The ALJ's Initial Decision

The FTC filed an administrative complaint against Impax in January 2017 charging that the reverse-payment settlement was an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. §45(a). (The FTC had already settled a related case against Endo.) Although Impax now disparages the FTC's administrative process as "the fox in charge of the henhouse" and claims

"the fix was in from the start" (Br.2), *Impax itself* demanded that the FTC use that process rather than suing in federal court.[3]

The case was tried before an administrative law judge who found that the reverse payment was large and unjustified, and thus anticompetitive, but that its effects on competition were "outweigh[ed]" by the procompetitive benefits of *other* parts of the settlement. ID157-58 (R163-64). Specifically, the ALJ found that Endo's no-AG agreement backed up by the Endo Credit were worth no less than $23 million to Impax and had the "purpose and effect" of "induc[ing] Impax to give up its patent challenge and agree not to launch a generic Opana ER until January 2013." *Id.* 6-7, 138-39 (R12-13, 144-45). The payment was not justified by avoided litigation costs or any services that Impax provided. *Id.* 114-16 (R120-22). The ALJ also found that Endo possessed market power—the ability to raise prices—in a product market consisting of brand and generic Opana ER. *Id.* 139-41 (R145-47). The ALJ nevertheless concluded that the settlement as a whole promoted competition by giving Impax a patent license allowing it to sell generic

[3] The FTC first sued Impax in district court, and Impax sought dismissal on the ground that the agency must "follow[] the path prescribed by Congress—an administrative proceeding under the FTC Act." Mem. of Law in Support of Defts' Mtn. to Dismiss, *FTC v. Endo Pharms Inc.*, 2:16-cv-01440-PD, ECF No. 69-2 at 10 (E.D. Pa. Jul. 12, 2016). All five Commissioners who voted unanimously to hold Impax liable were appointed after the complaint was issued.

Opana ER before Endo's existing and later-issued patents expired. *Id.* 145-46 (R151-52).

F. The Commission's Opinion And Final Order

The Commission unanimously reversed the ALJ's decision. The Commission assessed the record evidence under the antitrust rule of reason. Op.15 (R183). The plaintiff (here, FTC staff known as Complaint Counsel) first must "prove that the challenged restraint has a substantial anticompetitive effect that harms consumers in the relevant market." *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2284 (2018). The burden then "shifts to the defendant to show a procompetitive rationale for the restraint." *Id.* If the defendant succeeds, the burden "shifts back to the plaintiff to demonstrate that the procompetitive efficiencies could be reasonably achieved through less anticompetitive means." *Id.*

1. The Reverse Payment Harmed Competition

The Commission explained that in a reverse-payment case, a plaintiff's initial burden of showing harm to competition has two elements: (1) proof of "a large and unjustified payment" in exchange for "deferring entry into the market or for abandoning a patent suit"; and (2) market power. Op.16 (R184). The Commission ruled that Complaint Counsel satisfied both elements. *Id.* 17-31 (R185-99).

Impax did not dispute the ALJ's finding that it received a large and unjustified payment from Endo that induced it to abandon its patent challenge and agree to the 2013 entry date. *See id.* 19, 31 (R187, 199). The Commission found that the no-AG commitment conferred a valuable six-month generic monopoly, and that the Endo Credit allowed Impax to "share in the value created" should Endo "destroy" the generic market. *Id.* 19-20 (R187-88). The value of these provisions far exceeded any saved litigation costs, did not reflect any services Impax promised to provide, and could not be explained as anything other than compensation to induce Impax to accept the January 2013 entry date. *Id.* 18-19 (R186-87). The Commission held that the large and unjustified reverse payment amounted to Endo's "purchasing an exclusive right" to sell the product before January 2013. *Id.* 17 (R185).

The Commission reversed the ALJ's conclusion that the anticompetitive effects were merely "theoretical" because Impax would have been unlikely to launch before the agreement's January 2013 entry date. Op.22-24 (R190-92). "*Actavis* makes clear that the relevant anticompetitive harm in a reverse payment case is 'prevent[ion of] the *risk* of competition.'" *Id.* 23 (R191) (quoting *Actavis*, 570 U.S. at 157) (emphasis added by Commission). The Commission rejected the ALJ's conclusion that Impax was unlikely to have entered the market before 2013. Op.23 (R191). Instead, the Commission found "a real threat of competition from

Impax," as evidenced by Impax's preparations for an at-risk launch. *Id.* 24 & n.25 (R192); *see supra* p. 8. Because Complaint Counsel successfully demonstrated a risk of competition, the ALJ erred by "speculati[ng]" that Impax would not have competed. Op.24 & n.26 (R192). Had Impax posed no threat to Endo's monopoly, the reverse payment would have been an "irrational act." *Id.* 24 (R192) (citation omitted).

2. Impax Failed To Show A Procompetitive Justification For The Payment To Stay Out Of The Market

The burden then shifted to Impax to demonstrate a procompetitive justification for the restraint. Op.31 (R199). Impax claimed that the restraint it had to justify was the settlement agreement as a whole (including the patent license), and not just the payment itself. The Commission rejected that idea, explaining that "the relevant restraint is … the payment in exchange for the elimination of the risk of entry." *Id.* 32 (R200) (discussing *Actavis*, 570 U.S. at 157). That conclusion followed directly from *Actavis*, which defined the "specific restraint at issue" as "a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose" if the generic prevailed in patent litigation. *Id.* 33 (R201) (quoting *Actavis*, 570 U.S. at 153-54). *Impax* thus had the burden "to explain and to justify" the "reverse payment" to stay out of the market. *Id.* (quoting *Actavis*, 570 U.S. at 158).

The Commission concluded that Impax failed to show a "logical nexus" between the payment and any procompetitive objective. *Id.* 32 (R200) (quoting *N. Tex. Specialty Physicians v. FTC*, 528 F.3d 346, 368-69 (5th Cir. 2008)). It found that Impax had not demonstrated why "it needed to accept these payments in order to enjoy the procompetitive benefits of the patent license" or why it could not have obtained the very same patent license without the reverse payment. *Id.* 32, 37 (R200, 205). Rather, Impax did not dispute that the payment was meant to "prevent[] Impax from demanding an even earlier entry date." *Id.* 37 (R205).

3. Impax Could Have Achieved The Same Outcome With A Less-Restrictive Alternative

The Commission then held that even if the payment had a procompetitive justification, Impax could have achieved the benefits of a broad patent license by settling without the payment. *Id.* 39-42 (R207-10). As *Actavis* held, parties can settle Paragraph IV litigation by entering into licensing agreements allowing entry "prior to the patent's expiration," without sharing the brand's monopoly profits to prevent earlier entry. *Id.* 40 (R208) (quoting *Actavis*, 570 U.S. at 158). The Commission credited expert testimony showing that "branded and generic companies routinely—and far more often than not—settle patent litigation disputes without reverse payments." *Id.* The Commission also found that Impax lacked record support for its assertion that it secured the "earliest [entry] date that Endo was willing to offer." *Id.* 41 n.43 (R209). Instead, the Commission found that the

"only impediment" to a no-payment settlement was "the parties' desire to preserve and split between themselves monopoly profits," which is the essence of a violation under *Actavis*. *Id.* 42 (R210).

The Commission entered a remedial order prohibiting Impax from entering into future agreements likely to raise similar antitrust concerns. A320. The order did not invalidate any of Impax's current agreements.

SUMMARY OF ARGUMENT

Impax accepted a large payment to drop its patent suit and stay off the market for two-and-a-half years, allowing Endo to avoid the risk to its patents, to preserve its monopoly profits (which funded the payment to Impax), and to effectuate its monopoly-enhancing product hop. The arrangement bears every hallmark of an anticompetitive reverse payment under *Actavis*.

Impax concedes that the payment was large and not justified by any customary considerations like avoided litigation costs. It acknowledges further its belief that vulnerabilities in Endo's patents made a generic entry date in 2011 appropriate. It also concedes that, without payment, it would rather have taken its chances in court than wait to compete until 2013, *even if* Endo had agreed to license its current and future patents. In short, the agreement allowed Endo "to maintain supracompetitive prices to be shared" between the two companies "rather than face what might have been a competitive market—the very anticompetitive

consequence that underlies the claim of antitrust unlawfulness." *Actavis* 570 U.S. at 157.

Impax tries to spin its agreement as procompetitive, but in the process admits to the very facts that *Actavis* held makes a settlement anticompetitive. None of Impax's arguments holds water.

1. The Commission properly found anticompetitive harm under the first step of the rule of reason. Impax does not dispute that Endo had market power and made a large and unexplained payment to "prevent the risk of competition," which *Actavis* identified as "the relevant anticompetitive harm." *Id.* Those concessions alone satisfy the inquiry. Impax is wrong that the Commission had to determine what prices or output would have been in the absence of the agreement. Anticompetitive harm exists when conspirators with market power take actions with the *potential* to raise prices or exclude competitors.

The Commission was not required to adjudicate the patent's strength or calculate the odds of victory in the patent litigation before it could apply the rule of reason. *Actavis* rejected that very argument, holding instead that a large and unexplained payment from the patentee to the alleged infringer is itself a "workable surrogate for a patent's weakness." *Id.* 158. The harm to competition lies in buying away the *risk* of invalidity, even if that risk is small. *Id.*

The payment eliminated a significant risk of competition before 2013. Indeed, Impax admits that absent the payment it would have litigated rather than accepting a 2013 entry date, thus threatening Endo's patents. The threat was real because Impax was preparing to launch in 2010 or 2011, as Endo understood. Endo's paying Impax to stay off the market would have been wholly irrational if Impax posed no threat to its monopoly.

Unforeseeable events that left Impax as the only seller on the market cannot change the anticompetitive nature of the deal. Under basic antitrust principles, the competitive effects of an agreement are assessed as of the time it was made; hindsight cannot retroactively strip its anticompetitive character. That rule has particular relevance here since Impax is now paying Endo not to compete or to [redacted].

2. Impax did not meet its burden to show that the payment it received to stay off the market enhanced competition. It does not even try to invoke the justifications for a payment described in *Actavis*, such as saved litigation costs or fair value for services. And since Endo was willing to give Impax a license *and* a payment, it surely would have been willing to provide a license and *no* payment. The payment therefore was not "reasonably necessary to the accomplishment" of Impax's "legitimate goals" of competing in the generic market. *United States v. Realty Multi-List, Inc.*, 629 F.2d 1351, 1375 (5th Cir. 1980). Pharmaceutical

companies and their generic competitors routinely settle patent disputes without unjustified payments.

It is not enough for Impax to show that the settlement as a whole had the procompetitive effect of allowing generic entry before patent expiration. *Actavis* defined the "specific restraint" to be justified as "payment" by the brand company that "purchase[s] … the exclusive right to sell its product, a right it already claims but would lose if … the patent were held invalid or not infringed." 570 U.S. at 153-54. Even where a license allows entry before patent expiration, parties can harm competition by conspiring to divide monopoly profits prior to the agreed-upon date. Treating the license as the justification would undo *Actavis* by deeming *all* such agreements justified.

Impax is wrong that the payment was justified because it enticed Impax to accept licenses for current and future patents when Impax otherwise would have preferred to litigate. The claim defies logic and would apply to every anticompetitive reverse-payment deal, upending *Actavis*. Impax's stated unwillingness to settle without payment simply means that it believed litigation would secure an earlier entry date than licensed entry in 2013—and that the license to future patents was not sufficiently valuable to justify the delay. In other words, the payment induced Impax to accept a deal that it believed *worsened* its ability to compete. Endo and Impax guaranteed that earlier entry would never come to pass

and that consumers would pay monopoly prices in the meantime. That is not a procompetitive justification, but its antithesis.

3. Settling without the reverse payment would have been a viable less-restrictive alternative. In most cases, similarly situated parties settle patent challenges without reverse payments. The only thing preventing such a settlement here was the parties' preference to share monopoly profits rather than try to resolve their disagreements about the appropriate entry date. Contrary to Impax's claim, the law did not require the Commission to find that Endo and Impax *definitely* would have agreed on a no-payment alternative. A viable possibility—based on actual industry experience in analogous situations—is enough.

STANDARD OF REVIEW

The Commission's factual findings, "if supported by evidence, shall be conclusive," 15 U.S.C. §45(c), even if "alternative conclusions may be equally or even more reasonable and persuasive," *N. Tex. Specialty Physicians v. FTC*, 528 F.3d 346, 354 (5th Cir. 2008) (quotation omitted). The Court reviews the FTC's legal analysis and conclusions *de novo*, but "give[s] some deference" to the agency's "informed judgment that a particular commercial practice is to be condemned as 'unfair.'" *Id.* (quoting *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 454 (1986)).

ARGUMENT

In *Actavis*, the Supreme Court held that "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." 570 U.S. at 159. Here, the payment is large, bears no relationship to litigation costs or other services, and has no justification at all. Impax concedes that the payment induced it to accept an entry date and patent license it would otherwise have rejected as inferior to the result it expected from continued litigation. Br.45, 48, 53.

Impax has thus admitted to a textbook "anticompetitive agreement" under *Actavis*, in which the brand "induce[d] the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market." 570 U.S. at 154. Impax peppers its brief with colorful claims that the Commission "jerry-rigged" the rule of reason analysis to "allow the FTC to find all reverse-payment settlements anticompetitive without having to engage with the facts of each case." Br.2, 25. But Impax's own concessions establish virtually all of the necessary facts to find an antitrust violation.

I. THE SETTLEMENT CAUSED ANTICOMPETITIVE HARM

At the first step of the rule of reason, plaintiffs may establish anticompetitive harm with evidence of market power and a conspiracy that "created the potential for anticompetitive effects." *Doctor's Hosp. of Jefferson, Inc. v. Se. Med. Alliance, Inc.*, 123 F.3d 301, 310 (5th Cir. 1997). Here, the Commission found anticompetitive harm through evidence that Endo (1) had market power; and (2) paid Impax a share of monopoly profits to eliminate the risk of competition, which *Actavis* deems an "anticompetitive consequence[]." *See* Op.16-31 (R184-199); 570 U.S. at 156. Because Impax concedes both of these elements on appeal, a finding of anticompetitive harm necessarily follows.[4]

Impax claims these undisputed findings were merely a "threshold showing," insufficient in themselves to establish anticompetitive harm. Br.25. In Impax's view, the Commission had to "defin[e] the baseline level of competition absent the allegedly unlawful agreement" and determine "what prices or output should have been in a competitive market." Br.27. In other words, Impax argues that the Commission could find anticompetitive conduct only if it determined that Impax

[4] *Amici* Alliance for Accessible Medicines (AAM) and Washington Legal Foundation (WLF) erroneously claim the Commission improperly applied a "quick-look" review. AAM Br.15-17; WLF Br.9, 16. That is plainly untrue, since the Commission required Complaint Counsel to show market power and an unjustified payment to stay off the market. Quick-look review does not require plaintiffs to show "market power or market effects." *Realcomp II, Ltd. v. FTC*, 635 F.3d 815, 825 (6th Cir. 2011).

was likely to have "won the patent suit" and launched its generic at an earlier date absent the payment. Br.2, 17, 25-36. These arguments cannot be squared with the rule of reason or *Actavis*.

A. *Actavis* Establishes That Payment To Eliminate The Risk Of Competition Is The "Relevant Anticompetitive Harm"

Actavis defined the "relevant anticompetitive harm" as the use of a reverse payment "to prevent the risk of competition." 570 U.S. at 157. By making the payment, the brand is effectively buying "the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product." *Id.* 153-54. The payment distorts the competitive process by eliminating the generic's incentives to secure the earliest possible entry date and test the validity of the patents. *See id.* 154-58. Thus, unless a reverse payment has some other objective (such as saving litigation costs), it likely seeks "to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what *might have been* a competitive market—the very *anticompetitive consequence* that underlies the claim of antitrust unlawfulness." *Id.* 157, 159 (emphasis added).

Because elimination of risk is the anticompetitive harm, the antitrust tribunal need not "litigate patent validity" or quantify the risk of earlier competition. *Id.* Rather, "the size of an 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.* 158.

B. Impax Admits That It Accepted A Payment To Eliminate The Risk That It Would Compete With Endo

The anticompetitive harm here is obvious. Impax concedes (at Br.45, 48, 53) that it sought and received a large "payment in return for staying out of the market" from a pharmaceutical monopolist. *Actavis*, 570 U.S. at 154.[5] It posits no other justification for the payment. As a result, the market was deprived of the possibility of generic entry and the ensuing competition that drives prices lower. *See* IDF31, 441-42 (R17, 66). Endo continued to earn monopoly profits, which it shared with Impax.

As Impax confesses in its brief, it appraised the strength of Endo's patents and concluded they supported a licensing agreement "allowing it to begin selling oxymorphone ER in mid-to-late 2011." Br.7, 9 (discussing IDF116, 155 (R27, 32)). Yet Impax ultimately agreed to a *2013* launch date, which it says it would have found "unacceptable" but for the reverse payment. Br.45-46, 48, 53. Impax states directly that "if Endo had offered the same license but no payment, Impax would have *rejected* the deal and continued litigating." Br.48.

[5] Because Impax conceded both here and below that the settlement "included a reverse payment" (Br.3), *amici* economists and WLF may not argue otherwise.

These admitted facts present an archetype of the arrangement that *Actavis* deemed "anticompetitive": "using … monopoly profits to avoid the risk of patent invalidation or a finding of infringement." *Actavis*, 570 U.S. at 156. From Impax's perspective, it would have continued challenging the validity of Endo's patents but for the payment because it believed litigation would have yielded a *better* outcome than the 2013 entry date and licenses Endo was offering. Br.45, 48, 53. Impax's own expert explained that a generic manufacturer will reject a settlement when its "expected generic entry date under continued litigation" is earlier than the "generic entry date in that settlement." A89 ¶116. From Endo's perspective, the payment demonstrates its belief that the litigation posed a significant threat to its monopoly. The payment eliminated that threat, allowing Endo to "maintain supracompetitive prices … rather than face what might have been a competitive market." *Actavis*, 570 U.S. at 157.

Impax accuses the Commission of failing to "conduct[] a detailed analysis to determine the competitive effects of the Impax-Endo settlement," Br.23-24, but the Commission *did* perform that analysis, which only underscores the anticompetitive consequences of the payment here. *See* Op.7-8, 16-31 (R175-76, 184-99). As discussed at pp. 9-10, the payment was integral to Endo's product-hopping strategy to prolong its Opana ER monopoly and secure hundreds of millions in additional profits. Endo projected that Impax could launch after obtaining FDA approval in

2010 or after trial and appeals in 2011 (*see supra* p. 8), both well in advance of Endo's reformulated product, stymieing the product hop. IDF99-109 (R25-26). The 2013 date gave Endo the window it needed to complete the switch. Impax, aware of this, was paid extra for its forbearance.

Impax understood that the settlement would allow Endo to product hop and eliminate the generic market, but it went along with the plan anyway. Impax first demanded an "acceleration provision" allowing it to compete before Endo switched the market. Br.8 (discussing IDF138-39 (R30)). But when Endo instead offered a cash insurance policy to protect Impax's earnings, Impax decided to join the plan. *Id.* 9 (discussing IDF129 (R29)). *See also* Op.20 (R188); A116-21, 130-35. Together, Impax and Endo conspired to "maintain and to share patent-generated monopoly profits" rather than compete. *Actavis*, 570 U.S. at 158.

Impax now says that it had been "unlikely" to launch before the settlement's 2013 entry date (Br.54), claiming that the patent litigation, including appeals, may not have ended before 2013 (Br.36). But this claim cannot be squared with Impax's unequivocal admission that, absent the reverse payment, it would have *rejected* a 2013 entry date and kept litigating. Br.45, 48, 53. That admission is consistent with the Commission's finding, based on substantial evidence, that Impax posed a "plausible risk" of entering before 2013 in light of the preparations it was making for an at-risk launch. Op.24 & n.25 (R192). Impax secured DEA

approval, lined up buyers, manufactured product, projected 2010 or 2011 entry, and told the board of directors that oxymorphone ER was a "good candidate" to launch at risk. *See supra* p. 8. Impax posed a serious threat to Endo's monopoly, and the large and unjustified payment harmed competition by eliminating it.

C. The Commission Did Not Need To Adjudicate The Strength Of The Patents To Find Anticompetitive Harm

Actavis held explicitly that antitrust tribunals need not assess patent validity to find anticompetitive harm. 570 U.S. at 157-58. Impax nevertheless argues that the Commission needed to quantify "the patent's strength, which is the expected likelihood of the brand manufacturer winning the litigation." Br.35-36. In Impax's view, the Commission had to determine both who would have won the patent suit and the mathematical probability of that outcome. *Id*.

Actavis directly rejected that very argument because the anticompetitive harm is the elimination of the risk of competition, not its certainty. *See supra* Argument I.A. A large and unjustified payment to stay off the market harms competition even if the patents had only a "small risk of invalidity." 570 U.S. at 157. The payment "itself would normally suggest that the patentee has serious doubts about the patent's survival." *Id.*

Unsurprisingly, courts applying *Actavis* have consistently ruled that the mere "presence of a large and unjustified payment in a paragraph IV litigation settlement renders that settlement anticompetitive." *Nexium*, 842 F.3d at 61. "[T]o prove

anticompetitive effects, the plaintiff must prove … payment to prevent the risk of competition." *Smithkline Beecham*, 791 F.3d at 412; *accord King Drug Co. v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 416 (E.D. Pa. 2015). Plaintiffs "need not plead (or prove) the weakness of the … patent," but need only show "some perceived risk of … invalidity." *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 240 (D. Conn. 2015); *accord In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704, 720 (N.D. Ill. 2016).

The oddsmaking demanded by Impax therefore would prove nothing, since Impax admits that without the payment it would have rejected a 2013 entry date and continued to litigate in pursuit of an earlier date. Br.45, 48, 53. The Commission had no need to assess the strength of the patents because Impax *itself* was betting on pre-2013 entry without the payment. For that matter, the outcome of now-settled litigation is "fundamentally unknowable," so making such a projection "would be far too speculative to aid a [factfinder] in making a reasoned decision." *In re Androgel Antitrust Litig. (No. II)*, 2018 WL 298873, at *12 (N.D. Ga. Jun. 14, 2018).

Further, Impax's argument rests on the false premise that the Commission had to find *direct* evidence that the payment resulted in higher prices or reduced output. *See* Br.26-27. While that is one way to show anticompetitive effects, it is not the only one. The fundamental goal of antitrust law is the "protection of a

competitive process that brings to consumers the benefits of lower prices, better products, and more efficient production methods." *Clamp-All Corp. v. Cast Iron Soil Pipe Inst.*, 851 F.2d 478, 486 (1st Cir. 1988) (Breyer, J.) (emphasis added). Thus, plaintiffs can demonstrate harm with evidence that conspirators "raised prices, curtailed production, *or eliminated competition*, or that they had attempted to do so." *Hatley v. Am. Quarter Horse Ass'n*, 552 F.2d 646, 651 (5th Cir. 1977) (emphasis added); *accord Consolidated Metal Prods., Inc. v. Am. Petroleum Inst.*, 846 F.2d 284, 292-93 (5th Cir. 1988).

Plaintiffs therefore need not provide direct evidence of anticompetitive effects; they may show harm "indirect[ly]" through "proof of market power plus *some evidence* that the challenged restraint harms competition." *Am. Express Co.*, 138 S. Ct. at 2284 (emphasis added). When conspirators have market power, competition is harmed by actions with the "potential" to raise prices or lower output. *Doctor's Hosp.*, 123 F.3d at 310; *see also Ind. Fed'n of Dentists*, 476 U.S. at 460-62; *Realty Multi-List*, 629 F.2d at 1370, 1375, 1385.

Because conspiracies to eliminate potential competition are anticompetitive, the Commission correctly ruled that *Actavis* does not require evidence "that a generic drug would have been brought to market earlier but for the agreement." Op.23-24 (R191-92). The relevant anticompetitive harm "occurs when the branded manufacturer and its generic competitor replace the possibility of

competition with the certainty of none." *Id.* 24 (R192) (discussing *Actavis*, 570 U.S. at 157).

Impax's contrary approach is flatly illogical. It would allow a monopolist to buy off its prospective rivals and then defend itself on the ground that those rivals were uncertain to have competed anyway. "[T]he law does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition." 12 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶2030b (4th ed. 2013-18), discussing *Palmer v. BRG of Georgia*, 498 U.S. 46, 49 (1990) (payment to eliminate competitor is unlawful even if the parties had not "previously competed" in that market). This Court has recognized that a monopolist may "harm[] the market" by taking actions that "ha[ve] the *potential* to eliminate … competition." *Retractable Techs., Inc. v. Becton Dickinson & Co.*, 842 F.3d 883, 895 (5th Cir. 2016) (emphasis added).[6] Antitrust liability does not "turn on a plaintiff's ability or inability to reconstruct the hypothetical marketplace absent a defendant's anticompetitive conduct"; rather, "the defendant is made to suffer the uncertain consequences of its own undesirable

[6] Impax incorrectly suggests that monopolists are incapable of harming competition if the monopoly was "lawfully obtained." Br.27. Monopolists may harm the market through actions that "reasonably appear capable" of "*maintaining* monopoly power." *Retractable Techs.*, 842 F.3d at 891 (emphasis added, quotation and brackets omitted).

conduct." *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (en banc) (quotation omitted).

Amicus WLF wrongly claims the First Circuit's *Nexium* decision required the FTC to "demonstrate causation" by showing that the payment resulted in a later entry date. WLF Br.17. In fact, *Nexium* held precisely the opposite. The court explained that *private plaintiffs* seeking damages must generally demonstrate injury-in-fact by showing that a generic rival likely would have entered the market earlier "but for" the violation. 842 F.3d at 60. The court made clear that no such requirement applies to a "government enforcer," which stands in a different posture than private parties. *Id.* 59-60.

Impax incorrectly asserts that the California Supreme Court required plaintiffs to prove the entry date that would have been "justified by the strength of the patent." Br.33-34. To the contrary, the court observed that "*Actavis*'s analysis was not contingent on a particular level of uncertainty surrounding the patent." *In re Cipro Cases I & II*, 348 P.3d 845, 859 (Cal. 2015). *Cipro* explained that, in economic terms, anticompetitive harm occurs when a settlement results in a later generic entry date than what the "expected life" of the patent would merit. *Id.* 864. But the court went on to rule, consistent with *Actavis*, that parties need *not* litigate patent strength or validity, since the nature of the payment can create an inference that the parties settled for an entry date beyond the patent's expected life:

> If a brand is willing to pay a generic more than the costs of continued litigation, and more than the value of any collateral benefits in order to settle and keep the generic out of the market, there is cause to believe that some portion of the consideration is payment for exclusion beyond the point that would have resulted, on average, from simply litigating the case to its conclusion.

Id. 867. Thus, a large, unjustified payment to prevent potential generic competition is "sufficient to make out a prima facie case that the settlement is anticompetitive." *Id*.

Cipro also refutes Impax's claim that the Commission's ruling would invalidate all brand-generic settlements, even those "without a reverse-payment." *See* Br.17, 31-32, 34. As the California court explained, "[a]bsent payment, one can accept an agreement to postpone market entry as a fair approximation of the expected level of competition that would have obtained had the parties litigated." *Cipro*, 348 P.3d at 865. In that scenario, the generic would have an incentive to compete as soon as possible, thereby serving the interests of consumers. As a result, the Commission made clear that settlements "consisting only of a license to operate in a relevant market … will not ordinarily trigger antitrust scrutiny."

Op.22 (R190).[7] But if a brand is allowed to "share monopoly profits through a reverse payment," the generic will lose its incentive "to hold out for its best estimate of the average entry point it could obtain through litigation." *Cipro*, 348 P.3d at 867. Rather, the parties will jointly seek to "maximiz[e] their combined wealth by extending the monopoly as long as possible." *Id*. The unjustified *payment* makes a brand-generic settlement anticompetitive.

Equally baseless is Impax's claim that under the FTC's approach "Complaint Counsel will always be able to prove that reverse-payment settlements have an anticompetitive effect." Br.32. Again, reverse payments are anticompetitive only when they do not "reflect[] traditional settlement considerations" and instead involve the sharing of monopoly profits to eliminate the risk of competition. *Actavis*, 570 U.S. at 156. Impax has already given away the store by conceding that it accepted just this sort of payment (*see supra* Argument I.B), so it can hardly contend that the FTC would condemn a different settlement where the defendants proffer a legitimate explanation for the payment.

[7] Impax is wrong that the Commission contradicted the argument it made to the Supreme Court in *Actavis*. Br.34-35. There, as here, the Commission explained that patent settlements without a payment are "presumably" procompetitive, but that the most natural inference from "a substantial reverse payment is that … [it] purchased an additional increment of market exclusivity" beyond the perceived strength of the patents. *See* Brief of FTC, *Actavis*, No. 12-416, 2013 WL 267027, at *35-36 (Jan. 22, 2013).

Finally, *Actavis* did not, as Impax claims, "command that courts must 'strike a balance' between patent and antitrust policies" in each case. Br.25 (quoting *Actavis*, 570 U.S. at 148); *see also id.* 33. *Actavis* already struck that balance when it examined the rights conveyed by a patent and concluded that patent settlements based on traditional considerations are lawful while large and unjustified reverse payments to secure additional increments of market exclusivity are likely unlawful. 570 U.S. at 148, 151.

D. Hindsight Cannot Salvage An Agreement That Was Anticompetitive When Adopted

As shown, Impax took a payment in exchange for a deferred generic entry date that it otherwise would have rejected—the quintessential anticompetitive settlement under *Actavis*. Yet Impax claims the settlement "did not harm competition" because two years after the agreement, the PTO issued additional patents that would have "kept [Impax] out of the market *until 2023* because courts have concluded that the new patents are valid." Br.36 (emphasis in original); *see also* Br.54. Moreover, because Endo's product hop strategy ultimately failed and *Impax is now paying Endo to stay off the market*, *see* Op.46 (R214), Endo no longer sells Opana ER, leaving Impax's product as "the only generic on the market and, indeed, the only version of Opana ER available to consumers at all." Br.37, 54. To Impax, this chain of unanticipated events means that the original reverse-payment settlement did not injure competition.

Impax's conduct was anticompetitive regardless of new patent grants, court rulings, and other events that took place years after the settlement. Under antitrust law, hindsight cannot inoculate conduct that was anticompetitive at the time it occurred. "A court must ask whether an agreement promoted enterprise and productivity at the time it was adopted." *Polk Bros, Inc. v. Forest City Enters.*, 776 F.2d 185, 189 (7th Cir. 1985); *accord Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1306 (11th Cir. 2003). The federal antitrust enforcement agencies "assess the competitive effects of a relevant agreement as of the time of possible harm to competition." FTC & DOJ, *Antitrust Guidelines for Collaborations among Competitors* §2.4 (Apr. 2000).[8]

The "reasonableness of a patent settlement agreement cannot be made to depend on an *ex post* determination" of validity or infringement. 12 Areeda & Hovenkamp, *Antitrust Law* ¶2046e1. *Cipro* recognized similarly that "[j]ust as later invalidation of a patent does not prove an agreement when made was anticompetitive, later evidence of validity will not automatically demonstrate an agreement was procompetitive." 348 P.3d at 870.

[8] Available at https://www.ftc.gov/sites/default/files/documents/public_events/joint-venture-hearings-antitrust-guidelines-collaboration-among-competitors/ftcdojguidelines-2.pdf.

The Endo-Impax settlement harmed competition from the moment it was executed by eliminating the "risk of competition." *Actavis*, 570 U.S. at 157. Impax therefore cannot rely on future developments years later that it does not claim to have foreseen at the time of the transaction. In June 2010, as Endo's counsel later admitted, "[n]obody knew for sure whether these patents were going to issue … the Patent Office may never have issued the patents." A218-19. And whatever effects Impax foresaw, it concedes that, but for the reverse payment, it would have *rejected* a license to Endo's future patents and taken its chances in litigation. Br.48.

Reliance on after-the-fact events would make antitrust law unadministrable, since an agreement could be anticompetitive when entered, become procompetitive in response to a new development (*e.g.*, a district court patent ruling), and then become anticompetitive again in response to yet another unforeseen event (*e.g.*, reversal on appeal). Such a legal regime would be nonsensical.

II. IMPAX FAILED TO PROVIDE ANY LEGITIMATE PROCOMPETITIVE JUSTIFICATIONS FOR ACCEPTING THE REVERSE PAYMENT

At the second step of the rule of reason, "the burden shifts to the defendant to show a procompetitive rationale for the restraint." *Am. Express*, 138 S. Ct. at 2284. The Commission explained that the "relevant restraint" Impax had to justify was "the payment in exchange for the elimination of the risk of entry." Op.32-36 (R200-04). The Commission rejected Impax's claim that the payment was

procompetitive because it was part of an overall settlement that also included a license to Endo's current and future patents, which allowed Impax to enter the market before the patents expired and shielded Impax from additional infringement suits. It explained that "Impax does not make any argument that the [payments to exclude competition] have *themselves* protected Impax from the threat of patent litigation or that it needed to accept these payments in order to enjoy the procompetitive benefits of the patent license." Op.32, 36-39 (R200, 204-07).

On appeal, Impax first denies it had to justify the payment itself, claiming instead that the entire settlement constituted the relevant restraint of trade. Br.39-42. It then contends that in the context of the overall deal the payment was justified because it "induced" Impax to accept a settlement containing the license. Br.43-49. Both claims fail.

A. Impax Had To Justify The Payment To Stay Out Of The Market

The restraint of trade at issue here is Endo's sharing of its monopoly profits with Impax to eliminate the risk of competition before January 2013. As *Actavis* makes clear, when assessing the antitrust implications of the settlement of Paragraph IV litigation, "the specific restraint at issue" is a "payment" by the brand-name patentee that "purchase[s] … the exclusive right to sell its product, a right it already claims but would lose if … the patent were held invalid or not infringed." 570 U.S. at 153-54.

Even though the reverse payment was part of a larger contractual relationship (that is so in every case), Impax is wrong that it could offer justifications for any aspect of the agreement. Br.39-42. Its burden was to explain "*the presence of the challenged term* and show[] the lawfulness of *that term* under the rule of reason." *Actavis*, 570 U.S. at 156 (emphasis added). That is because a restraint "refers not to a particular list of agreements, but to a particular economic consequence." *Bus. Elecs. Corp. v. Sharp Elecs. Corp.*, 485 U.S. 717, 731 (1988). Here, the relevant "anticompetitive consequence" is the use of a "payment[]" to "maintain supracompetitive prices … rather than face what might have been a competitive market." *Actavis*, 570 U.S. at 157. Accordingly, the payment to stay off the market is the "challenged restraint," and Impax has the burden to show that it "enhances competition." *NCAA v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 104 (1984); *see* Op.32, 34-35 (R200, 202-03).

In keeping with *Actavis*, courts assessing reverse-payment settlements have demanded procompetitive justifications for the payment itself, not the agreement as a whole. The Third Circuit held that a reverse-payment defendant cannot escape liability by relying on "other elements of the settlement agreement." *Lipitor*, 868 F.3d at 256-57. A district court in Connecticut required the defendant to "explain the apparent 'missing' value for the patent-holder in a procompetitive way … in

which case the reverse payment may turn out to be justified." *Aggrenox*, 94 F. Supp. 3d at 243; *accord Opana ER*, 162 F. Supp. 3d at 719.

Impax cannot evade its burden to justify the payment by claiming it was "inextricably linked with" the beneficial effects of the licensing terms. Br.40. *Actavis* establishes that a license and a payment are *not* "inextricably linked," since parties may agree to early-entry patent licenses without reverse payments. 570 U.S. at 158. That is why the Court required defendants to justify their "reasons [for] prefer[ring] settlements that include reverse payments." *Id.*

Nor may Impax argue that "the license that kept Impax out of the market until January 2013 is the same one that allowed it unfettered market access once that date arrived." Br.41. This argument merely restates the "scope-of-the-patent test" rejected in *Actavis*. The Court was clear that defendants may *not* justify a reverse payment by claiming the settlement also conferred a license allowing entry before expiration of the patents, since those patents may be invalid or not infringed. 570 U.S. at 147. Indeed, the "settlement in *Actavis* itself" permitted entry "65 months before patent expiration," but that did not legitimize the payment to prevent the risk of earlier competition. *Smithkline Beecham*, 791 F.3d at 406-08.

Actavis recognized that "settlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition … to the consumer's benefit." 570 U.S. at 154. But the antitrust problem remains

when such a settlement *also* includes a "payment in return for staying out of the market." *Id.* That is because "the patentee leverages some part of its patent power … its supracompetitive profits" to eliminate the "risk of competition" prior to the licensed entry date. *Smithkline Beecham*, 791 F.3d at 406. This analysis does not change because the settlement included a license to future patents that may or may not issue—a standard provision in Hatch-Waxman settlements.[9] Even when a license allows "early" entry, "entry might have been earlier, and/or the risk of competition not eliminated, had the reverse payment not been tendered." *Id.* 408.

Deeming the license itself as the justification would legitimize every reverse payment. Brand companies would have a free pass to make large payments to eliminate the possibility of competition so long as the settlement also allows generic entry "before the expiration of the patent[s]." Br.37, 41, 54. That outcome would eviscerate *Actavis*.

Impax cites a district court opinion holding that a defendant could offer justifications unrelated to the payment itself. *See* Br.40, citing *In re Wellbutrin XL*

[9] Impax routinely seeks broad freedom-to-operate licenses when settling patent disputes. IDF565-66 (R81). The FTC has found that over 92 percent of Hatch-Waxman settlements included licenses to patents in addition to those at issue in the suit. *See* Agreements filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (FY 2016), https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/mma_report_fy2016.pdf.

Antitrust Litig., 133 F. Supp. 3d 734, 753 (E.D. Pa. 2015). That court relied on the false assumption that because the settlement was "agreed to as a whole," its effects should be "evaluate[d] as a whole," *id.* 753-74, overlooking *Actavis*'s teaching that it is the *payment* to stay off the market that harms competition and must be justified, *see* 570 U.S. at 153-54, 156-58. Indeed, *Wellbutrin* is inconsistent with the Third Circuit's controlling rulings in *Smithkline Beecham*, 791 F.3d at 408, and *Lipitor*, 868 F.3d at 256-57, both of which require that any procompetitive benefits must flow from the payment.[10]

B. Impax Did Not Show That The Payment Had Any Procompetitive Benefit

An asserted justification for a restraint of trade must have a "logical nexus" to the "specific activities that … are anticompetitive." *N. Tex. Specialty Physicians*, 528 F.3d at 368-70 *accord Realcomp II, Ltd. v. FTC*, 635 F.3d 815, 835 (6th Cir. 2011) (defendants must "demonstrate[] a connection" between the restraint and justifications). Impax failed to show how the payment it received to

[10]The other district court cases cited by Impax (Br.40) provide no support. In *In re Namenda Direct Purchaser Antitrust Litigation*, 331 F. Supp. 3d 152 (S.D.N.Y. 2018), the defendant attempted to justify only the payment itself. *Id.* 198.

Impax also cites the district court verdict form in *Nexium*, which asked whether a reverse payment "settlement" was anticompetitive. On review, the First Circuit found no error because the district court provided clarifying "jury instructions explaining how the presence of a large and unjustified *payment* in a paragraph IV litigation settlement renders that settlement anticompetitive." 842 F.3d at 61 (emphasis added).

stay off the market until 2013 promoted generic competition. As the Commission explained, Impax made no claim that the payment was justified in the ways anticipated by *Actavis*, by showing that it reflected saved litigation costs or the value of services Impax provided. Op.18-19 (R186-87). And while Impax claimed that the patent license it received from Endo was procompetitive, it failed to demonstrate that (1) the payment to exclude competition *itself* "protected Impax from the threat of patent infringement suits"; or (2) Impax "needed to accept" the payment "in order to achieve a settlement containing the broad patent license." Op.37 (R205). Accordingly, the Commission found no "link" between the restraint and the claimed benefits. *Id.* 36-39 (R204-07).

Impax acknowledges that it "theoretically" could have secured the very same patent license without also receiving a cut of Endo's monopoly profits. Br.47-48. It now asserts—though it did not say so before the Commission—that it found such a deal "unacceptable" and would have continued challenging the validity of Endo's patents in court. Br.45, 48, 53. But that just means that the payment convinced Impax to accept an agreed-upon entry date (and patent license) inferior to the result it anticipated securing in litigation. As explained in Argument I.B, this is not a procompetitive justification; it is the epitome of an anticompetitive agreement condemned by *Actavis*. 570 U.S. at 154.

1. Impax failed to show any reasonable need for the payment.

Impax argues that even if the payment was "anticompetitive standing alone," it was "reasonably related" to the goal of obtaining a license and therefore justified. Br.44-45. But that is not the law. Where a restraint does not itself promote competition, a defendant must explain why it was reasonably *necessary* to achieve a procompetitive end. If Impax could have competed "just as effectively" without the payment, then it is not procompetitive. *NCAA*, 468 U.S. at 114. In an analogous context, the Supreme Court held that the NCAA's restrictions on college football broadcasts did not advance allegedly procompetitive goals of "competitive balance" because a "variety of other restrictions" were "better tailored" to that end. *Id.* 119. A contrary rule would give defendants a free pass to enter anticompetitive agreements so long as they loaded up their contracts with other procompetitive terms that they could have obtained just as easily without the challenged restraint. *See* Op.36-37 n.40 (R204-05).

Impax claims that the Commission erred by failing to apply the doctrine of ancillary restraints (Br.44-45), but the Commission correctly observed that this doctrine only *supports* liability here. *See* Op.36-37 n.40 (R204-05). In *United States v. Addyston Pipe & Steel Co.*, 85 F. 271 (6th Cir. 1898) (Taft, J.), the court explained that parties may be allowed to restrain trade in ways "merely ancillary to the main purpose of a lawful contract." *Id.* 282. But it added the critical caveat

that an ancillary restraint is "void" when "the restraint exceeds the *necessity* presented by the main purpose of the contract." *Id.* (emphasis added). An ancillary restraint is unlawful if not "reasonably necessary" to the contract's objective. *Id.* 281; *accord Broad. Music, Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1, 19 (1979) (otherwise anticompetitive licenses justified where "reasonably necessary to effectuate" copyright protections).

Thus, in *Realty Multi-List*, this Court held that a defendant can justify a restraint as "ancillary" to a broader agreement only when it is "*reasonably necessary* to the accomplishment of the legitimate goals and *narrowly tailored* to that end." 629 F.2d at 1375 (emphasis added). If the challenged restraints "fail to measure up to these standards, the justification asserted for them fails." *Id.*; *see also id.* 1368-69, 1373, 1377. The burden to show necessity lies with the defendant. *Id.* 1380-81; *accord Pope v. Miss. Real Estate Comm'n*, 872 F.2d 127, 130 (5th Cir. 1989). Other circuits, as well as the FTC, have held the same. *See*, *e.g.*, *SCFC ILC, Inc. v. Visa USA, Inc.*, 36 F.3d 958, 970 (10th Cir. 1994); *Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 227-28 (D.C. Cir. 1986); *NaBanco v. VISA U.S.A., Inc.*, 779 F.2d 592, 601 (11th Cir. 1986); *In re Polygram Holding, Inc.*, 136 F.T.C. 310, 366, 2003 WL 25797195, at *23 (Jul. 24,

2003); *see also Major League Baseball Props., Inc. v. Salvino, Inc.*, 542 F.3d 290, 338-40 (2d Cir. 2008) (Sotomayor, J., concurring).[11]

Impax does not claim that it had a reasonable need for a reverse payment. Since Endo was willing to give Impax a license *and* a payment, it necessarily follows that Endo also would have been willing (indeed, preferred) to give a license and *no* payment. Op.41-42 (R209-10). Far from "armchair theorizing" (Br.48), that conclusion is obvious.

Requiring Impax to show a reasonable need for the payment would not, as Impax claims, "guarantee[] that [the FTC] will find essentially every reverse-payment settlement unlawful." Br.49. Impax could still have avoided liability by showing that the payment represented compensation for saved litigation costs or the value of services, or that it served some other legitimate purpose. For example, a generic company might be able to prove that the money was vital to developing the product and bringing it to market. Op.37 n.41 (R205). Impax made no such claims here.

[11] The Sixth Circuit's recent decision in *Medical Center at Elizabeth Place, LLC v. Atrium Health System*, 922 F.3d 713 (6th Cir. 2019), is not to the contrary. The sole question was whether restraints should be condemned as *per se* unlawful where they "plausibly relate" to a procompetitive purpose, and the court answered no. *Id.* 727. The court did not apply the rule of reason.

2. Impax's argument that the payment induced settlement shows that the payment was *anticompetitive*, not procompetitive.

Impax also argues that the payment aided competition by greasing the wheels for a deferred-entry settlement. It describes two proposed settlements with a 2011 generic entry date and no payment that Endo rejected, insisting instead on a 2013 date. Br.7-9, 45 (discussing IDF116, 154-56 (R27, 32-33)). Impax then acquiesced to Endo's desired 2013 date once Endo induced it with a large reverse payment. IDF158-65 (R33-34). Impax spins the payment as helping the parties to "bridge an otherwise insurmountable difference in positions," "find common ground," and "reach a deal." Br.46.

These are not procompetitive justifications for the reasons discussed in Argument I.B; they are the hallmarks of an anticompetitive agreement and could be raised every time parties settle Paragraph IV litigation with unjustified payments. The payment is precisely what "induce[d Impax] to abandon its [patent] claim with a share of [Endo's] monopoly profits that would otherwise be lost in the competitive market." *Actavis*, 570 U.S. at 154. To find the payment justified by the outcome that *Actavis* held to be anticompetitive tortures the decision's logic and would all but overrule the Supreme Court's decision.

Nor does the inclusion of a license to Endo's potential future patents affect the analysis. Impax acknowledges that "if Endo had offered the same license but

no payment, Impax would have *rejected* that deal and continued litigating." Br.48. This amounts to a direct admission that at the time of the settlement (when the reasonableness of the transaction must be judged, *see* Argument I.D.), Impax believed that the entry date and patent license it now touts as procompetitive were *inferior* to the result it expected to achieve through litigation. Impax thus struck a deal it knew would harm competition in exchange for money, which "demonstrates that the payment was *anticompetitive*, not procompetitive." Op.37 (R205). The payment did not "bridge" any gaps between the parties, but rewarded Impax for abandoning its patent claims and deferring competition until a date it admittedly considered "unacceptable." Br.45-46, 53.

3. Impax and Endo could have entered a procompetitive licensing agreement without an unjustified reverse payment.

Impax has failed to explain why it and Endo could not have struck a mutually satisfactory licensing deal if they had been acting with *legitimate* objectives rather than their desire to prolong Endo's monopoly and split the bounty. As *Actavis* establishes, Endo and Impax could have "settle[d] in other ways, for example, by allowing [Impax] to enter [Endo's] market prior to patent expiration, without [Endo] paying [Impax] to stay out prior to that point." 570 U.S. at 158. *Actavis* foresaw that defendants like Impax would deny that such settlements were feasible, and directed courts to ask *why* that is so. "If the basic

reason 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." *Id.*

That description fits this case to a T. For Endo, the payment ensured it could protect its monopoly long enough to execute the product hop (creating yet another monopoly); for Impax, settling with a reverse payment was more profitable than either settling without one or continuing the patent challenge. Because the record contains no other explanation for the payment, this case is a classic example of an agreement between pharmaceutical rivals to share monopoly profits that would not exist in a competitive market. *Actavis* could not be clearer that these are not valid reasons to settle with a reverse payment. *See* 570 U.S. at 158.

The Commission found no evidence that Impax ever made a legitimate attempt to bridge the gap between the parties' positions by, for instance, proposing entry in 2012. Op.41 n.43 (R209); *see* A222-24 (admission by Impax's lead negotiator that he did not recall seeking 2012 dates or whether Endo refused to

settle with entry before 2013).[12] And once Impax voiced concerns about Endo executing a product hop and sought an accelerated-entry clause to preempt it, Endo appeased Impax with a "make-whole" cash insurance policy (the Endo Credit) instead. IDF153 (R32). The antitrust laws prohibit parties from "us[ing] money to bridge their differences over the point when competitive entry is economically desirable," *Cipro*, 348 P.3d at 868-69, which is precisely what Endo and Impax did here.

The record and the Commission's lengthy experience in this industry showed that when brand and generic manufacturers genuinely strive to compromise on a generic entry date without a reverse payment, they are "far more [likely] than not" to succeed. Op.40 (R208). Indeed, of 160 agreements resolving brand-generic patent disputes in the first full fiscal year after *Actavis*, "over 80 percent involved no compensation flowing from the branded to generic firm." *Id.* After *Actavis*, "the rate of settlements containing reverse payments has declined … while the overall number of settlements is increasing." A239 ¶21 (Bazerman Expert Report).

[12] Impax wrongly claims that under the rule of reason, it need only offer a "nonpretextual" justification for the payment. Br.43. That language derives from *Microsoft*, which held that defendants also need to "substantiat[e]" their justifications and show that the "conduct serves a purpose other than protecting … [their] monopoly." 253 F.3d at 59, 66-67. Even so, Impax's failure even to explore an entry date between 2011 and 2013 shows that its "bridging the gap" justification for the payment is a pretext.

Even if parties acting in good faith cannot settle without payment, the public interest in settlement does not automatically trump the antitrust laws. "That some settlements might no longer be possible absent a payment in excess of litigation costs is no concern if the ones now barred would simply have facilitated the sharing of monopoly profits." *Cipro*, 348 P.3d at 869. If a generic thinks it would obtain a more favorable outcome through litigation than a proposed settlement—as Impax admits it did here (Br.48)—then there is no procompetitive basis for accepting a large reverse payment to forgo that chance. Not only is there a "public interest supporting judicial testing and elimination of weak patents," *Smithkline Beecham*, 791 F.3d at 398 (citation omitted), but should the generic prevail, the benefits "would flow in large part to consumers in the form of lower prices," *Actavis*, 570 U.S. at 154.

III. IMPAX COULD HAVE ACHIEVED ANY PROCOMPETITIVE BENEFITS THROUGH A LESS ANTICOMPETITIVE SETTLEMENT

Because Impax did not establish a procompetitive justification for its receipt of an anticompetitive reverse payment, the Court need not proceed further with the rule of reason analysis. If it does consider the third step of that inquiry, however, the Commission correctly determined that Impax and Endo could have attained any procompetitive benefits from the license in "less restrictive ways" by settling without a payment. *Am. Express*, 138 S. Ct. at 2291.

That is so largely for the reasons set forth in Argument II.B.3 above. As discussed, the license and the payment were both benefits flowing to Impax, which therefore could have accepted the license without also demanding the payment. As *Actavis* held, settling without a payment is viable *even if* the parties would have found it more profitable to share the brand company's monopoly profits. 570 U.S. at 158. The Commission properly found a "strong showing" that Endo and Impax could have readily settled without payment "[g]iven … the Supreme Court's analysis in *Actavis* and the decades of experience indicating that firms can and do settle Hatch-Waxman patent litigation without reverse payments." Op.41 (R209). Impax failed to rebut that showing by producing evidence proving that settling without a payment was *not* viable. *Id.*[13]

Impax complains that the Commission lacked proof that the parties would have *in fact* reached agreement on a settlement without a reverse payment. Br.51-53. That is the wrong standard: A less-restrictive alternative need only be "viable," *N. Am. Soccer League, LLC v. U.S. Soccer Fed'n, Inc.,* 883 F.3d 32, 45

[13] Impax claims this was improper "burden shifting." Br.51-52. That is wrong because the Commission did not shift Complaint Counsel's burden of *persuasion*; it gave Impax a burden of *production* to submit "rebuttal evidence" that "cast doubt on the accuracy" of the FTC's showing. *See Chicago Bridge & Iron Co. N.V. v. FTC*, 534 F.3d 410, 423 (5th Cir. 2008). "[O]nce the plaintiff has suggested a particular alternative, the defendant has the more manageable obligation of showing its inadequacy." 11 Areeda & Hovenkamp, *Antitrust Law*, ¶1914c.

(2d Cir. 2018), meaning that it is either "based on actual experience in analogous situations elsewhere or else fairly obvious," 11 Areeda & Hovenkamp, *Antitrust Law* ¶1913b. Here, as discussed, the Commission found that settling without a payment would have met both of these criteria.

The Commission thus did not need to find that the parties would have *definitely* struck a deal or what the exact parameters would have been. *See Microsoft*, 253 F.3d at 79 (plaintiffs have no duty to "reconstruct the hypothetical marketplace" without the violation). For instance, in *Smith v. Pro Football, Inc.*, 593 F.2d 1173 (D.C. Cir. 1978), the D.C. Circuit ruled that the NFL had viable less-restrictive alternatives to its anticompetitive draft system while adding that the court was "not required … to design a draft that would pass muster under the antitrust laws." *Id.* 1188. Neither *Smith*, nor any of the cases cited by Impax, suggests that a less-restrictive alternative is "viable" only on proof that all of the conspirators would have actually agreed to adopt it. That would erect an "impossible standard," for when defendants are "acting unlawfully to eliminate competition throughout their settlement negotiations, then it is unreasonable to expect a paper trail signifying rational, lawful business choices." *In re Solodyn Antitrust Litig.*, 2018 WL 563144, at *21 (D. Mass. Jan. 25, 2018).

Here, the less-restrictive alternative was at least viable. Endo surely would have been happier to give Impax the same license (or a better one) without also

making a large payment, and Impax was free to accept that deal. *See supra* p. 48. If Impax had believed that the 2013 entry date and licensing term advanced its competitive position, then it presumably would have taken that deal without payment. When Impax denies that a license-only settlement would have been "viable" (Br.53), it means that the settlement would have yielded a *worse* outcome than what Impax expected to receive by continuing the litigation, which shows only that the deal had no procompetitive rationale in the first place.

Finally, despite Impax's denials (Br.50-51), there is every reason to believe that Endo and Impax could have settled with an earlier entry date had they not pursued the anticompetitive end of prolonging Endo's monopoly and dividing up the profits. As the Commission found, it is "hard to imagine that" if Endo were relieved of having to pay Impax tens of millions of dollars, "Impax's key restriction under the settlement, *i.e.*, the entry date, would not have altered." Op.42 (R210) (discussing IDF446 (R67)). Because Impax admits taking a payment for a later entry date than it was otherwise willing to accept (Br.45, 48, 53), it follows that without such "consideration for additional delay in entering the market," *Cipro*, 348 P.3d at 871, the parties could have reached agreement on an earlier date.

Impax could have obtained a license to Endo's patents without an anticompetitive payment, but it took the payment in exchange for staying out of the

market. The Commission correctly ruled that the Endo-Impax settlement violated the antitrust laws.

CONCLUSION

For the foregoing reasons, the petition for review should be denied.

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December 9, 2019

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CERTIFICATE OF SERVICE

I certify that on December 9, 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.

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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 12,909 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 2010 in 14 point Times New Roman type.

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