

Opinion of the Commission

IN THE MATTER OF
IMPAX LABORATORIES, INC.

FINAL ORDER AND OPINION OF THE COMMISSION IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND SECTION 1 OF THE SHERMAN ACT

Docket No. 9373; File No. 141 0004

Final Order and Opinion, March 28, 2019

This case addresses Impax Laboratories, Inc.'s reverse-payment agreement with Endo Pharmaceuticals Inc. to obstruct lower-cost generic competition to Opana ER, one of Endo's core branded prescription drug products. The complaint, 165 F.T.C 960, alleges that Impax Laboratories, Inc. violated section 5 of the Federal Trade Commission Act through its agreement in restraint of trade with Endo Pharmaceuticals, Inc. to eliminate the risk of generic competition to Opana ER for at least 2½ years. In his Initial Decision, 165 F.T.C. 988, the Administrative Law Judge found that the evidence failed to demonstrate that the Challenged Agreement constituted an unreasonable restraint of trade in violation of Section 5 of the Federal Trade Commission Act and dismissed the Complaint. 165 F.T.C. 1197. Complaint Counsel appealed the Initial Decision and Respondent filed a cross-appeal. On October 11, 2018, the Commission heard oral arguments in this matter. The Commission reversed the Initial Decision finding that Impax had engaged in an unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, and an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

Participants

For the *Commission*: Daniel Bradley, Dan Butrymowicz, Synda Mark, Maren Schmidt, Eric Sprague, Jamie Towey, and Rebecca Weinstein.

For the *Respondent*: Anna Fabish and Ted Hassi, O'Melveny & Myers LLP.

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By Commissioner Noah Joshua Phillips, for the Commission:

I. INTRODUCTION

The Constitution empowers Congress to “promote the progress of science and useful arts” by creating intellectual property rights, including patents. U.S. CONST. art I, § 8, cl. 8. Congress has done so since the founding of our Republic and, today, the United States leads the world in, among other things, the development and manufacturing of pharmaceutical drugs, which save and enhance lives around the world.

But Americans too often pay more than they should for the prescription drugs they need. In 1984, Congress sought to address this problem by enacting the DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355) (1994) (“Hatch-Waxman Act”), which created a specialized process to encourage the market entry of generic prescription pharmaceutical drugs. Generic drugs contain the same active ingredients as branded drugs, but typically at a much lower cost. The Hatch-Waxman Act, together with other legislation at the federal and state levels, has facilitated a “dramatic rise in sales of generic drugs,” making them more widely available to

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Americans who would otherwise be forced to pay higher branded drug prices. *See* CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY (July 1998), <https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf>. Under the Hatch-Waxman Act, generic drugs with the same active pharmaceutical ingredients as, and bioequivalent to, branded drugs already approved by the Food and Drug Administration (FDA) can take advantage of an abbreviated regulatory review. If the generic drug manufacturer is the first to seek approval, the Hatch-Waxman Act can confer upon it six months of exclusive sales. Abbreviating the regulatory process and awarding the first filer an exclusive sales period together have encouraged competition in pharmaceutical drugs and, accordingly, provided greater access to healthcare at lower prices.

As explained below, where a patent protects the underlying drug and a generic manufacturer certifies that patent is invalid, unenforceable, or will not be infringed,¹ this certification automatically triggers the patent holder's ability to sue the generic. In this way, the Hatch-Waxman Act strikes a balance to encourage generic entry while protecting innovation, by giving the branded drug manufacturer an opportunity to assert its patent rights before the FDA approves the sale of the generic drug. This right allows the innovator to protect the congressionally authorized fruits of its labor (to the extent its patents are valid), maintaining the incentive to innovate that patent protection creates.

For decades, the Federal Trade Commission ("Commission") has prioritized efforts to make pharmaceutical drugs more affordable and accessible to American consumers by fostering competition between generic and branded drugs. That effort has included policing anti-competitive abuses of the regulatory process, and, as is relevant in this case, settlements of litigation brought by branded drug manufacturers against their generic competitors seeking to come to market using the Hatch-Waxman Act process.

This case involves a particular form of patent litigation settlement between a branded patent-holder and a generic challenger known as a "reverse payment" settlement. In a reverse payment settlement, the branded drug maker—the *plaintiff* in the patent infringement action—pays the patent challenger and alleged infringer—the *defendant*—to refrain from offering its generic drug for a period of time as part of a settlement of patent litigation. The value in the settlement flows in the opposite direction of what one would ordinarily expect, where the defendant and alleged infringer might pay the plaintiff intellectual property (IP) rights holder for allegedly violating those rights. *See FTC v. Actavis*, 570 U.S. 136, 152 (2013).

For years, the FTC challenged reverse payment settlements as anticompetitive.² Early on, some courts considering these settlements held that, so long as the generic entry date was

1 Otherwise known as a Paragraph IV certification. *See infra* Section II.A.

2 *See generally*, FTC Staff Study, Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions (Jan. 2010), <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf>.

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before the patent expired, the settlement was within the “scope of the patent” and therefore beyond the reach of the antitrust laws. *See, e.g., Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1332-1337 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212-213 (2nd Cir. 2006). Other courts agreed with the FTC that such settlements raise valid antitrust concerns, treating them as per se unlawful or subject to truncated “quick look” review. *See In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 908 (6th Cir. 2003); *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 214-218 (3d Cir. 2012), *judgment vacated by* 570 U.S. 913, 133 S.Ct. 2849 (2013), *reinstatement granted by* 2013 WL 5180857 (3d Cir. 2013). In *FTC v. Actavis*, 570 U.S. 136 (2013), the Supreme Court addressed this circuit split and made clear that the magnitude and direction of the reverse value flow in these settlements raise a red flag, suggesting that the parties may be using the settlement to split monopoly rents by paying would-be generic competitors to stay out of the market, and thereby insulating the brand from the risk of competition that would otherwise manifest. That led the Court to hold that reverse payment settlements, even when they limit competition within the scope of the patent, can still violate the antitrust laws, and are to be analyzed under the rule of reason. *Id.* at 158-60. This case provides the Commission our first opportunity to apply *Actavis*, and to develop the rule of reason analysis that it directs.

As described below, the facts of this case make clear that Respondent Impax Laboratories, Inc. (now Impax Laboratories LLC) (“Impax” or “Respondent”) contrived with Endo Pharmaceuticals, Inc. (“Endo”) to accomplish precisely what led the Court in *Actavis* to subject reverse payments settlements to antitrust scrutiny—*i.e.*, the elimination of the risk of competition in return for sharing monopoly rents.

On January 19, 2017, the Commission issued an Administrative Complaint alleging that Impax, a generic manufacturer, had entered into an unlawful reverse payment settlement with Endo, the maker of Opana ER, an extended-release formulation of oxymorphone, an opioid used to treat pain.³ During the administrative trial, Complaint Counsel submitted evidence that Endo agreed to pay Impax to abandon its patent challenge and to forgo entering the market with its lower-cost generic version of Opana ER until January 2013. IDF 124, 127, 129; ID at 138; Koch, Tr. 236, 239; RX364 at 0003-08, 0010-11 (definitions, patent settlement and license provisions of the Settlement and License Agreement between Endo and Impax (“SLA”)); *see also* CX3164 at 009-11 (Impax’s Responses to Requests for Admission No. 15 and 17).⁴ Rather than a simple

³ Endo is not before us in this case because it has settled the FTC’s claims against it regarding its 2010 patent settlement for Opana ER. *See* Stipulated Order for Permanent Injunction, *FTC v. Endo Pharm., Inc.*, No. 17-cv-00312-WHO (N.D. Cal., Feb. 2, 2017).

⁴ We use the following abbreviations in this opinion:

Compl.:	Complaint
ID:	Initial Decision
IDF:	Initial Decision Finding of Fact
Stip.	Joint Stipulations of Jurisdiction, Law, Fact, and Authenticity
Second Set of Stip.	Second Set of Joint Stipulations
CCAB:	Complaint Counsel’s Brief on Appeal
RB:	Respondent’s Answering Brief to Complaint Counsel’s Appeal Brief
CCRB:	Complaint Counsel’s Reply Brief on Appeal

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cash payment from Endo to Impax, Complaint Counsel argued that the reverse payment settlement involved an unlawful transfer of value in several forms: (1) freedom from generic competition during Impax’s first 180 days on the market by virtue of Endo’s agreement to refrain from offering an “authorized generic” version of Opana ER (the “No-AG Commitment”);⁵ (2) a contingent payment—ultimately worth \$102 million—designed to ensure that Impax recouped the value of the No-AG Commitment, in the event Endo destroyed the market for oxymorphone ER; and (3) a payment to Impax of \$10-40 million, purportedly for an independent development and co-promotion deal. RX364 at 0003-08, 0010-11; *see also* Koch, Tr. 234-39, 241; CX0326 (email attaching execution version of the Development and Co-Promotion Agreement).

Complaint Counsel alleged that Impax’s conduct denied patients the opportunity to purchase lower-cost generic versions of Opana ER until at least January 2013, and forced them, instead, to pay hundreds of millions of dollars a year more for Endo’s branded product. Complaint Counsel concluded that, in so doing, Impax violated Section 5 of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. § 45.

Impax denied that Endo agreed to pay or paid Impax to abandon its patent challenge or to forgo entering the market for generic Opana ER. Answer ¶ 3. Among other defenses, Impax asserted that the conduct had substantial procompetitive justifications, benefited consumers and the public interest, and avoided potential infringement of valid patents. Answer, Affirmative Defenses ¶ 8.

The case went to a 12-day trial before Chief Administrative Law Judge (“ALJ”) D. Michael Chappell. Judge Chappell heard live testimony from 18 witnesses and admitted into evidence over 1250 exhibits. ID at 3. In a 162-page decision issued on May 11, 2018, Judge Chappell found that Complaint Counsel had failed to prove a violation of Section 5 of the FTC Act, and dismissed the Complaint. Complaint Counsel filed a timely appeal. The Commission heard the parties’ oral arguments on October 11, 2018.

For the reasons set out below, the Commission reverses the Initial Decision, concludes that Impax has violated Section 5 of the FTC Act, and enters a cease and desist order.

II. LEGAL AND FACTUAL BACKGROUND

A. The Hatch-Waxman Act and the *Actavis* Decision

Under the Hatch-Waxman Act, when a manufacturer seeks to market a new prescription drug, it must submit a New Drug Application and undergo a long and costly testing process. The manufacturer’s application must identify the “number and the expiration date” of any relevant patents. 21 U.S.C. § 355(b)(1). Once the FDA has approved the drug, a manufacturer seeking to market a generic version may file an Abbreviated New Drug Application (ANDA) certifying that

⁵ An “authorized generic” drug typically refers to an approved brand name drug that is marketed without the brand name on its label. An authorized generic may be marketed by the brand name drug company, or another company with the brand company’s permission.

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the product contains the same ingredients as, and is biologically equivalent to, the brand-name drug. 21 U.S.C. § 355(j)(2)(A)(ii), (iv). The ANDA process “allow[s] the generic to piggy-back on the pioneer’s approval efforts” rather than conducting its own rigorous testing process. *Actavis*, 570 U.S. at 142.

To protect the branded manufacturer’s incentive to innovate, when a generic manufacturer submits an ANDA, it must assure the FDA that the generic drug will not infringe any valid patents covering the branded drug (as listed in the FDA’s official Orange Book). If the branded manufacturer has listed relevant, non-expired patents, the generic manufacturer may file what is known as a “Paragraph IV” certification declaring that those patents are “invalid or will not be infringed by the manufacture, use, or sale” of the generic drug.⁶ 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

Filing a paragraph IV certification “automatically counts as patent infringement” and entitles the brand manufacturer to sue. *Actavis*, 570 U.S. at 143; see 35 U.S.C. § 271(e)(2)(A). If the branded company files suit within 45 days, the FDA may not approve the generic drug for 30 months, while the parties litigate their patent dispute. *Actavis*, 570 U.S. at 143. If the courts resolve the patent litigation during this 30-month period, the FDA follows that determination. *Id.* If the patent case remains unresolved at the end of 30 months, the FDA may approve the generic. *Id.*; see 21 U.S.C. § 355(j)(5)(B)(iii). The generic manufacturer would then have the right to launch “at risk,”⁷ with the consequence that if the “court proceeding ultimately determines that the patent was valid and infringed, the generic manufacturer will be liable for the brand-name manufacturer’s lost profits despite the FDA’s approval.” *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 241 (3d Cir. 2017). These damages can be significant.

In adopting the Hatch-Waxman Act framework, Congress sought to give generic manufacturers a “special incentive” to be the first to file an ANDA challenging a branded drug’s patents under paragraph IV. See *Actavis*, 570 U.S. at 143. The first filer “will enjoy a period of 180 days of exclusivity” from other generic competition if it successfully brings the product to market. *Id.* at 143-44; see 21 U.S.C. § 355(j)(5)(B)(iv). The Hatch-Waxman Act accomplishes this by preventing other ANDA filers from entering the market during the exclusivity period, whenever that occurs. See 21 U.S.C. § 355(j)(5)(B)(iv). The exclusivity period can be worth hundreds of millions of dollars to a generic manufacturer. *Actavis*, 570 U.S. at 144. Because the Hatch-Waxman Act only prevents other ANDA filers from entering, however, the branded manufacturer may still distribute its own generic equivalent, commonly known as an “authorized generic” or “AG.” See *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 396 (3d Cir. 2015).

⁶ A Paragraph IV certification is not the only avenue; ANDA filers may also utilize Paragraphs I, II or III, certifying, respectively, that: patent information has not been filed, the relevant patent(s) have expired, or the date on which the patent(s) expire. See 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(III).

⁷ An “at risk” launch occurs when a generic firm begins marketing its product before a non-appealable decision in the relevant patent litigation. IDF 451.

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In *Actavis*, the Supreme Court considered the antitrust implications of reverse payment settlement agreements in which a branded drug manufacturer pays a generic entrant to abandon its patent challenge under the Hatch-Waxman Act and delay launching its product. The Court held that reverse payment settlements can have “significant adverse effects on competition,” even if they allow a generic rival to introduce its product before the end of the patent’s term—*i.e.*, within the temporal scope of the patent. *Actavis*, 570 U.S. at 148. These settlements essentially allow a branded manufacturer to buy “the exclusive right to sell its product, a right it already claims but would lose” were a court to declare the patent “invalid or not infringed.” *Id.* at 153-54. The settlement may keep drug prices at monopoly levels while “dividing that return between the challenged patentee and the patent challenger.” *Id.* at 154. In the process, “[t]he patentee and the challenger gain; the consumer loses.” *Id.* These “anticompetitive consequences will at least sometimes prove unjustified.” *Id.* at 156.

In a lawsuit challenging a reverse payment under *Actavis*, “offsetting or redeeming virtues are sometimes present.” *Id.* For example, a reverse payment may “amount to no more than a rough approximation” of the branded company’s saved litigation expenses or reflect “compensation for other services that the generic has promised to perform—such as distributing the patented item or helping to develop a market for that item.” *Id.* at 156; *see also id.* at 159. If a payment reflects such “traditional settlement considerations . . . there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.” *Id.* at 156.

But when a branded manufacturer makes a large, unexplained payment to a generic challenger, this “suggests that the payment’s objective is 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.* at 157. The payment “likely seeks to prevent the risk of competition,” which constitutes the “relevant anticompetitive harm.” *Id.* Preventing the risk of competition is the anticompetitive harm at issue in *Actavis*, and a large and unjustified payment from the plaintiff (the branded manufacturer) to the defendant (the generic manufacturer) triggers antitrust scrutiny because it may reflect the plaintiff’s dividing its monopoly profits to accomplish this goal.

The question presented in *Actavis* was whether a reverse payment settlement “can sometimes unreasonably diminish competition in violation of the antitrust laws.” *Id.* at 141. The Court held that the answer is yes. In so doing, it rejected abbreviated analysis either for or against liability. The Court rejected the “scope of the patent” test, which essentially held that reverse payment settlements were lawful so long as they did not prolong the life of the patent. *Id.* at 158. And it likewise rejected the Commission’s argument that reverse payment settlements should be considered “presumptively unlawful.” *Id.* at 158-59. The Court held that reverse payment settlements are to be analyzed under traditional rule of reason analysis. *Id.* Whether a reverse payment is anticompetitive “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.” *Id.* at 159. The Court “[le]ft to the lower courts the structuring of the present rule-of-reason antitrust litigation,” keeping in mind that the “basic question” in each case is whether a given reverse payment

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settlement agreement “unreasonably diminish[ed] competition in violation of the antitrust laws.” *Id.* at 160, 141.

B. Opana ER and Potential Generic Competition

Impax develops, manufactures, and sells generic drugs. IDF 3. This case considers its settlement of patent litigation initiated by Endo, the manufacturer of branded Opana ER. The settlement included a reverse payment to Impax in exchange for Impax’s agreement not to launch a competing generic drug until January 2013. As developed below in Section V.A.3, the reverse payment here consisted of the No-AG Commitment and the “Endo Credit,” a payment Endo would make in the event the Opana ER market declined in the two and a half years between the time of settlement and Impax’s entry date.⁸

In 2006, Endo received FDA approval for and launched Opana ER, an extended-release formulation of oxymorphone, an opioid used to treat pain. IDF 41-47. In 2007, Impax filed an ANDA to market a generic version of Opana ER and certified under paragraph IV that Endo’s patents were invalid, unenforceable, or would not be infringed. IDF 55-60. Impax was the first generic manufacturer to file an ANDA and paragraph IV certification for the five most popular dosage strengths of Opana ER, which comprised over 95 percent of Opana ER sales. IDF 173; Second Stip. ¶ 7. It was therefore entitled to 180 days of exclusivity from competition with other ANDA filers at those doses. IDF 174.

Endo timely sued Impax in January 2008, claiming that Impax’s ANDA infringed two of its patents, which expired in September 2013. IDF 53, 61, 68. The suit triggered the Hatch-Waxman Act’s 30-month stay, precluding the FDA from finally approving Impax’s ANDA until June 14, 2010 or until the patent dispute was resolved in Impax’s favor. IDF 62-63. Endo and Impax first discussed settlement in the fall of 2009, but Endo rejected Impax’s proposals for a generic entry date in July 2011, December 2011, or January 2012. IDF 112-18.

Endo reopened settlement talks with Impax on May 17, 2010, approximately three days after learning that the FDA tentatively approved Impax’s ANDA, three weeks before the patent trial was scheduled to begin, and one month before the 30-month stay would have expired. IDF 119-23, 283; Koch, Tr. 340-41. Endo recognized the possibility that Impax might launch its generic at risk upon receiving final FDA approval—expected the following month—or that Impax might launch after completing the patent trial and any relevant appeals “around June” of 2011. Stip. at 007 ¶ 17 (30-month stay set to expire on June 14, 2010); Koch, Tr. 340-41; Snowden, Tr. 417-18; CX4025 (Bingol Dep.) at 26; CX2564 at 094; CX2576 at 0001, 0003 (“If they wait for the appeal to play out, it will happen around June of next year [*i.e.*, 2011]”). Endo

⁸ As discussed further *infra* Section V.A.3.c, the circumstances surrounding the development and co-promotion agreement suggest it may also have been a means of masking value transferred in exchange for eliminating the risk of competition; but we need not decide whether the arrangement was a *bona fide* agreement for justified value. To the extent the \$10 million upfront payment under the agreement is unjustified, it simply increases the value of the overall reverse payment we find to be large and unjustified.

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sought a commitment from Impax that it would instead refrain from launching its generic until 2013. IDF 132, 147, 154, 156, 158.

Endo had a substantial financial interest in delaying Impax's generic entry. Endo forecast that, if Impax launched its generic at risk, Endo would lose 85 percent of its branded Opana ER sales within three months, and \$100 million in sales revenue within six months. IDF 133; *see also* CX1106 at 005 (Endo's July 2009 Strategic Plan: "Each month that generics are delayed beyond June 2010 is worth ~\$20 million in net sales per month."). To prevent this, Endo planned to remove original Opana ER from the market, replace it with a reformulated, "crush-resistant" version, and obtain additional patent protection and other advantages for the reformulated drug that would fend off competition. IDF 96-98, 102, 109.⁹ Doing so would move consumers to the reformulated version, effectively destroying the market for original oxymorphone ER, extending Endo's market power and negating the effect of Impax's entry. Koch, Tr. 238; CX5007 (Hoxie Rebuttal Report) ¶ 43 at 023; Mengler, Tr. 527. At the time of the 2010 settlement negotiations, Endo had not yet sought FDA approval for the reformulated product, but was forecasting a launch at some point in late 2010 or in 2011. *See* IDF 105.

Endo recognized that its reformulation plan could succeed only if it beat Impax's generic product to the market with enough time to transition patients away from original Opana ER. IDF 99-109. Patients cannot switch long-acting opioids overnight; the process instead requires careful supervision as physicians adjust dosages. IDF 106. Endo understood that it would take six to nine months to transition the market to the reformulated product. *Id.* It sought to protect its sales revenues from generic competition by completing this transition before Impax could launch its generic version of the original product; as developed below in Section II.C, the settlement at issue here was key to realizing this goal. IDF 97, 99-101, 103. Reformulating Opana ER in time would significantly reduce demand for Impax's generic product, since pharmacists would not be able automatically to substitute it for Endo's reformulated product, as they could for the original product. IDF 202, 204.¹⁰

Endo projected that its reformulation plan, if successful, would generate hundreds of millions of dollars in additional sales revenue for branded Opana ER. It predicted that, if reformulated Opana ER beat generics to the market, its peak-year sales would exceed \$199 million by 2016. IDF 99; CX2578 at 0008. By contrast, if generics launched before Endo could transition the market, Endo's peak projected annual sales in 2016 would be a mere \$10 million. IDF 99; CX2578 at 0008.

⁹ In some circumstances, this strategy of avoiding generic competition, commonly known as "product hopping," can itself violate the antitrust laws. *See, e.g., New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 659 (2d Cir. 2015) ("[W]e conclude that the combination of withdrawing a successful drug from the market and introducing a reformulated version of that drug, which has the dual effect of forcing patients to switch to the new version and impeding generic competition, without a legitimate business justification, violates § 2 of the Sherman Act.").

¹⁰ Generics may be automatically substitutable under state law for a branded drug only when they are therapeutically equivalent. Impax's generic was equivalent to the original product (which Endo was planning to withdraw), not the reformulated product. IDF 14, 29, 199-200. Automatic substitution is the primary mechanism for generic companies' sales. IDF 32.

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C. The Impax-Endo Patent Settlement

The trial in the Endo/Impax patent litigation commenced on June 3, 2010. IDF 73. Just a few days later, the parties settled. IDF 74. On June 8, 2010, they simultaneously executed two agreements: a Settlement and License Agreement and a Development and Co-Promotion Agreement (“DCA”), which was incorporated into the SLA. IDF 74, 245; Stip. at 007-08 ¶¶ 18-19; Second Stip. ¶ 26. Under the SLA, Impax agreed not to launch its generic Opana ER until January 1, 2013, two and one-half years later. IDF 124; RX364 at 0001-02, 0009 (SLA §§ 1.1, 4.1(a)). The settlement thus gave Endo a “clear path (until January 2013) to establish . . . demand” for the reformulated product. RX007 at 001 (Endo narrative for 3Q 2010 Earnings Call).

In return, Endo agreed to the No-AG Commitment, whereby it pledged not to sell an authorized generic to compete with Impax’s five dosage strengths of generic Opana ER during its 180-day first-filer exclusivity period. IDF 127; RX364 at 0010-11 (SLA § 4.1(c)). That concession would shield Impax from all generic competition (not just the competition from other ANDA filers that the 180-day exclusivity period provides) for six months after its January 2013 launch date. IDF 127, 130, 187. Impax considered the No-AG Commitment to be extremely valuable, since the absence of a generic rival meant that Impax would be able to sell more of its product and charge higher prices. IDF 172, 177, 179-83, 188-91; CX2753-004 (projecting that Impax’s profits during the exclusivity period would be \$53 million without an AG competitor but \$28.5 million with an AG).

The SLA contained a provision known as the “Endo Credit,” which would protect Impax in the event the Opana ER market declined in the two-and-a-half years between the time of settlement and Impax’s entry date. IDF 129. Impax feared—correctly, as it turns out—that Endo was planning to shift patients to a reformulated Opana ER before the generic launch date, which would impair the market for Impax’s generic product and “subvert the value of the deal.” IDF 139-43, 148-49, 204-05. To ensure against that possibility, Impax first sought an acceleration trigger allowing it to enter the market before 2013 should Endo sales fall below a certain threshold. IDF 137-39. The concept was that, in the event sales began dropping, Impax could enter the market early. This would have allowed competition, benefiting consumers. Endo rejected the acceleration trigger, but instead agreed to make a cash payment to Impax (*i.e.*, the Endo Credit) if Endo’s sales revenues for original Opana ER fell by more than 50% between their quarterly peak and the fourth quarter of 2012 (the quarter before Impax’s launch date). IDF 129, 147, 195; *see* RX364 at 0003-06, 0012 (SLA §§ 1.1, 4.4).¹¹ 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 had Endo not shifted the market away from original Opana ER. IDF 197-215.

The SLA also provided Impax with a license to Endo’s current and future patents covering original Opana ER, and a covenant by Endo not to sue Impax for infringing those patents. IDF 125-26, 567-68, 570, 592-93; RX364 at 0001-02, 0009-10 (SLA §§ 1.1, 4.1(a)-(b)).

¹¹ Conversely, the SLA provided that if Endo’s Opana ER sales *grew* by a certain percentage before Impax’s entry date, Impax would need to pay royalties to Endo. IDF 128; RX364-0012 (SLA § 4.3).

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At the time of the settlement, Impax knew that Endo had additional pending patent applications (whose outcomes were uncertain) and anticipated that Endo could acquire other patents. IDF 167, 569, 572. When negotiating settlements with brand companies, Impax regularly sought licenses to future patents to ensure that Impax's generics had freedom to operate without patent risk. IDF 565-66.

Under the DCA, Endo and Impax agreed to collaborate regarding the development and marketing of a potential Parkinson's disease treatment known as IPX-203. IDF 244, 246; RX365 (executed DCA). Endo agreed to make a \$10 million upfront payment to Impax within five days, plus up to \$30 million in additional "Milestone Payments" contingent on achieving certain benchmarks in developing and commercializing the product. IDF 247-48; RX365 at 0009 (DCA § 3.2). In addition, the parties agreed that Impax would promote IPX-203 to neurologists, while Endo would promote it to non-neurologists. IDF 249; RX365 at 0010-11 (DCA § 4.1). Endo would receive a share of the profits—100 percent of gross margins on sales resulting from prescriptions by non-neurologists—if IPX-203 ever reached the market. IDF 250; RX365 at 0009-10 (DCA § 3.4).

D. Developments after the Settlement Agreement

On June 14, 2010—six days after finalizing the SLA and DCA—Impax received final FDA approval to market its generic Opana ER at four dosage strengths. IDF 66.¹² Had Impax not settled with Endo, it would have been permitted to launch its generic product at risk as of that date. IDF 451-52. Coupled with the Hatch-Waxman Act, however, the settlement effectively precluded entry by Impax and by other generic manufacturers, which had to wait until Impax, the first filer, entered the market in January 2013 and then completed its six-month exclusivity period. IDF 449. *See In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 41 (1st Cir. 2016) ("[T]he first filer may create a bottleneck, as all other generic manufacturers must wait for the exclusivity period to end before launching their own generics.").

In March 2012, Endo introduced its reformulated Opana ER and stopped selling original Opana ER (as Impax had feared). IDF 110, 229-31. It then attempted to undermine the market for the original formulation. In August 2012, for instance, Endo publicly declared that the original product was unsafe. IDF 233.¹³ 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. IDF 236-37.

Between 2012 and 2014, Endo obtained additional patents related to Opana ER and asserted them against generic manufacturers of both the original and reformulated versions. IDF 575-77, 579-84. In 2015 and 2016, Endo won district court rulings enjoining manufacturers other

12 Impax received final approval for a fifth dosage strength on July 22, 2010. IDF 67.

13 Endo filed multiple citizen petitions with the FDA asking it to: (1) determine that original Opana ER was discontinued for safety reasons; (2) refuse to approve any ANDAs to market a generic version of the drug; and (3) withdraw its approval of Impax's generic. IDF 233; CX3203 (citizen petitions). In response, the FDA determined that Endo did *not* withdraw original Opana ER for safety reasons. IDF 235.

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than Impax from selling their generic versions of original Opana ER until as late as 2029, and enjoining all manufacturers, including Impax, from selling generic versions of reformulated Opana ER. IDF 578, 586-87. The Federal Circuit recently affirmed one of those rulings. *See Endo Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F. App'x 962 (Fed. Cir. 2018).

Impax has sold generic Opana ER continuously since January 2013 and is the only generic manufacturer that has not been enjoined from the market. IDF 596-97. Even so, the SLA did not fully protect Impax from the risk of litigation regarding Endo's patents. In May 2016, Endo sued Impax for breaching the SLA by failing to negotiate a royalty for the patents Endo acquired after the SLA and, consequently, for infringing those patents. IDF 589; CX2976 (Endo's Complaint for breach of contract and patent infringement). The parties settled that dispute in August 2017. ID 590-91; CX3275 (Contract Settlement Agreement), *in camera*.

In September 2017, Endo voluntarily withdrew its reformulated Opana ER from the market in response to a June 2017 FDA request. IDF 111. The FDA had determined that the benefits of the reformulated product no longer outweighed the risks that consumers would abuse it via injection. CX6048-0001 (June 8, 2017 FDA news release). As a result of that withdrawal and of Endo's decision to withdraw its original Opana ER product, Impax's generic original Opana ER is now the only extended-release oxymorphone product available to consumers. IDF 598.

E. The FTC's Complaint

In January 2017, the FTC issued an administrative complaint against Impax, alleging that its reverse-payment settlement with Endo was an unfair method of competition in violation of Section 5(a) of the FTC Act. Compl. ¶¶ 101-02. The Complaint charges that Impax agreed to abandon its challenge to Endo's patents and stay off the market for two and a half years in exchange for a payment of at least \$47 million (and potentially over \$100 million). Compl. ¶¶ 1, 3, 62, 67. According to the Complaint, a payment of this size could not be justified as either a reasonable measure of saved litigation costs or the value of any services that Impax provided. Compl. ¶¶ 68, 72-73. The Complaint alleges that the payment was designed to, and did, eliminate the risk that Impax would launch its generic version of Opana ER before January 2013. Compl. ¶ 94. Endo and Impax allegedly injured competition by splitting Endo's monopoly profits for themselves, while depriving consumers of access to generic drugs that could have saved them hundreds of millions of dollars. Compl. ¶¶ 4, 95-97.¹⁴

F. The Initial Decision

The ALJ held that Endo "provided Impax with a reverse payment, the purpose and effect of which was to induce Impax to give up its patent challenge and agree not to launch a generic

¹⁴ Prior to the evidentiary hearing before the ALJ, Complaint Counsel moved for partial summary decision to preclude Impax from offering certain procompetitive justifications for the settlement. The Commission denied the motion as premature because Impax had not received a full opportunity to articulate its procompetitive justifications and because the parties had not briefed the question of how the rule-of-reason inquiry should be structured. *See Impax Labs., Inc.*, 2017 WL 5171124, at *6, *9 & n.16 (F.T.C. Oct. 27, 2017).

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Opana ER until January 2013.” ID at 6-7. However, he further found that the “procompetitive benefits” of the agreement “outweigh[ed] the anticompetitive harm.” *Id.* at 7. The ALJ reached this conclusion by applying the rule of reason burden-shifting framework.

The ALJ held that the first step of the rule of reason analysis placed on Complaint Counsel the burden of showing that the Endo-Impax Settlement produced anticompetitive effects within the relevant market. ID at 91. That, in turn, entailed a showing that Endo provided “payment for delay, or, in other words, payment to prevent the risk of competition.” *Id.* at 98 (quoting *Smithkline Beecham*, 791 F.3d at 412). The ALJ observed that, under *Actavis*, the relevant anticompetitive harm from an unexplained reverse payment is the loss of the *risk* of competition. *Id.* at 100 (citing *Actavis*, 570 U.S. at 157) (emphasis supplied).

The ALJ held that the No-AG Commitment of the SLA gave Impax a six month monopoly on generic sales of Opana ER that was worth between \$23 and \$33 million in additional projected sales revenue to Impax, a value he assigned as part of the reverse payment. ID at 106, 114. As for the Endo Credit, the ALJ acknowledged that the provision eventually resulted in a cash payment of \$102 million to Impax; but he held that the Endo Credit should be valued as of the date of settlement. *Id.* at 113. At that point, the value of the Endo Credit was “uncertain ... and was contingent on unknown future events that were outside of Impax’s control.” *Id.* at 110. The ALJ thus did not assign independent value to the Endo Credit;¹⁵ instead, he found that the payment “fulfilled its purpose” of providing Impax the profits that it would have received during the 180-day exclusivity period with no AG in the event of a sharp decline in the market. *Id.* at 114. The ALJ then found that the value of the No-AG Commitment of the SLA, as secured by the Endo Credit, amounted to between \$23 and \$33 million. *Id.* The ALJ found that this amount substantially exceeded Endo’s saved litigation costs, was unjustified, and that the parties agreed to the provision as an inducement to compensate Impax for giving up its patent challenge and committing not to launch a generic Opana ER until January 2013. *Id.* at 116, 138. He found these facts demonstrated that the SLA included a payment to prevent the risk of competition. *Id.* at 138-39.

The ALJ found that the \$10 million upfront payment to Impax under the DCA was fair value for the profit-sharing rights given to Endo, and that the DCA was a *bona fide* product collaboration consistent with Endo’s business interests. ID at 132, 138. He found that the payment was therefore justified. *Id.* at 138.

The ALJ found that Endo possessed market power. ID at 139. Pharmaceutical patents “by their nature,” he explained, “often carry with them market power” because they provide “the legal right to exclude generic competition and the practical ability to profitably charge higher prices than generic competitors would charge.” *Id.* (quoting *In re Aggrenox Antitrust Litig.*, 199

15 The ALJ also rejected Complaint Counsel’s effort to prove a value for the Endo Credit through testimony of their expert economist, Dr. Roger Noll. ID at 111. Professor Noll calculated values of the Endo Credit and No-AG Commitment under four potential sales scenarios, *id.*, and opined that the value ranged from \$16.5 to \$62 million. Tr. 1473-77; CX5000 (Noll Expert Report) App. F at 240. The ALJ opined that Professor Noll failed to adequately describe or explain the bases for his assumptions or calculations. ID at 111.

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F. Supp. 3d 662, 668 (D. Conn. 2016)). He also took the view that, in this case, the “reverse payment settlement itself” was “strong proof of Endo’s market power,” since a firm lacking such power would have had no incentive to pay others to keep out of the market. *Id.* at 139-40 (discussing *Actavis*, 570 U.S. at 157). The ALJ further observed that regulatory barriers under the Hatch-Waxman Act, such as the 30-month stay on FDA approval of an ANDA, can serve to protect market power. *Id.* at 140. In the unique context of pharmaceutical reverse payments, he ruled, “the appropriate market in which to assess the anticompetitive effects . . . [is] the branded pharmaceutical product and its generic equivalents.” *Id.* at 97. At the time of settlement, “Endo had a 100% share of the market for oxymorphone ER,” *id.* at 140, and therefore possessed market power in a relevant market so defined. *Id.* at 139-40.

The ALJ held that, because Complaint Counsel had shown anticompetitive harm, the burden shifted to Respondent to demonstrate procompetitive benefits, the second step in the rule of reason analysis. *See generally* ID at 99, 141-47.

The ALJ rejected Complaint Counsel’s argument that he should consider only those benefits that justified the anticompetitive reverse payment itself, and held instead that he should assess *all* procompetitive effects of the Impax-Endo settlement agreement. ID at 99-100 (finding that “to condemn an agreement based on the reverse payment term alone is an approach that is too abbreviated to permit proper analysis” (internal quotation marks omitted)). Viewing the settlement as whole, the ALJ concluded that Impax had met its burden to show procompetitive benefits. *Id.* at 146. The agreements settled litigation, and the broad patent license that Impax obtained had provided consumers with uninterrupted and continuous access to generic Opana ER since January 2013. *Id.* Absent the broad license, Endo could have asserted its later-acquired patents against Impax and enjoined Impax from selling generic Opana ER, just as Endo has enjoined other unlicensed generic manufacturers. *Id.* at 145. The ALJ also considered the fact that the SLA enabled Impax to enter the market prior to the expiration of Endo’s Opana ER patents, but noted this fact was “not dispositive.” *Id.* at 146. The SLA enabled Impax to enter the market in January 2013, nine months before expiration of the initial Opana ER patents in September 2013, and sixteen years before the expiration of Endo’s after-acquired patents in 2029. *Id.* Thus, the ALJ found that Respondent met its burden of proving procompetitive benefits of the SLA. *Id.*

Having found that the Respondent met its burden to demonstrate procompetitive benefits, the ALJ shifted the burden to Complaint Counsel to establish that the benefits could have been achieved with a less restrictive settlement agreement. ID at 146. The ALJ determined that Complaint Counsel failed to meet their burden. *Id.* at 147. He rejected Complaint Counsel’s argument that the parties could have agreed to the very same patent license without a payment. *Id.* (finding that Complaint Counsel had not demonstrated that a settlement without a payment would have included the broad patent license). In reaching this conclusion, the ALJ noted that Impax twice proposed a settlement with a 2011 entry date and no reverse payment, and Endo rejected each proposal. *Id.* at 147, n.35.

The ALJ proceeded to assess the extent to which the Endo-Impax settlement harmed competition by actually delaying generic entry. ID at 150-58. He found the anticompetitive

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effects of the reverse payment to be “largely theoretical” because Impax would have been “unlikely” to launch its generic product before the agreement’s January 2013 entry date in any event. *Id.* at 156-57. Impax would not have launched at risk, he found, because it was a relatively small firm (less than \$1 billion in revenues) that could have faced “bet the company” damages in the event of an adverse patent ruling after entry. *Id.* at 150. The ALJ found that Impax had no history of launching at risk in analogous situations, and that its management had not sought the approval of its board of directors required for such a launch. *Id.* at 150-51. Furthermore, he found, Impax’s hypothetical entry after completion of the Endo-Impax litigation would not have occurred until “November 2011 at the earliest, and more likely [...] a date close to January 2013,” *id.* at 156, even if Impax had been successful. The ALJ based this finding on the opinion of E. Anthony Figg, Respondent’s expert, who testified regarding the time likely to be required for a hypothetical district court decision and for resolution of an appeal (and a possible remand) in the Endo-Impax patent litigation. *Id.* at 155-56.

The ALJ found that the procompetitive benefits of the SLA were, by contrast, “substantial,” because the broad patent license has allowed Impax to sell generic Opana ER “without interruption for more than five years” and because Impax’s product is now the “only available oxymorphone ER product” for consumers. *Id.* at 157; IDF 596-98. The ALJ concluded that the January 2013 entry date in the SLA, together with the broad patent license, enabled Impax’s 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. *Id.* at 157. Impax was able to continue selling its product without threat of patent infringement litigation due to its broad license. *Id.* “These actual consumer benefits,” the ALJ concluded, “outweigh the theoretical anticompetitive harm demonstrated in this case.” *Id.* Even if it were assumed that Impax would have entered the market as early as June 2010, the ALJ added, the benefits to consumers of uninterrupted access to generic Opana ER for more than five years (from 2013 through 2018) would still outweigh any harm from two and a half years of delayed generic entry. *Id.*

Accordingly, the ALJ found that the evidence failed to demonstrate that the Endo-Impax settlement was an unreasonable restraint of trade in violation of Section 5 of the FTC Act, and he therefore dismissed the Complaint. *Id.* at 158. Before the Commission, Complaint Counsel challenge the ALJ’s conclusions that Impax met its burden to identify cognizable procompetitive benefits and that the settlement at issue was not anticompetitive. Impax challenges the ALJ’s findings regarding market definition and power, but it does not challenge the ALJ’s finding that it received a large and unjustified payment.

III. STANDARD OF REVIEW

Under the applicable regulations, the ALJ issues an initial decision following administrative trial, 16 C.F.R. § 3.51, and the Commission reviews the ALJ’s findings of fact and conclusions of law *de novo*, considering “such parts of the record as are cited or as may be necessary to resolve the issues presented.” 16 C.F.R. § 3.54(a). The Commission may “exercise all the powers which it could have exercised if it had made the initial decision.” *Id.*; *see also* 5 U.S.C. § 557(b). The *de novo* standard of review applies to both findings of fact and inferences

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drawn from those facts. *See Realcomp II, Ltd.*, 2007 WL 6936319, at *16 n.11 (F.T.C. Oct. 30, 2009), *aff'd*, 635 F.3d 815 (6th Cir. 2011).

IV. JURISDICTION

Respondent does not dispute that the Commission has jurisdiction over it and over the conduct challenged in the Complaint. Section 5(a) of the FTC Act grants the Commission authority to prevent “unfair methods of competition in or affecting commerce” by “persons, partnerships, or corporations,” 15 U.S.C. § 45(a)(1)-(2). Impax is a corporation as “corporation” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44, over which the Commission has jurisdiction. *See* Stip. at 001-02 ¶¶ 4, 7. Impax’s acts and practices at issue are subject matter over which the FTC has jurisdiction. *Id.* at ¶¶ 5, 7.

V. ANALYSIS

The Complaint alleges that the SLA and associated acts and practices are an agreement to restrain competition and constitute an unfair method of competition in violation of Section 5 of the FTC Act. Compl. ¶¶ 101-102. To determine whether this conduct violates Section 5 of the FTC Act, we follow case law that has developed under Section 1 of the Sherman Act.¹⁶

In *Actavis*, the Supreme Court held that the rule of reason applies to reverse payment settlement cases, but explicitly left to the lower courts the task of structuring the inquiry. 570 U.S. at 160. Citing its holding in *California Dental Association v. FTC*, 526 U.S. 756 (1999), the Court directed trial courts to “avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on [...] the presence of significant anticompetitive consequences.” *Actavis*, 570 U.S. at 159-60. This case concerns a reverse payment settlement, the restraint within it, and the relationship between the two.

With the Supreme Court’s *Actavis* guidance in mind, we apply the burden-shifting analysis that courts have used in other rule of reason cases, as informed by the Supreme Court’s reasoning in *Actavis*. Under this framework, the plaintiff has the burden to prove that “the challenged restraint has a substantial anticompetitive effect that harms consumers in the relevant market.” *See Ohio v. American Express*, 138 S. Ct. 2274, 2284 (2018) (“*Amex*”); *Todd v. Exxon Corp.*, 275 F.3d 191, 206 (2d Cir. 2001) (“an actual adverse effect on competition”); *Law v. Nat’l Collegiate Athletic Ass’n*, 134 F.3d 1010, 1019 (10th Cir. 1998) (“substantially adverse effect on competition”); *United States v. Brown Univ.*, 5 F.3d 658, 668 (3d Cir. 1993) (“adverse, anti-competitive effects within the relevant product and geographic markets”).

¹⁶ The Commission’s authority under Section 5 of the FTC Act extends to conduct that violates the Sherman Act. *See*, FTC, Statement of Enforcement Principles Regarding “Unfair Methods of Competition” Under Section 5 of the FTC Act (Aug. 13, 2015), https://www.ftc.gov/system/files/documents/public_statements/735201/150813section5enforcement.pdf; *see also Actavis*, 570 U.S. at 145; *Cal. Dental Ass’n*, 526 U.S. at 762 & n.3; *FTC v. Motion Picture Advert. Serv. Co.*, 344 U.S. 392, 394-95 (1953); *Fashion Originators’ Guild of Am., Inc. v. FTC*, 312 U.S. 457, 463-64 & n.4 (1941). In this proceeding, our analysis under Section 5 is the same as it would be under Section 1 of the Sherman Act.

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Provided the plaintiff demonstrates anticompetitive harm, the burden shifts to the defendant to show a procompetitive rationale for the restraint. *Amex*, 138 S. Ct. at 2284; *Law*, 134 F.3d at 1019. If the defendant does so, then the burden shifts back to the plaintiff to demonstrate that the procompetitive efficiencies could reasonably be achieved through less anticompetitive means. *Amex*, 138 S. Ct. at 2284. If the plaintiff carries this burden, it prevails. 7 Areeda & Hovenkamp, ANTITRUST LAW ¶ 1507c, at 448 (4th ed. 2017). If the plaintiff does not, the adjudicator proceeds to weigh the harms and benefits against each other to judge whether the challenged behavior is, on balance, reasonable. *See Law v. NCAA*, 134 F.3d at 1019 (citing Areeda & Hovenkamp, *supra* ¶ 1502). Cases do not often reach the balancing stage.

A. Complaint Counsel’s *Prima Facie* Case under *Actavis*

Complaint Counsel’s first obligation is to make out a *prima facie* case, proving that the challenged restraint has a substantial anticompetitive effect in a relevant market. In the Hatch-Waxman Act litigation context, *Actavis* makes clear that a settlement involving a large and unjustified reverse payment raises a “red flag” that the parties may be agreeing to eliminate the risk of competition. A plaintiff may thus make out a *prima facie* case by proving a large, unjustified payment was made in exchange for deferring entry into the market or for abandoning a patent suit, plus the existence of market power. *See Nexium*, 842 F.3d at 59 (first step of rule of reason framed for the jury as requiring market power plus a large and unjustified payment). The ALJ found that Impax received a large and unjustified payment as part of the settlement at issue, and Impax does not challenge that finding before the Commission.

We likewise find that Impax received a large and unjustified payment. In addition, we conclude that Complaint Counsel met their burden here. Complaint Counsel successfully raised the inference that Endo and Impax agreed to the large and unjustified payment as an inducement to Impax to give up its patent challenge and to commit not to launch a generic Opana ER until January 2013—thereby eliminating the risk of any generic entry until that time—and they proved the requisite market power. *See Actavis*, 570 U.S. at 154. Complaint Counsel demonstrated that the risk of earlier entry was real: there was a plausible threat that Impax could have entered the market prior to the agreed-upon entry date. *See In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 240 (D. Conn. 2015) (plaintiff must prove large, unjustified payment “as part of [a] settlement in order to shore up *some perceived risk*” of competition (emphasis added)). And *Actavis* makes clear that eliminating the risk of competition is a cognizable harm under the antitrust laws. 570 U.S. at 157. Complaint Counsel further demonstrated that the relevant product market consisted of branded and generic oxymorphone ER, and that Endo held market power.

1. Large, Unjustified Payment Raises Inference of Anticompetitive Harm

The *Actavis* Court described certain inferences that can be drawn from a large, unexplained reverse payment in a patent settlement. Such a payment raises a red flag signaling that the parties may not merely be settling valid claims, but may actually be entering an unlawful agreement to maintain and to share the brand’s monopoly profits. As the Court explained, a large and unjustified reverse payment “may . . . provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that

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would otherwise be lost in a competitive market.” 570 U.S. at 154. Such payments “would be an irrational act unless the patentee believed that generic production would cut into its profits.” Herbert Hovenkamp, *Anticompetitive Patent Settlements and the Supreme Court’s Actavis Decision*, 15 MINN. J. L. SCI. & TECH. 3, 25 (2014). The presence of a large and unjustified payment may thus signal the presence of an unlawful agreement yielding competitive harm. See Aaron Edlin, *et al.*, *The Actavis Inference: Theory and Practice*, 67 RUTGERS U. L. REV. 585, 587, 591 (2015) (“The Court identified a large and unexplained payment as a suspicious act that suggests the patent holder is paying to limit competition.”); see, e.g., *Smithkline Beecham*, 791 F.3d at 394 (payment “may represent an unusual, unexplained reverse transfer of considerable value from the patentee to the alleged infringer and may therefore give rise to the inference that it is a payment to eliminate the risk of competition”).

2. Principles of Analysis for Evaluating Large, Unjustified Payments

To make out a *prima facie* case, any antitrust plaintiff must establish the existence or likelihood of substantial anticompetitive harm. See *Amex*, 138 S. Ct. at 2284; *Law*, 134 F.3d at 1019; *Brown Univ.*, 5 F.3d at 668 (“adverse, anti-competitive effects within the relevant product and geographic markets”). Under *Actavis*, this includes a demonstration that a “large and unjustified” reverse payment was made. 570 U.S. at 158.

When analyzing the size of the “payment” in a reverse payment case, factfinders should consider all value—cash and otherwise—that the branded drug manufacturer transfers to the generic through the settlement (including any side agreements that contemporaneous timing or other circumstances indicate should be considered part of the same transaction). See *infra* Section V.A.3; see generally *Smithkline Beecham*, 791 F.3d at 403 (*Actavis* is not limited to payments of cash and includes no-AG clauses).¹⁷ The Endo/Impax settlement included both a cash payment under the DCA and non-cash or contingent forms of value, including the No-AG Commitment, the Endo Credit, and the licenses granted to Impax, all of which should be considered in valuing the reverse payment. See *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704, 718 (N.D. Ill. 2016) (court should look at whether, “taken as a whole,” the total payment Impax received under the SLA, the No-AG Commitment, and the DCA was large and unjustified). Any other result would ignore the economic realities of the settlement by disregarding forms of consideration that the brand conveyed. This could create a perverse incentive for settling parties to shield the sharing of the brand’s monopoly profits through non-cash value transfers. See *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 549 (1st Cir. 2016) (holding that non-monetary reverse payments are subject to *Actavis* because the Supreme Court contemplated that “a disguised above-market deal, in which a brand manufacturer effectively overpays a generic manufacturer for services rendered, may qualify as a reverse payment”).

¹⁷ As one district court wrote, “[a] settlement agreement may be very simple or tremendously complex, and it may involve all manner of consideration; and if, when viewed holistically, it effects a large and unexplained net transfer of value from the patent-holder to the alleged patent-infringer, it may fairly be called a reverse-payment settlement.” *Aggrenox*, 94 F. Supp. 3d at 243.

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Contrary to Complaint Counsel’s argument that demonstrating a payment is “large,” along with a showing of market power, will establish a *prima facie* case, CCAB at 39-41, plaintiffs also need show that the reverse payment was “unjustified.” *Actavis*, 570 U.S. at 158; *Loestrin 24 Fe*, 814 F.3d at 552.

Establishing that the payment is not otherwise justified is necessary for demonstrating that the payment is purchasing an exclusive right and preventing the risk of competition. In other words, it is the basis for attributing anticompetitive harm to the patent settlement, and thus an essential part of plaintiff’s case. As explained by *Actavis*, “the potential for genuine adverse effects on competition” arises when the reverse payment “amounts to a purchase by the patentee of the exclusive right to sell its product,” a right that would be lost if the patent proved to be invalid or not infringed. 570 U.S. at 153-54 (internal quotation omitted).

The concepts of “large” and “unjustified” are closely linked, because the size of the payment must be evaluated relative to the legitimate value that may justify it. A “large” payment is one that exceeds the value of the avoided litigation costs, plus any other services the generic drug manufacturer provides to the branded firm. *See In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523, 543 (D.N.J. 2014), *rev’d on other grounds*, 868 F.3d 231 (3d Cir. 2017). Meanwhile, a payment is justified when it represents “traditional settlement considerations, such as avoided litigation costs or fair value for services.” *Actavis*, 570 U.S. at 156. *Actavis* directs us to look not merely at the absolute value of a payment, but also at benchmarks such as “[the payment’s] scale in relation to the payor’s anticipated future litigation costs [and] its independence from other services for which it might represent payment[.]” *Id.* at 159. *Actavis* thus requires that a plaintiff prove as part of its *prima facie* case that a payment was both large and unjustified. As discussed below, Complaint Counsel made that showing here.

Placing the burden on Complaint Counsel to demonstrate a “large and unjustified” payment in the *prima facie* case also finds support in the limited post-*Actavis* case law. *See, e.g., Nexium*, 842 F.3d at 59 (upholding jury verdict form with “large and unjustified” as part of *prima facie* case); *Loestrin 24 Fe*, 814 F.3d at 552 (to survive a motion to dismiss, plaintiff “must allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment”); *Smithkline Beecham*, 791 F.3d at 412 (requiring plaintiff to prove a payment for delay, with the “likelihood of a reverse payment bringing about anticompetitive effects” dependent on the payment’s size, its scale in relation to anticipated future litigation costs, and independence from other services); *In re Cipro Cases I & II* (“*Cipro*”), 348 P.3d 845, 865-66 (Cal. 2015) (requiring plaintiff to show that the value of the reverse payment exceeded the value of collateral products or services provided by the generic to the brand, plus anticipated future litigation costs); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2015 WL 5458570, at *7 (D. Mass. Sept. 16, 2015) (plaintiff bears “initial burden” to show a large and unjustified payment).

Complaint Counsel need not negate every conceivable justification for the payment, nor pre-emptively refute evidence of value not in their possession or control, to satisfy their *prima*

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facie burden.¹⁸ *Cf. Lipitor*, 868 F.3d at 255 (noting that in *Actavis*, the FTC’s complaint “did not preemptively negate justifications for the reverse payments”); *Cipro*, 348 P.3d at 867 (a party’s own litigation costs and the existence and value of any collateral products or services provided in the settlement are “matters about which the settling parties will necessarily have superior knowledge”); *In re K-Dur Antitrust Litig.*, 2016 WL 755623, at *13 (D.N.J. Feb. 25, 2016) (same). It suffices to show that the size of the payment exceeded the payor’s anticipated saved litigation costs plus the value to be rendered under the agreement and that no other clear justification presents itself. *See In re Androgel Antitrust Litig. (No. II) (“Androgel II”)*, 2018 WL 2984873, at *9 (N.D. Ga. June 14, 2018) (plaintiff’s burden is to show that “the settlement payments are . . . larger than what could reasonably be expected to cover such traditional settlement concerns as future litigation costs or the value of services rendered”).

3. Analyzing the Value Flow and Determining the Reverse Payment

The Initial Decision found that the No-AG Commitment of the SLA secured by the Endo Credit was an “unjustified reverse payment,” ID at 138, “the purpose and effect of which was to induce Impax to give up its patent challenge and agree not to launch a generic Opana ER until January 2013.” ID at 7. Impax has not appealed the ALJ’s conclusion that a large reverse payment helped induce settlement or that the payment was linked to the January 2013 entry date, *see* RB at 4 n.1, and we agree that Complaint Counsel have borne their burden.

We reiterate that, to determine in the first instance whether a settlement involves a suspicious reverse payment, the factfinder should consider all value flowing in the “reverse” direction, *i.e.*, to the generic. Not all of this value may properly be attributed as part of a “large and unjustified” payment, but whether it should be attributed as such can only be discerned after examining it in the light of the facts at hand. The value flowing to Impax in this case came in several forms, discussed in turn below.

a. The No-AG Commitment

First, Endo agreed to the No-AG Commitment, which obligated Endo not to market an “authorized generic” of Opana ER during the six months of Impax’s exclusivity. Koch, Tr. 235-36; Snowden, Tr. 392-93. In the wake of *Actavis*, several federal courts have held that the rule of reason governs both cash and in-kind payments—including no-AG commitments—arising in reverse payment settlements. Such concessions can be of “great monetary value” to the first-filing generic drug manufacturer, which would then enjoy a “generic monopoly instead of a generic duopoly” for those six months. *Smithkline Beecham*, 791 F.3d at 404-05; *see also Loestrin 24 Fe*, 814 F.3d at 549-52.

¹⁸ The shifting burdens of production characteristic of antitrust adjudication can address both plaintiffs’ information problem and defendants’ right to adduce evidence of justification. *See, e.g., Cipro*, 348 P.3d at 867; *K-Dur*, 2016 WL 755623, at *13 (once plaintiff shows that the payment was “large” in comparison to the expected future litigation costs, the burden of production shifts to the respondent to come forward with evidence that the value of collateral products and services suffices to bring the settlement’s value up to the value of the payment without reference to the delayed entry).

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The No-AG Commitment here would allow Impax to obtain greater revenues from its generic sales than it would if Endo entered and competed with an authorized generic. IDF at 187-89, 191. Impax valued this commitment between \$23-33 million in projected revenue, IDF 193, and Endo approximated the revenues it forwent to be \$25 million. IDF 192. As Complaint Counsel demonstrated, this value range exceeded substantially a reasonable estimate of costs saved from litigation (\$5 million, \$3 million of which was attributable to Endo).¹⁹ CX5000 (Noll Expert Report) at ¶ 375; Noll, Tr. 1463; IDF 77-81; ID at 115 (value of the reverse payment “substantially exceeded the estimated saved litigation costs”).²⁰

b. The Endo Credit

Second, the reverse payment settlement provided Impax significant value in the form of the Endo Credit, which Impax would receive if Endo moved the market away from original formulation Opana ER before Impax entered. The evidence at trial demonstrated that, at the time the parties entered the settlement, Endo was planning a “product hop” that would destroy the market for original Opana ER before Impax could bring its generic to market. IDF 96-107; Koch, Tr. 236-37; CX3205 at 001 (December 13, 2007 Endo memo: “There is also a life cycle management (LCM) imperative for Endo’s Opana ER franchise To ensure we continue to protect the franchise in the face of loss of regulatory exclusivity in June 2009, a [tamper resistant] formulation of ER will be important to secure. Without this LCM strategy, Opana ER is expected to lose about 70% of its sales within six months if generic entry occurs”); CX4010 (Mengler, Investigative Hearing Transcript (“IHT”)) at 21 (Impax feared “that Endo had a strategy in place that would have led to the elimination of the Opana ER market, destroying . . . all of [its] value and [its] ability to sell the generic.”). Evidence suggests that Endo negotiated for a later entry date to give it time to execute this scheme. *See* CX4014 (Hsu Dep.) at 156-57 (“Obviously that’s their goal” to transfer the market to a reformulated version before Impax could enter under the SLA); CX2724 (Endo’s plan to reformulate Opana ER and transition the market to the new product would be adversely affected if Impax launched its generic in June 2010). The evidence also showed that Impax suspected the plot and, fearful that Endo planned to destroy the value it had secured itself through the No-AG Commitment, demanded what became the Endo Credit. Mengler, Tr. 528, 531-35, 568. The credit would compensate Impax in the event Endo’s Opana ER dollar sales fell by more than 50 percent of their quarterly peak prior to Impax’s entering the market. RX364 at 0003-06, 0012 (SLA §§ 1.1, 4.4). This dynamic underscores the fact that Impax sought to share in the value created by agreeing with Endo to eliminate the risk of competition. In the event it launched as planned, there would be no

¹⁹ *Actavis* indicates it is appropriate to compare the size of the payment to the *payor’s* expected saved litigation costs, not the combined savings, *see* 570 U.S. at 159 (“[T]he 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”). This makes sense because it is the excess of Endo’s payment over its other savings or justified benefits that should be understood as directed toward buying market exclusivity. Whether we utilize the projected savings of Endo alone or the joint savings of the parties, however, the size of the reverse payment is unquestionably “large” by comparison.

²⁰ The parties have not pled, and therefore we do not reach, the separate question of whether all no-AG commitments are large and unjustified payments under *Actavis*.

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authorized generic. In the event plans went awry, and any sale of Opana ER was foreclosed or minimized, Impax still would profit from less competition. The credit ultimately resulted in Endo paying Impax \$102 million.

c. The DCA

Impax and Endo also entered into the DCA, a distinct written agreement that was negotiated and executed simultaneously with the SLA and incorporated into it. IDF 244-45, 284, 306, 308; *see also* ID at 124. Under the DCA, Endo agreed to make a \$10 million upfront payment to Impax, with the possibility of making \$30 million more in milestone payments, for the development of an early-stage Parkinson's disease drug known as IPX-203. IDF 244, 246-48. Under the DCA, Impax and Endo agreed to share promotional responsibilities for IPX-203 and Endo would be entitled to a share of the profits if the drug were successfully commercialized. IDF 249-50. The legal and temporal links between the DCA and the SLA led the ALJ to determine that the DCA's value to Impax should be included as part of the payment from Endo to Impax, and we agree. ID at 114; *see also In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 752 (E.D. Pa. 2014) ("the Licensing Agreement must be read in conjunction with the Co-Promotion and Manufacturing Agreements executed that same day").

The ALJ found, however, that the \$10 million payment in the DCA was fully justified by the benefits to Endo that the agreement conferred.²¹ In addition to the contemporaneity of the two agreements and the DCA's incorporation into the SLA, several additional facts in the record call into question this conclusion. *First*, the IPX-203 deal was evaluated on a timeline shortened to line up with the settlement negotiations, including an abbreviated analysis by Endo that ignored obvious risks. *See, e.g.,* Cobuzzi, Tr. 2592 (Endo group had two days to complete initial evaluation); CX2625 at 001 (Impax recognized that Endo was "on a tight time table" to complete the DCA "if they wish[ed] to settle prior to June 17."); RX072 at 0004, *in camera* [REDACTED]

[REDACTED]. *Second*, evidence suggests that Endo was only willing to enter into the deal as part of the settlement negotiations. *See* CX1005 at 064 (in 2008, a third party market research group engaged by Endo specifically rejected Impax's relevant Parkinson's disease products from the list of potential opportunities because generic versions of products were already on the market). *Third*, Endo had never previously made an upfront payment for a

21 The ALJ found that the DCA was a *bona fide* product development collaboration, and that the \$10 million payment was justified by the profit-sharing rights that the agreement gave to Endo, ID at 132, relying on, *inter alia*, evidence that: (1) both companies had a history of interest in Parkinson's disease treatments, *id.*; (2) Impax needed outside funding to advance the development of IPX-203, *id.*; (3) Endo did not consider the \$10 million upfront payment to be uncharacteristically large, and projected a rate of return of [REDACTED] percent on that payment, nearly [REDACTED] Endo's minimum requirements for a co-development deal, *id.*; and (4) Impax continued its development efforts regarding IPX-203 for years after executing the DCA, investing over [REDACTED] employee hours in work on the compound. *Id.* at 129.

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product on such an abbreviated timeline. Cobuzzi, Tr. 2565.²² Finally, in its business documents, Endo noted that the license deal for the DCA added significant topline revenue for Opana ER. CX1701-005. For its part, Impax's budget documents attribute the \$10 million it received under the DCA as [REDACTED] CX2701 at 004.

The peculiar circumstances surrounding the DCA suggest that the agreement may have been a means of masking value transferred in exchange for eliminating the risk of competition. To the extent that the \$10 million upfront payment is unjustified, however, it simply increases the value of the overall reverse payment that we have found already to be large and unjustified.²³ We thus need not decide whether the DCA was a *bona fide* agreement for justified value.

d. The Freedom to Operate License

Endo also granted Impax a broad patent license with respect to the oxymorphone ER products covered by Impax's ANDA. IDF 169-70; Figg, Tr. 1951-52. This license covers "any patents and patent applications owned by or licensed to Endo . . . that cover or could potentially cover" Impax's generic oxymorphone ER product. IDF 169-70. Complaint Counsel did not plead this term as part of the unlawful consideration for the settlement (Compl. ¶ 62), nor submit evidence attempting to value the license agreement. Noll, Tr. 1648.

Because the license granted Impax freedom to operate once the January 2013 date was past and thus provided value to Impax, it is correctly incorporated in an initial assessment of whether the settlement contained suspicious reverse payments. Although the Commission will look at all aspects of the transaction together for purposes of determining the size and justification of the value flow, we recognize the inherently procompetitive nature of the freedom to operate conferred by patent licenses. Hatch-Waxman Act patent litigation cannot be settled procompetitively without both an entry date and a license for the generic, so a payment consisting only of a license to operate in the relevant market—alone or with other clearly procompetitive terms—will not ordinarily trigger antitrust scrutiny, and so should not be considered part of a "large and unjustified" payment. *See Actavis*, 570 U.S. at 154 (distinguishing between "settlement on terms permitting the patent challenger to enter the market before the patent expires" which, alone, would bring about competition "to the consumer's

22 Through the testimony of a pharmaceutical expert, Dr. John Geltosky, Complaint Counsel describe numerous other irregularities in the DCA, including, for example: (i) that Endo's financial analysis did not assess the circumstances specific to the compound actually agreed upon, IPX-203, instead using commercial terms that related to a different compound in later-stage development, IPX-066, that Impax had originally considered but then declined to offer, CX5003 (Geltosky Expert Report) at ¶ 37; (ii) that Endo did not conduct a risk adjustment when calculating the net present value of the IPX-203 opportunity, Geltosky, Tr. 1084-85; (iii) that Endo failed to compare the pharmacokinetic data of IPX-203 with IPX-066, and thus did not analyze whether the newer compound would offer any benefits over the earlier one, CX5003 (Geltosky Expert Report) at ¶ 42; and (iv) that Endo failed to conduct a freedom-to-operate analysis of IPX-203 that would have revealed the level of intellectual property risk posed by the compound, *id.* at ¶¶ 49-50.

23 As explained below, *infra* Section V.B, because Impax failed to meet its burden to connect the alleged procompetitive justifications to the restraint at issue, leaving no need to balance competitive harms and benefits, whether we include any value from the DCA payment does not affect our ultimate conclusion.

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benefit,” and “payment in return for staying out of the market [which] simply keeps prices at patentee-set levels”); *accord In re Actos End Payor Antitrust Litig.*, 2015 WL 5610752, at *15-19 (S.D.N.Y. Sept. 22, 2015), *rev’d in part on other grounds*, 848 F.3d 89 (2d Cir. 2017) (holding that reverse payment did not include (i) acceleration clauses that allowed the generic to enter the market upon the entry of any other generic, and (ii) a license to enter as an authorized generic on a date certain). The parties have not argued that the licenses are part of such a payment, and nothing in the record suggests that it operated to enable Impax and Endo to split monopoly rents.

4. Restraint of Trade

The “large and unjustified payment” that triggers antitrust scrutiny under *Actavis* is consideration in exchange for a restraint of trade—which itself is a requirement of any claim under Section 1 of the Sherman Act. 15 U.S.C. § 1. The ALJ concluded that any competitive harm was “largely theoretical” because, for a variety of reasons,²⁴ Impax was unlikely to have introduced a generic Opana ER before January 2013, the agreed-upon entry date under the SLA. ID at 156-57. Complaint Counsel argue that the ALJ answered the wrong question—*i.e.*, that the harm *Actavis* recognizes is the elimination of *the risk of* competition, not proof that entry would actually or probably have occurred earlier. CCRB at 14. They also argue that the ALJ lacked a factual basis to draw the conclusion he did regarding the likelihood of generic competition. *Id.* Impax argues that Complaint Counsel must prove that entry earlier than January 2013 was reasonably probable in the absence of the challenged agreement; and it contends that the risk of launching “at risk” coupled with the litigation delay made competition before January 2013 unlikely. RB at 35-37.

We agree with Complaint Counsel. The Hatch-Waxman Act context is unique, as are the reverse payment settlements that arise within it. These payments flowing in the “wrong” direction signal that a settling party is being compensated for not competing when it otherwise might. The Supreme Court thus instructs us to inquire into whether and how such reverse payments distort competition. In *Actavis*, the Court recognized the inherently probabilistic nature of the underlying facts surrounding the settlement of Hatch-Waxman Act litigation: patent validity; patent infringement; the outcome of patent litigation; the willingness and ability of the generic drug manufacturer to launch at risk; and so on. Requiring a fact-finder later to conclude whether and on what date competition would have occurred asks too much. That is why *Actavis* makes clear that the relevant anticompetitive harm in a reverse payment case is “prevent[ion of] the *risk of* competition.” *Actavis*, 570 U.S. at 157 (emphasis added); *see also Smithkline Beecham*, 791 F.3d at 408 (the “antitrust problem” in *Actavis* “was that, as the Court inferred, entry *might* have been earlier, and/or the risk of competition not eliminated, had the reverse payment not been tendered” (emphasis added)).

Antitrust liability can thus attach even where the parties entered into the settlement without knowing for certain that they were, in fact, eliminating competition:

24 The ALJ pointed to the length of time necessary to resolve the patent litigation (ID at 156), the financial risk associated with launching “at risk” (*id.* at 150), the fact that Impax’s board had not approved doing so (*id.* at 151), and the company’s track record of not doing so (*id.* at 150-51).

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The patent here may or may not be valid, and may or may not be infringed. A valid patent excludes all except its owner from the use of the protected process or product. . . . But an *invalidated* patent carries with it no such right. . . . The paragraph IV litigation in this case put the patent's validity at issue, as well its actual preclusive scope. The parties' settlement ended that litigation.

Actavis, 570 U.S. at 147 (internal quotation and citation omitted). The Court considered eliminating even a small risk of generic entry to be a cognizable harm. *See id.* ("The owner of a particularly valuable patent might contend, of course, that even a small risk of invalidity justifies a large payment. But, be that as it may, the payment (if otherwise unexplained) likely seeks to prevent the risk of competition. And, as we have said, that consequence constitutes the relevant anticompetitive harm."). *See also Cipro*, 348 P.3d at 864 ("Every restraint of trade condemned for suppressing market entry involves uncertainties about the extent to which competition would have come to pass.").

Three corollaries flow from the *Actavis* approach. *First*, where the evidence establishes that competition actually was eliminated—that a generic drug would have been brought to market earlier but for the agreement—a *fortiori* that establishes an antitrust harm. *Second*, 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. *Third*, and between those two poles, in a reverse payment settlement case, the "relevant anticompetitive harm," occurs when the branded manufacturer and its generic competitor replace the possibility of competition with the certainty of none. *Actavis*, 570 U.S. at 157. To establish such a harm in this case, then, Complaint Counsel bear the burden of proving that there was a risk of competition to eliminate—*i.e.*, that Impax would compete with Endo for sales of branded Opana ER. They must demonstrate facts to support that risk, but need not prove—as the ALJ required—that competition was likely. Put differently, our test for Sherman Act liability is whether the generic drug manufacturer might plausibly have entered the marketplace prior to the agreed entry date. *See Androgel II*, 2018 WL 2984873, at *10 ("[Defendants] argue[d] that the FTC failed to show that the settlements *actually* delayed entry. That may well be true, but that is not what the FTC needs to prove in order to show an antitrust harm. As discussed above, the FTC only needs to prove that the Defendants entered into the settlements in order to avoid the risk of a competitive market.").

In this case, ample evidence supports the proposition that there was a real threat of competition from Impax. The FDA approved the Impax ANDA in June 2010, meaning Impax was permitted to launch a generic Opana ER at risk. Senior management had considered launching "at risk," and the company had taken a number of steps to prepare.²⁵ Impax's incentive

25 Impax executives identified a 2010 launch as a "key goal," repeatedly forecasting it. *See, e.g.*, CX2562-002 (2010 Company Key Goals); CX2824-001 and tab "Jan Forecast Bottles" (Jan. 2010 Monthly Forecast indicating launch date of June 2010); CX2829 at tab "may 10 Forecast bottles" (May 2010 Monthly Forecast – same); CX5000 (Noll Expert Report) at ¶ 371 and App. D (summarizing 27 forecasts). Company executives repeatedly presented "at risk" launch in June 2010 to the Board of Directors. *See* CX2662-012; CX2663-001. And the company took steps to prepare, getting DEA approvals, manufacturing product, obtaining letters of intent, and completing process validation. CX2882-001; IDF 537-40; Engle, Tr. 1758-62. The company obtained "Quota"—the amount of a

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to do so was likely bolstered by Endo's plans to product hop. *See* Mengler, Tr. 527; Hoxie, Tr. 2707. A large payment would be an "irrational act" unless the patentee believed such a payment would preserve its profits. Herbert Hovenkamp, *Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision*, 15 MINN. J. L. SCI. & TECH. 3, 25 (2014). *See also Androgel II*, 2018 WL 2984873, at *9 ("Rather than having to litigate the merits of any underlying patent suits or establish a theory of causation, the Supreme Court said that courts can look to the 'size of the payment . . . [to] be able to assess its likely anticompetitive effects'"). We therefore find there was a plausible risk that Impax could have entered earlier than January 2013 but for the agreement.²⁶

The record makes clear that the SLA eliminated a risk of competition from Impax. How likely it was to launch, when, and precisely how much competition was eliminated are difficult questions that may require much speculation to resolve. Because we resolve this case before reaching the weighing of anticompetitive harms and procompetitive benefits, we need not do so.

5. Market Power

Under the rule of reason a plaintiff must generally prove that the defendant possessed market power in the relevant market.²⁷ *See, e.g., Leegin Creative Leather Prods., Inc. v. PSKS, Inc.* 551 U.S. 877, 885-6 (2007) (rule of reason includes inquiry into the existence of market power) (citations omitted); *United States v. Visa U.S.A., Inc.*, 344 F.3d 229, 237 (2d Cir. 2003) (plaintiff "must demonstrate that the defendant conspirators have 'market power' in a particular market for goods or services"); *Gordon v. Lewistown Hosp.*, 423 F.3d 184, 213 (3d Cir. 2005) (market power necessary in order for court to presume anticompetitive effects). We find, as did the ALJ, that Endo possessed the requisite market power and, accordingly, that Complaint Counsel met their burden. *See* ID at 139-41.

a. General Principles

Market power is the ability to charge prices above what would prevail in a competitive market by restricting output below competitive levels. *See Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of the Univ. of Okla. ("NCAA")*, 468 U.S. 85, 109 n.38 (1984) (citing, *inter alia*, *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 27 & n.46 (1984)); *Ball Mem'l Hosp., Inc. v. Mutual Hosp. Ins.*, 784 F.2d 1325, 1335 (7th Cir. 1986) (Easterbrook, J.) ("Market power

controlled substance, like oxymorphone, that the DEA permits a company to purchase in a particular year—from the DEA. *See* Camargo, Tr. 965-66.

²⁶ This is not to say that Impax *would* have entered earlier but for the agreement. As explained, the ALJ erred in asking whether Impax would have entered earlier. The relevant question is whether it was plausible Impax *could* enter earlier, which tells us whether a risk of entry—the harm *Actavis* instructs us to guard against—was eliminated.

²⁷ However, "[s]ince the purpose of the inquiries into market definition and market power is to determine whether an arrangement has the potential for genuine adverse effects on competition, 'proof of actual detrimental effect, such as a reduction of output,' can obviate the need for an inquiry into market power, which is but a 'surrogate for detrimental effect.'" *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 460-61 (1986) (quoting Areeda & Hovenkamp, *supra* ¶ 1511).

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comes from the ability to cut back on the market’s total output and so raise price”); 2B PHILLIP E. AREEDA, ET AL., ANTITRUST LAW ¶ 501 at 109 (4th ed. 2014) (“Market power is the ability to raise price profitably by restricting output.”). Relatedly, courts have defined “monopoly power” as the “power to control prices” by limiting output or to “exclude competition.” *See, e.g., United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956); *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 (3d Cir. 2007) (citing *United States v. Grinnell Corp.*, 384 U.S. 563, 571 (1966)).

A plaintiff can prove market power directly through evidence of control over prices and output or the exclusion of competition; a court also can infer such power from proof of a firm’s large percentage share of the relevant market. *Broadcom*, 501 F.3d at 307; *Geneva Pharms. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 500 (2d Cir. 2004) (citing *Tops Mkts., Inc. v. Quality Mkts., Inc.*, 142 F.3d 90, 98 (2d Cir. 1998)); *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 652 (2d Cir. 2015); *United States v. Microsoft Corp.*, 253 F.3d 34, 51 (D.C. Cir. 2001) (*per curiam*).

A valid patent may confer market power, but does not always do so. *See Ill. Tool Works Inc. v. Independent Ink, Inc.*, 547 U.S. 28 (2006). There may be so many equivalent substitutes for the patented article that the patentee cannot exercise market power. U.S. DEP’T OF JUSTICE & FED. TRADE COMM’N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY § 2.2 (Jan. 2017). Alternatively, there may be few economically close substitutes such that ownership of the patent allows the patentee to extract durable monopoly profits during the patent’s life. *See* HERBERT HOVENKAMP, ET AL., IP AND ANTITRUST, § 4.02 (Nov. 2017).

To establish market power, a plaintiff typically first defines the relevant antitrust market. *See, e.g., City of New York v. Grp. Health Inc.*, 649 F.3d 151, 155 (2d Cir. 2011); *Worldwide Basketball & Sport Tours, Inc. v. NCAA*, 388 F.3d 955, 962 (6th Cir. 2004). The *Actavis* Court did not conduct a rule of reason analysis, and did not define a relevant market. But its decision recognized that a branded drug and its generic equivalents could—and, in the reverse payment context, often would—together constitute an antitrust-relevant market. The Court noted that the large size of a payment is a “strong indicator of power” over prices, because a firm “without that power [is unlikely] to pay ‘large sums’ to induce ‘others to stay out of *its* market.’” *Actavis*, 570 U.S. at 157 (emphasis added) (quoting 12 HERBERT HOVENKAMP, ANTITRUST LAW ¶ 2046 at 351 (3d ed. 2012)); *see also King Drug Co. of Florence v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 414 (E.D. Pa. 2015). As the district court in *Aggrenox* observed, although it is “conceivable that the patented drug faced such fierce competition from therapeutically similar drugs that it could not be sold at supracompetitive prices,” it is “vanishingly unlikely” that a large reverse payment would be made in such a case. 199 F. Supp. 3d at 666.

b. Analysis and Conclusions Regarding Market Power

Based on a thorough review of the factual record, we find that the relevant product market in this case consists of branded and generic oxymorphone ER, not all long acting opioids

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(“LAOs”), as Impax claims.²⁸ We further find, as did the ALJ, that Endo possessed market power.²⁹ See ID at 139-41.

The determination of what constitutes the relevant product market “hinges . . . on a determination of those products to which consumers will turn, given reasonable variations in price.” *United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA*, 296 F. Supp. 3d 1142, 1167 (N.D. Cal. 2017) (quoting *Lucas Auto. Eng’g, Inc. v. Bridgestone/Firestone, Inc.*, 275 F.3d 762, 767 (9th Cir. 2001)). Specifically, our goal in this market definition exercise is to determine whether sufficient users would switch away from oxymorphone ER in response to a small but significant, non-transitory price increase [a “SSNIP”] to make the increase unprofitable. See *FTC v. Whole Foods Mkt., Inc.*, 548 F.3d 1028, 1038 (D.C. Cir. 2008). This requires examining whether products are close economic substitutes.³⁰ See Areeda & Hovenkamp, *supra* ¶ 562a at 390-92 (relevant market includes “close substitutes” that exhibit high cross-elasticity of demand). In conducting this examination, the relevant question is how consumers respond to increases from competitive pricing levels.³¹ Evidence of competitive effects may help to inform the inquiry. U.S. DEP’T OF JUSTICE & FED. TRADE COMM’N, HORIZONTAL MERGER GUIDELINES § 4 (2010).

Complaint Counsel argued that branded and generic oxymorphone ER comprise the antitrust-relevant market. In an effort to shed light on cross-elasticities between various LAO products, Complaint Counsel’s expert, Professor Noll, examined whether events that affected prices and quantities in the sale of one product were reflected in changes in prices and quantities for the other product. Noll, Tr. 1374. If they were not, he reasoned, then the products were not in the same relevant market. *Id.* at 1375. Professor Noll examined the effects of entry of the generic drug on the branded product at the time that entry occurred. *Id.* at 1377. His review established that the entry of the former correlated to a drop in the quantity sold of the latter. *Id.* at 1380. Based on these results, he found that generic and branded oxymorphone ER were in the same relevant market. Professor Noll repeated the process of examining entry effects for other candidate LAOs (including extended release versions of oxycodone, hydromorphone, morphine, tapentadol, buprenorphine, fentanyl, and hydrocodone ER) on Opana ER’s sales to determine if they were part of the relevant market. Noll, Tr. 1386-87; CX5000-194 at Exh. 4. In each case, he

28 The parties do not dispute that the relevant geographic market is the United States.

29 Market definition and market power are always fact-intensive questions. Although in most cases arising in the *Actavis* context, a brand and its generics will constitute the relevant product market, this is not to suggest that a brand and its generics will, in every case or context, necessarily constitute the relevant product market. See, e.g., *Mylan Pharms. Inc. v. Warner Chilcott PLC*, 838 F.3d 421, 437 (3d Cir. 2016) (finding the relevant market consisted of all oral tetracyclines used to treat acne).

30 Due to data limitations, neither side’s economic expert was able to conduct a SSNIP test directly or to measure cross-elasticities through econometrics. See Noll, Tr. 1514-17; Addanki, Tr. 2476-77.

31 If the allegedly anticompetitive conduct is already permitting supracompetitive pricing, a larger percentage of consumers might turn to alternatives in the face of *additional* price increases than would do so if prices increased from a competitive level—thereby artificially and erroneously inflating the apparent size of the product market. See Areeda & Hovenkamp, *supra* ¶ 539.

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found that the abrupt rise and fall in sales of Opana ER in 2010-2012 did not reflect a parallel fall and rise in the sales of the other LAOs and determined that the latter were not part of the relevant market. CX5000 at ¶ 183; *see also id.* at ¶¶ 158, 161-64, 166-67, 169, 172, 175, 177, and 179. Based on this analysis Professor Noll concluded that oxymorphone ER (both generic and branded versions) is a relevant product market.

Impax, on the other hand, argued the appropriate market consists of all LAOs. Unlike Professor Noll, Impax's expert, Dr. Addanki, did not study the effects that brand or generic entry in other LAOs had on quantities sold of oxymorphone ER or *vice versa*. Rather, Dr. Addanki based his view on other sources of information including, *inter alia*: (1) clinical guidelines for treatment of chronic pain, including FDA labels and other resources such as data showing that multiple LAOs are used for the same indication, Addanki, Tr. 2241-43, 2247; (2) business documents from Endo and other industry participants suggesting that they viewed other LAOs as being in the same market as Opana ER, *id.* at 2257-66; and (3) evidence suggesting that competition existed between and among various LAOs at the three levels of the market: physicians, insurers, and patients, *id.* at 2253.

Professor Noll's sales volume analysis addressed economic substitution more directly than did Dr. Addanki's approach. Oxymorphone ER sales exhibited large share shifts and price reductions in response to generic entry—but not in response to entry by other LAOs. Sales of Opana ER declined when generic oxymorphone was introduced and as generic sales increased. CX5000 (Noll Expert Report) at ¶ 119 and Exhs. 2A1, 2A3, 2A5, 2A6 and 2A7. Sales of other LAOs were either far less responsive, or not responsive at all, to the introduction of oxymorphone ER. *Id.* at ¶¶ 162-64 (OxyContin), ¶ 169 (hydromorphone ER, a.k.a. Exalgo), ¶ 172 (buprenorphine ER, a.k.a. Butrans), ¶ 175 (fentanyl ER), ¶ 179 (tapentadol ER, a.k.a. Nucynta ER). When Professor Noll examined whether sales of other LAOs affected sales of Opana ER (or *vice versa*), he found that the drugs' sales generally did not exhibit negative correlations, suggesting that—unlike generic oxymorphone ER—they did not take sales from each other. *Id.* at ¶¶ 162-63 (sales of OxyContin and oxymorphone ER generally “rose and fell in parallel”), ¶ 169 (introduction of Exalgo had “no apparent effect” on sales of Opana ER), ¶ 172

_____ ; ¶ 175 (availability of generic fentanyl ER did not inhibit rapid growth of Opana ER sales through the end of 2011); ¶ 177 (entry of Zohydro did not substitute for sales of oxymorphone ER); ¶ 179 _____

_____. The sales volume evidence thus supports the proposition that generic oxymorphone ER, but not other LAOs, is in the same relevant market as branded oxymorphone ER.³²

32 Impax would disregard this evidence as reflecting mere “visual inspection” of LAO sales trends. RB at 34. But courts have accepted exactly this type of analysis in other pharmaceutical cases. *See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 522-23 (E.D.N.Y. 2005), *aff'd in part*, 544 F.3d 1323 (Fed. Cir. 2008); *Teikoku Pharma*, 296 F. Supp. 3d at 1174-75; *SmithKline Corp. v. Eli Lilly & Co.*, 427 F. Supp. 1089, 1118-19 (E.D. Pa. 1976), *aff'd*, 575 F.2d 1056 (3d Cir. 1978). Where, as here, patterns of generic substitution are clear, “we do not need to do economic gymnastics to determine whether the defendant had market power[.]” *Aggrenox*,

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This evidence is consistent with economic research showing that generic entry is, by far, the most important source of price competition for pharmaceuticals—generally far more important than different compounds in the same therapeutic class. *See* CX5000 (Noll Expert Report) at ¶¶ 76-79 (citing, *inter alia*, Fiona Scott Morton & Margaret Kyle, *Markets for Pharmaceutical Products*, in 2 HANDBOOK OF HEALTH ECONOMICS, 763-823 (M. Pauly, et al., eds., 2011); Ernst Berndt & Joseph Newhouse, *Pricing and Reimbursement in U.S. Pharmaceutical Markets*, in OXFORD HANDBOOK ON THE ECONOMICS OF THE BIOPHARMACEUTICAL INDUSTRY (P. Danzon & S. Nicholson, eds., 2012); Ernst Berndt, *Pharmaceuticals in U.S. Health Care: Determinants of Quantity and Price*, 16:4 J. ECONOMIC PERSPECTIVES 45-66 (2002)). Where generic entry occurs, it tends to displace a large share of branded sales and to do so at a much lower price, as occurred here. *Id.* at ¶¶ 77-78. Consequently, it is not surprising that courts frequently define product markets to encompass a single active ingredient. *See, e.g., Barr Labs.*, 386 F.3d at 496 (defining a market for generic warfarin sodium); *Teikoku Pharma*, 296 F. Supp. 3d at 1176 (defining a market for 5% lidocaine patches, *i.e.*, Lidoderm and its generic equivalents); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 389 (D. Mass. 2013) (concluding that the relevant market consisted of the brand and generic alone); *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 680-81 (E.D. Mich. 2000) (accepting plaintiffs’ pleadings that a single brand of a drug and its generic bioequivalents constituted the relevant market). *But cf. Mylan Pharms. Inc. v. Warner Chilcott PLC*, 838 F.3d 421, 437 (3d Cir. 2016) (finding a relevant market for all oral tetracyclines used to treat acne).

Impax’s argument that the relevant market includes all LAOs has both factual and analytical limits. From a factual perspective, as Complaint Counsel’s medical expert, Dr. Seddon Savage, testified, opioids differ according to their biological receptors, pharmacokinetic profiles, and adverse side effects, including adverse interactions with other drugs. Savage, Tr. 689-92, 702; CX5002 (Savage Expert Report) ¶¶ 51, 115-16. Of significance for this case, oxymorphone is one of the few opioids that is not metabolized by the CYP450 enzyme. Savage, Tr. 716; *see also* CX5000 (Noll Expert Report) at ¶¶ 142-43. This means that oxymorphone is less likely to cause adverse interactions with the many other drugs that *are* metabolized by that same enzyme, such as some antibiotics, anticoagulants, beta blockers, statins, and tranquilizers. *See* Savage, Tr. 716-18; CX5000 (Noll Expert Report) at ¶ 143. Oxymorphone also has a longer half-life than oxycodone, hydrocodone, morphine, and other LAOs, resulting in longer duration of action.

199 F. Supp. 3d at 668; *see also* *McWane*, 2014 WL 556261, at *14 (F.T.C. 2014), *aff’d*, *McWane, Inc. v. FTC*, 783 F.3d 814 (11th Cir. 2015); ABA Section of Antitrust Law, *Mergers and Acquisitions* 55 (3d ed. 2008).

In contrast, Impax gives considerable weight to evidence that utilization of alternatives to OxyContin increased when the University of Pittsburgh Medical Center health plan eliminated coverage of OxyContin while maintaining coverage of Opana ER, morphine sulfate ER, fentanyl patches, and methadone. *See* RX087 and discussion at Addanki, Tr. 2302-09. However, the participants’ shift from OxyContin to the remaining drugs still covered by the formulary may reflect little more than a tendency of participants in a particular health plan to keep that health plan and to maintain in-formulary coverage. Dr. Addanki does not explain why this experience would generalize to reflect the likely competitive effects of changes in price or product availability involving consumers at large nor did he know the amount of the price increase at issue, which might have been far larger than the SSNIP usually considered when defining a market. Addanki, Tr. 2505.

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Savage, Tr. 720. Switching a patient from Opana ER to generic oxymorphone would yield much more predictable results than switching to a different opioid molecule, because the generic oxymorphone would operate on the patient's pain receptors in the same manner and with the same side-effect profile. *Id.* at 715. In any event, while functional interchangeability is certainly relevant to market definition, it is not the end of the analysis. *See, e.g., Meijer, Inc. v. Barr Pharms., Inc.*, 572 F. Supp. 2d 38, 58 (D.D.C. 2008) (functional interchangeability is probative but "certainly not dispositive"); *see also Barr Labs.*, 386 F.3d at 496 (defining market for generic warfarin sodium alone, despite functional interchangeability with branded version); *United States v. Archer-Daniels-Midland Corp.*, 866 F.2d 242, 248 (8th Cir. 1988) (functionally interchangeable sweeteners were separate product markets because "a small change in the price of [one] would have little or no effect on the demand for [the other]").

Dr. Addanki's evidence of product marketing and discounting does not convince us to place all LAOs in the same relevant market. Even a monopolist might engage in the sorts of brand-building and product differentiation activities that Dr. Addanki catalogues, such as visiting potential customers (*i.e.*, doctors) and advertising in medical journals. That is because even a monopolist may benefit from stimulating demand through promotional activities and because, at a sufficiently high price, it faces some substitutes to which it will want to avoid losing sales. The relevant question is the *degree* of constraint that these other products offer.³³ Dr. Addanki failed to undercut Professor Noll's showing that generic oxymorphone ER was a far more effective constraint on Opana ER than were the other LAOs. For example, his limited evidence of direct-to-patient discounting lacks data about the size of these programs and provides no showing that the programs had a significant effect on either average net prices or sales of the products. *See* CX5004 (Noll Rebuttal Report) at ¶ 66.³⁴ Consequently, we find that Complaint Counsel adequately proved a relevant market confined to branded and generic oxymorphone ER.

We find that Endo clearly held market power in this highly concentrated market. Prior to entry by Actavis in 2011, Endo was the only player on the market—in other words, it had a monopoly. *See* CX5000 (Noll Expert Report) ¶ 189. After Actavis entered for two generic, low-sales dosages and prior to generic entry by Impax, Endo held more than a [REDACTED] percent market share, and the Herfindahl-Hirschman Index ("HHI") exceeded [REDACTED]. *Id.* at ¶ 189 & Exhs. 6A and 6B. Thus, during the critical period when Endo and Impax entered the SLA and during

33 *See Coal Exps. Ass'n v. United States*, 745 F.2d 76, 92 n. 20 (D.C. Cir. 1984) ("[A]ll firms, even the pure monopolist . . . are subject to limits established by market forces. The issue is how effective are the limits.").

34 Impax's citation to our settlement and relevant market definition in *King Pharm., Inc. & Alparma, Inc.*, No. C-4246 (F.T.C. Feb. 2, 2009), buttresses rather than undercuts our relevant market definition here. RB at 50. As Impax mentions, the Commission's settlement identified a relevant market for oral LAOs. Impax does not mention, however, that the Commission proceeded in the same sentence to identify a "narrower market for oral long-acting morphine sulfate in which [the respondents' products] compete directly with each other." Complaint, ¶ 11. The Commission intervened in King Pharmaceuticals' proposed acquisition of Alparma because the transaction would have joined the two leading producers of morphine sulfate oral LAOs, unacceptably raising concentration in that relevant market, and the Commission obtained a divestiture of King's morphine sulfate product. FTC Press Release, FTC Intervenes in King Pharmaceuticals Acquisition of Rival Alparma Inc. (Dec. 29, 2008) <https://www.ftc.gov/news-events/press-releases/2008/12/ftc-intervenes-king-pharmaceuticals-acquisition-rival-alparma> (attaching Commission Complaint and Decision and Order).

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which the parties' agreement prevented Impax from entering, Endo held shares sufficient to support market power. *Id.* at ¶ 192.³⁵

Additional evidence supports our market power findings. Generic oxymorphone ER entry caused Opana ER to lose market share and the average price of oxymorphone ER to fall. CX5000 (Noll Expert Report) at ¶ 122. [REDACTED]

[REDACTED] *Id.* at ¶ 120. [REDACTED]

[REDACTED] *Id.* That indicates pre-entry prices were above the competitive level. Noll, Tr. 1381-82; see *Aggrenox*, 199 F. Supp. 3d at 667 (“if competitive prices were being charged before the patented drug had a generic competitor, then the entry of new [generic] competitors would not result in a substantial change in price”). Endo’s documents and testimony further support the conclusion that generic entry caused substitution and price reductions. See, e.g., CX1106-005 (“Each month that generics are delayed beyond June 2010 is worth about \$20 million in net sales per month.”); CX1320-007 (2010 revenue forecast incorporating the working assumption that after generic entry in July 2011, “15% brand volume remains after 3 months”); CX4004 (Engle, IHT) at 245 (indicating that Actavis’ entry caused some lowering of prices and that Actavis won some business from Endo).

The substantial evidence of Endo’s market power is consistent with the inference permitted by *Actavis*: that the presence of a large and unjustified payment may itself signal market power. 570 U.S. at 157 (finding that a firm “without that power [is unlikely] to pay large sums to induce others to stay out of its market”). If the payor-patentee lacked market power before generic entry due to competition from other drugs, prices for the brand drug already would have been competed down to the competitive level and there would be no monopoly profits left to protect by a large reverse payment. See *Aggrenox*, 199 F. Supp. 3d at 667.

Strong record evidence further demonstrates that Endo’s market power was durable and protected by substantial entry barriers. IDF 90-95. Endo’s patents could be (and were effectively) used to exclude competitors who wished to market and sell oxymorphone ER. See *Aggrenox*, 199 F. Supp. 3d at 668. The Hatch-Waxman Act’s regulatory procedures build in timing constraints affecting generic entry, as described above. First, if a branded drug company files a patent infringement suit against a Paragraph IV ANDA filer, the Hatch-Waxman Act provides a 30-month stay before the FDA can approve the ANDA. IDF 93-94. Second, non-first-filer Paragraph IV ANDA applicants have to wait at least 180 days after the first filer has entered before they can enter a market. *Id.* Thus, Endo had the power to delay entry to the market even if its patents were eventually found to be invalid or not infringed. IDF 95. These barriers are in addition to more general barriers such as brand loyalty and DEA regulation of opioids, (CX5000

35 Using net sales revenue, Endo’s market share between 2013 and the end-date of available data in Q1 2017 always exceeded [REDACTED] percent and usually was around [REDACTED] percent. CX5000 (Noll Expert Report) at ¶ 191 & Exh. 6. Throughout that period, HHI based on net sales revenue exceeded [REDACTED], and HHI based on total prescriptions was above [REDACTED]; both figures substantially exceed the Horizontal Merger Guidelines’ threshold of HHI 2,500 denoting a highly concentrated market. *Id.* at ¶ 191.

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(Noll Expert Report) at ¶¶ 15, 63, 195-96; IDF 508, 522-26), not to mention the need to develop a product suitable for receiving FDA approval and to build up the necessary launch inventory. Noll, Tr. 1409-10; IDF 12, 513. In the pharmaceutical industry, manufacturing and production issues can seriously impact a company's ability to enter and remain on the market. In this very case, Novartis Consumer Health, Inc. ("Novartis"), the company that manufactured Opana ER for Endo, experienced a plant shutdown by the FDA that resulted in a full-blown "supply chain crisis" for Endo. CX4017 (Levin Dep.) at 136-38. Endo's high share in the market for oxymorphone ER, combined with the presence of substantial entry barriers, lead to the conclusion that Endo possessed market power.

We find significant record evidence demonstrating the relevant market consists of branded and generic oxymorphone ER and that Endo commanded market power.

B. Procompetitive Justifications

Because Complaint Counsel have established a *prima facie* case showing that Impax harmed competition, "the burden shifts to [Impax] to show a procompetitive rationale for the restraint." *Amex*, 138 S. Ct. at 2284. As discussed, the ALJ found that the No-AG Commitment and Endo Credit 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 at 6-7. Impax does not challenge that finding on appeal. *See* RB at 4 n.1.

The ALJ concluded that while the *reverse payment for delay* impaired generic competition, *other provisions* of the settlement between Impax and Endo benefited competition and salvaged the entire agreement from antitrust condemnation. The settlement included a broad license and covenant-not-to-sue covering all patents related to original Opana ER that Endo owned or might acquire. ID at 142-44; IDF 567-70, 592-93. According to the ALJ, these provisions allowed Impax to enter nine months before expiration of Endo's original patents and protected Impax when Endo acquired additional patents and asserted them to enjoin other drug manufacturers from marketing generic versions of Opana ER. ID at 143-44, 146; IDF 573-81, 588, 596. Although other manufacturers were barred from the market until 2029, the broad license has shielded Impax from the "threat of patent infringement litigation relating to original Opana ER." ID at 144, 146; IDF 594, 596. The ALJ thus found that, on balance, the settlement promoted competition by ensuring that consumers have continued access to generic Opana ER. ID at 144, 146; IDF 594, 596. Impax urges us to sustain these findings.

We disagree with the ALJ because we find that Impax did not sustain its burden of linking the procompetitive benefits to the challenged restraint. Impax failed adequately to link the alleged procompetitive justifications to the challenged restraint, which—as the ALJ acknowledged—was the use of a reverse payment to eliminate the risk of generic entry before January 2013. ID at 100-02; *Actavis*, 570 U.S. at 157. Impax does not make any argument that the No-AG Commitment or Endo Credit (or any portion of the \$10 million DCA payment) 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. Impax thus fails to overcome the anticompetitive effect, which *Actavis* anticipated, from reverse payments

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“independen[t] from other services for which it might represent payment,” and “lack[ing] [] any other convincing justification.” 570 U.S. at 159.

1. Impax Has Failed to Show that the Restraint Furthered any Procompetitive Justifications

After Complaint Counsel made a *prima facie* case of anticompetitive harm, it became Impax’s burden to show that the “*challenged restraint* enhances competition.” *NCAA*, 468 U.S. at 104 (emphasis added). For purposes of procompetitive justifications, we look at the specific restraint, not the agreement as a whole. Even if an agreement between competitors generally benefits competition, this does not validate a restraint that “makes no significant contribution to the alleged justification.” *Areeda & Hovenkamp*, *supra* ¶ 1505a. For example, in *NCAA*, the Supreme Court held that even though the NCAA’s member institutions had a legitimate interest in adopting rules to promote “competitive balance” among football teams, the NCAA’s specific restrictions on telecasts were “not even arguably tailored” to serve that interest. 468 U.S. at 117-19. Thus, to justify a challenged restraint, Impax must “articulate the specific link between the challenged restraint and the purported justification,” and demonstrate that the restraint in fact “advance[s] procompetitive goals.” *Polygram Holding, Inc.*, 136 F.T.C. 310, 347 (2003), *enforced*, *Polygram Holding, Inc. v. FTC*, 416 F.3d 29 (D.C. Cir. 2005); *see also N. Tex. Specialty Physicians v. FTC*, 528 F.3d 346, 368-69 (5th Cir. 2008) (defendant must show that the restraint bears a “logical nexus to [the] claimed efficiencies,” meaning that the efficiencies either “result from or are in any way connected to” the restraint); *Realcomp II, Ltd. v. FTC*, 635 F.3d 815, 835 (6th Cir. 2011) (affirming FTC’s finding that the respondent had not “demonstrated a connection” between the restraint and the proffered rationale); *Visa*, 344 F.3d at 238, 243 (explaining that defendants “must provide a procompetitive justification for the challenged restraint,” and sustaining district court’s finding that “no evidence” showed that the restraint advanced the proffered justifications).

As explained below, we hold that the relevant restraint here is the payment in exchange for the elimination of the risk of entry, *Actavis*, 570 U.S. at 157, and that defendant must adduce facts tying any cognizable procompetitive benefits to the elimination of this risk. Impax points to the fact that the payments coincided in the SLA with the broad license, the entry date, and other terms, and argues that any benefits deriving from a reverse payment settlement as a whole are cognizable, and therefore that it need not prove any link between the actual restraint and the benefits. That is wrong, and Impax has failed to meet its burden. Even if Impax had established a link, Complaint Counsel can prevail by showing that the restraint was not reasonably necessary to achieve the alleged procompetitive benefits, which they have accomplished by identifying a less restrictive alternative. *See Areeda & Hovenkamp*, *supra* ¶ 1505; *North Texas*, 528 F.3d at 368-69; *Realcomp*, 635 F.3d at 835; *Polygram*, 136 F.T.C. at 347.

a. What is the Restraint Impax Must Justify?

The parties cross swords on the foundational question of what constitutes the challenged “restraint” in this case. The ALJ, like Complaint Counsel, defined the restraint as “the payment in conjunction with a restriction on the generic’s ability to compete.” CCRB at 6; *see ID* at 99

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(defining the restraint as “the use of the payment to restrain potential generic competition”), 141 (similar). Impax, on the other hand, argues that when a plaintiff challenges a specific agreement, “all aspects of that agreement are at issue”; and, therefore, maintains that it can offer any procompetitive benefit arising from the agreement, even if that benefit is not tied to, or does not derive from, the specific restraint within the larger agreement. RB at 18-19. We conclude that the ALJ’s and Complaint Counsel’s interpretation is more consistent with *Actavis*, which instructs that the commitment not to enter in exchange for a large and unjustified payment constitutes the relevant restraint.

In *Actavis*, the Supreme Court recognized the large and unjustified payment in exchange for not entering the market was the red flag that put such settlements into the rule of reason analysis. It referred to 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 patent litigation were to continue and the patent were held invalid or not infringed.” 570 U.S. at 153-54. Such a “payment in return for staying out of the market” would “keep[] prices at patentee-set levels,” allowing the brand and generic manufacturers to “divid[e]” the profits of the branded drug’s continued monopoly. *Id.* at 154. The Court conceded that patent licenses “permitting the patent challenger to enter the market before the patent expires” bring about competition; but, recognizing the need to scrutinize the “specific restraint” within the settlement, stressed that competitive harm arises when the patentee makes a reverse payment to preclude the risk of *even earlier* competition. *Id.*

The *Actavis* Court recognized the defendant has the burden to explain and justify the payment itself, not the settlement as a whole: “[A] reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; one who makes such a payment may be unable to explain and to justify it.” *Id.* at 158; *accord Lipitor*, 868 F.3d at 256 (on motion to dismiss, noting the “defendants have the burden of justifying the rather large reverse payment here, and they offer no reason why those other elements of the settlement agreement do so”). Thus, an antitrust defendant cannot salvage an anticompetitive reverse payment merely by pointing to unrelated terms in the same settlement agreement, but must justify “the presence of the *challenged term* and show[] the lawfulness of *that term* under the rule of reason.” *See Actavis*, 570 U.S. at 156 (emphasis added). The “likelihood of a reverse payment bringing about anticompetitive effects depends upon,” *inter alia*, “its independence from other services for which it might represent payment and the lack of any other convincing justification.” *Id.* at 159.

Impax argues that a “payment alone” is not a restraint. RB at 13-14. We agree. But nor can we decouple the payment from the agreement not to enter. As we have explained, *Actavis* instructs that a large and unjustified payment is the red flag signaling anticompetitive harm. 570 U.S. at 154. A generic manufacturer’s commitment to stay out of the market until the licensed entry date *in exchange for* such a payment is, accordingly, the relevant restraint. *Id.*

Despite *Actavis*’s focus on the payment for not entering, Impax contends it is a basic principle of antitrust law that a restraint of trade consists of the “sum total” of the parties’ contractual relationship, rather than the specific provisions alleged to be anticompetitive. RB at

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14.³⁶ But, as Impax itself notes, the Supreme Court has explained that a restraint of trade “refers not to a particular list of agreements, but to a particular *economic consequence*.” *Id.* at 13 (quoting *Bus. Elecs. Corp. v. Sharp Elecs. Corp.*, 485 U.S. 717, 731 (1988)) (emphasis added by Impax). Here, *Actavis* defines the relevant “*anticompetitive consequence*” as the sharing, through a reverse payment, of supracompetitive prices between the patentee and the generic challenger “rather than face what might have been a competitive market.” *See* 570 U.S. at 157 (emphasis added). That consequence cannot be justified by unrelated terms that merely happen to coincide in the same contract. Rather, the defendant must adduce facts, beyond mere assertion, to link the benefits to the restraint.

The Court in *Actavis* instructed us to apply the rule of reason to determine whether an apparently anticompetitive payment to stay out of the market can be justified. 570 U.S. at 159. Impax has offered no such justification. None of the cases Impax cites supports its position that we should consider the competitive effects of the parties’ entire contract rather than the allegedly anticompetitive terms. In *NCAA*, the Court, applying the rule of reason, “assume[d] that most of the regulatory controls of the NCAA are justifiable” and “procompetitive,” but held that the NCAA had failed to justify its specific restrictions on TV broadcasts. 468 U.S. at 99, 117. Likewise, in *National Society of Professional Engineers v. United States*, 435 U.S. 679 (1978), the Court evaluated the effects of a professional association’s “ban on competitive bidding” rather than the association’s code of ethics as a whole. *Id.* at 695. Most recently, in *Amex*, the Supreme Court treated the restraint as Amex’s “antisteering provisions in its contracts with merchants,” rather than the entire contracts. 138 S. Ct. at 2283.³⁷

We have followed this approach in our own cases. In *Polygram*, we evaluated the effects of joint venture members’ agreement not to discount their separate competing products, rather than the effects of the venture at large. 136 F.T.C. at 353. And, in *Realcomp*, we explained that while the “creation and operation” of a real estate multiple-listing service benefitted competition, the *specific* restraints on listings by lower-priced and limited-service brokers did not. 2007 WL 6936319, at *21-43.

Impax also invokes post-*Actavis* pharmaceutical cases (RB at 15, 17-19), but nearly all of them support Complaint Counsel’s position that the restraint is the commitment not to enter, made in exchange for a large and unjustified payment, rather than the entire agreement. For example, the California Supreme Court, applying *Actavis* to state antitrust law, described the restraint as a “limit on the settling generic challenger’s entry into the market” in exchange for “cash or equivalent financial consideration flowing from the brand to the generic challenger.”

36 Impax derives the “sum total” language from a treatise which explained that “the content of the restraint is the sum total of everything that the parties have ‘agreed’ about *and that is alleged to injure competition*.” PHILLIP E. AREEDA & HERBERT HOVENKAMP, FUNDAMENTALS OF ANTITRUST LAW § 15.02[D] (rev. ed. 2018) (emphasis added). Impax appears to misread this passage, which makes clear that the restraint only consists of the portions of an agreement that are alleged to injure competition.

37 *See also Cal. Dental Ass’n*, 526 U.S. at 778 (evaluating the effects of a professional association’s advertising restrictions rather than its entire ethics code); *Ind. Fed’n of Dentists*, 476 U.S. at 451 (analyzing a dental federation’s rule prohibiting members from submitting x-rays to dental insurers when making claims for benefits).

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Cipro, 348 P.3d at 865. “That payment for delay is condemned . . . by federal antitrust law, and its purchase as part of a settlement agreement is an unlawful restraint of trade.” *Id.* at 871. *See also Aggrenox*, 94 F. Supp. 3d at 243 (noting that defendants might be able 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, or to be entirely illusory”); *Lipitor*, 868 F.3d at 256.

Impax misinterprets *In re Loestrin 24 Fe Antitrust Litigation*, 261 F. Supp. 3d 307 (D.R.I. 2017), in which the district court declared that it was “looking at the whole of the settlement to determine its alleged effect on competition.” *Id.* at 331. The court in that case adopted this “holistic look” at the motion to dismiss stage for the purpose of determining whether the various forms of compensation to the generic company “amounted to a large and unjustified reverse payment.” *Id.*; *accord Niaspan*, 42 F. Supp. 3d at 752. The *Loestrin* court did not hold (or even suggest) that a defendant could successfully have a case dismissed by relying on provisions *unrelated* to the payment in exchange for eliminating competition.

Impax cites only to one case holding, on summary judgment, that the court would “evaluate the settlement as a whole, and not in a piecemeal, provision-by-provision approach.” *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 753 (E.D. Pa. 2015). We decline to follow *Wellbutrin*, to the extent it is inconsistent with *Actavis*’s instruction that the burden is on the defendant to justify the restraint itself.³⁸

Impax argues that we should treat the entire settlement as the restraint because Complaint Counsel “challenge the settlement (and separate DCA) as a whole, engaging in an unbounded effort to establish anticompetitive impact.” RB at 16. But this mischaracterizes Complaint Counsel’s allegations, which clearly challenge specific attributes of the settlement. Compl. ¶¶ 74-75. And as explained above, this argument is incorrect as a matter of law.

Impax then accuses Complaint Counsel of attempting to “have it both ways,” arguing they seek to “gerrymander respondents’ defenses” by failing to allege that the broad patent license, a “value-conveying term,” was part of the restraint, and thereby precluding Impax from citing the license as a justification. RB at 16. But *Actavis* defines the restraint and, as discussed above in Section V.A.3.d, there is no evidence in the record here, let alone convincing evidence, to indicate that this license—which facilitated entry—was itself part of a suspicious reverse payment.

Complaint Counsel and the ALJ correctly defined the restraint as the use of the reverse payment to restrain generic competition, *i.e.*, payment for delayed entry. We next consider whether Impax bore its burden to demonstrate that this restraint significantly aided any procompetitive objectives.

³⁸ *Wellbutrin* was, factually, a very different case. It did not involve the core harm about which *Actavis* warns us, namely, the elimination of the risk of competition. *Id.* at 754. Rather, the “Wellbutrin Settlement specifically contemplated that the generic manufacturer would continue its patent challenge and allowed the generic to enter immediately upon a finding of patent invalidity, maintaining the risk of patent invalidation or a finding of non-infringement even after the settlement.” *Id.* at 754.

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b. Did the Restraint Produce any Procompetitive Effects?

An antitrust defendant cannot simply cite procompetitive benefits in the abstract, but must show that those benefits bear a “logical nexus” to the restraint. *North Texas*, 528 F.3d at 368-69; *Realcomp*, 635 F.3d at 835; *Polygram*, 136 F.T.C. at 347. A defendant’s purported justifications are “entirely immaterial” unless they “are actually promoted significantly by the restraint.” *Areeda & Hovenkamp*, *supra* ¶¶ 1505a, 1511c; *see NCAA*, 468 U.S. at 114 (upholding lower court’s finding that the restraint “produced [no] procompetitive efficiencies” because “NCAA football could be marketed just as effectively without the [restraint]”); *Graphic Prods. Distribs. v. ITEK Corp.*, 717 F.2d 1560, 1576 (11th Cir. 1983) (“[M]erely offering a rationale for a . . . restraint will not suffice; the record must support a finding that the restraint . . . does indeed have a pro-competitive effect.”); *O’Bannon v. NCAA*, 802 F.3d 1049, 1072 (9th Cir. 2015) (concluding what while “a restraint that broadens choices [is] procompetitive . . . we fail to see how the restraint at issue in this particular case . . . widens recruits’ spectrum of choices”). Under *Actavis*, in the context of a reverse-payment settlement, the defendant needs to show that the reverse payment leads to more competition than would have resulted without the payment. *See* 570 U.S. at 156, 158.

The Initial Decision did not require a link between the reverse payment and the purported procompetitive benefits. After properly defining the restraint as the use of a reverse payment to eliminate the risk of earlier generic competition, it held that “procompetitive benefits arising in connection with the *settlement agreement as a whole* are properly considered as part of a well-structured rule of reason analysis.” ID at 141 (emphasis added).³⁹ This was an incorrect statement of law. The rule of reason properly credits only justifications promoted by the challenged restraint in reverse-payment settlement cases.⁴⁰ Impax bears the burden to demonstrate this link.

We must therefore ask whether Impax has established that the restraint—a large and unjustified reverse payment to prevent pre-2013 entry—advanced any procompetitive objectives. The ALJ found that the settlement agreement contained a broad patent license allowing Impax to introduce its generic in January 2013, shielding it from lawsuits claiming infringement of patents that Endo acquired after the settlement, and thereby providing consumers continuous access to

39 Although the ALJ cited our October 2017 order denying Complaint Counsel’s motion for summary decision in this proceeding, we held only that it was too early for decisions regarding the admissibility and utility of purported procompetitive benefits. We deemed Complaint Counsel’s motion “premature” pending “development of a record, ordering of that record under a proposed rule-of-reason framework, and ultimately briefing of disputed issues concerning the appropriateness of that framework and of its application to the facts presented.” *Impax*, 2017 WL 5171124, at *10.

40 A contrary rule would allow parties to skirt liability for anticompetitive behavior by inserting unrelated provisions into their contracts and claiming that those provisions benefited competition. Requiring that the challenged restraint itself further any alleged procompetitive benefits is also consistent with the ancillary restraints doctrine. “To qualify as an ‘ancillary’ restraint, ‘an agreement eliminating competition must be subordinate and collateral to a separate, legitimate transaction,’ and it must also ‘be related to the efficiency sought to be achieved.’” *Polygram*, 136 F.T.C. at 366 (quoting *Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 224 (D.C. Cir. 1986)).

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Opana ER since 2013. ID at 141, 144-46. Even if these benefits were realized, however, Impax still would need to tie those benefits to the challenged restraint.

Impax never attempts to make that showing. Impax does not claim that the No-AG Commitment and Endo Credit (or any portion of the \$10 million DCA payment) *themselves* protected Impax from the threat of patent infringement suits. Nor does Impax argue that it needed to accept these payments in order to achieve a settlement containing the broad patent license. Instead, Impax asserts that it “would not have entered the challenged [settlement] without the broad patent license.” RB at 17. But that does not address the right question. The appropriate question is whether Endo and Impax could have reached a similar licensing agreement without a *reverse payment* for delayed generic entry.⁴¹

As Complaint Counsel explain, because “both the payment and the . . . license were benefits flowing to Impax,” Impax readily could have accepted the license without also accepting a payment. CCAB at 20. For Endo’s part, “because [it] was willing to give both the large payment and the license to Impax, it certainly would have been willing to give *less* (*i.e.*, just the license and not the payment).” *Id.* Thus, Complaint Counsel posit, the “only reasonable explanation” for the payment was that it prevented Impax from demanding an even earlier entry date, which demonstrates that the payment was *anticompetitive*, not procompetitive. *Id.* at 21. Impax does not attempt to rebut Complaint Counsel’s reasoning or argue that it needed to accept a payment in order to receive a patent license. Indeed, Impax does not appeal the ALJ’s finding that the payment had the “purpose and effect” of delaying entry. ID at 6-7. And, as we further explain in Section V.C below, even if Endo and Impax *preferred* to settle by sharing Endo’s monopoly profits in exchange for delayed entry, this does not show that a less-anticompetitive settlement was unattainable.

We do not hold today that a defendant cannot adduce facts linking procompetitive benefits within a settlement to a payment for delayed entry. Beyond coincidence with the SLA, however, Impax has simply not done so.

Rather than attempting to demonstrate how the reverse payment furthered its procompetitive justifications, Impax offers a series of legal arguments attempting to bypass this requirement. Impax posits that the rule of reason does not require *any* connection between the challenged restraint and its proffered justifications, provided the justifications coincide in an agreement with the restraint. RB at 19. It seeks to distinguish our *Polygram* decision—where we ruled that the respondent must “articulate the specific link between the challenged restraint and purported justification”—by observing that we were only applying “quick look” review, not the

41 In a pre-*Actavis* decision, we recognized the “hypothetical” possibility that a “cash-starved” generic company might argue that it can “enter earlier and more effectively if it receives some up-front support from the pioneer manufacturer.” See *Schering-Plough Corp.*, 136 F.T.C. 956, 1001 (2003), *vacated*, *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), *abrogated by Actavis*, 570 U.S. at 153. Similarly, we acknowledged other possibilities such as that “[a] judgment-proof generic manufacturer may be willing to hold out for ‘unreasonable’ settlement terms because its downside risks of damage exposure are small.” *Id.* at 1002. Impax makes no such claims here. Nor, for that matter, does it claim it would not have pursued a Paragraph IV filing without the prospect of obtaining a No-AG Commitment.

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full-blown rule of reason. RB at 19 (discussing *Polygram*, 136 F.T.C. at 347). But quick-look review only affects the showing required for plaintiff to demonstrate anticompetitive harm, not the defendant's burden to assert procompetitive justifications. *See, e.g., Deutscher Tennis Bund v. ATP Tour, Inc.*, 610 F.3d 820, 831 (3d Cir. 2010). In *Polygram*, we held that a procompetitive justification is not even "plausible" unless it bears a "specific link" to the restraint. 136 F.T.C. at 347; *accord Actavis*, 570 U.S. at 153 (noting the potential for the "specific restraint at issue" to harm competition). Under quick-look review, it is only when the defendant meets this "plausibility" standard (and the proffered justification is cognizable under the antitrust laws) that the factfinder will conduct a "more searching inquiry into whether the restraint may advance procompetitive goals." *Id.* at 345-47. Here, by contrast, Impax received a full opportunity to demonstrate procompetitive effects under the rule of reason, and still failed to argue any link existed between the specific restraint and its procompetitive goals.

Impax also suggests that the Supreme Court's 2018 decision in *Amex* marked a sea change in the law by "look[ing] at the record as a whole, including procompetitive benefits arising from factors other than the [restraint]." RB at 19-20. But the Court in fact declared the opposite, explaining that once the plaintiff makes a showing of anticompetitive effects, the defendant must "show a procompetitive rationale *for the restraint*." *Amex*, 138 S. Ct. at 2284 (emphasis added). The *Amex* Court did not actually reach the stage of analyzing procompetitive benefits, explaining that the sole issue on appeal was "whether the plaintiffs have carried their initial burden of proving that Amex's antisteering provisions have an anticompetitive effect." *Id.* at 2284, 2287, 2290.

Impax claims it should not be required to link the restraint to its procompetitive justifications at the second step of the rule of reason because "it is the *plaintiff's* burden to establish the absence of any connection" at the third step, which considers the existence of a less-restrictive alternative. RB at 19. Impax again misunderstands its duties at the second step. At this stage, Impax has the burden to show that the restraint "*further*s . . . legitimate objectives" and "*promotes* a legitimate goal." *Brown Univ.*, 5 F.3d at 679 (emphasis added). A restraint cannot "further" or "promote" a procompetitive goal unless it has a clear "connection" to it. Coincidence within a settlement is not enough. It is only when a defendant makes that connection that the burden shifts back to the plaintiff to show a less restrictive alternative. *Id.* That the plaintiff is entitled to offer rebuttal evidence does not relieve defendant of making the initial showing.

For the same reasons, we reject the contention that the early entry facilitated by the reverse payment settlement should be weighed against the competitive harm identified here. Impax has not tied the freedom-to-operate license, which facilitated entry prior to expiration of the after-acquired patents, to the restraint, as discussed above. And, as discussed, the nine month early entry on the initial Opana ER patents almost surely would have been *longer* absent the reverse payments.

Finally, we find the general policy favoring settlements cannot save this anticompetitive reverse payment settlement. While settling litigation is typically favored under the law, it is not a trump card. As *Actavis* teaches, the mere fact that a reverse payment settles litigation does not

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immunize otherwise anticompetitive conduct. 570 U.S. at 153-58. Given that Impax has failed to identify any other cognizable efficiencies,⁴² we conclude that the policy favoring settlements does not, on its own, save the anticompetitive conduct at issue here.

In sum, Impax does not argue that: (1) the No-AG Commitment, the Endo Credit, or any portion of the DCA payment have *themselves* allowed Impax to sell its generic product free of patent-infringement claims; (2) a settlement including the broad license was only available because Impax accepted a payment; or (3) the reverse payment furthered the procompetitive objectives of the license in some other way. Because it has not linked the payment for deferred entry that constitutes the challenged restraint to an asserted justification, Impax has not identified a procompetitive benefit that could offset the restraint's anticompetitive harm.

2. Conclusions Drawn from Impax's Failure to Demonstrate Procompetitive Benefits

Accordingly, we conclude that Impax has failed to establish any procompetitive justifications for its acceptance of a large reverse payment to delay generic entry. In combination with our conclusion that Complaint Counsel have established that the reverse payments caused anticompetitive harm, the failure to establish a procompetitive justification brings the rule-of-reason analysis to its end. Because Impax's conduct had significant anticompetitive consequences and Impax has not established any cognizable procompetitive justifications for these consequences, this conduct constitutes an unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, and an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

C. Even if Impax's Procompetitive Justifications Were Valid, Complaint Counsel Have Shown a Less Restrictive Alternative

Had Impax borne its burden to connect creditable procompetitive justifications to the restraint at issue (for example, if Impax had proven the broad patent license offered cognizable efficiencies), the burden would then shift to Complaint Counsel to demonstrate "that the procompetitive efficiencies could be reasonably achieved through less anticompetitive means." *Amex*, 138 S. Ct. at 2284. *See also Brown Univ.*, 5 F.3d at 678-79; *Law*, 134 F.3d at 1019; *Visa*, 344 F.3d at 238; *Areeda & Hovenkamp*, *supra* ¶ 1505; U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS § 3.36(b). We hold that Complaint Counsel have demonstrated that Impax could have obtained the proffered benefits by settling without a reverse payment for delayed entry—which is a practical, less restrictive alternative.

The Initial Decision devoted a single paragraph to this issue. *See ID* at 146-47. The ALJ found that Complaint Counsel failed to show that a "hypothetical [alternative] settlement could

⁴² For clarity, we define "cognizable efficiencies" here to mean those procompetitive justifications that meet all the requirements to be considered legitimate and thus to be counted against any anticompetitive effects, which includes that they be sufficiently related to the restraint at issue. *See U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR COLLABORATIONS AMONG COMPETITORS* § 3.36.

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have, or would have, included the broad patent license,” noting that Endo had twice rejected Impax’s simple settlement proposals with 2011 entry dates and no reverse payments. ID at 147 & n.35. We disagree.

The *Actavis* Court repeatedly recognized that settling without a reverse payment is often a feasible, less anticompetitive alternative. *See* 570 U.S. at 158 (“[P]arties may well find ways to settle patent disputes without the use of reverse payments.”). Imposing antitrust liability for reverse payments “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 expiration, without . . . paying the challenger to stay out prior to that point.” *Id.* at 158. The “premise” behind *Actavis*, a leading treatise recognizes, “is that there are better, less anticompetitive ways to settle these disputes.” Areeda & Hovenkamp, *supra* ¶ 2046c3 (3d ed. Supp. 2017).

Additional evidence confirms this insight. Complaint Counsel’s expert, Professor Max Bazerman, testified that “[t]he empirical evidence supports the conclusion that settlements are very viable without reverse payments.” CX5001 (Bazerman Expert Report) at ¶ 20; *see also id.* at ¶¶ 21, 23. Professor Bazerman pointed to, *inter alia*, Commission studies—covering more than a decade—that demonstrate the feasibility of these settlements. Section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires pharmaceutical companies to file with the FTC and the Department of Justice agreements between branded and generic manufacturers regarding the manufacture, marketing, and sale of generic versions of brand-name drugs. *See* Pub. L. No. 108-173, 117 Stat. 2066 (codified in relevant part at 21 U.S.C. § 355 note). Professor Bazerman found that for fiscal years 2004-2009 these studies showed that only 30 percent of the patent settlements filed with the FTC involved both compensation from the branded firm to the generic firm and restrictions on generic entry. CX5001 (Bazerman Expert Report) at ¶ 21, citing FTC Staff Report, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2009 (Apr. 2011), <https://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/mmreport2009.pdf>. Similarly, in the first full fiscal year after *Actavis*, the FTC learned of 160 final agreements resolving patent disputes between branded and generic manufacturers, and found that over 80 percent involved no compensation flowing from the branded to the generic firm. *Id.*, citing FTC Staff Report, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Summary of Agreements Filed in FY 2014 (Jan. 2016), <https://www.ftc.gov/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement-0>. The testimony demonstrates 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*.

Here, Complaint Counsel argue that a less anticompetitive settlement along the lines suggested in *Actavis* was obvious as a matter of “[b]asic common sense.” CCAB at 25. Since Endo “was willing to trade money for its preferred 2013 entry date,” it certainly would have been willing to offer the same license and entry date (or possibly an earlier date) without also making

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a large payment to Impax. *Id.* Thus, according to Complaint Counsel, there is no basis in the record to conclude that Impax needed to receive a multi-million dollar payment in order to obtain the procompetitive benefits of a broad patent license and pre-expiration entry date. *Id.*; CCRB at 11; see *Smithkline Beecham*, 791 F.3d at 412.

Impax responds by charging that Complaint Counsel’s proffered alternative was not “possible.” RB at 25-26. Impax further responds that Complaint Counsel’s no-payment alternative would be “no less restrictive of competition” because “Impax would still have launched its product on the exact same date and given up its patent challenge in the exact same manner.” RB at 14, 25 (emphasis omitted). See also Oral Arg. Tr. 59:10-59:12; 63:17-63:21 (counsel arguing Impax received “the earliest date that Endo was willing to offer”).⁴³ Impax’s argument boils down to the assertion that the proffered alternative was not offered or agreed to, and that the combination of Endo’s desire to further delay competition and Impax’s desire to share in monopoly rents prevented this alternative from arising.

Given, however, the Supreme Court’s analysis in *Actavis* and the decades of evidence indicating that firms can and do—frequently and successfully—settle Hatch-Waxman patent litigation without reverse payments, Impax needed to support its assertion that a no-payment settlement was impossible with evidence rebutting Complaint Counsel’s strong showing. See *Areeda & Hovenkamp*, *supra* ¶ 1914c. It may do so by “showing that the proffered alternative is either unworkable or not less restrictive” based on the facts in evidence. *Id.* (“The defendant’s own business expertise and experience is the likely source of information concerning the viability of proffered less restrictive alternatives.”).⁴⁴ In this specific context, where Supreme Court jurisprudence and decades of agency experience highlight the viability of the alternative, we need more in order to dismiss it. Other facts showing the impossibility of such terms in a given case might suffice, but such facts are not in this record.

A restraint is unlikely to survive scrutiny where, as here, it appears the parties’ desire to preserve and split between themselves monopoly profits is the only impediment to their settling on terms that other parties routinely use to settle similar litigation. See *Actavis*, 570 U.S. at 158.

43 The record does not support Impax’s assertion. After Endo rebuffed Impax’s specific proposals for earlier entry dates (including a 2011 entry date and one as late as January 2012), Impax acceded to Endo’s proposals for a much later, 2013, entry date and a large reverse payment. IDF 116, 155. Although Impax’s lead settlement negotiator, Christopher Mengler, asserted at trial the Endo was adamant about preventing pre-2013 entry (Mengler, Tr. 565-67), in his previous sworn testimony he admitted that he did not remember discussing entry dates prior to 2013 with Endo. See CX4010 (Mengler, IHT) at 45-54. Specifically, Mengler professed no recollection of (1) whether Impax ever “tried to get a date earlier than January of 2013”; (2) how Endo reacted to the prospect of an earlier date; or (3) whether Endo ever told Impax that it would “not settle the litigation” with an entry date before 2013. *Id.*

44 See also C. Scott Hemphill, *Less Restrictive Alternatives in Antitrust Law*, 116 COLUM. L. REV. 927, 982 (2016) (“If plaintiffs have the burden of persuasion, defendants ought to bear a burden of production. Defendants have better access to information about their reasons for adopting a particular practice.”); *Wilk v. Am. Med. Ass’n*, 671 F. Supp. 1465, 1483 (N.D. Ill. 1987) (faulting defendant for failing to establish that an alternative was impractical or unworkable), *aff’d*, 895 F.2d 352 (7th Cir. 1990). Cf. *United States v. H & R Block, Inc.*, 833 F. Supp. 2d 36, 91 (D.D.C. 2011) (finding a proffered efficiency not merger-specific when defendant had failed to present evidence showing why an alternative would not be feasible).

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The facts that are before us make it hard to imagine that, if apparently material contract terms—worth at least \$23 million—were removed, Impax’s key restriction under the settlement, *i.e.*, the entry date, would not have altered. As the ALJ found, and as we have discussed, it is “unlikely” that a brand company would pay a generic “anything more than saved litigation costs, only to obtain entry on the date the [generic] would have entered anyway.” IDF 446. 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. *See* CX5001 (Bazerman Report) at ¶ 17; *Cipro*, 348 P.3d at 865, 871; *Smithkline Beecham*, 791 F.3d at 405 n.23. Furthermore, a no-payment settlement with an earlier entry date would clearly be less restrictive of competition because it would give consumers earlier access to generic drugs at substantial discounts from the branded drug price. IDF 31, 442.

We therefore conclude that Complaint Counsel have demonstrated an alternative to the reverse payment settlement that would have achieved the procompetitive benefits Impax proffered (had Impax proven them cognizable) through significantly less anticompetitive means. A no-payment settlement allowing pre-2013 generic entry would have been a practical alternative for both Impax and Endo, but they chose instead to exchange sizeable payment for a later entry date. They destroyed the risk of competition and enriched themselves at the expense of consumers.

* * *

For the foregoing reasons, we hold that: (1) Complaint Counsel satisfied their *prima facie* burden to demonstrate harm to competition arising from the reverse payment settlement at issue; (2) Impax failed to show that the challenged restraint furthered any cognizable procompetitive justifications; and (3) even if Impax had satisfied this burden, Complaint Counsel identified a viable less restrictive alternative that has been used to settle hundreds of similar pharmaceutical patent litigations. Because the record provides two independent bases to reject Impax’s procompetitive justifications, we do not need to reach the balancing stage of the rule of reason.

Impax has thus engaged in an unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, and an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

VI. REMEDY

Having found a violation of Section 5, we are empowered to enter an appropriate order to prevent a recurrence of the violation. 15 U.S.C. § 45(a)(2). The Commission has wide latitude to fashion a remedy, provided that the remedy chosen has a reasonable relation to the unlawful practices found to exist. *See, e.g., FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 394-95 (1965); *FTC v. Nat’l Lead Co.*, 352 U.S. 419, 429 (1957); *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 612-13 (1946). The scope of the remedial order is not strictly limited to the respondent’s past transgressions but can effectively “close all roads to the prohibited goal, so that [the Commission’s] order may not be by-passed with impunity.” *FTC v. Ruberoid Co.*, 343 U.S. 470, 473 (1952).

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Complaint Counsel have requested that we enter a cease and desist order that contains three major prohibitions against specified conduct by Impax. Specifically:

- Paragraph II.A of Complaint Counsel’s Proposed Order would enjoin Impax from entering into a reverse payment patent settlement that includes an agreement not to compete by the generic filer plus a payment by the NDA holder to the generic filer. It covers all potential forms of reverse payments, including no-AG commitments and business transactions entered within 45 days of a patent settlement. Proposed Order, Paragraph I.W. It carves out payments that are unlikely to be anticompetitive, such as saved litigation expenses, rights to market generic products, or provisions facilitating the regulatory approval of the generic’s product. *Id.*
- Paragraph II.B of the Proposed Order would bar Impax from “entering any agreement that prevents, restricts, or in any way disincentivizes competition between oxymorphone ER products.” This provision would not affect existing agreements.
- The parties’ First Amendment to the 2010 SLA (“2017 Amendment”) [REDACTED]
[REDACTED]
[REDACTED]. CX3275-013. Paragraph II.C of the Proposed Order requires Impax to pay royalties to Endo regardless of whether another oxymorphone ER product enters the market. [REDACTED]
[REDACTED]

Impax argues that no relief is needed (even assuming that the SLA is found to violate the Act), and further argues that each of the specific prohibitions identified above is overbroad and unwarranted. We reject several of Impax’s arguments but find that others have merit. As discussed below, we include Complaint Counsel’s first proposed prohibition and part of their second proposed prohibition in our Final Order but decline to include the third prohibition.

A. The Need for a Remedy

Respondent argues that Complaint Counsel have failed to show there is a “cognizable danger” that Respondent will repeat the condemned conduct, and therefore asserts that the Commission cannot enter prospective relief. *See* RB at 62-64, citing, *inter alia*, *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953). We disagree and find that Complaint Counsel have shown the requisite danger of recurrence.

Impax’s motivation to enter the reverse-payment settlement with Endo arose from the parties’ joint incentive to split the monopoly profits that Endo could earn from Opana ER rather than see those profits competed away by generic entry. *Actavis*, 570 U.S. at 154. This incentive is enduring and is not limited to the oxymorphone ER market. It is, unfortunately, a feature of infringement litigation under the Hatch-Waxman Act statutory framework generally. *See* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design*

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Problem, 81 N.Y.U. L. Rev. 1553, 1560 (2006) (because only the first generic ANDA filer can receive the “bounty” of 180-day exclusivity, the brand’s strategy of “buying off” the first generic challenger is effective in heading off the most potent threat to entry); *Cipro*, 348 P. 2d at 854 (Hatch-Waxman Act legal regime means that, “regardless of the degree of likely validity of a patent, the brand and first-filing generic have an incentive to effectively establish a cartel” through a reverse payment settlement) (citing Hovenkamp, *supra* ¶ 2046 at 351). Although the number of settlements involving reverse payments has decreased following the Supreme Court’s *Actavis* decision, as discussed above in Section V.C, the data also reveal that this practice has not disappeared. The persistence of this incentive supports the grant of prospective relief here. *See Polygram*, 416 F.3d at 38-39 (upholding FTC cease and desist order because the condition that gave rise to the unlawful agreement – namely, the record company’s fear that a new release by an artist may lose sales to an artist’s older albums owned by a competitor – is recurrent in the record industry and would give the respondent the same incentive to enter future unlawful agreements).

Moreover, Impax remains an active participant in the pharmaceutical industry and regularly engages in patent infringement litigation. *See* CX3271-030 (Impax 2015 Annual Report describing Impax as “routinely subject” to patent infringement litigation brought by branded pharmaceutical manufacturers). Thus, settling patent litigations will likely continue to be a significant part of Impax’s business. *See FTC v. Accusearch Inc.*, 570 F.3d 1187, 1202 (10th Cir. 2009) (court upheld prospective relief in part because respondent remained in the business and had the capacity to engage in similar unfair acts or practices in the future). Given the persistent nature of the incentives for reverse payment settlements, and Impax’s likely continued participation in patent infringement litigation, we consider the prospective relief to be warranted here.⁴⁵

B. The Asserted Overbreadth of the Order

We next turn to Respondent’s specific concerns with the terms of the Proposed Order. Respondent contends that the prohibition on reverse payment settlements in Paragraph II.A is overbroad in that its coverage of “any Payment” would prevent Impax from purchasing materials or services from a branded company for fair value. RB at 64-65. As the dispute in this proceeding over the DCA milestone payments illustrates, whether a payment is for fair value can be a topic of intense debate. The Proposed Order here appropriately short-circuits future argument: having violated the law, a respondent “must expect some fencing in.” *Nat’l Lead*, 352 U.S. at 431. Moreover, the Proposed Order does not ban all sales of goods and services, but only those that are either (i) expressly contingent on entering a brand/generic settlement agreement, or (ii) occur within 45 days before or after such a settlement. Proposed Order, Paragraph I.W. Respondent does not explain why, if there were independent business reasons for a fair value transaction, it could not enter such a transaction outside of these restrictions.

⁴⁵ In fact, although our ruling is not dependent on this point, Impax’s claim that it has no history of similar violations may be questioned; Impax has entered into at least one other patent settlement with a branded firm alleged to include a large, unjustified reverse payment. *See In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2018 WL 563144 (D. Mass. Jan. 25, 2018).

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Next, Respondent argues that the provision banning “any agreement that prevents, restricts, or in any way disincentivizes competition between Oxymorphone ER Products” is problematic. Proposed Order, Paragraph II. B. Respondent first contends, erroneously, that this provision relates only to the challenged *product* and not the challenged *practice*. RB at 65, citing *Nat’l Lead*, 352 U.S. at 428 (improper remedy if “no reasonable relation to the unlawful practices found to exist”). In fact, the provision relates to both the product and the practice. Here, the gravamen of our holding is that Impax and Endo entered into an agreement that “prevent[ed]” and “restrict[ed]” competition for sales of oxymorphone ER. There is thus an amply close nexus between the condemned conduct and the agreements that the Proposed Order forbids. *See FTC v. Mandel Bros., Inc.*, 359 U.S. 385, 393 (1959) (the Commission “may fashion its relief to restrain other like or related unlawful acts”) (quotation omitted).

We do agree, however, with Impax to the limited extent that we find the proposed ban on agreements that “disincentivize[]” competition to be vague and potentially overbroad. For example, if Impax entered a procompetitive agreement that increased the supply of oxymorphone ER products, this might be seen as “disincentivizing” third-party entry into the market because it would make such entry less profitable. Yet such an agreement is obviously not the intended target of the remedial order. The Order that we enter has language barring agreements that “prevent[] or restrict[]” competition in oxymorphone ER products but omits the term “disincentivizes.” We also accept Complaint Counsel’s suggestion to add the following underlined text to clarify the meaning of the Order:

- Paragraph II.B: Respondent shall not enter any agreement with another Oxymorphone ER Manufacturer or Applicant that prevents or restricts competition between Oxymorphone ER Products.
- Paragraph I Definitions: “Oxymorphone ER Manufacturer or Applicant” means any company that has an Oxymorphone ER NDA or ANDA, has filed an Oxymorphone ER NDA or ANDA, or is preparing to file an Oxymorphone ER NDA or ANDA.

Finally, Impax opposes Complaint Counsel’s proposal to nullify Impax’s rights under the 2017 Amendment to the SLA while maintaining its royalty obligation to Endo. [REDACTED]

[REDACTED] CX3275 at 013-014, §§ 1(h)-(i), 4(a). [REDACTED]

[REDACTED] The Proposed Order would require Impax to pay royalties [REDACTED] until Endo’s additional patents expire, regardless of whether Endo or another firm actually enters the market.

Impax raises three concerns about Complaint Counsel’s proposal. First, Impax argues that the 2017 Amendment is not a reverse payment but is exactly the kind of “commonplace settlement form” that *Actavis* leaves untouched. RB at 66, quoting *Actavis*, 570 U.S. at 152. Second, Impax argues that Complaint Counsel have not investigated the 2017 Amendment, taken

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discovery regarding it, adduced evidence at trial regarding it, or formally challenged it. *Id.* Thus, says Impax, it would violate basic notions of administrative law to condemn it as anticompetitive. *Id.* at 67. Third, Impax argues that Complaint Counsel did not suggest until after the trial that they intended to invalidate the 2017 Amendment. Thus, Impax asserts, it would violate due process to enter an adverse finding against the 2017 Amendment at this stage. *Id.*

We do not share Impax's confidence that the 2017 Amendment is an ordinary settlement unremarkable under *Actavis*. As noted in Section II.D above, Endo has now exited the market for oxymorphone ER. [REDACTED]

[REDACTED] This could continue the sharing of monopoly profit on sales of the Opana ER formulation, with Impax now in the role of a monopolist and Endo in the role of a potential entrant paid to stay out of the market. Nonetheless, the fact remains that the contractual provision at issue was neither investigated nor litigated below. Under these circumstances, we believe it would be unwise and inequitable to strip Impax of its rights under the 2017 Amendment, while leaving it with its obligations.⁴⁶ We accordingly omit this provision from our Final Order.

46 Below, Complaint Counsel first sought, at the conclusion of the administrative trial, to nullify the 2017 Amendment in its entirety. CC Post-Trial Br. at 76. Facing what could have been the elimination of its royalties, Endo successfully moved to intervene in the ALJ proceeding for the limited purpose of participating in post-trial briefing to protect what it described as its "due process rights[]" and its contract rights" under the August 2017 settlement agreement. Non-Party Endo Pharmaceuticals Inc.'s Unopposed Motion for Limited Intervention and Memorandum in Support, Docket No. 9373 (Jan. 2, 2018). Endo argued that Complaint Counsel's request to nullify the 2017 Amendment "violate[d] the most basic principles of due process and [was] a brazen attempt at governmental overreach." Intervenor Endo Pharmaceuticals, Inc.'s Opposition to Complaint Counsel's Findings and Proposed Relief Regarding the Endo-Impax 2017 Settlement Agreement 1 (Jan. 16, 2018). On this appeal, Complaint Counsel modified their remedial request to require, [REDACTED]

[REDACTED] See Proposed Order, Paragraph II.C.

Final Order

FINAL ORDER**I. Definitions**

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. “Commission” means the United States Federal Trade Commission.
- B. “Impax” or “Respondent” means Impax Laboratories LLC (formerly Impax Laboratories, Inc.), its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Impax, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “505(b)(2) Application” means an application filed with the United States Food and Drug Administration pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b)(2).
- D. “ANDA” means an Abbreviated New Drug Application filed with the United States Food and Drug Administration pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j).
- E. “Authorized Generic” means a Drug Product that is manufactured pursuant to an NDA and Marketed in the United States under a name other than the proprietary name identified in the NDA.
- F. “Brand/Generic Settlement” means any agreement or understanding that settles a Patent Infringement Claim in or affecting Commerce in the United States.
- G. “Brand/Generic Settlement Agreement” means a written agreement that settles a Patent Infringement Claim in or affecting Commerce in the United States.
- H. “Branded Subject Drug Product” means a Subject Drug Product marketed, sold, or distributed in the United States under the proprietary name identified in the NDA for the Subject Drug Product.
- I. “Commerce” has the same definition as it has in 15 U.S.C. § 44.
- J. “Control” or “Controlled” means the holding of more than 50% of the common voting stock or ordinary shares in, or the right to appoint more than 50% of the directors of, or any other arrangement resulting in the right to direct the management of, the said corporation, company, partnership, joint venture, or entity.

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- K. “Drug Product” means a finished dosage form (e.g., tablet, capsule, solution, or patch), as defined in 21 C.F.R. § 314.3(b), approved under a single NDA, ANDA or 505(b)(2) Application, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.
- L. “Executive and General Counsel Staff” means the Respondent’s Executive Team, including the Chief Executive Officer, the Chief Financial Officer, the General Counsel, the Chief Compliance Officer, Presidents of divisions within Respondent, including the Generics Division and Specialty Pharm Division, and all attorneys in the Respondent’s office of General Counsel.
- M. “Generic Entry Date” means the date in a Brand/Generic Settlement Agreement, whether certain or contingent, on or after which a Generic Filer is authorized by the NDA Holder to begin manufacturing, using, importing, or Marketing the Generic Subject Drug Product.
- N. “Generic Filer” means a party to a Brand/Generic Settlement who controls an ANDA or 505(b)(2) Application for the Subject Drug Product or has the exclusive right under such ANDA or 505(b)(2) Application to distribute the Subject Drug Product.
- O. “Generic Product” means a Drug Product manufactured and/or sold under an ANDA or pursuant to a 505(b)(2) Application.
- P. “Market,” “Marketed,” or “Marketing” means the promotion, offering for sale, sale, or distribution of a Drug Product.
- Q. “NDA” means a New Drug Application filed with the United States Food and Drug Administration pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b), including all changes or supplements thereto that do not result in the submission of a new NDA.
- R. “NDA Holder” means a party to a Brand/Generic Settlement that controls the NDA for the Subject Drug Product or has the exclusive right to distribute the Branded Subject Drug Product in the United States.
- S. “No-AG Commitment” means any agreement with, or commitment or license to, the Generic Filer that prohibits, prevents, restricts, requires a delay of, disincentivizes, or imposes a condition precedent upon the research, development, manufacture, regulatory approval, or Marketing of an Authorized Generic.

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- T. “Oxymorphone ER Manufacturer or Applicant” means any company that has an Oxymorphone ER NDA or ANDA, has filed an Oxymorphone ER NDA or ANDA, or is preparing to file an Oxymorphone ER NDA or ANDA.
- U. “Oxymorphone ER Product” means any extended-release tablet containing oxymorphone that is the subject of an NDA, ANDA, or 505(b)(2) Application.
- V. “Patent Infringement Claim” means any allegation threatened in writing or included in a complaint filed with a court of law that a Generic Product may infringe one or more U.S. Patents held by, or licensed to, an NDA Holder.
- W. “Payment by the NDA Holder to the Generic Filer” means a transfer of value by the NDA Holder to the Generic Filer (including, but not limited to, a No-AG Commitment, money, goods, or services), regardless of whether the Generic Filer purportedly transfers value in return, where such transfer is either (i) expressly contingent on entering a Brand/Generic Settlement Agreement, or (ii) agreed to during the 90 days period starting 45 days before executing a Brand/Generic Settlement Agreement and ending 45 days after executing a Brand/Generic Settlement Agreement. The following, however, are not Payment by the NDA Holder to the Generic Filer:
1. compensation for the NDA Holder’s saved future litigation expenses, but only if the total compensation the NDA Holder agrees to provide to the Generic Filer during the 90 day period starting 45 days before and ending 45 days after executing the Brand/Generic Settlement Agreement does not exceed a maximum limit, which is initially set at \$7,000,000 and shall be increased (or decreased) as of January 1 of each year by an amount equal to the percentage increase (or decrease) from the previous year in the annual average Producer Price Index for Legal Services (Series Id. PCU5411—5411--) (currently reported at <https://download.bls.gov/pub/time.series/pc/pc.data.63.ProfessionalandTechnicalServ>) published by the Bureau of Labor Statistics of the United States Department of Labor or its successor;
 2. the right to Market, as of an agreed upon Generic Entry Date, Generic Product(s) in the United States under an ANDA or 505(b)(2) Application (i) that is controlled by the Generic Filer and was not transferred to the Generic Filer by the NDA Holder or (ii) to which the Generic Filer has a license from a party other than the NDA Holder;
 3. provisions to facilitate, by means other than the transfer of goods or money, the Generic Filer’s ability to secure or maintain final regulatory approval, or commence or continue the Marketing, of a Generic Product,

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by, inter alia, providing covenants, waivers, permissions, releases, dismissals of claims, and/or authorizations; and

4. waiver or a limitation of a claim for damages based on prior Marketing of the Generic Subject Drug Product, but only if the NDA Holder and the Generic Filer do not agree, and have not agreed, to another Brand/Generic Settlement for a different Drug Product during the 90 day period starting 45 days before and ending 45 days after the execution of the Brand/Generic Settlement; and
 5. a continuation or renewal of a pre-existing agreement between an NDA Holder and a Generic Filer but only if: (i) the pre-existing agreement was entered into at least 90 days before the relevant Brand/Generic Settlement Agreement, (ii) the terms of the renewal or continuation, including the duration and the financial terms, are substantially similar to those in the pre-existing agreement, and (iii) entering into the continuation or renewal is not expressly contingent on agreement to a Brand/Generic Settlement.
- X. “Subject Drug Product” means the Drug Product for which one or more Patent Infringement Claims are settled under a given Brand/Generic Settlement. For purposes of this Order, the Drug Product of the NDA Holder and the Generic Filer to the same Brand/Generic Settlement shall be considered to be the same Subject Drug Product.
- Y. “U.S. Patent” means any patent issued by the United States Patent and Trademark Office, including all divisions, reissues, continuations, continuations-in-part, modifications, or extensions thereof.

II. Prohibited Agreements

IT IS FURTHER ORDERED that:

- A. Respondent is prohibited from entering into any Brand/Generic Settlement that includes:
1. (i) a No-AG Commitment and (ii) an agreement by the Generic Filer not to research, develop, manufacture, distribute, Market, or sell the Subject Drug Product for any period of time; or
 2. (i) any Payment by the NDA Holder to the Generic Filer and (ii) an agreement by the Generic Filer not to research, develop, manufacture, distribute, Market, or sell the Subject Drug Product for any period of time.

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- B. Respondent shall not enter any agreement with another Oxymorphone ER Manufacturer or Applicant that prevents or restricts competition between Oxymorphone ER Products.

III. Compliance Program

IT IS FURTHER ORDERED that Respondent shall design, maintain, and operate an Antitrust Compliance Program that sets forth the policies and procedures Respondent has implemented to comply with this Order and with the antitrust laws. The Antitrust Compliance Program shall include:

- A. Designation and retention of an antitrust compliance officer or director to supervise the design, maintenance, and operation of the program;
- B. Training regarding Respondent's obligations under this Order and the antitrust laws for Executive and General Counsel Staff within 30 days after this Order becomes final and at least annually thereafter;
- C. Certification by each Executive and General Counsel Staff member that she or he has received the training required in Paragraph III.B;
- D. Policies and procedures for employees and representatives of Respondents to ask questions about, and report violations of, this Order and the antitrust laws confidentially and without fear of retaliation of any kind;
- E. Policies and procedures for disciplining employees and representatives of Respondents for failure to comply with this Order and the antitrust laws; and
- F. The retention of documents and records sufficient to record Respondents' compliance with its obligations under this Paragraph III of this Order, including but not limited to records showing that employees and representatives of Respondents have received all trainings required under this Order during the preceding two years.

IV. Reporting Requirements

IT IS FURTHER ORDERED that

- A. Respondent shall file a verified written report to the Commission ("compliance report"):
 - 1. 90 days after the date this Order is issued; and

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2. One year after the date this Order is issued, and annually for the next 19 years on the anniversary of that date, and
 3. At such other times as the Commission may require.
- B. In each compliance report, Respondent shall describe the manner and form in which Respondent intends to comply, is complying, and has complied with this Order, including by submitting:
1. a copy of any additional agreement with a party to a Brand/Generic Settlement to which Respondent is a signatory if (i) the relevant Brand/Generic Settlement Agreement includes an agreement by the Generic Filer not to research, develop, manufacture, Market or sell the Subject Drug Product for any period of time, and (ii) the relevant additional agreement is entered within a year of executing the Brand/Generic Settlement Agreement;
 2. copies of all documents that contain or describe an agreement that relates to one or more Oxymorphone ER Products and is an agreement between Respondent and (i) any holder of an NDA, ANDA or 505(b)(2) for any Drug Product, or (ii) any Oxymorphone ER Manufacturer or Applicant; and
 3. Copies of the certifications required by Paragraph III.C and the policies and procedures required by Paragraphs III.D and III.E.
- provided that*, Respondent does not need to submit any agreements, correspondence or other documents that Respondent submitted to the Commission with a prior verified written report required by this provision.
- C. Each compliance report submitted pursuant to this Paragraph shall be verified by a notarized signature or sworn statement of the Chief Executive Officer or other officer or employee of the Respondent specifically authorized to perform this function, or self- verified in the manner set forth in 28 U.S.C. § 1746. Commission Rule 2.41(a), 16 C.F.R. § 2.41(a), requires that the Commission receive an original and two copies of each compliance report. A paper original of each compliance report shall be filed with the Secretary of the Commission and electronic copies shall be transmitted to the Secretary at ElectronicFilings@ftc.gov, and the Compliance Division at bccompliance@ftc.gov.

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- D. This Order does not alter the reporting requirements of Respondent pursuant to Section 1112 of the Medicare Prescriptions Drug, Improvement, and Modernization Act of 2003.

V. Change of Corporate Control**IT IS FURTHER ORDERED** that

- A. Respondent shall notify the Commission at least 30 days prior to:
1. Any proposed dissolution of Impax Laboratories LLC;
 2. Any proposed acquisition of, or merger or consolidation involving Impax Laboratories LLC; or
 3. Any other change in Respondent, including assignment or the creation, sale, or dissolution of subsidiaries, if such change may affect compliance obligations arising out of this Order.
- B. Respondent shall submit any notice required under this paragraph electronically to the Secretary of the Commission at ElectronicFilings@ftc.gov and the Compliance Division at bccompliance@ftc.gov.

VI. Access Provisions

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, upon written request and five days' notice to the relevant Respondent, made to its principal place of business as identified in this Order, registered office of its United States subsidiary, or its headquarters office, the notified Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. Access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all business and other records and all documentary material and electronically stored information as defined in Section 2.7(a)(1) and (2) of the Commission's Rules, 16 C.F.R. § 2.7(a)(1) (2), in the possession or under the control of the Respondent related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized representative of the Commission and at the expense of the Respondent; and
- B. To interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

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VII. Termination

IT IS FURTHER ORDERED that this Order shall terminate March 28, 2039.

By the Commission.

Complaint

IN THE MATTER OF

**SANDPIPER OF CALIFORNIA, INC.,
AND
PIPERGEAR USA, INC.**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL
TRADE COMMISSION ACT

*Docket No. C-4675; File No. 182 3095
Complaint, April 16, 2019 – Decision, April 16, 2019*

This consent order addresses Sandpiper of California, Inc.’s and PiperGear USA, Inc.’s marketing, sale, and distribution of bags and wallets with claims that the products are made in the United States. The complaint alleges that Respondents violated Section 5(a) of the Federal Trade Commission Act by representing that all of their products are all or virtually all made in the United States when, in fact, more than 95% of Respondent Sandpiper’s products are imported as finished goods, and approximately 80% of Respondent PiperGear’s products are either imported as finished goods or contain significant imported components. The consent order prohibits Respondents from making U.S.-origin claims for their products unless either: (1) the final assembly or processing of the product occurs in the United States, all significant processing that goes into the product occurs in the United States, and all or virtually all ingredients or components of the product are made and sourced in the United States; (2) a clear and conspicuous qualification appears immediately adjacent to the representation that accurately conveys the extent to which the product contains foreign parts, ingredients or components, and/or processing; or (3) for a claim that a product is assembled in the United States, the product is last substantially transformed in the United States, the product’s principal assembly takes place in the United States, and United States assembly operations are substantial.

Participants

For the *Commission*: *Julia Solomon Ensor.*

For the *Respondents*: *Daniel J. Navigato, Navigato & Battin, LLP.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Sandpiper of California, Inc., a corporation, and PiperGear USA, Inc., a corporation (collectively, “Respondents”), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Sandpiper of California, Inc. (“Sandpiper”) is a California corporation with its principal office or place of business at 687 Anita Street, Suite A, Chula Vista, CA 91911.
2. Respondent PiperGear USA, Inc. (“PiperGear”) is a California corporation with its principal office or place of business at 687 Anita Street, Suite A, Chula Vista, CA 91911.
3. Respondents Sandpiper and PiperGear have operated as a common enterprise while engaging in the unlawful acts and practices alleged below. Because these Respondents