UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES

In the Matter of	)	
Impax Laboratories, Inc., a corporation,	)	**DOCKET NO. 9373**
Respondent	)	

COMPLAINT COUNSEL'S POST-TRIAL REPLY BRIEF

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The evidence lays out a paradigmatic antitrust violation under the Supreme Court's decision in *FTC v. Actavis,*133 S. Ct. 2223 (2013). By May 2010, Impax posed an imminent threat to Endo's Opana ER franchise, having just received tentative FDA approval for its generic oxymorphone ER product. Entry of Impax's generic product would benefit consumers by providing a less-expensive, therapeutically equivalent alternative to Opana ER. Faced with this threat, Endo offered to pay Impax not to launch its generic product. Endo provided a valuable promise that it would not compete with an authorized generic during Impax's exclusivity period,

Credit provisions might have been worthless. But it does not explain why its primary negotiator said he would "love" a worthless No-AG provision and viewed a worthless Endo Credit provision as "super, super important" to Impax's willingness to accept the settlement, or why its Chief Financial Officer informed investors that the combination of two worthless provisions—the No-AG and Endo Credit—ensured that Impax would realize value from the settlement "almost no matter what happens."

Impax argues that its reverse-payment agreement was actually procompetitive because the settlement included a license to future patents Endo might obtain, and that license has allowed it to continue selling generic oxymorphone ER after Endo successfully enforced some of those patents against other generics. But it simply ignores the well-established principle that any procompetitive objective is "entirely immaterial unless it is served by the challenged restraint." 7 Areeda, ¶ 1505a. Indeed, Impax makes no claim—and offers no evidence—that Endo's payment actually helped it obtain a broad patent license.

Impax touts the current availability of its generic version of Opana ER as a "boon for consumers," but elsewhere argues that the presence of that same product in the market before 2013 would have made no difference to consumers because they could use other long-acting opioids if Opana ER were too expensive. Impax does not even try to reconcile this obvious contradiction. Further, in arguing that other long-acting opioids were appropriate substitutes, Impax simply ignores the determinative market definition inquiry: cross-elasticity of demand, i.e., whether doctors would switch patients from oxymorphone to other long-acting opioids if the relative price of oxymorphone increased. The undisputed economic evidence shows that they would not—and did not. Impax offers no cross-elasticity analysis, and no response to Complaint Counsel's analysis.

reservation date was from a negotiation posture

Indeed, Endo has launched AGs in response to generic entry for numerous other products—including an immediate release oxymorphone product. (CCRF ¶ 623).

C. Endo never planned to time its launch of Reformulated Opana ER to avoid the Endo Credit

Impax claims that Endo "planned" to delay the launch of its Reformulated Opana ER until the fourth quarter of 2012—to avoid paying the Endo Credit—and then immediately switch the entire market to the reformulated product in as little as two months, making the the No-AG provision worthless when Impax launched in January 2013. Impax Br. at 18, 53. But Endo had no such plan. (CCRF ¶¶ 632, 637). No contemporaneous documents suggest that Endo even considered the Endo Credit as a factor in deciding when to launch Reformulated Opana ER. To the contrary, the unrebutted documents and testimony show that successfully reformulating Opana ER, a major strategic initiative for Endo to extend and protect its second-biggest product, was far more important than any one-time Endo Credit payment. (CCRF ¶¶ 205, 207, 1425-26).

Endo anticipated that it could make more than a billion dollars in additional sales if its switch strategy succeeded. (CCF ¶¶ 75-78; CCRF ¶ 594). And Endo knew that the success of its market switch depended on transitioning the market *before* generic entry. (CCF ¶¶ 75-78; CCRF ¶ 594). It also knew that it could take up to a year to accomplish this. (CCF ¶¶ 80, 482, 486-87). Thus, it was always Endo's plan to launch Reformulated Opana ER as early as possible to ensure a smooth transition of patients to the new product. (CCRF ¶ 209). Indeed, as early as December 2007, Endo's "Priority #1" for its Reformulated Opana ER introduction was to "Beat Generics by 1 Year." (CCF ¶ 75). After agreeing to the Endo Credit, Endo maintained its intention to launch Reformulated Opana ER as soon as possible. (CCRF ¶ 209).

The only evidence Impax identifies to support its claim that this "late switch strategy" was "exactly what Endo planned to do" (Impax Br. at 53) is a pair of documents describing

Endo's 2012 budget. Impax Br. at 18, 53. That budget nominally identified August 2012 as a "targeted launch date" for Reformulated Opana ER, with conversion taking two to three months. (CCRF ¶ 636-37). But neither document indicates Endo selected the August 2012 date to evade the Endo Credit provision. To the contrary, this August 2012 launch plan *would have triggered an Endo Credit payment*. In that scenario, Endo would have completed its two or three month conversion no later than halfway through the fourth quarter of 2012. To achieve such a rapid switch, sales in the first half of that quarter would have declined rapidly; sales in the second half would have been zero. Thus, total fourth quarter sales would have fallen by more than 50% from the quarterly peak sales, triggering the Endo Credit payment. (CCRF ¶ 636-37).

Far from showing a plan to avoid the Endo Credit, then, these documents instead confirm that Endo was willing to incur it in order to secure a successful market conversion. (CCF ¶ 484; CCRF ¶ 209; *see also* CCRF ¶¶ 636-37). Indeed, Impax's own economic expert agreed that Endo's goal was not to minimize its potential payment obligation to Impax, but to maximize its overall profits: "if [Endo] could make profit elsewhere by incurring the Endo [C]redit, they would." (CCF ¶ 477).

Argument

I. The Rule-of-Reason Framework

Actavis held that reverse-payment agreements between branded drug manufacturers and their potential generic competitors are subject to antitrust scrutiny under the rule of reason. *Actavis,* 133 S. Ct. at 2237. Application of the rule of reason follows a three-step burden-shifting framework. Under the first step, a plaintiff can make a *prima facie* showing of harm to competition by showing that the conduct at issue is of a type with the potential for genuine

adverse effects on competition and that the parties to that agreement had sufficient market power to harm competition.[1] In the context of a reverse-payment agreement, the conduct at issue is an agreement by a generic company not to enter the market for some specified period of time in exchange for a large payment from the brand. The relevant anticompetitive harm is that the agreement prevents the risk of competition by subverting the competitive process, which would otherwise protect consumer interests when the incumbent and the generic patent challenger agree to settle patent litigation. *See* CC Br. at 22-23. Once Complaint Counsel satisfies its *prima facie* case, the burden falls on the defendant to justify the large payment. *Actavis*, 133 S. Ct. at 2235-36.[2]

A. The assessment whether a reverse payment is large and unjustified is part of the rule of reason analysis, not a special threshold burden of proof

Despite the rule of reason's standard burden-shifting framework set forth above, Impax argues that reverse payment agreements are immune from antitrust scrutiny unless Complaint Counsel first satisfies a special threshold burden of proof. According to Impax, "Complaint Counsel may not proceed under the rule of reason until it proves the existence of a 'large and unjustified' payment." Impax Br. at 31. Impax's threshold burden standard is wrong for multiple reasons. First, it finds no support in the Supreme Court's opinion. Second, contrary to settled law, it would place the burden on the antitrust plaintiff to identify and disprove possible

[1] *See e.g., Realcomp II, Ltd. v. FTC*, 635 F.3d 815, 827 (6th Cir. 2011) ("Market power and the anticompetitive nature of the restraint are sufficient to show the potential for anticompetitive effects under a rule-of-reason analysis, and once this showing has been made Realcomp must offer procompetitive justifications."); *Sullivan II v. Nat'l Football League*, 34 F.3d 1091, 1097 (1st Cir. 1994); *United States v. Brown Univ. in Providence in the State of R.I.*, 5 F.3d 658, 669 (3d Cir. 1993); *In the Matter of 1-800 Contacts, Inc.*, No. 9372, at 120 (Initial Decision, Oct. 27, 2017).

[2] *See also* Areeda, ¶ 1507c ("Once the plaintiff satisfies its burden of persuasion on the existence of a significant restraint, it will prevail unless the defendants introduce evidence sufficient to allow the tribunal to find that the defendant's conduct promotes a legitimate objective.").

justifications for the reverse payment before the defendant even asserts them. Third, it would require unnecessarily precise and

sufficient justification for the payment.[5] But Impax would have the Court inquire into these very same elements twice, the difference being that in the first iteration, the plaintiff is forced to anticipate and negate possible justifications that the defendant might or might not actually offer. Such an unprecedented and inefficient approach would make no sense and would run counter to the general legal principle that place evidentiary burdens on the party most likely to possess evidence of the matter at issue. *See* Areeda, ¶ 1505. If the Supreme Court had intended such a dramatic departure from standard rule-of-reason analysis, it surely would have said so.

2. Impax seeks to avoid its burden to show a procompetitive justification for the challenged conduct

Under standard rule of reason analysis, a finding that conduct threatens competition shifts the burden to the defendant to justify the challenged conduct. If the defendant fails to satisfy that burden, antitrust law condemns the restraint. *See* Areeda, ¶1507c ("Once the plaintiff satisfies its burden of persuasion on the existence of a significant restraint, it will prevail unless the defendants introduce evidence sufficient to allow the tribunal to find that the defendant's conduct promotes a legitimate objective."). *Actavis* specifically adopted this same approach. 133 S. Ct. at 2236 ("An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason."). Under Impax's theory, however, the only inquiry into Impax's justifications for the payment occurs *before* the rule of reason even applies, and, at this purportedly "distinct stage[] in the analysis," all burdens are placed on the *plaintiff*. Impax Br. at 31-32, 130. Impax's continued reliance on its erroneous threshold burden argument simply

[5] *See, e.g.*, *In re Lipitor Antitrust Litig.*, 868 F.3d at 256-57 (*Actavis* "clearly placed the onus of explaining or justifying a large reverse payment on *antitrust defendants*.") (emphasis in original).

highlights its inability to offer any legally sound and factually credible justification for the large payment it received from Endo. *See infra* Part II.

3. Impax misunderstands the plaintiff's burden to prove the payment was large

Complaint Counsel has shown that the payments Impax received substantially exceeded any reasonable measure of saved litigation costs and are therefore "large." CC Br. at 36-43. Impax, however, contends that saved litigation costs is an improper benchmark for a large payment. It insists that consideration of saved litigation costs is only relevant to assessing justifications. Impax Br. 31-32. In addition, Impax argues that proof that the payments here are large requires an elaborate calculation of a precise "expected value" of the No-AG and Endo Credit provisions at the time of settlement. Impax Br. at 55-57. Impax is wrong on both counts.

First, the Supreme Court specifically instructs that the reverse payment's scale should be assessed "in relation to the payor's anticipated future litigation costs." *Actavis*, 133 S. Ct. at 2237; *see also In re Loestrin Fe Antitrust Litig.*, 814 F.3d 538, 551 (1st Cir. 2016) ("[T]he size of the reverse payment, particularly as it relates to potential litigation expenses, is central to the antitrust query."). *Actavis* explained that the antitrust concern with reverse payments is that a brand company will pay a portion of its monopoly profits to "induce the generic challenger to abandon its claim," thereby preventing the risk of competition. 133 S. Ct. at 2235-36; *see also id.* (payment to the patent challenger "to prevent the risk of competition" is "the relevant anticompetitive harm"). Thus, a reverse payment is sufficiently "large" to cause an anticompetitive effect if it exceeds the brand's saved litigation costs and is sufficient to induce the generic to abandon its patent challenge and agree to stay off the market. CC Br. at 36, citing *Cephalon*, 88 F. Supp. 3d at 416-17. Impax cites no case to the contrary and offers no alternative benchmark.

Second, Complaint Counsel need not prove a precise expected value of the No-AG and

B. Proof that Endo possessed market power forecloses Impax's claim that Complaint Counsel relies on a *per se* theory

Both sides agree that Complaint Counsel's *prima facie* case includes a showing that Endo had market power in a relevant market at the time of the settlement. *See* Impax Br. 32-33. That acknowledgement alone puts to rest Impax's repeated accusations (Impax Br. 39-41, 102) that Complaint Counsel relies on a *per se* or "quick look" theory of liability. *See, e.g.*, *Cephalon*, 88 F. Supp. 3d at 416 (rejecting contention that the burden-shifting framework requiring proof of market power amounted to "quick look" approach).

Further, in discussing market power, Impax ignores entirely the Supreme Court's explanation in *Actavis* that a large reverse payment is a "strong indicator" of market power:

> [W]here a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring that harm about in practice. At

In this case, Complaint Counsel showed that Endo paid Impax a large reverse payment—a "strong indicator of power." CC Br. at 32-43; *Actavis*, 133 S. Ct. at 2236; *see also infra* Part II. But Complaint Counsel showed much more than that: the market analysis of Stanford University Professor Roger Noll confirms the presence of market power in this case. Professor Noll found that other long-acting opioids were not close *economic* substitutes for Opana ER, did not meaningfully constrain Endo's prices, and exhibited low cross elasticity of demand with Opana ER. (CCF ¶¶ 654-811). *See* CC Br. at 51-56. As a result, he concluded that the relevant antitrust market was limited to brand and generic oxymorphone ER products and that Endo had substantial market power at all relevant times. (CCF ¶¶ 498-501, 812). Complaint Counsel's responses to Impax's market power arguments are set forth below in Part III.

1. No case law supports Impax's "actual delay" standard

Notably, in its entire 141-page brief, Impax never acknowledges the Supreme Court's clear instruction that the "relev

looking to the four payment-related factors the Supreme Court identified in *Actavis*. *See id*. at 865-69. It did not require an attempt to reconstruct a hypothetical but-for world, as Impax suggests.[6] Indeed, *Cipro* concluded that a reverse payment, if large and unjustified, would be anticompetitive even though the relevant patent in that case had been found valid and infringed in subsequent litigation. *Id*. at 870.

Impax's third case, *In re Wellbutrin XL Antitrust Litigation*, 868 F.3d 132 (3d Cir. 2017), is even more off the mark. Impax Br. at 36. Impax points to the Third Circuit's statement that "there was no delay associated with the 300 mg product and the analysis in *Actavis* does not apply." *Id*. (quoting *In re Wellbutrin XL*, 868 F.3d at 163). But the court was merely distinguishing between the two dosage strengths of the product, only one of which (the 150 mg product) was alleged to have been restrained by the challenged reverse-payment agreement. As the court explained in the passage just before the sentence Impax quotes, the other product (the 300 mg) entered the market immediately upon FDA approval. *Id*. at 163. Moreover, with respect to the 150 mg product, the Third Circuit did not hold that proof of actual delay is required to prove a violation. Instead, it affirmed solely on the ground that the private plaintiffs had failed to show antitrust injury, an essential element of the antitrust standing requirement that applies to private antitrust plaintiffs. *See id*. at 169-70, 170 n.64. Complaint Counsel has no such injury requirement. *See In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 60 (1st Cir. 2016).

In sum, Impax cites no case that reads *Actavis* to require proof of "actual delay."

[6] *Cipro* uses the word "delay" as shorthand for a restriction on entry. *See* 348 P,3d at 865 ("That a plaintiff challenging a reverse payment settlement must establish the settlement limits the challenging generic's entry is self-evident. If the settlement contains no component of delay and permits the generic to enter the market and compete fully and immediately, there is no restraint of trade and no potential for antitrust concern.").

2. Impax misconstrues standard rule of reason analysis

Having failed to support its "actual delay" argument with any applicable case law, Impax misconstrues standard rule of reason analysis. First, it argues that the rule of reason assesses competitive conditions before and after the restraint was imposed. Impax Br. at 36. But that proposition does not help Impax. The record here amply shows that, before the reverse-payment agreement, there was a risk of competition from Impax's generic version of Opana ER. CC Br. at 9-12, 18-19, 45-46; *see also infra* Part IV.B. After the agreement, there was no risk of competition until January 1, 2013. CC Br. at 45-46.

Second, Impax points out that an anticompetitive effect can be established by demonstrating an actual increase in prices or decrease in output. Impax Br. at 34-37. That is true, but those are not the only ways to prove the requisite effect.[7] As far back as *Board of Trade of City of Chicago v. United States*, it has been clear that courts look to "the nature of the restraint and its effect, *actual or probable*" to determine whether a challenged restraint amounts to a rule of reason violation. 246 U.S. 231, 238 (1918) (emphasis added). Thus, "a demonstration of defendant's market power, [] combined with the anticompetitive nature of the restraints, provides

[7] *See, e,g, United States v. Brown Univ. in Providence in the State of R.I.*, 5 F.3d 658, 668 (3d Cir. 1993); *Sullivan v. Nat'l Football League*, 34 F.3d 1091, 1097 (1st Cir. 1994). Cases cited by Impax do not hold otherwise. *See* Impax Br. at 37, citing *Procaps S.A. v. Patheon, Inc*., 845 F.3d 1072, 1084 (11th Cir. 2016) (To show that the alleged restraint has had an anticompetitive effect, plaintiff "may establish either (1) that the restraint had an 'actual detrimental effect' on competition, or (2) that the restraint had the potential for genuine anticompetitive effects and that the conspirators had market power in the relevant market. . . . By the time of the second summary judgment briefing, Procaps had bound itself to proceed only on the first theory—that there were actual detrimental effects on competition."); *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 407-08 (3d Cir. 2016) ("Without evidence of substantial foreclosure or anticompetitive effects, Eisai has failed to demonstrate that the *probable effect* of Sanofi's conduct was to substantially lessen competition in the relevant market, rather than to merely disadvantage rivals. Unlike in *LePage's, Dentsply*, and *ZF Meritor*, Lovenox customers had the ability to switch to competing products. They simply chose not to do so." (emphasis added)).

the necessary confidence to predict the likelihood of anticompetitive effects." *In the Matter of Realcomp II, Ltd.*, No. 9320, 2009 FTC LEXIS 250, at *90 (F.T.C. Oct. 30, 2009), aff'd, *Realcomp II, Ltd v. FTC*

Impax asserts that Complaint Counsel must prove that any less restrictive alternative would have occurred and would have resulted in an earlier-entBr. e t132-33. Buttive a

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burden-shifting analysis under the 'quick look' approach and the rule of reason is that under the former the plaintiff's case does not ordinarily include proof of [market] power . . . .").

Second, Impax asserts that Professor Noll failed to analyze whether the payment was "large." Impax Br. at 39. But Professor Noll extensively assessed of the size of the No-AG/Endo Credit portion of the payment under any reasonable scenario. *See infra* Part II.B. Finally, Impax attacks Professor Noll for failing to consider "other justifications" for Impax's payment, such as its so-called "carrot and stick" argument and the broad patent license. Impax Br. 39. Professor Noll addressed and rebutted the opinions offered by Impax's economic expert. (CCF ¶¶ 1012-30). But he understandably did not speculate about the merits of "other justifications" that Impax might ultimately decide to assert in this case. And in any event, as discussed below, the justifications that Impax has asserted here are legally flawed and factually unsupported. *See infra* Part II.B, Part IV.C & D.

II. Complaint Counsel proved that Impax received two large payments from Endo

Impax contends that Complaint Counsel failed to prove that either the $10 million payment under the DCA or the No-AG agreement and Endo Credit was "large" because "Complaint Counsel failed to present any evidence that would allow this Court to 'assess the value' of the alleged payment terms." Impax Br. at 41. But Impax's assertion that Complaint Counsel must prove some precise "expected value" of Endo's payments is incorrect and unsupported.

A. The $10 million DCA payment was large and was not justified by the profit sharing rights Endo received in that agreement

Complaint Counsel's opening brief showed that Endo's $10 million upfront payment to Impax under the DCA was large because it exceeded Endo's saved litigation costs and was sufficient to induce Impax to stay out of the market. CC Br. at 36, 45. Impax offers two

responses. First, Impax suggests that Complaint Counsel failed to prove that the rights Endo received in the DCA did not justify the $10 million payment. Impax Br. at 42. Second, Impax argues that the unrebutted opinions of Complaint Counsel's expert on pharmaceutical business development deals should be disregarded as irrelevant because he did not assign a precise value to the rights provided in the DCA. We address each argument below.

1. Impax did not prove that Endo's $10 million DCA payment was justified by any rights to IPX-203

Impax complains that Complaint Counsel did not prove that the $10 million DCA payment was not "fair value" for the "bundle of rights Endo received" under the DCA. Impax Br. at 45-46. But proving such a justification is *Impax's* burden, not Complaint Counsel's. *Actavis*,

"piggy" demands for substantially increased development milestone payments. (CCF ¶¶ 302-03; CCRF ¶¶ 406, 414). By industry standards, $10 million was an extraordinarily large upfront

} (CCF ¶ 1160). **{** **}** (CCRF ¶¶ 479-81).

Third, Impax relies on an Endo financial analysis that, based on testimony of Endo's own witnesses, was deeply flawed. As Impax notes, that analysis projected a positive net present value and internal rate of return, ostensibly indicating that Endo "expected [the DCA] to be profitable." Impax Br. at 44. But Endo had already agreed to pay $10 million before that analysis was even conducted. **{**

} (CCRF ¶¶ 427, 433). **{**

} to give an accurate picture of an agreement's present value. (CCF ¶¶ 1194-98, 1212); *see also* Impax Br. at 56 ("[H]ighly uncertain outcomes often carry little to no expected value."); (CCRF ¶ 427) (Dr. Cobuzzi acknowledged that "the net present value of a product that has more risk would be lower").

{

} (CCF ¶¶ 1211-16).[12] Yet

[12] Mark Bradley, who conducted the financial analysis, testified that he took no steps to account

Impax's own witnesses acknowledged that the probability of the product being approved at all was "fairly low." (CCF ¶ 295). **{**

}[13] Put simply, an analysis with so many flawed inputs cannot produce a reliable result. (CCF ¶ 1218). As Endo financial analyst Mark Bradley explained, "garbage in, garbage out." (CCF ¶ 1194).

Fourth, Impax incorrectly asserts that the payment structure in the DCA—a $10 million upfront payment plus milestones—mitigated Endo's risk because it specified exactly how much Endo was obligated to pay and no more. Impax Br. at 43-44. While Endo knew *how much*

Finally, Impax suggests that the DCA was fair value for Endo's $10 million payment

Complaint Counsel to *disprove* Impax's justification before the burden shifted to Impax to prove its justification. That is nonsensical, and unsupported.

Second, the Court does not need an expert valuation to find that the rights in the DCA did not justify the $10 million payment. In *Nexium*, the district court held there was sufficient evidence to conclude that a contemporaneous business agreement was an unjustified payment where it was "formally extraneous" to the patent litigation, was something the generic "would not have secured" by winning the litigation, and "had the potential to be highly lucrative" for the generic." *In re Nexium Antitrust Litig.*, 42 F. Supp. 3d 231, 263-64 (D. Ma. 2014). The DCA has all of those features. Similarly, another district court found a range of evidence sufficient to support a finding of an unjustified payment, including expert witness testimony that the services obtained were "unnecessary and unwarranted," that the brand "disregarded its corporate 'guiding principles' and due diligence checklist," and that the agreements "were outside of the industry's norms." *Cephalon*, 88 F. Supp. 3d at 419-20. To Complaint Counsel's knowledge, no court has ever adopted Impax's view that a plaintiff must calculate a mathematical value to show that a payment is not justified as part of a contemporaneous business arrangement.

Third, applying the *Actavis* standard does not require "second guessing" Endo's business judgment. Impax Br. at 46-49. Rather, the key factual question under *Actavis* is whether Endo paid Impax $10 million for the services it obtained in the DCA, or whether it instead made the payment to "induce [Impax] to abandon its claim with a share of its monopoly profits. 133 S.Ct. at 2235. Circumstantial evidence can be particularly relevant to answer this question where the payment vehicle is more complicated than cash. *See Nexium*, 42 F. Supp. 3d at 263-64; *Cephalon*, 88 F. Supp. 3d at 420-21.

Here, Dr. Geltosky showed that Endo did not treat the DCA like a normal pharmaceutical business development deal. Among many unusual features, Dr. Geltosky explained that the deal was negotiated in a small fraction of the time it would usually take and that Endo's diligence on IPX-203 was far less robust than would be typical. This testimony was corroborated by unrebutted contemporaneous Endo business documents showing that Endo ordinarily followed a procedure nearly identical to what Dr. Geltosky described as standard—but which Endo ignored for the DCA. (CCF ¶¶ 1121, 1123, 1138-39).[16] Dr. Geltosky also opined that the $10 million upfront payment was unusually large given that IPX-203 was in the early stages of development. He explained that a deal for a pre-clinical product of this type would normally involve little if any guaranteed money, and increasing milestone payments as the product showed potential in development. This too was corroborated by unrebutted evidence about Endo's normal practice: Dr. Cobuzzi did not recall any other development and co-promotion agreements where Endo paid $10 million upfront for a preclinical product like IPX-203. (CCRF ¶ 453). Indeed, consistent with Dr. Geltosky's opinion, Dr. Cobuzzi identified two other Endo development deals for early stage products, but in both of those deals, "there was no cash up front. It was contingent upon successful completion of certain milestones." (CCRF ¶ 453).

In support of its argument that Dr. Geltosky's opinions are irrelevant, Impax points to this Court's, and the Eleventh Circuit's, decisions in *Schering-Plough*. Impax Br. at 47-48. But neither this Court nor the Eleventh Circuit found the testimony of the parties' pharmaceutical business development experts irrelevant. And the fact that a different business agreement

[16] For example, Endo's own "BD [Business Development] Transaction Process, Negotiation Through Closing" shows that doing a deal at Endo normally takes "~6 months – 1 year from initial evaluation to deal close"—a timeframe consistent with Dr. Geltosky's opinion. (CCF ¶¶ 1105, 1110, 1113, 1123).

justified a different payment in a different case says nothing about the $10 million DCA payment here. In fact, the DCA is nothing like the side deal in *Schering-Plough*: in *Schering-Plough*, the Eleventh Circuit found that (1) the brand company acquired a late-stage drug, not an unformulated concept as in this case; (2) the brand evaluated clinical research results showing that the drug was an improvement over existing therapies; (3) the valuation was conducted by employees who were unaware of the patent case, and was corroborated by a separate valuation done on a similar product outside the context of any patent settlement; and (4) the brand had a long documented and ongoing interest in licensing the precise type of product at issue. *Schering-Plough v. FTC*, 402 F.3d 1056, 1059, 1068-70 (11th Cir. 2005). As discussed above, the opposite is true here.

Taken in its entirety, the record plainly shows that Endo agreed to make the $10 million payment not to obtain the potential profit-sharing rights in IPX-203, but instead to secure Impax's agreement not to enter the market before 2013. Impax certainly had no illusions about why Endo was paying it: it described the $10 million payment as **{**

} (CCF ¶ 1084).[17]

B. The No-AG agreement and Endo Credit were a large and unjustified payment

At trial, Complaint Counsel established that the No-AG agreement and Endo Credit amounted to a large payment to Impax. As demonstrated by contemporaneous Impax documents and witness testimony, Impax expected that these provisions would work in tandem to ensure that it received tens of millions of dollars in value "almost no matter what happens." (CCF ¶¶

1. Calculating a precise expected value is not necessary because the range of possible values for the No-AG and Endo Credit demonstrate that the payment was large in any reasonable scenario

As discussed above, the unrebutted record evidence shows that Impax projected the No-AG provision to be worth at least $20 million. If it lost these profits due to a market switch, Impax expected that the Endo Credit would make it whole for the profits it otherwise would have earned during its exclusivity period. (CCF ¶¶ 275, 413-14, 467-68). This evidence, by itself, is sufficient to show that the No-AG/Endo Credit provisions represented a large payment to Impax. *See Lamictal*, 791 F.3d at 404-05 (a no-AG agreement can be a large reverse payment under *Actavis* because it allows the generic to realize "great monetary value" by transferring profits that the brand "would have made from its authorized generic to the settling generic—plus potentially more, in the form of higher prices").

In addition to this evidence, however, Professor Noll calculated the minimum values of the No-AG agreement and Endo Credit to Impax. Impax tries to downplay Professor Noll's analysis as merely four "examples" of "'possible' payment outcomes." Impax Br. at 50, 57. But Professor Noll calculated the value of the No-AG agreement and Endo Credit *in every plausible scenario*. (CCF ¶¶ 466-72). His analysis shows that the combination of the No-AG and Endo Credit provisions would virtually always result in a payment of at least $16.5 million to Impax, and likely far more:

> If sales of Original Opana ER remained flat between 2010 and 2013, the No-AG agreement would be worth at least $33 million to Impax. (CCF ¶ 469).
>
> If sales of Original Opana ER grew between June 2010 and January 2013, the value of the No-AG provision would grow accordingly; for example, if Opana ER sales reached their real-world peak when Impax entered in January 2013, the No-AG agreement would be worth at least $53 million. (CCF ¶ 467).
>
> If Original Opana ER sales declined by about half before 2013, but not enough to trigger the Endo Credit, the No-AG would provide at least $16.5 million to

Impax. (CCF ¶ 471).

If Original Opana ER sales declined even more, Impax would realize less than $16.5 million in value from the No-AG agreement, but would receive a cash payment under the Endo Credit. If triggered, the *smallest possible* Endo Credit payment would be $62 million. (CCF ¶ 470). Of course, the Endo Credit payment had the potential to be much higher; the provision ultimately yielded a payment of $102 million.[18] (CCF ¶ 444).

Professor Noll's analysis confirms that the No-AG and Endo Credit worked together exactly as intended, and ensured that Impax received a large payment "almost no matter what happened." (CCF ¶ 438 (quoting Koch, Tr. 264-65)). Dr. Addanki offers no criticism of this analysis. (CCF ¶ 479). Nor does Impax challenge or rebut any of Professor Noll's calculations. Instead, Impax insists that the only way to "determine whether the Endo Credit and No-AG terms constituted a large 'payment' to Impax" is "to calculate their expected value at the time of the settlement." Impax Br. at 56. An expected value is the "probability-weighted sum of every conceivable event." (CCRF ¶ 1423). Calculating an expected value would require (1) identifying every conceivable event; (2) determining the present value of each event; and then (3) discounting the value of each event by the specific probability of that event occurring. (CCRF ¶ 1423). Notably, Impax's own economic expert concedes that such a calculation is not "in any practical sense doable." (CCF ¶ 479).

Proof of a large payment, however, does not require the impossible efforts Impax demands. Instead, using information available to Impax at the time of the settlement, Professor

[18] Impax asserts that the $102 million Endo Credit payment is "attributable to events that neither party could have foreseen in June 2010" because Opana ER sales grew faster than expected and then declined sharply after the Novartis supply disruption. (Impax Br. at 53-54). This argument misses the point entirely. Professor Noll calculated that, even if sales of Opana ER did not grow at all after June 2010, the ***smallest possible payment*** under the Endo Credit (if triggered) was $62 million. (CCF ¶ 470). Impax does not challenge this calculation. Thus, any possible payment under the Endo Credit—whether $62 million, $102 million or some number in between—is unquestionably large.

Noll showed that the reverse payment would be large under any reasonable scenario: if the Endo Credit was not triggered, Impax would have made *at least* $16.5 million in additional profits as a result of the No-AG; if the Endo Credit was triggered, Impax would make *at least* $62 million. (CCF ¶¶ 466-72). In all of these scenarios, the value of the No-AG and Endo Credit was at least

have had to quickly transition patients to the reformulated product in about two months so that the market for Original Opana ER was gone before Impax entered in January 2013. (CCF ¶ 474). Even a small miscalculation would have been costly. If the market converted faster than expected, fourth quarter sales of Original Opana ER could have dropped below 50%, triggering an Endo Credit payment of at least $62 million. (CCF ¶ 470). If the market converted slower than expected, generic entry would undermine Endo's ability to complete the transition to its reformulated product, dramatically reducing the overall sales of its Opana ER franchise. (CCF ¶¶ 244-45).

Not surprisingly, Endo never even considered this approach. Instead, Endo's long-standing strategy to maximize the value of its Opana ER franchise—as reflected by internal planning documents and confirmed by executive testimony—was always to launch Reformulated Opana ER as soon as possible and "smoothly transition" patients from the original to reformulated version. (CCF ¶¶ 75, 482-87). Endo knew that a smooth transition required that patients be switched *before* generics entered the market, and that the transition process could take the better part of a year. (CCF ¶¶ 80, 483, 486-87). Thus, as early as 2007, Endo's "Priority #1" for Reformulated Opana ER was to "Beat Generics by 1 Year." (CCF ¶¶ 75, 484). As of April 2010, Endo's plan was to launch Reformulated Opana ER in "March 2011, but could range from Dec-10 to Jun-11." (CCF ¶¶ 484, 1453). Even after entering into the agreement with Impax, Endo maintained its intention to launch Reformulated Opana ER as soon as possible. In November 2010, Endo's "[c]urrent planning assumption" was "to stop shipping all OPANA ER by October 1, 2011." (CCRF ¶ 209). Although Endo's failure to get FDA approval for Reformulated Opana ER in time later made this date infeasible, no contemporaneous planning

documents mention or even suggest that Endo might strategically delay its launch to avoid paying the Endo Credit. (CCF ¶¶ 83, 489).

Endo's "launch early" strategy made perfect sense. In January 2010, Endo projected that switching the market to Reformulated Opana ER ahead of generic entry could result in an additional $1 billion in revenues over five years. (CCRF ¶ 594; CCF ¶¶ 75-78, 242-45, 482-84, 605). But these additional revenues were contingent on Endo completing its reformulation strategy before generic oxymorphone ER hit the market. (CCF ¶¶ 244-45; 482-83). Impax offers no reason why Endo would jeopardize these substantial revenues and the continued growth of its second-most important drug simply to avoid making a smaller one-time payment under the Endo Credit. (CCRF ¶ 594). Indeed, Impax's own economic expert acknowledges that Endo's goal was not to minimize its potential payment obligation to Impax, but to maximize its overall profits: "if [Endo] could make profit elsewhere by incurring the Endo [C]redit, they would." (CCF ¶ 477).

Impax essentially ignores all of this compelling eviden

and converted the entire market in 2-3 months (by October 2012), then sales of Original Opana ER would disappear early in the fourth quarter, triggering an Endo Credit payment. (CCRF ¶ 636). Thus, even if accurate, the very documents Impax cites confirm that Endo never planned to strategically evade the Endo Credit obligation.[19]

The testimony of Mr. Smolenski is similarly unhelpful to Impax. Although Mr. Smolenski raised the possibility of a "zero payment" scenario, he never modeled or assigned a probability to it. (CCF ¶ 475). He described the scenario as "probably unlikely," and acknowledged that the Endo Credit would "provide[] nice protection assuming things play out as expected." (CCF ¶ 481; CCRF ¶ 632). Indeed, Impax's chief negotiator thought that it was "super, super important"—a "deal-breaker"—for Impax to get protection for the value it expected under the SLA. (CCF ¶ 427; CCRF ¶¶ 569, 581). And he believed that the Endo Credit achieved that protection. (CCRF ¶ 635). He judged the possibility of Mr. Smolenski's possible downside scenario to be "so unlikely it wasn't worth worrying about" and determined that it did not even "r[i]se to the threshold enough" to mention to other Impax executives. (CCF ¶¶ 480-81; CCRF ¶ 569).[20] And even after Mr. Smolenski informed other executives, Impax continued to tell investors that, due to the "protection built into the agreement" in the form of the Endo Credit, Impax "should have a reasonable outcome almost no matter what happens." (CCF ¶ 438; CCRF ¶ 569).

[19] Impax also cites the testimony of Endo executive, Alan Levin. But Mr. Levin never stated that Endo planned to launch Reformulated Opana ER in a way that would avoid the Endo Credit. He testified that he did not remember when Endo planned to launch Reformulated Opana ER and that "we may have looked at a range of possible

In any event, there is no need to exclude the possibility of a zero-value outcome to show that these provisions had significant value to Impax at the time of the agreement. *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 n.22 (D. Mass 2013) (rejecting the notion that contingent liabilities are without any value). Impax recognizes that payments with an

large at the time of the settlement. (CCF ¶¶ 462, 474). As Dr. Addanki concedes, one possible value of the No-AG agreement was $102 million. (CCF ¶ 479). We know this because it happened. (CCF ¶ 328). Because the actual outcome resulted in an enormous payment, and because the vast majority of the other possible scenarios would result in payments of tens of millions of dollars, the expected value of the No-AG agreement and Endo Credit was greater than saved litigation costs unless the zero-payment scenario was overwhelmingly likely to result. (CCF ¶¶ 466-72).

Professor Noll constructed a numerical example to illustrate this point. He assumed only two possible outcomes: the $102 million payment that actually occurred and a zero payment. (CCRF ¶ 639). He concluded that, in order for the expected value in this example to fall below $5 million (an estimate of saved litigation costs), the probability of the zero-payment scenario

never have been willing to risk the enormous profits it stood to gain from successfully transitioning the market to Reformulated Opana ER merely to avoid a much smaller, one-time payment to Impax. Impax thus anticipated it would have "a reasonable outcome almost no matter what happen[ed]" and dismissed the zero payment scenario as "so unlikely it wasn't worth worrying about." (CCF ¶¶ 480-81; CCRF ¶ 632).

willingness to accept the a later entry date. (CCF ¶¶ 224 (showing discussions between Impax's CEO and Impax's President of the Generics Division about delaying sales in exchange for

(procompetitive justification not cognizable where it is pretextual); *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 197 (3d Cir. 2005) (same).

III. Complaint Counsel proved that Endo possessed monopoly power in a properly defined market for oxymorphone ER products

In this case, Impax and Endo entered into a collusive agreement to keep a potential competitor off the market. That agreement interf

Impax resulted in substantial savings for consumers who switched to Impax's lower cost product. (CCF ¶¶ 636-37). And Impax's oxymorphone sales came overwhelmingly from Endo's Opana ER product—not from other long-acting opioids. (CCF ¶¶ 673, 684, 694, 700, 706, 710, 715).

These facts show that comp

By contrast, when cross elasticity is low, even functionally interchangeable products are not in the same relevant antitrust market because they are not able to constrain each other's prices.

To correct for this price disconnect and improve competition in the pharmaceutical industry, Congress and state legislatures have created a two-part regulatory structure. First, the Hatch-Waxman Act streamlines the approval process for generic drugs—which are essentially copies of the branded version with the same active ingredient and in the same dose (CCF ¶¶ 548-50)—and provides incentives to generic manufacturers to launch their products as early as possible. *Actavis*, 133 S. Ct. at 2228. Second, "all 50 states and the District of Columbia have drug substitution laws," which "either permit or require pharmacists to dispense a therapeutically equivalent, lower-cost generic drug in place of a brand drug absent express written direction from the prescribing physician." *Namenda*, 787 F.3d at 644-45. Generic substitution laws correct for the price disconnect between doctors and payers by allowing the pharmacy—which is

The undisputed data confirm that generic oxymorphone ER products were closer substitutes for Opana ER than other LAOs, and that other LAOs had not previously constrained Opana ER to a competitive price. The 2013 entry of lower-priced generic versions of Opana ER had an enormous effect on Endo's sales and significantly lowered the average price of oxymorphone ER. (CCF ¶¶ 628-44). "[I]f competitive prices were being charged before the patented drug had a generic competitor, then the entry of new competitors would not result in a substantial change in price." *Aggrenox*, 199 F. Supp. 3d at 667.

Impax acknowledges the unusual institutional features of the pharmaceutical industry. It discusses them at length in its brief. Impax Br. at 63-65. But it draws entirely the wrong lessons. First, Impax believes that basic economic principles of market analysis do not apply in the pharmaceutical industry. Impax's economic expert, Dr. Addanki, explained that the "institutional idiosyncrasies" of pharmaceutical markets had a "profound effect on how [he] analyze[d] competition" and led him to a "very different" approach to market definition than in an "everyday case." (CCRF ¶ 1002 ("[T]he methods used to analyze and assess a relevant market in prescription pharmaceuticals are different from the ones economists may use in other industries.")). Dr. Addanki made no effort to test cross elasticity of demand between Opana ER and other LAOs, and instead focused on the functional similarities between those products. This departure from standard antitrust economics was unwarranted and inappropriate. Indeed, Dr. Addanki made the same mistake in another recent case, and that district court specifically rejected his view that traditional economic principles of market definition are different when dealing with pharmaceuticals: "[e]ven in the pharmaceutical market [] cross-elasticity must be demonstrated between products to establish

argument that cross elasticity of demand need not be shown because of the unique characteristics of the pharmaceutical market).

Second, Dr. Addanki essentially ignores the regulatory framework—the Hatch-Waxman Act and state substitution laws—that enables and promotes generic competition. He chose not to look at the competitive effect of generic entry. (CCF ¶ 910). He did not include generic oxymorphone ER products in his analysis of formulary placement. (CCF ¶¶ 946-47; CCRF ¶ 996). Nor did he consider whether generics were closer substitutes for branded Opana ER, or whether they exhibited greater cross elasticity of demand than other LAOs. (CCF ¶¶ 934-35). The fact that federal and state laws affect the way generic products compete in the market cannot be ignored. To the contrary, this type of regulatory reality is critically important in defining the relevant market. For example, in *United States v. Archer-Daniels-Midland*, the Eighth Circuit considered whether sugar and high fructose corn syrup (HFCS) were in the same relevant antitrust market. 866 F.2d at 246 (8th Cir. 1988). Although the court noted that "sugar and HFCS are functionally interchangeable for all uses," it could not "ignore the fact that Congress has enacted a sugar program that has artificially inflated the price of sugar." As a result of this regulatory scheme, "the HFCS monopolist is able to exercise excess market power" because it could raise its price to just below the artificially high sugar price without losing sales." *Id.* Accounting for these industry realities, the court concluded that sugar and HFCS were not reasonably interchangeable substitutes. *Id.*

Rather than consider the relevant regulatory context in assessing market definition and market power in this case, however, Dr. Addanki conspicuously chose to ignore it. But as the Supreme Court has made clear, "antitrust analysis must sensitively recognize and reflect the

distinctive economic and legal setting of the regulated industry to which it applies." *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411–12 (2004).

2. Some degree of functional interchangeability between LAOs does not establish they are in the same relevant market

Impax contends that all LAOs are "interchangeable for treatment of the exact same

More fundamentally, Dr. Addanki's analysis does not answer the central antitrust question because it focuses on *functional* interchangeability rather than cross elasticity—that is, whether the choice between different long-acting opioids is driven by small differences in price as opposed to some other factor, such as clinical reasons. (CCF ¶ 920). *See Lidoderm*, 2017 WL 5068533, at *17 "("Defendants' analysis—essentially ignoring cross-elasticity—creates a vastly overbroad market."). In fact, the medical evidence confirms that there is little cross elasticity between oxymorphone ER products and LAOs based on other molecules. Endo itself often touted oxymorphone's "distinct pharmacologic properties compared with modified-release oxycodone.") Tr

containing one opioid molecule to a generic version of the same molecule is easier and more predictable. (CCF ¶ 755).

In fact, the only specific reason Impax identifies as causing doctors to switch between LAOs—opioid rotation therapy—actually confirms that these decisions are made for medical, not pricing, reasons. (CCRF ¶ 971)

710, 715). This substitution pattern occurred even though Impax’

Impax Br. at 75. But "the mere fact that a firm may be termed a competitor in the overall marketplace does not necessarily require that it be included in the relevant market for antitrust purposes." *Staples*, 970 F. Supp. at 1075. That requires a showing of cross elasticity.

Impax does little more than point to Endo's use of the words "competitor" and "market" without considering the broader context of Endo's business documents. For example, Impax highlights a sworn court declaration submitted in May 2010 by Endo's Senior Director of Marketing, Demir Bingol. Impax Br. at 77. Impax points out that Mr. Bingol referred to an "LAO market," but ignores that in the same declaration he also referred to a "market for Opana ER sales." (CCRF ¶ 1004). This seeming contradiction demonstrates that Mr. Bingol was using "market" in a general business sense, not an antitrust sense.

More importantly, though, the *facts* relayed by Mr. Bingol's declaration confirm that generic oxymorphone ER is a far superior economic substitute for Opana ER than other LAOs. (CCRF ¶ 1004; CCF ¶¶ 609-10, 939). According to Mr. Bingol's sworn declaration, without generic competition Endo did not need to decrease the price of Opana ER to compete with non-oxymorphone LAOs. To the contrary, Endo expected to increase its Opana ER sales and profits despite the availability of numerous other LAOs. (CCRF ¶ 1004; CCF ¶ 609, 939). But the availability of generic oxymorphone ER would drastically change this situation: "in the ordinary course of business, Endo has projected that it will lose at least 70-80% of its market share within three months of the launch of a generic substitute for Opana ER in the commercially significant tablet strengths . . ." (CCF ¶¶ 610). And once Impax launched, "the net effective price Endo is able to charge for Opana ER will irreversibly erode. Endo will be forced to make contractual price concessions in the form of larger rebates to MCOs and the like." (CCRF ¶ 1004). Thus, "[t]o the extent Endo has any chance of competing with Impax for sales of Opana ER, Endo will

b) Impax identifies no evidence of cross elasticity of demand at the payor level

To support its broad market definition, Impax also points to what it claims is evidence that {[redacted]} Impax Br. at 79. Impax relies on an analysis of LAO formulary placement by its economic expert, Dr. Addanki, but that analysis does not show that other LAOs were close competitors to Opana ER. Indeed, the fact that generic oxymorphone ER was able to enter at a lower price and take substantial sales demonstrates that formulary competition—such as it was—was insufficient to reduce prices to a competitive level and dissipate Endo's market power. (CCF ¶¶ 684, 878, 906-11; CCRF ¶ 990).

Even taken at face value, Dr. Addanki's review of formulary placement says nothing about cross elasticity between Opana ER and other LAOs. Dr. Addanki reached the general conclusions that "most plans did not place all LAOs on the same formulary tier," that different plans placed Opana ER in more or less favorable positions, and that formularies generally exhibited "churn" as the relative position of each LAO changed over time. Impax Br. at 82-83. But these conclusions do not even establish price competition, let alone high cross elasticity of demand. Dr. Addanki admitted that he did not analyze or even know why any LAOs were put in certain formulary positions. (CCF ¶ 944; CCRF ¶¶ 836, 996). Thus, his analysis cannot show that any switching between Opana ER and other LAOs occurred for price reasons at all, let alone because of a small but substantial price increase. Indeed, internal Endo documents demonstrate that switching from one LAO to another plays a small role in the overall marketplace. The vast majority of LAO sales (89%) are to continuing patients. (CCRF ¶ 839). Of the remaining sales, 8% are to new patients and only 3% are the result of switching from one LAO to another. (CCRF ¶ 839).

Moreover, Dr. Addanki's analysis entirely ignored generic oxymorphone ER and all other generic LAOs. (CCRF ¶ 996; CCF ¶¶ 946-47). Endo has publicly acknowledged that it would have to compete vigorously with generic Opana ER for formulary placement. (CCRF ¶

2017 WL 5068533, at *20. Indeed, "[e]ven a complete monopolist can seldom raise his price without losing some sales; many buyers will cease to buy the product, or buy less, as the price rises." *Fortner Enters., Inc. v. U.S. Steel Corp.*, 394 U.S. 495, 503 (1969). Thus, the fact that Endo provided discounts to payers to sell more Opana ER provides no insight into whether Opana ER's price was already elevated due to market power, or the degree of cross elasticity between Opana ER and other products. (CCRF ¶¶ 915, 996; CCF ¶¶ 928-33).

c) Impax offers no evidence of cross elasticity at the patient level

Impax also points to evidence of co-pay assistance programs (coupons or rebates that reduced patients' insurance copays) and argues that "[w]e would not expect to see such ubiquitous, aggressive price discounting ***unless*** Opana ER competed against other LAOs in the relevant market." Impax Br. at 87-88. But Impax does not point to any evidence that patients switched LAOs as a result of these copay discounts. To the contrary, the unrebutted real-world sales and price data show no pattern of substitution between Opana ER and other LAOs, despite these coupons. (CCRF ¶ 899). Indeed, it is not clear how price competition at the patient level even *could* lead to switching on any meaningful scale because, as Impax observes earlier, "the initial product choice rests not with the end consumer [the patient], but with the prescriber (typically a physician)." Impax Br. at 64. Thus, this evidence "simply shows that, in order to grow the market for what defendants repeatedly characterize as a unique product, price concessions and rebates for [the product] were necessary." *Lidoderm*, 2017 WL 5068533, at *20; (*see also* CCF ¶ 726 (oxymorphone is a "molecule with distinct pharmacologic properties"); CCRF ¶ 883 ("Oxymorphone is a unique molecule.")).

Moreover, these price changes are orders of magnitude higher than the small but substantial price increase used to test cross elasticity (which is normally around 5%). (CCRF ¶¶ 899-915). Impax's examples indicate co-pay reductions amounting to a 100% discount, and

coupons that "greatly reduce" out-of-pocket expenses or "eliminat[e] them completely." (CCRF ¶¶ 899, 902). It is well-established that large changes in price may lead consumers to switch to imperfect substitutes outside the relevant market. *See* Richard A. Posner, *Antitrust Law: An Economic Perspective* at 150 (1976) ("[A]t a high enough price, even poor substitutes look good to the consumer."); *Insight Equity v. Transitions Optical, Inc.*, 252 F. Supp. 3d 382, 390 (D. Del. 2017) ("At the inflated supracompetitive price, consumers will substitute to products they would not substitute to at a competitive price."); *see also United States v. Alcoa*, 148 F.2d 416, 425-26 (2d Cir. 1945) ("[S]ubstitutes are available for

prescriber level is even less compelling because a physician's primary concerns are the health and safety of his or her patients, not drug costs or formulary placement. (CCRF ¶¶ 892, 894-98).

e) Impax misunderstands the Commission's conclusion in *King Pharmaceuticals*

Finally, Impax points to Commission statements in a different case, *King Pharmaceuticals*, to support its argument that the relevant market includes all LAOs. Impax fixates on the Commission's use of the word "market" to describe the limited competition among all oral LAOs. But as the result makes clear, the Commission did *not* define all oral LAOs as the relevant antitrust market. In that matter, the Commission would not allow the owners of the only two morphine sulfate LAOs to merge unless one of them divested its product. It found that these two products, based on the same molecule, "compete[d] most directly with each other," and that the "loss of head-to-head competition" between them "would result in higher prices for branded ER morphine sulfate."[30] The Commission found that the proposed merger "would cause significant anticompetitive harm by eliminating actual, direct and substantial competition"—despite the availability of other LAOs, which had "the same mechanisms of action, similar indications, similar dosage forms and similar dosage frequency," but were "based on distinct chemical compounds."[31]

The Commission thus ordered the companies to divest one of the two morphine sulfate products even though those products together made up less than 20% of total LAO sales. ("The most significant of the other oral LAOs is Purdue Pharma L.P.'s OxyContin, which is four times

[30] *See* Analysis of Agreement Containing Consent Order to Aid Public Comment, *In the Matter of King Pharmaceuticals, Inc. and Alpharma Inc.*, File No. 081-0240, 74 Fed. Reg. 295, 296 (Jan. 5, 2009).

[31] *Id.* at 296.

larger than Avinza and Kadian, combined.").[32] The Commission could not have reached this conclusion if LAOs based on different molecules were close economic substitutes for morphine sulfate LAOs. The Commission's conclusion in the *King Pharmaceuticals* matter is therefore entirely consistent with Complaint Counsel's approach here to defining an oxymorphone ER relevant market.

B. Impax does not dispute that Endo had market power in a market for oxymorphone ER products

Although Impax argues that the relevant market includes all oral LAOs, it appears to concede that if Complaint Counsel is correct that the market is limited to oxymorphone ER products, Endo had market power at the relevant time. Impax does not contest that: (1) Endo was the only seller of oxymorphone ER products in 2010 and up until generic oxymorphone ER entered (CCF ¶ 830); (2) Endo never had less than **{ }** of the market for oxymorphone ER products (CCF ¶ 841); and (3) there are substantial barriers to entry (CCF ¶¶ 843-52). In short, if the relevant antitrust market is correctly limited to oxymorphone ER products, Impax does not dispute that Endo had market power. (CCRF ¶ 1002).

C. Complaint Counsel carried its burden to prove market power

Impax's arguments on market power merely repeat, or elaborate on, its market definition arguments:

Cross elasticity and generic entry. First, despite Professor Noll's unrebutted conclusion that Opana ER exhibited high cross elasticity of demand with generic oxymorphone ER and low cross elasticity of demand with other LAOs, Impax complains that Professor Noll did not calculate the precise cross elasticity of demand. Impax Br. at 96-97. But even Dr. Addanki

[32] *Id.*

Indeed, Professor Noll's conclusion is corroborated by Impax's own testimony. Impax's marketing director, Todd Engle, testified that he believed Impax's generic oxymorphone took sales *only* from other oxymorphone products. (CCRF ¶¶ 981-82). Impax did not consider the price of any other LAO in setting the price for its generic oxymorphone. (CCF ¶¶ 650-53). Similarly, when considering the market potential for its generic oxymorphone ER, Impax considered only the market for Opana ER. (CCF ¶¶ 645-49). If there were high cross elasticity between oxymorphone LAOs and non-oxymorphone LAOs, then Impax's cheaper generic product would have taken sales not just from Opana ER, but also from the numerous other, more expensive branded LAOs. The fact that this did not happen illustrates the lack of cross elasticity between oxymorphone LAOs and non-oxymorphone LAOs. (CCF ¶¶ 684, 694, 700, 706, 710, 715).

Impax's brief does not substantively respond to any of this evidence. Instead, it notes only that it "would not be surprising" if Impax's and Actavis' generic products "***were*** more successful than other generic LAOs in stealing share from Endo's Opana ER" because "Actavis' product benefitted from an AB-rating and Impax specifically focused its marketing efforts on Opana ER prescribers." Impax Br. at 96-97. But the fact that Impax's marketing efforts were so successful in taking share from Opana ER—as compared to other LAOs—is precisely what shows that other LAOs were not close economic substitutes for Opana ER but generic oxymorphone was. (CCF ¶¶ 498-501). And that success cannot be attributed to automatic substitution because Impax's product was not AB-rated to Opana ER. (CCF ¶ 579).

Therapeutic differences and switching costs. Impax complains that Professor Noll did not show that product differences between Opana ER and other LAOs were "economically material." Impax Br. at 93. But Professor Noll showed this unequivocally. He conducted an

unrebutted analysis showing the economic effect of these distinctions: LAOs based on different molecules did not demonstrate cross elasticity of demand with each other. (CCRF ¶ 1000). Impax also notes that Dr. Addanki concluded that different LAOs may be prescribed for the same diagnosis. Impax Br. at 93. But as discussed previously, Dr. Addanki did nothing to show that the physician prescribing practices he pointed to had anything to do with price, let alone cross elasticity. *See supra* Part III.A.

Impax further argues that Professor Noll did not "quantify" the switching costs, and cites medical expert testimony that switching was "simple." Impax Br. at 93-94. Once again, Impax misses the forest for the trees. Professor Noll's analysis and the unrebutted medical expert testimony shows that whatever the exact amount of the switching costs, they were high enough that consumers did not switch between LAOs of different molecules in response to a small but significant price differential. (CCRF ¶ 986; CCF ¶¶ 658-68).

Pricing documents. Endo's business documents rarely discussed or considered the price of other LAOs, indicating that those products were not influencing Endo's Opana ER price. (CCF ¶¶ 721-40). Impax underscores how few such documents exist by referencing only a single email discussing the price of Purdue's OxyContin. Impax Br. at 94-95. Impax also argues that Endo tracked its competitors' couponing. For the reasons mentioned earlier, these documents relating to discounting are entirely consistent with a firm with market power that wants to sell as much of its product as possible. *See supra* Part III.A.3.

Promotional materials. Instead of competing with other LAOs on price, Endo focused its marketing and promotional efforts on differentiating Opana ER based on Opana ER's unique clinical properties. (CCF ¶¶ 721-36; CCRF ¶¶ 878-80, 882-83). This strategy results in decreased cross elasticity of demand. After all, the entire goal of this type of marketing is to convince

purchasers that other products are not appropriate substitutes, even if they are cheaper. It is hard to imagine Endo spending so much on this kind of promotion if it was not effective. *See* Impax Br. at 89. And although promoting based on differentiation does not establish market power on its own, it is part of the "detailed mosaic" that confirms and explains the economic evidence. *See* Impax Br. at 62.

Output. Impax also claims that Complaint Counsel did not present evidence that Endo restricted output. Impax Br. at 100. This ignores that maintaining supracompetitive pricing, even at the same output level, is evidence of market power. (CCF ¶ 961). Impax's argument is also incorrect. As Professor Noll showed, Dr. Addanki's analysis did not look at the data on a granular enough level. The quarterly wholesale sales data plainly show that Impax's entry increased the output of oxymorphone ER products. (CCF ¶¶ 963-64). But even under Dr. Addanki's flawed approach, the data show that entry of Impax's oxymorphone ER halted a decline in oxymorphone ER output. Thus, Impax's entry increased oxymorphone ER output relative to what it would have otherwise been. (CCF ¶ 965).

Direct Evidence. Finally, Impax attempts to respond to Professor Noll's conclusion that market power could also be

Impax Br. at 102. Instead, consistent with *Actavis* and its progeny, Complaint Counsel satisfied its *prima facie* case by showing a large reverse payment and Endo's market power. *See, e.g.*, *Cephalon*, 88 F. Supp. 3d at 416.

Impax attempts to equate Endo's payment to eliminate the risk of competition with the exclusive dealing agreement in *In re McWane*, 2014 WL 556261 (F.T.C. Jan. 20, 2014). Impax Br. at 104-05. But this case is nothing like *McWane*. There, the Commission affirmed the ALJ's conclusion that an exclusive dealing agreement between McWane and its distributor, Sigma, was not a horizontal arrangement between potential competitors. Although Sigma had explored the possibility of independent entry, it "lacked the financial means" to do so. *Id.* at **35.* Thus, because McWane and Sigma were not potential competitors, their agreement did not eliminate a risk of competition.

In this case, unlike *McWane*, there is no dispute that the challenged agreement is a horizontal agreement between potential competitors. Impax has never contended that it lacked the financial means to enter. Indeed, prior to its agreement with Endo, Impax was actively considering entering, and taking concrete steps to do so. (CCRF ¶ 1158). Thus, this case more closely resembles *United States v. Microsoft Corp.*, 253 F.3d 34 (D.C. Cir. 2001) (en banc). *See* CC Br. at 27. In *Microsoft*, the D.C. Circuit acknowledged there was "insufficient evidence to find that, absent Microsoft's actions, Navigator and Java already would have ignited genuine competition in the market for Intel-compatible PC operating systems." *Id*. at 78. But it observed that "neither plaintiffs nor the court can confidently reconstruct a product's hypothetical . . . development in a world absent the defendant's exclusionary conduct." *Id.* "To some degree," therefore, "'the defendant is made to suffer the uncertain consequences of its own undesirable conduct.'" *Id.*, quoting 3 Areeda, ¶ 651c.

Thus, the D.C. Circuit rejected Microsoft's argument that the government was required to establish that Java or Navigator, if left alone, would actually have developed into viable platform substitutes for Windows. Instead, to establish anticompetitive effects, the government needed only to show that "(1) as a general matter the exclusion of nascent threats is the type of conduct that is reasonably capable of contributing significantly to a defendant's continued monopoly power and (2) Java and Navigator reasonably constituted nascent threats at the time Microsoft engaged in the anticompetitive conduct at issue." *Id*. at 79 (relying on finding that "both Navigator and Java showed potential as middleware platform threats.").

The same is true in this case. Here, as in *Actavis*, "the specific restraint at issue [a monopolist's large payment to a potential competitor to stay off the market] has the potential for genuine adverse effects on competition." 133 S. Ct. at 2234. As discussed in Part IV.B. below, the evidence shows that at the time of settlement there was a significant risk that Impax would launch its generic Opana ER product before January 2013. Thus, under standard rule of reason analysis, the nature of the restraint combined with Endo's market power establishes the restraint is *prima facie* anticompetitive. CC Br. at 21-22.

B. Impax's agreement to a payment to stay off the market eliminated the risk that generic entry would occur before January 2013

Under *Actavis*, an incumbent's purchase of a patent challenger's agreement to stay off the market to eliminate "the risk of competition" is the relevant anticompetitive harm. 133 S.Ct. 2236. The evidentiary record here amply shows that (1) there was risk that Impax would have entered before January 1, 2013, and (2) the payment worked as intended to prevent that risk of competition.

1. There was a significant risk that Impax would prevail in the patent litigation and launch generic Opana ER before January 2013

As part of its "actual delay" argument, Impax asserts that Complaint Counsel must prove "that Impax would have prevailed in the original patent litigation" and necessarily entered before January 1, 2013. Impax Br. at 112. Impax is wrong as a matter of law.

In *Actavis*, the Supreme Court made clear that rule-of-reason analysis of a reverse payment does not "require the courts to insist . . . that the Commission need litigate the patent's validity, empirically demonstrate the virtues or vices of the patent system, present every possible supporting fact or refute every possible pro-defense theory." *Id*. at 2237. Instead, the Court instructed the trial court to answer the "basic question": whether the reverse payment allows the incumbent to avoid the risk of competition by "maintain[ing] and [] shar[ing] patent-generated monopoly profits." *Id*. at 2237-38. Indeed, the Court observed that removal of an uncertain risk of invalidity or noninfringement, even if small, cannot justify an otherwise unexplained large payment:

> 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.

Actavis, 133 S. Ct. at 2236.

For this reason, the Supreme Court stated that it is "normally not necessary to litigate patent validity to answer the antitrust question (unless, perhaps, to determine whether the patent litigation is a sham)." *Id*. at 2236.[33] In reaching this conclusion, the Supreme Court agreed with

[33] *See, e.g., In re Aggrenox Antitrust Litig.*

virtually every court to consider a reverse payment challenge that litigating the patent merits inside an antitrust case would be "time consuming, complex, and expensive," and neither necessary nor desirable. *Id.* at 2234. Instead, the Court explained—again—that the focus is on the *payment*:

> An unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent's survival. And that fact, in turn, 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 2236.

Despite the Supreme Court's clear language, Impax nonetheless asks this Court to credit the opinion of its patent law expert, Mr. Figg, that Impax was "more likely than not" to lose the original patent case. Impax Br. at 114. But the point is not whether Impax absolutely would have won, or absolutely would have lost the patent case; no one knows what would have happened if the patent case continued. Instead, the point is that there was a *risk* that Impax would have won, and therefore a risk that Impax would have entered before January 1, 2013. Mr. Figg's opinion is not to the contrary. Indeed, by its very terms, Mr. Figg's opinion concedes that Impax's chance of prevailing in the patent litigation was significant (potentially up to 49 percent). That risk of an Impax victory ended with the 2010 reverse payment agreement. Impax does not argue otherwise.

Moreover, Mr. Figg's opinion is not based on any methodology for predicting patent litigation outcomes. (CCF ¶¶ 1370-1378). He conceded that the outcome of patent litigation is inherently uncertain and acknowledged that he lost some cases he thought he would win. (CCRF

02521-WHO, 2017 WL 5068533, at *5 (N.D. Cal. Nov. 3, 2017) ("I disagree that plaintiffs need to prove *in this case* that Watson *would have* won its patent litigations. That turducken is not only unappetizing as a matter of judicial efficiency, it is not required (or even suggested) by the *Actavis* opinion." (footnote omitted)).

¶ 1387) He offered no methodology to assess the reliability of his prediction about the likely outcome of Endo's patent suit, let alone his opinion that any reasonable litigant at the time of settlement would have made the same prediction. (CCF ¶1370) Mr. Figg's opinion that Impax was more likely than not to lose the patent suit is merely his subjective view and is based on an incomplete review of the underlying record in the case. (CCF ¶¶ 1372-74).[34]

Perhaps aware that its patent merits defense cannot be reconciled with *Actavis*, Impax puts greater weight on its contention that even a final Federal Circuit victory for Impax in the patent suit may not have occurred until after January 2013. Impax Br. at 106-109. But Mr. Figg's opinions on this topic, which are the sole basis for this argument, are likewise unreliable and lack any valid methodology. To reach this prediction, Mr Figg layers one guess on top of another about the possible time frames for (1) a district court decision, (2) a decision in a potential appeal to the Federal Circuit (depending on the substance of the district court's ruling), and (3) a possible remand proceeding (which would depend in turn on the substance of any Federal Circuit ruling). The uncertainties embedded in this exercise are significant, as Mr. Figg himself acknowledges. (CCRF ¶ 1089). Moreover, his guestimate of the earliest date for a Federal Circuit decision for Impax is contradicted by the evidence. Impax and Endo—both of which had information that Mr. Figg lacked—each projected an earlier date in 2011 for a possible Impax

[34] In addition, Mr. Figg ignores facts suggesting that Endo believed that the two patents it asserted against Impax would be unlikely to block generic versions of Opana ER. Those patents (Nos. 5,662,933 and 5,958,456, issued in 1997 and 1999 respectively) are titled "Controlled Release Formulation (Albuterol)." (CCRF ¶ 1066). Albuterol is a bronchodilator, not an opioid. (CCRF ¶ 1062) Although patent information is required to be submitted with a new drug application, Endo did not submit the requisite information about these patents for listing in the FDA Orange Book until many years later, and only after Impax filed an application for FDA approval of a generic version of Opana ER. (CCRF ¶ 1062).

victory in the Federal Circuit. CC Br. 46; (CCF ¶¶ 166, 592 (Impax viewed mid-2011 as "base

would have had different incentives. If it was even concerned about the ‘482 patent, it might

1129). Second, Impax executives speculated that, if they launched at risk in the near term, they might be able to catch Endo off guard and enjoy a few lucrative weeks as the sole generic before facing competition from an Endo AG, netting millions of dollars in extra sales. (CCRF ¶ 1129). Dr. Addanki's theories are also contradicted by Endo's contemporaneous business documents, which show that it projected possible entry from Impax as early as mid-2010, and that, at the time of settlement Endo was concerned about what such generic entry would do to its Opana ER sales and its ability to launch a reformulated version of Opana ER. (CCF ¶¶ 58-71, 75-82).

Indeed, notwithstanding Dr. Addanki's insistence that such a launch would have been economically irrational, Impax never ruled out an at-risk launch prior to the June 2010 reverse payment agreement. On the contrary, the evidence shows that, until the reverse-payment agreement, Impax was "absolutely" considering a launch before a final appellate ruling. (CCRF ¶ 1209; *see also*

> The same day, Dr. Hsu directed Impax President of Generics, Chris Mengler, to "alert BOD [board of directors] with potential oxymorphine [*sic*] launch," even though "we will have a special Board conference call *when we do decide to launch at risk on a later date*." (CCRF 1206, 1213 (emphasis added); *see also* CCF ¶ 139).
>
> Impax President of Generics Chris Mengler explained in his May 2010 Board presentation that the "Current Assumption" was an oxymorphone ER at-risk launch in the second quarter of 2010. He told the Board of Directors that oxymorphone ER was "a good candidate for an at-risk launch." (CCRF ¶¶ 1209, 1218).
>
> Impax represented to the district court that it would not launch at-risk during the trial (which was to end on June 17, 2010), just three days after the date Impax expected to receive final FDA approval), but it would not commit to forgo a launch beyond that date. (CCRF ¶ 1206; CCF ¶ 142).

Second, Impax makes much of the fact that management never sought Board of Directors authorization for an at-risk launch of generic Opana ER. Impax Br. at 119-122. But the absence of a decision to launch is hardly the same as an affirmative decision *not* to launch before a final appellate decision. Prior to its June 8 agreement with Endo, the evidence clearly shows Impax senior management was considering an at-risk oxymorphone ER launch. Impax's agreement to stay off the market until January 2013, however, obviated any need for further consideration or Board involvement. (CCRF ¶ 1237).[38]

Finally, Impax attempts to dismiss all of the steps it took to be in a position to launch generic Opana ER as merely "routine launch preparedness efforts" that are undertaken with all products. But it makes no sense for a company to expend significant resources to be in a position to launch if it is not considering doing so anytime in the near future. (CCRF ¶ 1162). This is

[38] By the time of the Board meeting on May 25 and 26, 2010, Impax was already more than a week into settlement discussions with Endo. (CCF ¶¶ 219-29). Impax was not eligible for final FDA approval until June 14, 2010 (CCF ¶¶ 109, 112), and had represented to the district court that it would not launch at-risk until the end of the trial on June 17, at the earliest (CCF ¶ 142). Given that Impax and Endo reached agreement in principle on June 3, 2010 (CCF ¶ 257), and entered a definitive settlement agreement on June 8, 2010 (CCF ¶ 317), Board approval of an oxymorphone ER at-risk launch became unnecessary. (CCRF ¶ 1237).

market—but on the broad patent license in the SLA, asserting that "Impax's freedom to operate under the SLA is central to assessing the deal's procompetitive benefits." Impax Br. at 127. But Impax makes no claim—and offers no evidence—that the payments from Endo served to further an objective to obtain a broad patent license (something it says it seeks in every patent settlement). Nor can it: Impax cannot plausibly suggest that it needed to be paid to accept a broad patent license that benefited it.

Rather than attempt to justify the challenged payment, Impax instead insists that, on balance, the SLA's procompetitive benefits exceed any anticompetitive effects because the broad patent license gave Impax freedom to operate regardless of Endo's later-acquired patents. But such balancing is not necessary or appropriate unless and until the defendant has offered a legitimate justification for the restraint. *See* CC Br. at 60-71. Impax has not met its burden to show that *the payment* furthered a procompetitive objective. That failure ends the rule of reason analysis. The absence of a sufficient justification means there are no countervailing procompetitive benefits from the challenged restraint to weigh against Complaint Counsel's *prima facie* showing of harm to competition.

Impax's argument to the contrary rests primarily on a statement in the Commission's summary disposition opinion that the extent to which a settlement allows entry before patent expiration "*may be* relevant *if* balancing anticompetitive harms and procompetitive benefits becomes necessary." Comm. Summary Disposition Op. 12 (emphasis added). But, as discussed above, the balancing inquiry only is "necessary" if the case is not resolved under the three-step burden shifting framework applied in rule of reason cases. Here, Impax loses at step two.

D. Impax cannot rely on benefits that may flow from the settlement agreement as a whole rather than the large payment to stay off the market

Because Impax has not shown that the challenged payment provisions served any legitimate objective, it has failed to meet its burden to justify the challenged restraint. That restraint is therefore unreasonable and unlawful. Attempting to salvage its argument, however, Impax incorrectly asserts that procompetitive benefits "must be assessed with reference to the Settlement Agreement as a whole" rather than

stay off the market would not raise the concern that potential competitors are sharing the rewards of avoiding competition:

> We concede that settlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition, again to the consumer's benefit. But settlement on the terms said by the FTC to be at issue here—***payment in return for staying out of the market***—simply keeps prices at patentee-set levels, potentially producing the full patent-related $500 million monopoly return while dividing that return between the challenged patentee and the patent challenger. The patentee and the challenger gain; the consumer loses.

Actavis, 133 S. Ct. at 2234-35 (emphasis added).

Thus, what Impax labels a "nonsensical" focus on the payment (Impax Br. at 131) is precisely the inquiry that *Actavis* mandates. *See id*. at 2237 (explaining that the rule of reason inquiry into anticompetitive effect focuses on four factors related to the payment). It is the presence of a large payment to induce the generic patent challenger to stay off the market that distinguishes reverse payment agreements from ordinary patent settlements; and it is the large payment that must be justified.

Third, Impax points to district court cases that purportedly consider the benefits of the settlement as a whole in assessing the defendant's justifications. But these cases merely held that courts should take a "holistic" approach in determining what the settling parties actually agreed to, for example by considering together physically separate written agreements executed on the same day as the settlement.[39] Nothing in any of these cases suggests that such a holistic approach

[39] *See, e.g.*, *In re Loestrin 24 Fe Antitrust Litig*., 2017 WL 3600938, at *15 (D.R.I. Aug 8, 2017) (noting "complexity" of agreements and need to look at each settlement agreement as a whole "to determine whether plausible claims have been set forth"); *In re Aggrenox Antitrust Litig*., 94 F. Supp. 3d 224, 243 (D. Conn. 2015) (in a case involving "a complicated transaction involving a series of agreements settling separate litigation over two drug patents," the entire set of agreements should be viewed "holistically" when deciding whether the plaintiffs had plausibly alleged a reverse payment); *In re Niaspan Antitrust Litig*., 42 F. Supp. 3d, 735, 752 (E.D. Pa.

displaces the defendant's burden to justify the challenged restraint by showing that the restraint itself furthers some procompetitive objective. Indeed, such a rule would be untenable in practice: it would encourage parties to throw anticompetitive restraints into otherwise procompetitive ventures in the hope that the overall procompetitive arrangement outweighed the anticompetitive harm.

generic’s refusal to settle without

This alternative settlement would be equally effective in achieving Impax's asserted objective to obtain a broad license and "freedom to operate" if Endo obtained future patents. Impax does not contend otherwise or suggest that the license in any way depended on the payments. Indeed, Impax has never contended that this less restrictive, "no-payment" alternative would have been impractical or ineffective in achieving any benefits flowing from the broad patent license.

Third, Impax misconceives the concept of a less restrictive alternative when it asserts that Complaint Counsel would need to identify the specific entry date to which the parties would have agreed absent the payment. Impax Br. at 133. A less restrictive alternative is one that eliminates the restraint and still provides the asserted procompetitive benefits, such as an NCAA television plan without the provisions the Supreme Court held were unlawful. *NCAA*, 468 U.S. at 117 (distinguishing "[t]he specific restraints on football telecasts that are challenged in this case" from NCAA rules tailored to achieve its legitimate objective of maintaining a competitive balance among amateur athletic teams). Here, the restraint is the agreement to stay off the market in exchange for a large payment; the less-restrictive alternative is a settlement without the large payment. Impax's contention that Complaint Counsel must identify a specific no-payment settlement with an earlier entry date is just another version of Impax's incorrect argument that Complaint Counsel must prove what would have happened in the hypothetical but-for world. And it is wrong for the same reason that Impax's "delayed entry" argument fails: at its core, it simply reflects Impax's persistent denial that the relevant harm under *Actavis* is sharing monopoly profits to eliminate the risk of competition, not certain "delay" resulting from the particular entry date that Endo purchased.

Impax is also wrong that the evidence excludes the availability of a less-restrictive no-payment settlement simply because Endo did not offer an entry date earlier than January 2013 during the actual negotiations. Impax. Br. at 133. As Impax's economic expert testified, negotiating positions in settlement are often posturing, and thus cannot be a basis for inferring a branded drug firm's true "reservation date," that is, the earliest generic entry date that it was willing to accept. (CCF ¶ 1017-18). Consequently, as Dr. Addanki concedes, he does not know

deal), but with a generic entry date of July 2011—the same date Endo had granted to another generic challenger. (CCF ¶ 276). Endo refused the earlier entry date, but then discussed "better terms on the co-promote deal." (CCF ¶ 278).

V. The proposed order is a proper exercise of the Commission's remedial authority

Once a violation is found, the Commission has an obligation to order effective relief to protect the public from future violations and to restore competitive conditions to the marketplace. Thus, Section 5 of the FTC Act mandates that, upon determining that a challenged practice is an unfair method of competition, the Commission "***shall*** issue . . . an order requiring such person . . . to cease and desist from using such method of competition or such act or practice." 15 U.S.C. § 45(b) (2018) (emphasis added); *FTC v. Nat'l Lead Co.*, 352 U.S. 419, 428 (1957) (confirming Commission's power to issue cease and desist order). Such relief is necessary and appropriate unless there is no "cognizable danger" that Respondent will engage in future violations of the same type. *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953).

Despite this clear standard, Impax insists that even if Complaint Counsel were to establish an antitrust violation, "no remedy would be appropriate." Impax Br. at 134. Impax's lead argument—that any remedy here would be "unnecessary and unjust" because it predated *Actavis*'s purported change in law—is wholly misplaced. Impax Br. at 135. As Impax concedes, *Actavis* applies to agreements entered before the Supreme Court's June 2013 decision. Impax Br. at 30 n.10. To suggest that a court must apply *Actavis* to pre-2013 agreements but cannot order

not found to have violated the law. CC Br. at 71-72. The fencing-in relief here is reasonably related to the violation f

Impax complains that a ban on agreements that "disincentivize" competition between oxymorphone ER products is ambiguous. Impax Br. at 137-38. But the 2017 Agreement between Impax and Endo is a clear example of offending conduct that would fall under the ban. **{** [redacted] **}** Such a provision plainly disincentivizes competition in the oxymorphone ER market. (CCF ¶¶ 1427-28, 1487-90)

To support its purported confusion over the revised order, Impax proposes a hypothetical arrangement with another drug company "to supply a low-price generic drug at near marginal cost" as an agreement that might disincentivize a brand company from competing. Impax Br. at 138. But Impax's speculative concerns over such an arrangement are meritless. Paragraph II.B is limited to agreements restricting competition *between oxymorphone ER products*. Impax presents no basis to believe that its hypothetical agreement would plausibly occur in the oxymorphone ER market, given Impax's current presence in that market.

***Modified Paragraph II.C*:** Paragraph II.C addresses Impax's obligations with respect to its 2017 agreement with Endo, but now affects only the offending portion of the 2017 agreement. As a result, it does not deprive Endo of its rights under that agreement. Specifically, revised Paragraph II.C provides that, so long as the 2017 agreement remains in effect, Impax may not enforce the portion of the agreement that conditions Impax's obligation to pay royalties on the absence of any competing oxymorphone ER product. As explained above, under the 2017 agreement, **{** [redacted] **}** (CCF ¶¶ 1427-28, 1487-90) As revised,

{

} Thus, this modification resolves Endo's due process objection.[44]

Impax's objections to the provisions affecting the 2017 agreement, on the other hand, should simply be rejected. Impax asserts that any remedial action with respect to the 2017 agreement would require an amendment to the complaint and proof that the 2017 agreement is independently unlawful. Impax Br. 135-36. But Paragraph II.C is appropriate fencing-in relief. The violation in this case is Impax's agreement to preserve Endo's oxymorphone ER monopoly in exchange for a share of Endo's monopoly profits. The 2017 agreement is the mirror image: the parties agreed to preserve Impax's current oxymorphone ER monopoly and share the resulting profits.

It is well-settled that "those caught violating the Act must expect some fencing in." *Nat'l Lead Co.*, 352 U.S. at 431. And it is entirely proper for an order to "include such additional provisions as are necessary to preclude

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. "Contract Settlement Agreement" means the Contract Settlement Agreement, including all exhibits thereto, entered as of August 5, 2017, between Impax and Endo Pharmaceuticals Inc. (CX3275).

K. "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.

L. "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.

M. "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.

N. "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.

O. "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.

P. "Generic Product" means a Drug Product manufactured and/or sold under an ANDA or pursuant to a 505(b)(2) Application.

Q. "Market," "Marketed," or "Marketing" means the promotion, offering for sale, sale, or distribution of a Drug Product.

R. "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.

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 and 45 days before and ending 45 days after the execution of the Brand/Generic Settlement.

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.

III.Compliance Program

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 any holder of an NDA, ANDA or 505(b)(2) for any Drug Product;

3.

Appendix 2

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. “Contract Settlement Agreement” means the Contract Settlement Agreement, including all exhibits thereto, entered as of August 5, 2017, between Impax and Endo Pharmaceuticals Inc. (CX3275).

~~J.~~K. “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.

~~K.~~L. “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.~~M. “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.~~A. ~~“First Amendment to the 2010 Settlement and License Agreement” means the Contract Settlement Agreement, including all exhibits thereto, entered as of August 5, 2017, between Impax and Endo Pharmaceuticals Inc. (CX3275).~~

N. “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

R. “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.

S. “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.

T. “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.

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.

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, 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 and 45 days before and ending 45 days after the execution of the Brand/Generic Settlement.

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.

B. Respondent is prohibited from entering into or being party toshall not enter

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

5. Copies of the certifications required by Paragraph III.C and the policies and procedures required by Paragraphs III.D and III.E.

February 14, 2018

By: /s/ *Charles A. Loughlin*
Charles A. Loughlin

Counsel Supporting the Complaint

CERTIFICATE FOR ELECTRONIC FILING

I certify that the electronic copy sent to the Secretary of the Commission is a true and correct copy of the paper original and that I possess a paper original of the signed document that is available for review by the parties and the adjudicator.

February 14, 2018 By: /s/ *Charles A. Loughlin*
Charles A. Loughlin