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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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Table of Contents

Table of Authorities

Cases

Statues

Other Authorities

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, the Endo Credit "insurance" provision, and $10 million in up-front cash. Impax accepted this large payment—that ultimately amounted to more than $100 million—and agreed to stay out of the market for more than two years, until January 1, 2013. Endo's payment cannot be explained or justified as compensation for any services Impax agreed to provide. Under *Actavis*, this reverse-payment agreement is an unlawful sharing of Endo's monopoly profits to avoid the risk of competition.

Impax's lengthy defense to this evidence is a series of misguided arguments and distractions. Despite its length, though, Impax's response is most notable for what it does not say, rather than for what it does.

Impax argues that Complaint Counsel must prove what actually would have happened if Impax and Endo did not settle. But it never mentions *Actavis'* clear statement that the "relevant anticompetitive harm" in a reverse-payment case is that potential competitors "prevent the risk of competition" by settling patent litigation with an agreement that "maintain[s]" and "share[s] patent-generated monopoly profits." 133 S. Ct. at 2236-37.

Impax contends that the $102 million it received under the Endo Credit is not a large payment because there was some undefined, theoretical possibility that the No-AG and the Endo

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.

Finally, Impax insists that the settlement allowed for *earlier* generic entry because, without the challenged agreement, it never would have entered the market until after January 1, 2013. But Impax has no answer for why Endo would agree to pay Impax large sums—ultimately $112 million—to *accelerate* generic competition to one of its most important products. This Court should find that Impax's agreement with Endo was an antitrust violation, and enter Complaint Counsel's narrowly tailored proposed order to prevent it from entering similar agreements in the future.

Impax misstates key facts

Impax's post-trial brief and proposed findings of fact contain numerous factual misstatements and misrepresentations. Complaint Counsel addresses these errors in detail in its reply findings of fact, but highlights a few here:

First, there is no evidence that Impax "sought and obtained the earliest entry date Endo would permit." Impax Br. at 12. Endo's negotiating positions tell us nothing about the true "reservation date" it was willing to accept, and Impax never pressed the issue. Instead, it repeatedly accepted compensation in exchange for backing off requests for an earlier date.

Second, contrary to Impax's current assertions, the No-AG provision was a significant and valuable term to Impax, and Impax worked to protect its value by insisting on the Endo Credit.

Third, Endo did not plan to strategically launch its Reformulated Opana ER to avoid paying the Endo Credit. Endo's plan was always to launch Reformulated Opana ER as early as possible to ensure a smooth transition of patients before generic oxymorphone ER entry.

A. Impax did not seek or obtain the earliest possible entry date

Impax contends that it "sought and obtained the earliest entry date Endo would permit." Impax Br. at 12. To be sure, Impax initially wanted to launch its generic oxymorphone ER "as

early as possible." (CCF ¶ 122). But it never pressed this issue because, from the very first discussions, Endo offered Impax a No-AG provision to stay out of the market until 2013. (CCF ¶¶ 227-31; CCRF ¶¶ 142, 201). Impax recognized that it could make more money by accepting the No-AG provision and postponing its launch than by pushing for an earlier date without any compensation. (CCRF ¶ 126). As a result, the settlement negotiations focused on refining Endo's compensation package, not earlier entry dates. (CCF ¶¶ 251-70, 278, 300-03).

Indeed, every time Impax requested an earlier entry date, it quickly backed off in return for an increased payment from Endo. (CCRF ¶142; CCF ¶ 222). First, Impax sought an acceleration trigger that would allow it to enter the market earlier if sales of Original Opana ER declined. Endo rejected this proposal, but instead offered a cash "make good" payment—which ultimately became the Endo Credit—to compensate Impax for any lost market opportunity. (CCF ¶¶ 253-70). Impax accepted this payment provision and stopped seeking an earlier date. (CCRF ¶ 142). Later, Impax suggested dropping the compensation terms under discussion and entering a "simple settlement" with a July 2011 entry date—the same date Endo had granted to another generic company. (CCRF ¶ 142). Endo refused, but increased the milestone payments in the DCA. (CCRF ¶ 142). Again, Impax accepted the additional payment and stopped asking for an earlier entry date. (CCRF ¶ 142).

Simply put, because every Endo offer included payments, Impax has no idea what entry date Endo would have been willing to offer without a payment. Impax's economic expert acknowledged he could not determine the earliest entry date Endo would have been willing to offer, and agreed that Endo may well have been willing to accept an earlier date even if it insisted otherwise in negotiations. (CCF ¶¶ 1443-44). As Dr. Addanki explained, regardless of what Endo might have said during negotiations, you cannot "infer what someone's true

reservation date was from a negotiation posture in a settlement negotiation." (CCF ¶ 1444). And if Endo were willing to accept a January 2013 entry date while making what turned out to be $112 million in payments to Impax, it follows that Endo would have been willing to agree to an earlier date without such a substantial payment. (CCRF ¶¶ 615, 1504-08).

B. Impax wanted and highly valued the No-AG agreement

Impax implies that Endo's No-AG promise was not an important part of the settlement agreement because it was "not the subject of any meaningful negotiation" and Impax "accepted [it] without discussion" while focusing on other provisions. Impax Br. at 17. But Impax did not need to negotiate over the No-AG provision; it entered the negotiations wanting a No-AG agreement and got it immediately. (CCRF ¶ 201). After that, Impax's primary focus was on obtaining the "super, super important" Endo Credit provision to protect its anticipated No-AG profits. (CCRF ¶¶ 192, 609). None of this supports Impax's suggestion that it did not value the No-AG provision; it shows the opposite. In fact, both Impax's CEO and chief negotiator were clear that getting a No-AG provision is "among the more important things" in a settlement negotiation. (CCF ¶¶ 231, 1483-84; CCRF ¶¶ 201, 623-26).

Impax also claims that "Endo was willing to offer the No-AG provision because it never expected to launch an authorized generic version of Opana ER." Impax Br. at 17. Not so. Endo was actively preparing to launch an AG "on word/action of first generic competitor." (CCF ¶ 85 ("If Impax launches, Endo will launch its authorized generic. . . .")). It designed a generic tablet, obtained labels, created new SKUs, informed drug wholesalers of its intent to launch, and manufactured enough authorized generic product to support a launch as early as June 2010. (CCRF ¶ 616). And Endo had strong incentives to meet generic competition with an AG. It projected that an AG could offset more than a third of its lost Opana ER sales. (CCRF ¶ 616).

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 potentially impossible calculations to show that a payment was "large."

1. *Actavis* did not create a threshold burden of proof

Impax cites no case holding that *Actavis* imposes a threshold burden of proof before application of the rule of reason. There is none. As one court succinctly explained: "[N]owhere in the *Actavis* opinion does the Supreme Court state that plaintiffs bear a 'threshold burden' of demonstrating that the reverse payment was large and unjustified." *King Drug Co. of Florence, Inc. v. Cephalon, Inc*., 88 F. Supp. 3d 402, 414 (E.D. Pa. 2015) ("*Cephalon*"). Instead, Impax quotes snippets from cases addressing a plaintiff's burden at the *pleading* stage,[3] not at the proof stage. CC Br. at 29-30 (noting the distinction between a plaintiff's pleading burden at the pleading stage and its proof burden at the evidentiary stage).[4]

In fact, every court to address burdens of proof under *Actavis* has held that the plaintiff must establish a "large" payment as part of its *prima facie* case, and the defendant must show a

[3] *See* Impax Br. 31-32, citing *In re Loestrin 24 Fe*, 814 F.3d 538, 552 (1st Cir. 2016); *In re Loestrin 24 Fe*, 261 F. Supp. 3d 307, 330 (D.R.I. 2017); *In re Actos End Payor Antitrust Litig*., No. 13-CV-9244, 2015 WL 5610752, *11-12 (S.D.N.Y. Sept. 22, 2015); *In re Lipitor Antitrust Litig*., 868 F.3d 231 (3d Cir. 2017); *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis PLC*, No. 15-cv-6549, 2016 WL 4992690, *13 (S.D.N.Y. Sept 13, 2016).

[4] In addition to the appellate court decisions in *In re Lipitor Antitrust Litig*., 868 F.3d 231, 251-52 (3d Cir. 2017), and *King Drug Co. of Florence, Inc. v. Smithkine Beecham Corp.*, 791 F.3d 388, 411-12 (3d Cir. 2015) ("*Lamictal*") cited in Complaint Counsel's opening brief, other reverse payment cases also acknowledge this distinction between the plaintiff's burden at the pleading stage and the burden of proof at the evidentiary stage. *See, e.g., In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-md-02503, 2015 WL 5458570, at *7 (D. Mass. Sept. 16, 2015) ("In light of the language and reasoning in *Actavis* and the persuasive weight of cases imposing an initial burden on plaintiffs to *allege* plausibly a large and unjustified payment, the Court concludes that the direct purchasers must bear this initial burden, but such allegations *then shift the burden of persuasion to Defendants to justify the challenged payments*.") (emphasis added); *Cephalon*, 88 F. Supp. 3d at 412-13, 416. Impax ignores this distinction.

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 Endo Credit provisions to demonstrate that those provisions provided value to Impax in excess of saved litigation costs. According to Impax, Complaint Counsel had to identify every possible payment outcome, calculate the value of the provisions under each outcome, and then discount that value by the probability of each outcome occurring. Impax Br. at 55-57. Notably, Impax's own economic expert states that this type of expected value calculation is impossible to perform. (CCF ¶ 479 (such a calculation is not "in any practical sense doable")). More fundamentally, however, such exacting precision is not necessary. As *Actavis* emphasized, in proving its case under the rule of reason, the FTC need not "present every possible supporting fact . . . irrespective of the minimal light it may shed on the basic question—that of the presence of significant unjustified anticompetitive consequences." 133 S. Ct. at 2237-38 (citing 7 Areeda, ¶ 1508c).

In other words, the inquiry into the size of a reverse payment is not an abstract accounting exercise. It is a tool to help answer the "basic question": whether the payment likely induced the generic to abandon its patent challenge and agree to stay off the market. The "large payment" inquiry thus helps assess "the likelihood of a reverse payment bringing about anticompetitive effects." *Actavis*, 133 S. Ct. at 2237; *see also Cephalon*, 88 F. Supp. 3d at 417 ("As *Actavis* explains, the relevant inquiry is what would induce *the generic* to stay off the market.") (emphasis in original).

As discussed below, the record in this case provides a wealth of evidence to assess the value of the payments and from which to conclude that, at the time of settlement, Impax expected a sufficiently large payment to induce it to accept a January 1, 2013 entry date. *See infra* Part II.B.

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 least, the 'size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power'—namely, the power to charge prices higher than the competitive level. An important patent itself helps to assure such power. Neither is a firm without that power likely to pay 'large sums' to induce 'others to stay out of its market.'

Actavis, 133 S.Ct. at 2236 (internal citations omitted). This conclusion flows naturally from the Supreme Court's teaching in *FTC v. Indiana Federation of Dentists* that, in any rule of reason case, "the purpose of the inquiries into market definition and market power is to determine whether an arrangement has the potential for genuine adverse effects on competition." 476 U.S. 447, 460 (1986). The inquiry need not always involve an "elaborate market analysis." *Id*; *see also Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 779 (1999) ("[I]t does not follow that every case attacking a less obviously anticompetitive restraint . . . is a candidate for plenary market examination"). Rather, what is required "is an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint." *Id*. at 781.

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.

C. *Actavis* defines the relevant anticompetitive effect in this case

Impax's defense in this case rests in substantial part on its incorrect argument that a rule-of-reason violation can only be established with proof that the Endo-Impax settlement agreement resulted in an "actual delay" in Impax's launch of generic Opana ER. Impax Br. at 39-40. But a central teaching of *Actavis* is that "the relevant anticompetitive harm" in a reverse-payment case is that potential competitors "prevent the risk of competition" by settling patent litigation with an agreement that "maintain[s] and [] share[s] patent-generated monopoly profits." 133 S. Ct. at 2236-37. As *Actavis* recognizes, a large payment to induce the generic to forestall entry harms the competitive process because it distorts the bargaining process that ordinarily would be expected to protect consumer interests. *See* CC Br. at 22-23. *Actavis* teaches that avoiding "what might have been a competitive market" by this subversion of the competitive process is "the anticompetitive consequence that underlies the claim of antitrust unlawfulness." 133 S. Ct. at 2236.

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 "relevant" anticompetitive effect is payment to prevent "the risk of competition." *Actavis*, 133 S. Ct. at 2236. And while Impax asserts that "numerous courts" have held that a plaintiff in a reverse payment case must prove "that the settlement in fact delayed competition" to establish a violation (Impax Br. at 36), none of the three cases it cites support that claim. The Third Circuit's decision in *King Drug Company of Florence, Inc. v. Smithkline Beecham Corporation*, 791 F.3d 388 (3d Cir. 2015) ("*Lamictal*"), made clear that, rather than actual delayed entry, "the antitrust problem" in *Actavis* "was that, as the [Supreme] Court inferred, entry *might have been earlier*, and/or the risk of competition not eliminated, had the reverse payment not been tendered." *Id*. at 408 (emphasis added). Impax points to the phrase "payment for delay" in the Third Circuit's decision, but ignores that the court used this phrase (which *Actavis* did not use) as shorthand for "payment to prevent the risk of competition." 791 F.3d at 412; *see also id.* at 402 ("a reverse payment inducing delay—i.e., a 'payment in return for staying out of the market'") (quoting *Actavis*, 133 S. Ct. at 2234-35); *id.* at 411 ("payment *for delay* (or, that is, to eliminate the risk of patent invalidity or noninfringement)") (emphasis in original). *Lamictal* teaches that, "to prove anticompetitive effects," a plaintiff's burden is to prove "payment to prevent the risk of competition," not actual delay. *Id*. at 412.

In re Cipro Cases I & II, 348 P.3d 845 (Cal. 2015), likewise did not hold that a plaintiff must prove that the agreement at issue "in fact delayed competition" to establish a rule of reason violation. Impax Br. at 37. *Cipro* explained that the rule-of-reason analysis under *Actavis* seeks to assess whether a reverse-payment agreement "eliminates competition beyond the point at which competition *would have been expected* in the absence of the agreement." *Id*. at 865 (emphasis added). To answer that question, *Cipro* directed lower courts to assess the *payment*,

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*, 635 F.3d 815, 827 (2011).[8] Lower courts applying *Actavis* have focused on the nature of the challenged restraint—a branded drug firm's large payment to the generic patent challenger to stay off the market—and observed that the natural tendency of such a restraint would be to induce the generic to accept a later entry date than it would otherwise accept.[9]

As *Actavis* makes clear, the relevant anticompetitive effect Complaint Counsel needs to show from the challenged agreement in this case is the prevention of the *risk* of competition. *Actavis*, 133 S. Ct. at 2236. By definition, showing that this risk was eliminated does not require a showing that the risk would have become a reality in the marketplace. *See* 12 Areeda ¶ 2030b (antitrust law "does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition"); *see also* infra Part IV.A. And this anticompetitive effect—the elimination of the risk of competition between June 2010 and January 2013—undisputedly occurred.

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[8] *See also Realcomp II, Ltd. v. FTC*, 635 F.3d 815, 827 (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.").

[9] *See, e.g.*, *Lamictal*, 791 F.3d at 405 ("[W]hen the parties' settlement includes a no-AG agreement, the generic also presumably agrees to an early entry date that is later than it would have otherwise accepted."); *In re Niaspan Antitrust Litig*., 42 F. Supp. 3d 735, 752 (E.D. Pa. 2014) ("[W]ith a no-AG provision, a generic would be willing to agree to a later entry date than it would otherwise agree to in order to settle a patent-infringement case."); *United Food & Commercial Workers Local 1776 & Participating Employers Health & Welfare Fund v. Teikoku Pharma USA, Inc*., 74 F. Supp. 3d 1052, 1071 (N.D. Cal. 2014) ("[I]ncentiviz[ing] [the generic] to accept an entry date later than it otherwise would have. . . . is precisely the harm that *Actavis* sought to prevent.").

In effect, Impax's "actual" delay argument seeks to impose on Complaint Counsel a requirement to prove injury-in-fact and causation, proof that is required only of private plaintiffs, who must establish standing to sue under the Clayton Act. *See* CC Br. at 26. As the First Circuit explained, the question whether there is evidence that a generic "would have launched . . . earlier" is not part of assessing "the existence of an antitrust violation," but instead part of showing that the antitrust violation caused an injury. *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 60 (1st Cir. 2016). The government need not prove a violation caused actual injury. This distinction between government law enforcement and private antitrust suits rests on an important difference in the respective roles of the public and private plaintiffs: the interest of a private plaintiff is to "remediate an injury," while the interest of the government is "to 'prevent and restrain' violations of the antitrust laws along with the attendant social costs such violations can cause." *Id.*[10]

Impax's actual delay argument is thus misplaced in this government enforcement suit. As in *United States v. Microsoft Corporation*, to establish a violation, the government need only show that "as a general matter the [defendant's conduct] is the type of conduct that is reasonably capable of contributing significantly to a defendant's continued monopoly power," viewed "at the time [the defendant] engaged in the anticompetitive conduct." 253 F. 3d 34, 79 (D.C. Cir.

[10] Here, Impax not only conflates proof of violation and proof of injury-in-fact, but then compounds its error by seeking to impose on the government a *higher* burden than private plaintiffs face to recover damages. *See, e.g., In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2018 WL 563144, at *14 (D. Mass. Jan. 25, 2018) (private plaintiffs could establish that they suffered injury from a reverse payment agreement with "some evidence" of patent invalidity or noninfringement, and were not required "to prove that the generic *would have* won, only that it *could have* won") (emphasis in original); *United Food & Commercial Workers Local 1776 & Participating Employers Health & Welfare Fund v. Teikoku Pharma USA*, No. 14-md-02521-WHO, 2017 WL 5068533, at *5 (N.D. Cal. Nov. 3, 2017) (to prove antitrust injury causation, plaintiffs need show "some evidence" that the generic could have won the patent litigation).

2001). Impax's agreement with Endo to "maintain and to share patent-generated monopoly profits" amply meets that standard. *Actavis*, 133 S. Ct. at 2237.

D. Impax misunderstands the rule of reason inquiry into less restrictive alternatives

Because Complaint Counsel proved its *prima facie* case under the rule of reason, Impax has the burden to justify the large payments. Impax has not done so,[11] ending the rule-of-reason inquiry in Complaint Counsel's favor without any need to consider less restrictive alternatives. *See, e.g.*, Areeda, ¶ 1913c ("[A] showing of possible less restrictive alternatives is part of the 'burden shifting' procedure that goes on in a rule of reason case and is required only if the preceding inquiries warrant it.").

Even if the Court were to get to this third step of the rule-of-reason framework—assessing the existence of a less restrictive alternative to achieve the asserted procompetitive objective—the Impax/Endo agreement is still unlawful. While Impax points to benefits from the broad patent license it obtained in settlement, it offers no evidence or any suggestion why it could only get such a license in a settlement with a large payment. And *Actavis* makes clear that a less restrictive alternative was available. As the Supreme Court observed, drug companies "may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, *without the patentee paying the challenger to stay out prior to that point*." 133 S. Ct. at 2237 (emphasis added). *See infra* Part IV.B. Because the payment was not reasonably necessary to achieve the purported procompetitive benefit, the restraint must be condemned. *See* CC Br. 28-29, citing 7 Areeda, ¶ 1511c.

[11] Impax asserts that it need not justify the payment, but that argument cannot be reconciled with *Actavis* or standard rule-of-reason analysis. *See* CC Br. at 67-71.

Impax asserts that Complaint Counsel must prove that any less restrictive alternative would have occurred and would have resulted in an earlier-entry date. Impax Br. at 132-33. But that is just a retread of its argument that the only cognizable antitrust harm here is "actual" delayed entry. That argument is wrong for the reasons set forth above. *See supra* Part I.C.

E. Professor Noll's analysis follows *Actavis*

Impax attempts to portray the opinions of Complaint Counsel's expert economist, Stanford University Professor Roger Noll, as untested and inconsistent with case law. But Professor Noll's analysis is precisely the economic approach underpinning the Supreme Court's decision in *Actavis*. Professor Noll concludes, as an economic matter, that a reverse payment agreement creates an anticompetitive effect by preventing the risk of competition if: (1) the brand had market power; and (2) the brand made a large and unjustified reverse payment to the generic as part of an agreement for the generic not to enter. (CCF ¶¶ 498-501, 828-42, 966-87).

Thus, Professor Noll undertook the very inquiry that *Actavis* requires in a rule of reason analysis of a reverse payment agreement. That is, he assessed the payment's "size [CCF ¶¶ 452-97], its scale in relation to litigation costs [CCF ¶¶ 452-57], its independence from other services for which it might represent payment [CCRF ¶ 1403], and the lack of any other convincing justification." *Actavis*, 133 S. Ct. at 2237 (describing the rule of reason inquiry into "the likelihood of a reverse payment bringing about anticompetitive effects"). Cases following *Actavis* reflect the same approach. *See Lamictal*, 791 F.3d 388; *Cephalon*, 88 F. Supp. 3d 402; *Cipro*, 348 P.3d 845.

Impax's criticisms of Professor Noll are without merit. First, Impax tries to portray Professor Noll's analysis as effectively a rule of per se illegality. (Impax Br. 38-41). But per se illegality requires no inquiry into market power. Indeed, a showing of market power is a hallmark of a rule of reason analysis. See Areeda, ¶ 1914d. ("The main difference between the

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*, 133 S. Ct. at 2236. ("An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present."). On that score, Impax fell woefully short.

Impax contends that Endo's Senior Vice President of Business Development, Robert Cobuzzi, and his team analyzed "the IPX-203 product concept," and reviewed information from Impax about IPX-203 before signing the deal. Impax Br. at 42. Impax also claims that a financial analysis prepared by Endo proves that the DCA was "a good deal" for Endo. Impax Br. at 44. None of this justifies the $10 million payment.

First, Dr. Cobuzzi admitted at trial that Endo offered to pay Impax $10 million upfront and $5 million in milestones **{** [redacted] **}** (CCF ¶¶ 306-07, 1083). In other words, Endo was willing to pay $10 million in guaranteed money without even knowing what it was getting in return. (CCRF ¶¶ 397, 422). After later learning that IPX-203 was an unformulated, untested concept in the earliest phase of development, Endo not only continued to offer the same $10 million upfront payment it had offered for IPX-066, a product in late stage FDA development, but acceded to Impax's additional

"piggy" demands for substantially increased development milestone payments. (CCF ¶¶ 302-03; CCRF ¶¶ 406, 414). By industry standards, $10 million was an extraordinarily large upfront payment for an early stage deal. (CCF ¶ 1221). These facts confirm that Endo was not paying for a development project with its $10 million, but instead for Impax's commitment not to compete with its generic Opana ER product until January 1, 2013.

Impax claims that Endo knew enough about IPX-203 to commit to a guaranteed $10 million payment because it had promising information about IPX-066, to which IPX-203 (then called only "066a") was intended as a follow-on product. **{** [redacted] **}** (CCF ¶¶ 1157-58). **{** [redacted] **}** (CCRF ¶¶ 390-91, 440). Thus, without knowing specifically what IPX-203 was or how it would improve on IPX-066 (CCRF ¶ 342), Endo had no meaningful way to assess IPX-203's commercial viability as a follow-on.

Second, in reviewing what limited information it had about IPX-203 itself, Endo disregarded its normal diligence procedure, which takes approximately four months, (CCF ¶ 1109), and conducted only three days of cursory diligence to "check the box." (CCF ¶ 299; CCRF ¶¶ 410-11, 414). **{** [redacted] **}**, (CCF ¶ 1159), so it instead used data and commercial estimates from IPX-066—a different product. (CCF ¶¶ 1162, 1203; CCRF ¶¶ 397, 422). **{** [redacted] **}** (CCF ¶¶ 1162-65; CCRF ¶¶ 326, 399). Indeed, as Complaint Counsel's expert Dr. John Geltosky noted, Endo's diligence was so rushed it **{** [redacted]

[redacted] (CCF ¶ 1160). [redacted] (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. [redacted] (CCRF ¶¶ 427, 433). [redacted] 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").

[redacted] (CCF ¶¶ 1211-16).[12] Yet

[12] Mark Bradley, who conducted the financial analysis, testified that he took no steps to account for any risks related to IPX-203's development or commercial success. (CCF ¶ 1213). [redacted]

Impax's own witnesses acknowledged that the probability of the product being approved at all was "fairly low." (CCF ¶ 295). {[redacted]}[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* it was paying, it did not know what it was paying *for*. (CCRF ¶¶ 390-91, 440). And Impax does not explain why Endo would be willing to guarantee so much money upfront for a highly risky product rather than condition that money on successful progress in development, as is standard industry practice. (CCF ¶¶ 1223-28). Indeed, the only risk Endo plausibly mitigated through the DCA was the risk of competition. *See Actavis*, 133 S. Ct. at 2236. In fact, a high-level internal Endo document makes clear that the benefit to Endo from the DCA was that it "add[ed] significant topline revenue for Opana"—a result that had nothing to do with IPX-203 and everything to do with Impax's agreement not to compete until 2013. (CCF ¶ 1084).

[redacted] (CCF ¶¶ 1213, 1215).

[13] {[redacted]} (CCF ¶¶ 1208-09; *see also* CCF ¶¶ 1206-10).

Finally, Impax suggests that the DCA was fair value for Endo's $10 million payment because—over seven years after the DCA was signed—IPX-203 "continues to show tremendous promise." Impax Br. at 45. But Impax neglects to mention that **{** **}** (CCF ¶ 1261; CCRF ¶¶ 356, 481-83, 489). **{** **}** (CCRF ¶¶ 479-81). {**}** (CCF ¶ 1261; CCRF ¶¶ 356, 481-83, 489). **{** **}** (CCF ¶¶ 1256-63). Indeed, outside the context of the patent settlement, Endo consistently demonstrated that it was not actually interested in Impax's Parkinson's disease drugs. (CCF ¶¶ 1086-89 (Endo was not actively looking for Parkinson's products in 2010.); CCF ¶¶ 1090-92 (In 2008, Endo's development consultant had ruled out IPX-066 as a worthwhile collaboration because the market opportunity was too weak.)).

2. The totality of the evidence shows that Endo's $10 million payment is not justified as compensation for the services Impax provided in the DCA

Complaint Counsel has developed an extensive record rebutting Impax's explanation for the $10 million payment in the DCA. This record includes evidence that the DCA was negotiated as part of the Opana ER patent litigation settlement (CCF ¶¶ 1066-84), that Endo evaluated the DCA on a "condensed" timeline so that it could be finalized in tandem with the settlement (CCF ¶¶ 1125-27), that Endo was willing to enter into the deal only as part of the settlement negotiations, and that Endo's business consultant had previously ruled out Impax's carbidopa/levodopa products as worthwhile stand-alone investments. (CCF ¶¶ 1090-92). The

record also shows that Endo offered the same $10 million upfront payment despite a significant change in the product under discussion (CCF ¶¶ 232-39, 1082-83), even though it had never previously made any upfront payment for a pre-clinical product like IPX-203. (CCF ¶¶ 1133). And the evidence shows that many aspects of the DCA, including its negotiation, due diligence, strategic fit, and payment terms were not consistent with Endo's, or the industry's, usual business practices. (CCF ¶¶ 1085-1255).

Impax claims that the Court should disregard this overwhelming evidence because Complaint Counsel's expert in pharmaceutical business development, Dr. John Geltosky, did not conduct an after-the-fact valuation of the DCA. Impax Br. at 46.[14] In fact, Impax makes the remarkable assertion that the testimony of Dr. Geltosky, an expert with more than 35 years of experience in the pharmaceutical industry who has seen thousands of pharmaceutical business development opportunities on both the buyer and seller side, is *irrelevant* and should be ignored.[15] Impax's arguments are wrong for three reasons.

First, the law is clear that *Impax*—not Complaint Counsel—has the burden to prove that any payment was justified. *See Actavis*, 133 S. Ct. at 2236-37; *Lamictal*, 791 F.3d at 412 ("Second, the burden shifts to the defendant to show 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." (internal quotation omitted)). Impax would effectively require

[14] Impax also makes the absurd claim that Complaint Counsel's economic expert, Professor Roger Noll, opined that "the DCA should be thrown out of the case." Impax Br. at 49. Professor Noll actually said that, "*if* [Dr. Geltosky] didn't provide a sufficiently well-documented rationale for the conclusion that the payment was unjustified, then you would pull it out of the case." (Noll, Tr. 1582-83). Professor Noll went on to say that "you don't have to estimate the price in order to reach a conclusion about [justification]." (Noll, Tr. 1583).

[15] Impax made no such objection to Dr. Geltosky's unrebutted report or testimony at trial, and for good reason: the argument is frivolous.

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 {[redacted]} (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 ¶¶ 438, 466).

[17] Additionally, one of Endo's lead researchers for the DCA described the DCA as "part of the Impax/Opana deal." (CCRF ¶ 349).

As late as May 2010, Impax was modeling its potential profits for generic oxymorphone ER with and without an AG competitor. (CCF ¶ 413 (citing CX2830 and CX2831 (Impax models from May 2010))). The models consistently concluded that a No-AG provision would be worth at least $23 million to Impax. (CCF ¶¶ 413-14). This evidence is unrebutted.

But Impax was concerned that it might not realize this value from the No-AG agreement. (CCF ¶ 418). Impax feared that if Endo introduced a reformulated version of Opana ER, the market for its generic oxymorphone product might collapse before the proposed January 2013 entry date. (CCF ¶¶ 418-22). To protect against this potential lost value, Impax insisted on the Endo Credit. (CCF ¶¶ 249-50; 429-38). Endo and Impax spent significant time and energy tweaking the Endo Credit formula so that it would provide "an approximation of the profits . . . that Impax would have earned" by selling oxymorphone ER without AG competition. (CCF ¶ 275; *see also* CCF ¶¶ 251-69, 274). And because of the protection it received through the Endo Credit, Impax expected "a reasonable outcome almost no matter what happens." (CCF ¶ 438). Impax either would make tens of millions of dollars in additional sales of oxymorphone ER because it was not facing competition from an Endo AG, or it would receive a comparable amount through a "make good" payment under the Endo Credit. (CCF ¶¶ 438, 466).

Impax attempts to dismiss this uncontroverted evidence on two grounds. First, it claims that Complaint Counsel must calculate a precise "expected value" to account for the uncertain future value of these provisions. Second, it suggests that the No-AG/Endo Credit payment cannot be large unless Complaint Counsel excludes the hypothetical possibility—however remote—that these provisions could result in zero value. Neither is persuasive.

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 three times larger than saved litigation costs. (CCF ¶ 472; CCRF ¶ 643). Because the value of the reverse payment is large in every plausible scenario, there was no need for Professor Noll to undertake the impossible task of trying to calculate a precise, mathematical "expected value" of the payment.

2. The hypothetical possibility that Impax might obtain no value does not show that the payment was not large

Despite the uncontroverted evidence that it expected to realize tens of millions of dollars—and did realize $102 million—from the No-AG and Endo Credit provisions, Impax argues that there was no large payment because, under one theoretical scenario, Impax might have derived no value under either term. Impax Br. at 55. Impax points to a hypothetical possibility, mentioned by a single Impax employee, that Endo could delay the launch of Reformulated Opana ER until late 2012, but then switch the market so quickly that (a) it destroyed the market for Original Opana ER but (b) did not trigger any payment under the Endo Credit. Impax Br. at 52-53. Executing this implausible strategy would have required an enormous amount of precision and luck, and would have required Endo to risk its entire reformulation effort—an effort that Endo forecasted could earn it over $1 billion in additional revenue. (CCRF ¶ 594).

First, Endo would have had to delay its Reformulated Opana ER launch until late in the fourth quarter of 2012 to ensure that total sales for that quarter did not drop below 50% of Opana ER's peak sales—which would have triggered the Endo Credit. (CCF ¶ 474). Next, Endo would

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 evidence, relying instead on two 2012 Endo documents and the speculation of one Impax employee, Ted Smolenski. Impax Br. at 53. None of this supposed evidence, however, supports Impax's "late-switch" argument. Both documents refer to a potential scenario identified in Endo's 2012 budget that "contemplated a targeted [Reformulated Opana ER] launch of Aug[ust] 2012 and full conversion within 2-3 months." (CCRF ¶ 636). There is no hint that Endo selected this launch date to evade the Endo Credit, rather than simply planning to launch at the earliest date Endo then thought was feasible. Indeed, one of the documents noted "significant uncertainties" about the launch and cautions that Endo was "particularly concerned" that 2-3 months might not be enough time to transition patients. (CCRF ¶ 636). Moreover, if Endo launched its reformulated product in August 2012,

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 launches as part of the budgeting effort." (CCRF ¶ 636; Levin, Dep. 131-32).

[20] Impax's economic expert, Dr. Addanki also did not assess the likelihood of the zero payment scenario, saying only that it was "possible." (CCF ¶¶ 476-77).

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 unknown value may nonetheless be valuable. Impax Br. at 55-56. But it contends that "highly uncertain outcomes often carry little to no expected value." *Id.* Impax uses the example of a lottery ticket with a one in 100 million chance of hitting a $100 million jackpot having an expected value of only $1. Impax Br. at 56. Impax's math is right, but its lottery ticket example completely misses the point. It confuses uncertainty about *whether* an agreement will have any value with uncertainty about *what* the precise value will be. Impax's hypothetical lottery ticket is almost certainly worth nothing, but has a remote possibility of being worth $100 million. In that situation, the expected value is low.

Here the opposite is true. The No-AG/Endo Credit provisions were almost certain to be worth $16.5 to $62 million or more (even though the precise value was unknown), but had a very remote possibility of being worth nothing. (CCF ¶¶ 466-91). When an uncertain event will provide large value in virtually any scenario, it is not necessary to calculate the precise expected value to know that the expected value is large. For example, if a scratch-off lottery ticket has a 5% chance of no payment, a 20% chance of $20 million, a 30% chance of $30 million, a 25% chance of $40 million, a 15% chance of $50 million, and a 5% chance of $100 million, the expected value is enormous, even though there is considerable uncertainty about the precise payout.

Thus, even if there had been some small possibility of a zero payment scenario, it would not alter the conclusion that the expected value of the No-AG agreement and Endo Credit was

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 would have to be 92%. (CCF ¶ 488). Impax argues—and Professor Noll acknowledges—that this illustrative example does not represent the full range of possible outcomes. Impax Br. at 57; (*see also* CCRF ¶ 639). But Impax misses the point. Professor Noll is not suggesting that those are the only two outcomes. Other, more complex examples could be constructed to illustrate this point, but they would all demonstrate the same thing: that the probability of zero payment would need to be extremely large for the expected value of the No-AG and Endo Credit to fall below the value of saved litigation costs. (CCRF ¶ 639). As multiple Impax employees observed, the probability of a zero payment scenario was, at best, "unlikely." (CCRF ¶ 632).

Impax's "zero payment" argument begs a more fundamental question: why would Impax, a sophisticated pharmaceutical company, knowingly sign an agreement in which a "super, super important," "dealbreaker" provision had this potentially fatal flaw? The only reasonable conclusion is that it would not. Impax knew what the record plainly demonstrates: Endo would

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).

3. Impax does not explain or justify either provision

Under *Actavis*, "[a]n 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." 133 S. Ct. at 2236. Impax failed to meet its burden to explain either the No-AG agreement or the Endo Credit.

First, Impax makes no attempt to justify the No-AG agreement. It merely notes that the term "appeared in the very first term sheet" and that it "was not subject to any further negotiation." Impax Br. at 61. Neither of these facts "show[s] the lawfulness of that term under the rule of reason." *Actavis*, 133 S. Ct. at 2236. Indeed, they simply reflect that Impax entered the settlement negotiations wanting a No-AG agreement and got one. (CCF ¶¶ 231, 406-08).

Impax also contends that, because the negotiated entry date moved from March 2013 to January 2013 after the No-AG term was introduced, it could not have been "exchanged for an agreement by Impax to delay its entry." Impax Br. at 61-62. This is both logically and factually incorrect. The relevant question is not whether Impax was able to negotiate a slightly earlier entry date and keep the No-AG agreement, but instead whether Impax would have accepted the January 2013 entry date *without* the No-AG agreement. *See Actavis*¸133 S. Ct. at 2235 ("The payment may instead provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market."). Here the evidence directly links the No-AG provision to Impax's

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 settlement with a No-AG provision), 1035, 1046-47 (quoting CX5001 at 34 (¶ 63) (Bazerman Report) ("The branded-to-generic payments provide a bridge to compensate Impax for sacrificing those potential near-term and future profits")); *see also Lamictal*, 791 F.3d at 405 ("[W]hen the parties' settlement includes a no-AG agreement, the generic also presumably agrees to an early entry date that is later than it would have otherwise accepted.").

Second, while Impax purports to explain the Endo Credit as part of a "carrot and stick" to "discourage Endo from transitioning to a reformulated Opana ER product" (Impax Br. at 61), that is not a cognizable justification. It is anticompetitive—not procompetitive—for competitors to reach an agreement that discourages the launch of a new product that consumers might prefer. *See Polygram Holding, Inc. v. FTC*, 416 F.3d 29, 38 (D.C. Cir. 2005) ("A restraint cannot be justified solely on the ground that it increases the profitability of the enterprise that introduces the new product, regardless whether that enterprise is a joint venture or a solo undertaking."); *Chicago Prof'l Sports Ltd. P'ship v. Nat'l Basketball Ass'n*, 754 F. Supp. 1336, 1359 (N.D. Ill. 1991), *aff'd*, 961 F.2d 667 (7th Cir. 1992) ("Maximizing revenues and 'protecting the value' of individual team or NBA contracts are not legitimate justifications by themselves for restraining trade."). Moreover, not a single contemporaneous document supports Impax's "carrot and stick" explanation. (CCF ¶¶ 1055-65). Instead, unrebutted evidence demonstrates that the Endo Credit was designed as a "'make good' payment" to "correct for the loss in the value of the market" for Impax's generic product if Endo introduced a reformulated version of Opana ER. (CCF ¶¶ 254-55, 1059-63); *see also Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 484 (1992)

(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 interfered with the competitive process by preventing the risk of competition from generic oxymorphone ER until January 1, 2013. (CCF ¶ 335). The market power inquiry seeks to determine, in essence, whether Impax's generic entry would have mattered. If Endo did not have market power, Impax's entry would make no difference to consumers; the price of Opana ER already would have been at the competitive level because any attempt by Endo to extract a higher price would have resulted in sales being lost to other LAOs. (CCF ¶ 499). As explained in *In re Aggrenox Antitrust Litig.*, "if 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." 199 F. Supp. 3d 662, 667 (D. Conn. 2016); *see also Craftsmen Limousine, Inc. v. Ford Motor Co.*, 491 F.3d 380, 388 (8th Cir. 2007) (competitor without market power would not be able to "raise price above the competitive level without losing so many sales so rapidly that the price increase is unprofitable and must be rescinded" (quoting William A. Landes & Richard A. Posner, *Market Power in Antitrust Cases*, 94 Harv. L. Rev. 937, 937 (1981))).

The uncontroverted facts, however, show the opposite is true. Both Impax and Endo projected that Impax's generic product would be substantially cheaper than Endo's branded Opana ER and would take substantial sales from Opana ER. (CCF ¶¶ 58, 70, 585-627). And they were right: when Impax launched its generic product in 2013, it came in at a lower price and captured roughly half of oxymorphone ER sales. (CCF ¶ 629-37, 641-42). Competition from

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 competition from generic oxymorphone *mattered* to consumers. It lowered the average price of oxymorphone ER, took substantial sales from branded Opana ER, and saved consumers money. And that is the essence of the market power inquiry under the rule of reason: market power is not an end in itself, "but a surrogate for detrimental effects." *Indiana Fed'n of Dentists*, 476 U.S. 447, 471 (1986) (internal quotations omitted); *see also Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 782 (1999) (Breyer, J., concurring in part) ("classical" market power question is "[d]o the parties have sufficient market power to make a difference?").

Impax asks this Court to ignore these fundamental and undisputed economic facts and conclude that the market was already fully competitive based primarily on anecdotal evidence that Endo viewed Opana ER as competing, to some limited degree, with other LAOs. Doing so would require the Court to ignore the reality that competition from Impax's generic product *did* matter to consumers—and that it only could have mattered if Endo had market power.

A. The relevant market does not include non-oxymorphone LAOs

Impax's market analysis is based on a fundamental error: it equates the antitrust analysis of "reasonable interchangeability" with *functional* interchangeability—the simple fact that consumers can use two products to accomplish the same ends. It is certainly true that products in the same relevant market are functionally interchangeable. But not all functionally interchangeable products are "reasonably interchangeable" in an antitrust sense. *FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1074 (D.D.C. 1997) ("The Supreme Court did not stop after finding a high degree of functional interchangeability between cellophane and other wrapping materials in the *E.I. du Pont de Nemours* case.").

Rather, for antitrust cases, reasonable interchangeability turns on cross elasticity of demand. *Telecor Comm'cns Inc. v. Sw. Bell Tel. Co.*, 305 F.3d 1124, 1131 (10th Cir. 2002) (reasonable interchangeability "may be measured by, and is substantially synonymous with, cross-elasticity"). An antitrust product market must "be drawn narrowly to exclude any other product to which, within reasonable variations in price, only a limited number of buyers will turn; in technical terms, products whose 'cross elasticities of demand' are small." *Times Picayune Pub. Co. v. United States*, 345 U.S. 594, 612 n.31 (1953).[21] Two products should thus be considered to be in same relevant product market only if their cross elasticity is high, meaning that a small increase in the price of one will cause enough consumers to switch to the other product to make the price increase unprofitable. (CCF ¶¶ 516-18; CCRF ¶ 876); *see also Rosefielde v. Falcon Jet Corp.*, 701 F. Supp. 1053, 1067 n.23 (D.N.J. 1988) (product is price elastic if "a slight increase in price . . . will result in a large drop in demand as customers begin to use the substitute product").[22]

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[21] *See also In re Solodyn Antitrust Litig.*, No. 14-md-02503, 2018 WL 563144, at *6 (D. Mass. Jan. 25, 2018) ("Even if Solodyn were functionally interchangeable with other branded products, however, circumstantial evidence of market definition also requires a showing of economic interchangeability with these therapeutic alternatives. Demonstrating economic interchangeability requires analysis of Solodyn's cross-price elasticity of demand with respect to products allegedly in the same market." (internal citations omitted)); ABA Model Jury Instructions in Civil Antitrust Cases (2016), A-108 n.2 ("In assessing whether products are within the relevant market, the jury must consider not only whether the products are functionally similar but also whether the products are economically interchangeable. Thus, there must be cross-price elasticity of demand.").

[22] *See also Twin City Sportservice, Inc. v. Charles O. Finley & Co.*, 512 F.2d 1264, 1271 (9th Cir. 1975) ("[W]here there is a high degree of substitutability in the use of two commodities, it may be said that the cross-elasticity of demand between them is relatively high, and therefore the two should be considered in the same market."); *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 437-38 (3d Cir. 1997) ("Products in a relevant market are characterized by a cross-elasticity of demand, in other words, the rise in the price of a good within a relevant product market would tend to create a greater demand for other like goods in the market." (internal quotations omitted)).

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. *See e.g., In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 327 (D.R.I. 2017) ("Products are not reasonably interchangeable merely because they share similar forms or functions, but rather 'such limits are drawn according to the cross-elasticity of demand for the product in question—the extent to which purchasers will accept substitute products in instances of price fluctuation and other changes.'" (quoting *In re Nexium*, 968 F. Supp. 2d 367, 387-88 (D. Mass. 2013))); *United Food & Comm. Workers Local 1776 v. Teikoku Pharma USA*, No. 14-MD-02521-WHO, 2017 WL 5068533, at *19 (N.D. Cal. Nov. 3, 2017) ("*Lidoderm*") ("Consistent with the bulk of the case law, something *more* than therapeutic equivalency is required to define the relevant antitrust product market. There must be some showing of cross-elasticity.").[23]

In this case, only Professor Noll answered the cross elasticity question. He examined what happened to the price and sales volume of Opana ER when lower-priced, generic versions of non-oxymorphone LAOs were introduced. He found that the entry of non-oxymorphone generic LAOs did not materially affect Opana ER sales, demonstrating low cross elasticity between oxymorphone ER and those other opioid molecules. (CCF ¶¶ 898-99, 903; CCRF ¶¶ 982-84). Similarly, sales of non-oxymorphone LAOs were not materially affected by the introduction of lower-cost generic oxymorphone ER. (CCF ¶¶ 982-84, 903). By contrast, the introduction of generic oxymorphone ER had a significant effect on the sales volume of branded

[23] *See also, U.S. Anchor Mfg., Inc. v. Rule Indus., Inc.*, 7 F.3d 986, 996 (11th Cir. 1993) (excluding functionally similar products where there was insufficient evidence of cross elasticity); *Archer-Daniels-Midland Co.*, 866 F.2d at 248 (functionally interchangeable sweeteners in separate markets because "a small change in the price of [one] would have little or no effect on demand for [the other]").

Opana ER, indicating high cross elasticity. (CCF ¶ 900). Professor Noll's analysis demonstrates that—contrary to Impax's arguments—the relevant market includes LAOs based on the oxymorphone molecule, both branded and generic (which show a high cross elasticity of demand with one another), but does not include non-oxymorphone LAOs (which show little cross elasticity with oxymorphone products). Impax's economic expert did not examine cross elasticity. (CCF ¶ 902).

1. Impax's market definition fails to account for the commercial realities of generic competition

Impax acknowledges that "market definition must take into account the realities of competition"—particularly in the pharmaceutical industry. Impax Br. at 63 (quoting *1-800 Contacts*, at 24). But Impax ignores the single most important commercial reality of pharmaceutical competition: the elaborate regulatory system "designed to speed the introduction of low-cost generic drugs to market." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012). This regulatory scheme was created "because the pharmaceutical market is not a well-functioning market." *New York ex rel. Schnedierman v. Actavis PLC*, 787 F.3d 638, 645 (2d Cir. 2015) ("*Namenda*"). Unlike most markets, "the party who selects the drug (the doctor) does not fully bear its costs, which creates a price disconnect." *Id.* at 646. In other words, as Impax states, "the consumer, the decision maker, and the payer of most of the costs are all disjointed." Impax Br. at 64 (quoting Addanki, Tr. 2215).[24]

[24] Given this undisputed reality of the prescription pharmaceutical industry, Impax's attempt to draw an analogy between prescription long-acting opioids and over-the-counter painkillers is unavailing. Impax Br. at 73. For over-the-counter medication, the patient typically selects the medication and pays the full cost, and therefore has an incentive to take relative prices into account. In contrast, LAOs are tightly regulated controlled substances, and are dispensed by prescription only. (CCRF ¶ 967; CCF ¶ 561-63). Physicians do not pay for prescription drugs, and therefore have little incentive to take relative prices of drugs into account when prescribing

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 sensitive to price—to easily substitute a cheaper generic drug for the brand version without involving the doctor. *Id.* at 646.

Because of this regulatory structure, generic drugs are uniquely close competitors to their branded counterparts. *See* CC Br. at 50-51 (collecting cases). As Impax witnesses explained, automatic substitution of a generic drug for the brand is the primary way generic manufacturers make their sales. (CCF ¶ 418). Given these commercial realities, the unique competitive role of generics "cannot be seriously debated." *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, n.27 (11th Cir. 2003). Indeed, Impax concedes that it "would not be surprising" if an AB-rated generic was "more successful than other generic LAOs in stealing share from Endo's Opana ER." Impax Br. at 96-97.

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them. (CCRF ¶ 967). As a result, pharmaceutical companies devote substantial resources to differentiating branded drugs based on therapeutic benefits, not price—thereby *decreasing* the intensity of price competition between branded products. This does not occur for over-the-counter medication. (CCRF ¶ 967).

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 a market definition that includes them." *Solodyn*, 2018 WL 563144, at *8; *see also Lidoderm*, 2017 WL 5068533, at *16-17 (rejecting the

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 conditions." Impax Br. at 69-70. This argument misses the mark both as a legal and factual matter. (CCRF ¶¶ 925, 988). First, it simply answers the wrong legal question. Even if all LAOs can be used to treat chronic pain (Impax Br. at 75), that is only a starting point for the market definition inquiry. "For every product, substitutes exist." *Times-Picayune Pub. Co.*, 345 U.S. at 612 n.31. But that does not mean all possible substitutes are part of the same relevant antitrust market. Rather, "[t]he circle must be drawn narrowly to exclude any other product to which, within reasonable variations in price, only a limited number of buyers will turn." *Id.*[25] Indeed, because the proper market analysis turns on cross elasticity, courts have repeatedly found

[25] *See also, e.g.*, *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 327 (D.R.I. 2017) ("Products are not reasonably interchangeable merely because they share similar forms or functions, but rather '[s]uch limits are drawn according to the cross-elasticity of demand for the product in question—the extent to which purchasers will accept substitute products in instances of price fluctuation and other changes.'") (quoting *Nexium*, 968 F. Supp. 2d at 387-88); *U.S. Anchor Mfg., Inc. v. Rule Indus.*, 7 F.3d 986, 996 (11th Cir. 1993) (excluding branded anchors that were "functionally interchangeable with their equivalent counterparts among the generic brands" because there was "no support for finding significant cross-elasticity" between the products); *Archer-Daniels-Midland Co.*, 866 F.2d at 246; *FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1074, 1080 (D.D.C. 1997) (despite fact that consumable office supplies were "identical whether they are sold by Staples or Office Depot or another seller of office supplies" and therefore had "perfect 'functional interchangeability,'" consumable products sold by office superstores were in a different relevant antitrust market because of low cross elasticity with the same products sold by other types of stores); *Solodyn*, 2018 WL 563144, at *5-6 ("Even if Solodyn were functionally interchangeable with other branded products, however, circumstantial evidence of market definition also requires a showing of economic interchangeability with these therapeutic alternatives.").

pharmaceutical products to be in separate markets even when they were functionally interchangeable to treat the same conditions.[26]

Second, as a factual matter, Impax significantly overstates the interchangeability of Opana ER and other LAOs. Impax cites an analysis by its economic expert, Dr. Addanki, which purportedly shows that all LAOs "are used to a greater or lesser extent for dozens upon dozens of diagnoses." Impax Br. at 70-71. But when analyzed correctly, the data actually show that certain LAOs are much more likely to be prescribed for certain conditions, and, conversely, many LAOs are not prescribed at all for certain conditions. (CCF ¶¶ 921-26).[27] Thus, contrary to Impax's conclusion, Dr. Addanki's analysis indicates that LAOs based on different molecules are *not* used interchangeably to treat any chronic pain condition.

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[26] *See Lidoderm*, 2017 WL 5068533, at *17-21 (concluding as matter of law that the relevant market excluded other functionally interchangeable drug products where there was "no significant cross-elasticity of demand" between them); *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1064 (3d Cir. 1978) (finding that cephalosporin antibiotics did not demonstrate "significant positive cross-elasticity of demand" with other antibiotics and were therefore in a separate relevant market despite "a certain degree of interchangeability among all antibiotics"); *Nexium*, 968 F. Supp. 2d at 388 (noting that Nexium would need to have significant positive cross elasticity of demand with other drugs to be considered part of the same relevant market); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1319 n.40 (S.D. Fla. 2005) (market limited to branded and generic terazosin hydrochloride, excluding other hypertension drugs); *In re Ciprofloxacin Hydrocholoride Antitrust Litig.*, 363 F. Supp. 2d 514, 523 (E.D.N.Y. 2005) (market limited to ciprofloxacin, excluding other antibiotics in same family); *see also FTC v. Lundbeck, Inc.*, 650 F.3d 1236, 1240-43 (8th Cir. 2011) (affirming that the only two drugs indicated for treating a serious birth defect were in separate product markets).

[27] For example, oxycodone is prescribed 90 percent of the time for pain from rotator cuff problems. The other five LAOs included in Exhibit 4 are hardly ever used to treat pain from rotator cuff problems. These other LAOs, therefore, are unlikely to be close substitutes of oxycodone for patients with rotator cuff problems. Moreover, for 81 of the diagnoses, at least one LAO was not used at all. For 39 diagnoses, oxymorphone ER was not used at all. If a drug is not prescribed for a condition, it cannot be a close substitute for a drug that is prescribed for that condition. Thus, Exhibit 4 *undercuts* Dr. Addanki's analysis. (CCRF ¶ 720).

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 most other opioids." (CCF ¶ 726). Both medical experts agree that there are differences among long-acting opioids, and that it is important for prescribers to be aware of these differences. (CCF ¶ 504-10, 746-49, 759-60; CCRF ¶¶ 918, 960, 1000). And it is undisputed that different patients can respond differently to different opioid molecules in terms of effectiveness and side effects. (CCF ¶ 507). For this reason, opioid treatment requires trial and error to find the best molecule for a specific patient. (CCF ¶ 509; CCRF ¶ 931). The medical expert testimony makes clear that these clinical considerations—not small price changes—drive prescribing patterns. Indeed, Impax's medical expert testified that he would not generally even be *aware* of an LAO price change unless it was dramatic. (CCF ¶ 565; CCRF ¶¶ 892, 894).

Moreover, once a patient finds a clinically appropriate LAO, there are significant costs to switching between opioid molecules because the process must be supervised by a medical doctor. (CCF ¶ 663-64, 752-54; CCRF ¶¶ 986-87). Both medical experts agreed that safety and clinical concerns trumped price, and that a small price change would not lead them to switch between LAO molecules. (CCF ¶ 660, 665-67). By contrast, switching a patient from an LAO

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). As Impax notes, "many physicians employ 'opioid rotation therapy,' whereby the physician rotates a patient among different LAOs *to avoid tolerance to any medication and to maintain pain relief at lower doses*." Impax Br. at 72 (emphasis added). There is no evidence that doctors use opioid rotation therapy to react to small but significant price increases.

All of this is consistent with Endo's views. In 2012, faced with a recall by its Opana ER manufacturer, Endo reminded the FDA that switching patients from Opana ER to other opioids was difficult and must be carefully managed by medical professionals. (CCF ¶¶ 734-35). Endo even advised doctors to *stop* prescribing Opana ER to new patients while it faced the supply disruption because there would be "no therapeutically equivalent or pharmaceutically alternative substitute product available" to turn to once supply ran out. (CCF ¶ 736).

In all, the available evidence points to a very different conclusion about interchangeability than the one Impax draws: because of the clinical differences between oxymorphone and other opioid molecules, there is considerable economic substitution among oxymorphone ER products, but very little economic substitution between oxymorphone ER products and LAOs based on different molecules. (CCRF ¶¶ 982-84, 996). Indeed, when Impax's generic oxymorphone ER entered the market, it took nearly half of Reformulated Opana ER's sales—the only other oxymorphone LAO on the market. (CCF ¶ 629-37). But it had no discernible impact on the sales of non-oxymorphone LAOs. (CCF ¶¶ 673, 684, 694, 700, 706,

710, 715). This substitution pattern occurred even though Impax's generic oxymorphone ER was not AB-rated to Endo's Reformulated Opana ER and therefore could not be automatically substituted at the pharmacy. (CCF ¶ 579). If oxymorphone ER were reasonably interchangeable with non-oxymorphone LAOs, Impax's cheaper product should have taken sales from them as well.[28] (CCF ¶ 672, 684; CCRF ¶ 798). The fact that it did not speaks volumes.

3. Impax's purported evidence of LAO competition does not establish cross elasticity of demand

Impax provides what it claims are examples of economic competition between Opana ER and other LAOs. But none of these examples actually demonstrate reasonable interchangeability: they do not show that consumers switched between Opana ER and other, non-oxymorphone LAOs in response to small but significant price differences. (CCRF ¶¶ 836, 839, 862, 892, 894-95, 899). Instead, they show that Endo consistently emphasized that Opana ER had unique properties that limited its interchangeability with other LAOs, and offered discounts to encourage payers, patients, and prescribers to increase their volume of Opana ER. (CCRF ¶¶ 878, 882-83, 939, 967). These facts are all consistent with market power. (CCF ¶¶ 564-66, 661-67).

a) Endo's marketing materials are focused on product differentiation rather than price competition

Citing selected business documents from Endo and other branded LAO manufacturers, Impax contends that "LAO manufacturers viewed LAOs as competing in a single market."

[28] Correspondingly, Endo's documents show that it was not worried about cheaper generic versions of other LAO molecules. For example, in June 2009, Endo determined that the entry of generic OxyContin would have no effect on its marketing strategy for Opana ER. (CCF ¶ 718; CCRF ¶ 882). Endo's Opana ER brand manager explained that view: "Our molecule was still a better fit for different types of patients. Whether there's generic OxyContin or not didn't necessarily change that dynamic." (CCF ¶ 718).

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

have to try to negotiate by significantly increas[ing] the rebates it has presently." (CCRF ¶ 1004; CCF ¶¶ 610, 939). No other LAO would have this type of competitive effect. *See Solodyn*, 2018 WL 563144, at *8 (evidence that brand's forecasts only projected generic versions of the same product, and not other brand products, "as likely to lower [] prices and capture branded sales" supports finding that the market is limited to brand and generic equivalents).

Impax also points to Endo's internal business documents, but those documents rarely mention the relative price of other LAOs. (CCF ¶¶ 721, 733, 737-39; CCRF ¶¶ 878, 882-83). Instead, those documents make clear that Endo's primary marketing goal was to *differentiate* Opana ER from other LAOs so that it did not have to compete with them on price. (CCF ¶¶ 722-32, 941; CCRF ¶¶ 878, 882-83). Endo repeatedly emphasized "why [Opana ER] is different and why it would be needed by certain patient types." (CCF ¶ 728; CCRF ¶ 960; *see also* CCF ¶¶ 726, 729-32, 769-70; CCRF ¶ 999).

This type of product differentiation is not price competition. To the contrary, it increases brand loyalty and makes it *less* likely that consumers will switch brands in response to small price changes. *See Solodyn*, 2018 WL 563144, at *8 (documents and marketing plans describing brand drug product as "having 'unique pharmacokinetics" and "emphasiz[ing] the therapeutic differences [the brand product] provided, or its 'clinical efficacy,' rather than benefits [the brand] offered on a price dimension" support a finding that market did not include other branded products); *see also* Lawrence A. Sullivan, et al., The Law of Antitrust: An Integrated Handbook 69 (3d ed. 2015) (noting that product differentiation is an entry barrier that can contribute to market power); *FTC v. Tenneco, Inc.*, 433 F. Supp. 105, 111 (D.D.C. 1977) (same); (CCF ¶¶ 940-42). As a result, product differentiation *contributes* to market power; it does not eradicate it. (*See* CCF ¶¶ 822, 852, 941).

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 ¶ 1004). But Dr. Addanki excluded generic drugs from his analysis. (CCRF ¶ 996; CCF ¶¶ 946-47). When asked why, he explained "I know what's going to happen[,] [g]enerics are going to be on tier one uniformly or virtually uniformly." (CCF ¶ 946). But that makes it *more* important, not less, to consider the effect of generics on competition for formulary placement. *See supra* Part III.A.1. Even if there were limited competition between Opana ER and other branded LAO products for formulary placement, as Dr. Addanki acknowledges, competition from generic oxymorphone ER would be much more intense. Thus, even if Dr. Addanki's formulary analysis shed any light on the level of competition between Opana ER and other LAOs, it would be highly misleading because excluding generics—the most effective competitors—would yield a distorted picture. (CCF ¶ 947).[29]

Impax also provides anecdotal evidence that Endo offered rebates to secure formulary placement, but that is neither unusual nor inconsistent with market power. As the *Lidoderm* court explained, "

> [E]vidence that physicians and MCOs were concerned about the 'high' price of Lidoderm and prescribed more or made more available where prices were lower or significant rebates were provided does not mean that the *other* products on the market . . . constrained the price of Lidoderm. It simply shows that, in order to grow the market for what defendants repeatedly characterize as a unique product, price concessions and rebates for Lidoderm were necessary.

[29] Dr. Addanki's analysis is also flawed for a further reason: he included three drugs with the *same* opioid molecule, morphine, as an active ingredient. Because these three drugs shared the same molecule, they were much more likely to have similar characteristics and be good substitutes for one another than to Opana ER. Dr. Addanki's analysis therefore overstates the overall degree of competition among LAOs. (CCF ¶ 948).

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 almost all commodities, and to raise the price enough is to evoke them."). Thus, even if Impax had provided some evidence that patients switched as the result of a 100% price change (which it has not), that would not demonstrate cross elasticity of demand.

d) Impax offers no evidence of cross elasticity at the prescriber level

Impax contends that evidence of marketing to doctors establishes relevant competition. But again Impax is referring not to price competition, but to product promotion, which emphasizes the clinical distinctions between Opana ER and other LAOs. (CCRF ¶¶ 878-99). Endo spent considerable resources to tell doctors that they should not substitute non-oxymorphone LAOs for Opana ER. (CCF ¶¶ 726-35, 761, 769, 781-83, 790). This type of product differentiation tends to undermine price competition by emphasizing non-price factors. *See supra* Part III.A.3(a). Perhaps recognizing this, Impax asserts only that there is "a relationship" between Endo's promotional efforts and price competition because, as part of its promotional efforts, Endo informed physicians about formulary placement. Impax Br. at 89-90. But telling doctors about the result of formulary placement—even if that placement resulted from price competition—is not itself price competition. And Impax's arguments about formulary placement fail for all the reasons discussed above. Indeed, reliance on formularies at the

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.*

agreed that it was not possible to calculate cross elasticity of demand precisely with the available data. (CCF ¶ 655; CCRF ¶ 982). And, as one of the leading antitrust scholars has explained, the kind of detailed econometric calculations Impax insists on are only necessary "when patterns are not obvious." Areeda and Hovenkamp, Antitrust Law, ¶ 562b (updated Sept. 2017); *see also In the Matter of McWane, Inc.*, No. 9351, 2014 WL 556261, at *15 (FTC Jan. 30, 2014), aff'd, 783 F.3d 814, 829-30 (11th Cir. 2015) ("Econometric analysis can be a valuable tool for defining a market, but it is only one of several that may be used for that purpose."); ABA Section of Antitrust Law, *Mergers and Acquisitions* at 55 (3d Ed. 2008) ("In a world of imperfect price and quantity data from which to analyze elasticities, qualitative evidence of a buyer's willingness to substitute one good or service for another often provides the principal evidence of the boundaries of a relevant market.").

In this case, Professor Noll analyzed market events to infer the lack of cross elasticity. (CCF ¶¶ 654-55; CCRF ¶¶ 981-82). He observed that the entry of cheaper generic oxymorphone took substantial sales from Opana ER, but had little to no effect on the sales or price of other branded LAOs. (CCF ¶¶ 641-43, 684, 694, 700, 706, 710, 715, 906-09; *see also* CCF ¶¶ 585-627). Correspondingly, entry of cheaper generic versions of other LAOs had little to no effect on the sales or price of branded Opana ER. (CCF ¶¶ 670-716). Given this evidence, Professor Noll concluded that there was a high cross elasticity of demand between Opana ER and generic oxymorphone ER, and low cross elasticity between Opana ER and other LAOs. (CCRF ¶¶ 981-82). Dr. Addanki did not address this evidence or conduct any analysis of cross elasticity. (CCF ¶ 902; CCRF ¶ 817). He does not explain how other LAOs can be close economic substitutes for Opana ER when they do not exhibit cross elasticity with it. (CCF ¶ 902; CCRF ¶ 817). Thus, Impax has no basis on which to argue that Professor Noll's analysis or conclusion was erroneous.

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 observed directly because Endo had the ability to exclude competition and to charge a price significantly higher than would be set in a competitive market. (CCF ¶¶ 857-58). Endo was able to exclude other oxymorphone ER products through its patents and litigation settlement agreements. (CCF ¶¶ 859-63). Professor Noll was able to observe that Endo consistently increased the price of Opana ER significantly above the competitive level. (CCF ¶¶ 864-81). **{** [redacted] **}** (CCF ¶¶ 882-96). Impax argues that none of these facts is conclusive of market power. But each of these facts are

indicators of market power. And taken together, they provide strong support to Professor Noll's conclusion that Endo's Opana ER had market power at the time of the settlement. Regardless, "Plaintiffs need not prove or prevail by showing market power by direct evidence if they succeed in doing so by circumstantial evidence," *Solodyn*, 2018 WL 563144, at *12, as Complaint Counsel has done at length.

IV. Impax failed to rebut Complaint Counsel's *prima facie* showing of anticompetitive effects

As discussed above, abundant evidence shows that Impax agreed to a large and unjustified reverse payment to prevent the risk of competition until January 1, 2013. Impax's various attempts to rebut this compelling *prima facie* case share a fundamental flaw: they ignore *Actavis* and underlying rule of reason principles.

A. *Actavis*'s determination of the relevant anticompetitive effect governs this case

Impax's contention that Complaint Counsel failed to prove anticompetitive effects rests on its incorrect premise that the only way to demonstrate an anticompetitive effect is to prove that "Impax would have begun selling Opana ER any earlier in the but-for world." Impax Br. at 103. It asserts that anything less than proof of actual delayed generic entry amounts to a "per se theory" of liability. Impax Br. at 102. But as discussed in Complaint Counsel's opening brief, Impax's "actual delay" argument ignores both (1) the express teaching of *Actavis* that "the relevant anticompetitive harm" from the patent challenger's agreement to stay off the market in exchange for a large payment is that it "prevent[s] the risk of competition," 133 S. Ct. 2236; and (2) standard rule of reason doctrine, which holds that anticompetitive effects can be shown based on the nature of the restraint and the existence of market power. CC Br. at 21-27.

That is precisely what Complaint Counsel has proven here. Complaint Counsel is not asking this Court to "infer anticompetitive effects from the mere presence of a reverse payment."

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.*, 94 F. Supp. 3d 224, 240 (D. Conn. 2015) (plaintiffs "need not plead (or prove) the weakness of the [] patent because the patent's ultimate validity is not at issue"); *United Food & Comm. Workers Local 1776 v. Teikoku Pharma USA*, No. 14-MD-

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 case" scenario); CCF ¶¶ 65, 370 (Endo deemed appellate decision likely in June 2011)).

More importantly, Mr. Figg's speculation about the possible course of the patent litigation confirms that the timing and outcome of the litigation was uncertain and presented a significant risk to Endo. The reverse payment agreement prevented that risk of competition, and therefore caused anticompetitive harm. Contrary to Impax's assertions, the rule of reason does not require a government plaintiff or this Court to "reconstruct the hypothetical marketplace" absent a monopolist's exclusionary conduct. *Microsoft*, 253 F.3d at 79. Antitrust law "does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition." 12 Areeda, ¶ 2030b.

Finally, Impax contends that even if it had prevailed in the original patent suit before January 2013, a different patent (the '482 patent) issued in December 2010 to another pharmaceutical company, Johnson Mathey, "would have blocked Impax's entry." Impax Br. at 109. But this prediction is so attenuated it merited no more than a footnote in Mr. Figg's report. In fact, Impax makes no claim that the '482 patent was ever successfully asserted against any party. While Johnson Mathey notified both Endo and Impax of the '482 patent, it never sued either one for infringement, even though Endo was on the market and earning substantial revenues from its existing oxymorphone product.[35] Nonetheless, Dr. Addanki hypothesizes that, had the litigation continued, Endo would have had an incentive to acquire the '482 patent from Johnson Mathey before it did in March 2012, so that it could have asserted it against Impax to block its entry in 2011. Impax Br. at 109-10. But in this hypothetical marketplace, Impax also

[35] The '482 patent was partially invalidated in 2013 (CCRF ¶ 235) and Endo ultimately stipulated to its invalidity. (CCF ¶¶ 1399, 1401).

would have had different incentives. If it was even concerned about the '482 patent, it might have taken different actions: it might have sought a license from Johnson Mathey; it might have felt a greater urgency to launch its product at risk to realize the benefit of its 180-day exclusivity; or it might have decided to enter into a no-payment settlement with Endo providing a broad patent license that would provide freedom to operate.

In other words, there are many possible scenarios for how events might have played out had the original litigation continued past June 2010. What actually would have happened is highly uncertain and unknowable. But, what is clear is that this uncertain future posed risks to Endo that generic entry might occur before January 2013 and Endo paid Impax to eliminate those risks.

2. There was a significant risk that Impax might launch before final resolution of Endo's patent infringement suit

The record evidence likewise shows that at the time of the reverse-payment agreement there was a risk to Endo that Impax might launch generic Opana ER before final resolution of Endo's patent infringement suit. CC Br. at 45-46. (CCF ¶¶ 127-213). None of Impax's arguments contradict this basic fact.

First, Impax relies on Dr. Addanki's assertion that "it would make complete economic sense for Impax to view a launch at risk as a money losing proposition," given the possibility of damages and loss of the Hatch-Waxman exclusivity period. Impax Br. at 119. But Impax makes no attempt to reconcile Dr. Addanki's opinion with the extensive evidence that Impax was actively considering launching before a final appellate decision. And Dr. Addanki ignores two strong incentives weighing in favor of Impax launching generic Opana ER: First, Impax was worried Endo might destroy Impax's market opportunity by shifting the market to a reformulated product, and wanted to get on the market before that could happen. (CCF ¶¶ 121-26; CCRF ¶

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* ¶ 1207).[36] For example:

- According to the Company's Key Goals, Impax's "financial success" in 2010 would "hinge heavily on [its] success" in oxymorphone, among other key products. (CCF ¶ 127-30; *see also* CCRF ¶ 1209).

- On May 14, 2010, Impax's CEO Larry Hsu told his team that he preferred to "make launch decision based on court decision on the [preliminary injunction motion]."[37] (CCF ¶ 131).

[36] Although Impax's counsel elicited testimony from Mr. Koch at trial that Impax never intended to launch at-risk, that testimony is contradicted by Impax's contemporaneous business documents, the testimony of Impax's CEO, and Mr. Koch's own testimony at this investigational hearing, deposition, and on cross-examination. (CCRF ¶ 1212 (agreeing that oxymorphone ER at-risk launch was under consideration in May 2010); CCRF ¶ 1212 (never reached a decision to proceed or a decision not to proceed with an at-risk launch); CCRF ¶ 1212 (acknowledging that Impax was considering whether to launch Opana ER at risk in 2010)).

[37] Endo moved for a preliminary injunction on May 21, 2010, after learning of Impax's grant of tentative approval. (CCF ¶ 140). After Impax agreed that it would not launch its generic oxymorphone ER product "through and including the last trial day as presently scheduled," the court terminated Endo's motion for a preliminary injunction. (CCRF ¶ 1214).

- 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).

particularly true for a small company, like Impax, with "limited capacity." Indeed, Impax's CEO made clear that Impax's decision to prepare for launch, particularly for a first-to-file product such as oxymorphone ER, takes considerable resources and has a real impact on Impax's ability to manufacture and timely deliver other products. (CCRF ¶ 1263) Thus, Impax executives in charge of production testified that the timing of pre-launch preparations are not necessarily tied to FDA approval, but instead depends on a case-by-case evaluation, and a product's "particular circumstances" and "specifications." (CCRF ¶¶ 1239-41). In particular, Impax considers whether the product is one where it has "first to market" eligibility, as well as the existence of on-going patent litigation. (CCRF ¶ 1239)

In any event, all of Impax's arguments concerning at-risk launch erroneously presuppose that Complaint Counsel must prove Impax *would have* launched at risk in 2010. But Complaint Counsel need only show that there was a real risk of competition from an at-risk launch sometime before 2013. A wealth of evidence shows that there was.

C. Impax failed to show that Endo's payment served to promote its objective to obtain a broad patent license in the SLA

It is well established—and Impax does not dispute—that under the rule of reason, a *prima facie* showing by the plaintiff shifts the burden to the defendant to show that the restraint promoted some legitimate, procompetitive objective. *See, e.g.*, 7 Areeda, ¶ 1504b (after *prima facie* showing of harm, "the burden shifts to the defendant to show that the restraint in fact serves a legitimate objective"). *See also* CC. Br. at 21, 28-30, 60-71. And as the leading antitrust law treatise makes clear: "An allegedly legitimate objective is, of course, entirely immaterial unless it is served by the challenged restraint." 7 Areeda, ¶ 1505a.

Despite this well-established principle, Impax fails to present evidence or even argument to meet that burden. It urges this Court to focus not on the restraint—the payment to stay off the

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 challenged payment. Impax Br. at 130. This argument fails for three reasons.

First, Impax merely repeats its argument that Complaint Counsel (not Impax) must prove that the large payment was unjustified before even proceeding to a rule of reason analysis. By putting the burden on Complaint Counsel to disprove any justifications for the payment, Impax seeks to avoid its obligation to prove that any procompetitive benefits flowed from the payments. No court has ever adopted Impax's argument, and its premise that *Actavis* implicitly created a threshold burden is untenable. *See supra* Part I.A.

Second, Impax contends that it need not justify the payment because the SLA—not the payment—is the "restraint." But, as in *Actavis*, the "specific restraint at issue" here is "payment in return for staying out of the market." 133 S. Ct. at 2234. *See* Complaint ¶ 50 ("Endo agreed to pay Impax to abandon its patent challenge and to refrain from launching its generic version of Opana ER until January 1, 2013."); *see also* Complaint ¶ 2 ("Faced with Impax's threat to its lucrative Opana ER franchise, Endo bought off its potential competitor."); Complaint ¶ 3 ("In June 2010, Endo agreed to pay Impax to abandon its patent challenge and forgo entering the market with its lower-cost generic version of Opana ER for 2½ years, until January 2013."). *Actavis* thus refers to the *payment* as "the challenged term" that "the antitrust defendant" must justify (133 S. Ct. at 2236), because, absent such a payment, an alleged infringer's agreement to

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.

Impax further errs when it relies on the district court decision in *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp.3d 734 (E.D. Pa. 2015), *aff'd on other grounds*, 868 F.3d 132 (3d Cir. 2017). On appeal of that decision, the Third Circuit implicitly rejected the analysis of procompetitive justifications that Impax asserts here, noting that the *payment*—not other terms of the settlement—may be "unjustified in the sense of being unexplained." 868 F.3d at 162. Nor did the Commission's summary disposition opinion endorse or approve the *Wellbutrin* district court's analysis. *See* Impax Br. at 131. The Commission merely noted that the district court had deemed "the context of the broader settlement agreement" to be relevant to the assessment of procompetitive justifications. Comm. Summary Disposition Op. 12-13. In fact, the Commission filed an amicus brief in the Third Circuit in 2016 explaining that the *Wellbutrin* district court committed multiple fundamental legal errors in its rule-of reason-analysis, including (1) failing to require the defendants to prove that the reverse payment, rather than certain other aspects of the settlement agreement, promoted the asserted procompetitive benefits, and (2) assuming that a

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2014) (reading together separate written agreements executed the same day in assessing whether plaintiffs plausibly alleged the existence of a reverse payment).

generic's refusal to settle without a large payment to stay off the market could demonstrate that the payment was reasonably necessary to achieving those benefits.[40]

E. Complaint Counsel has identified an equally effective, less restrictive alternative

If a defendant succeeds in showing that the challenged restraint serves to promote a legitimate objective, then—and only then—the rule of reason inquiry moves to the third step of the burden-shifting framework: consideration of less restrictive alternatives. Impax's argument that Complaint Counsel did not demonstrate such an alternative fails for three reasons.

First, Complaint Counsel does not need to demonstrate any less restrictive alternative because Impax failed to prove that the large reverse payment it received from Endo promoted any legitimate procompetitive objective. *See* CC Br. at 60-71; *see also supra* Part IV.C & D.

Second, Complaint Counsel has repeatedly identified a specific less restrictive way to achieve the same asserted procompetitive benefits: settling with Endo without the large payment to stay off the market. This alternative is both obvious and substantially less restrictive; it eliminates the harm to the competitive process that underlies the antitrust concern with large reverse payments. *See, e.g.*, *Actavis,* 133 S. Ct. at 2236 (describing "concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of non-infringement"). Indeed, the Supreme Court expressly identified this less restrictive alternative:

> [T]he fact that a large, unjustified payment risks antitrust liability does not prevent litigating parties from settling their lawsuit. They may, as in other industries, settle in other ways, for example by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, *without the patentee paying the challenger to stay out* prior to that point."

Id. at 2237 (emphasis added).

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[40] Brief of Federal Trade Commission as Amicus Curiae in Support of No Party at 23-25, *In re Wellbutrin XL Antitrust Litig.*, Nos. 15-3559, 15-3591, 15-3681 & 15-3652 (3d Cir. Mar. 11, 2016).

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 whether Endo would have been willing to accept an entry date earlier than January 2013 without the payments. (CCF ¶ 1017-18).

Moreover, "it is not surprising that no evidence shows that defendants were contemplating anything other than the actual [s]ettlement." *Lidoderm*, 2017 WL 5068533 at *38. Requiring evidence of a specific no-payment settlement would be an "impossible standard" to meet, *Solodyn*, 2018 WL 563144 at *21, when, as here, a large payment in the form of a No-AG provision was part of the settlement from the beginning. (CCF ¶¶ 228, 230-31). But common sense dictates that, rather than including a reverse payment that resulted in a $102 million payment, Endo might have agreed to an earlier date if it need not make that payment. (CCF ¶ 1441); *see also supra* Part I.C.1. And the evidence undeniably shows that Endo was willing to trade money for its preferred 2013 entry date. Each time Impax sought an earlier entry date, Endo responded with additional compensation. For example, Impax sought an acceleration trigger that would move up Impax's entry date prior to 2013 if branded Opana ER sales dropped below a certain level. (CCF ¶¶ 251-52). Endo rejected the accelerated entry, but agreed to sweeten the pot with the Endo Credit, which would pay Impax rather than face earlier entry through an acceleration provision. (CCF ¶¶ 1051-52). Then Impax suggested a "simple settlement" which would drop the compensation terms (No-AG provision, Endo Credit and side

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

any remedy in such cases makes no sense. And it would render the general principle of retroactivity of Supreme Court decisions, and the remand in *Actavis* itself, meaningless.[41]

Second, Impax argues that Complaint Counsel's proposed relief is overly broad and would bar procompetitive arrangements, such as settlements containing a broad patent license. Impax Br. at 137. But the proposed order does not bar all transfers of value from the branded drug manufacturer to the generic patent challenger. As explained in Complaint Counsel's opening brief, the proposed order expressly carves out various types of value transfers from the scope of the general prohibition of reverse-payment agreements, including the right to market the ANDA product. CC Br. at 73-74. Thus, covenants not to sue and licenses to future patents that allow the marketing of a generic product, such as the patent license Impax received in the SLA, would not constitute a "payment" for purposes of the order. See Proposed Order, I.W.2 and 3 (Definition of "Payment by the NDA Holder to the Generic Filer").

The definition of "payment" also carves out payments representing avoided litigation costs up to $7 million and independent business transactions entered outside of a 45-day window before and after settlement. *See* Proposed Order, I.W, I.W.1. These exceptions address the two types of justifications that *Actavis* identified. Impax's objection that the order would bar certain payments that might be justified under *Actavis* is merely a complaint that the order contains "fencing-in" relief designed to prevent recurrence of unlawful conduct. But it is well-established that the Commission may bar certain conduct that would be permitted if engaged in by someone

[41] A case is moot if it is impossible for a court to grant any effectual relief whatever to the prevailing party. *See, e.g., Chafin v. Chafin*, 133 S. Ct. 1017, 1023 (2013); *Knox v. Serv. Emps. In'tl Union, Local 100*, 132 S. Ct. 2277, 2287 (2012).

not found to have violated the law. CC Br. at 71-72. The fencing-in relief here is reasonably related to the violation found, and thus entirely proper.[42]

With respect to the August 2017 agreement ("2017 Agreement") between Impax and Endo, Intervenor Endo has raised a distinct concern: that proposed relief against Impax pertaining to the oxymorphone ER market might deprive Endo of contractual rights under that agreement. As a result, Complaint Counsel is submitting along with this brief a revised proposed order, to avoid any impact on Endo's rights. The revised proposed order, which appears at Appendix 1, modifies Paragraphs II.B. and II.C.:[43]

***Modified Paragraph II.B*:** Paragraph II.B would bar Impax from "entering any agreement that prevents, restricts, or in any way disincentivizes competition between Oxymorphone ER products." As modified, this provision restricts Impax's ability to enter into *future* agreements involving extended-release oxymorphone that threaten competition in that market. Revised Proposed Order, II.B. This revised provision would not deprive Endo of any rights granted under an existing agreement with Impax, such as the agreement Endo and Impax entered in August 2017 to amend the 2010 SLA.

[42] *See, e.g., Nat'l Lead Co.*, 352 U.S. at 428 (a remedy is proper as long as it has a "reasonable relation to the unlawful practices found to exist."); *FTC v Ruberoid Co.*, 343 U.S. 470, 473 (1952) ("to attain the objectives Congress envisioned," the Commission "must be allowed effectively to close all roads to the prohibited goal, so that its order may not be by-passed with impunity"); *In re Toys "R" Us, Inc.*, 126 F.T.C. 695, 697 (1998) (fencing-in remedy may reasonably "include such additional provisions as are necessary to preclude the revival of the illegal practices" (internal quotations omitted)); *Rubbermaid, Inc., v. FTC*, 575 F.2d 1169, 1172 (6th Cir. 1978) ("The Commission may be properly concerned not only with the open and formal implementation of agreements exactly like those entered in the past, but also with the possibility that past unlawful conduct will be perpetuated in some more subtle form in the future.").

[43] We have also included as Appendix 2 a redline comparing the revised proposed order with Complaint Counsel's initial proposed order.

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,

{[redacted]} 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 the revival of the illegal practices." *In re Toys "R" Us, Inc.*, 126 F.T.C. 695, 697 (1998) (internal quotations omitted). The order in *Toys "R" Us* barred the company from certain refusals to deal that would ordinarily be permissible unilateral conduct. *Toys "R" Us, Inc. v. FTC*, 221 F.3d 928, 939 (7th Cir. 2000). The Seventh Circuit affirmed the provision, holding that "[t]hese refusals to deal were the means TRU used to accomplish the unlawful result, and as such they are subject to regulation by the Commission." *Id.* at 940. Impax's 2017 agreement with Endo is likewise a revival of the same means the parties used in 2010 to accomplish the violation here: the sharing of monopoly profits to prevent the risk

[44] Complaint Counsel does not object to providing Endo and Impax with an opportunity to respond to these modifications, should the Court wish to do so.

of competition. Thus, the prohibition in Paragraph II.C is appropriate fencing-in relief regardless of whether the 2017 agreement constitutes an independent antitrust violation.

Finally, Impax objects to the order provisions requiring Impax to establish an internal compliance program, file compliance reports and make records available. Impax Br. at 138-40 As we have noted, such provisions are standard in Commission orders. CC Br. at 77.

In sum, the proposed order's provisions are reasonably tailored to the violation that occurred and appropriate to prevent a recurrent violation. Indeed, Impax offers nothing to undermine the conclusion that, absent the proposed relief, **{** [redacted] **}** (CCF ¶¶ 1460-84). Indeed, Impax's current CEO has made clear his intention to "always" seek a No-AG provision in any litigation settlement. (CCF ¶¶ 1481-84). The proposed relief is necessary to prevent such anticompetitive behavior in the future.

Respectfully submitted,

Dated: February 14, 2018

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Counsel Supporting the Complaint

Appendix 1

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

	)	PUBLIC
In the Matter of	)	
	)	Docket No. 9373
Impax Laboratories, Inc.,	)	
a corporation.	)	

[PROPOSED] ORDER

I. Definitions

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

A. "Commission" means the United States Federal Trade Commission.

B. "Impax" or "Respondent" means Impax Laboratories, Inc., its directors, officers, employees, agents, representatives, successors (including any combination of Impax Laboratories, Inc. and Amneal Pharmaceuticals LLC), and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Impax Pharmaceuticals, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

C. "505(b)(2) Application" means an application filed with the United States Food and Drug Administration pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b)(2).

D. "ANDA" means an Abbreviated New Drug Application filed with the United States Food and Drug Administration pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j).

E. "Authorized Generic" means a Drug Product that is manufactured pursuant to an NDA and Marketed in the United States under a name other than the proprietary name identified in the NDA.

F. "Brand/Generic Settlement" means any agreement or understanding that settles a Patent Infringement Claim in or affecting Commerce in the United States.

G. "Brand/Generic Settlement Agreement" means a written agreement that settles a Patent Infringement Claim in or affecting Commerce in the United States.

H. "Branded Subject Drug Product" means a Subject Drug Product marketed, sold, or distributed in the United States under the proprietary name identified in the NDA for the Subject Drug Product.

I. "Commerce" has the same definition as it has in 15 U.S.C. § 44.

J. "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.

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. Patents held by, or licensed to, an NDA Holder.

W. "Payment by the NDA Holder to the Generic Filer" means a transfer of value by the NDA Holder to the Generic Filer (including, but not limited to, a No-AG Commitment, money, goods, or services), regardless of whether the Generic Filer purportedly transfers value in return, where such transfer is either (i) expressly contingent on entering a Brand/Generic Settlement Agreement, or (ii) agreed to during the 90 days period starting 45 days before executing a Brand/Generic Settlement Agreement and ending 45 days after executing a Brand/Generic Settlement Agreement. The following, however, are not Payment by the NDA Holder to the Generic Filer:

1. compensation for the NDA Holder's saved future litigation expenses, but only if the total compensation the NDA Holder agrees to provide to the Generic Filer during the 90 day period starting 45 days before and ending 45 days after executing the Brand/Generic Settlement Agreement does not exceed a maximum limit, which is initially set at $7,000,000 and shall be increased (or decreased) as of January 1 of each year by an amount equal to the percentage increase (or decrease) from the previous year in the annual average Producer Price Index for Legal Services (Series Id. PCU5411—5411--) published by the Bureau of Labor Statistics of the United States Department of Labor or its successor;

2. the right to Market, as of an agreed upon Generic Entry Date, Generic Product(s) in the United States under an ANDA or 505(b)(2) Application (i) that is controlled by the Generic Filer and was not transferred to the Generic Filer by the NDA Holder or (ii) to which the Generic Filer has a license from a party other than the NDA Holder;

3. provisions to facilitate, by means other than the transfer of goods or money, the Generic Filer's ability to secure or maintain final regulatory approval, or commence or continue the Marketing, of a Generic Product, 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 shall not enter any agreement that prevents, restricts, or in any way disincentivizes competition between Oxymorphone ER Products.

C. [redacted]

III.Compliance Program

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

A. Designation and retention of an antitrust compliance officer or director to supervise the design, maintenance, and operation of the program;

B. Training regarding Respondent's obligations under this Order and the Antitrust Laws for Executive and General Counsel Staff within 30 days after this Order becomes final and at least annually thereafter;

C. Certification by each Executive and General Counsel Staff member and each that she or he has received the training required in Paragraph III.C;

D. Policies and procedures for employees and representatives of Respondents to ask questions about, and report violations of, this Order and the Antitrust Laws confidentially and without fear of retaliation of any kind;

E. Policies and procedures for disciplining employees and representatives of Respondents for failure to comply with this Order and the Antitrust Laws; and

F. The retention of documents and records sufficient to record Respondents' compliance with its obligations under this Paragraph III of this Order, including but not limited to records showing that employees and representatives of Respondents have received all trainings required under this Order during the preceding two years.

IV. Reporting Requirements

IT IS FURTHER ORDERED that

A. Respondent shall file a verified written report to the Commission ("compliance report"):

1. 90 days after the date this Order is issued; and
2. One year after the date this Order is issued, and annually for the next 19 years on the anniversary of that date, and
3. At such other times as the Commission may require.

B. In each compliance report, Respondent shall describe the manner and form in which Respondent intends to comply, is complying, and has complied with this Order, including by submitting:

1. a copy of any additional agreement with a party to a Brand/Generic Settlement to which Respondent is a signatory if (i) the relevant Brand/Generic Settlement Agreement includes an agreement by the Generic Filer not to research, develop, manufacture, Market or sell the Subject Drug Product for any period of time, and (ii) the relevant additional agreement is entered within a year of executing the Brand/Generic Settlement Agreement;
2. copies of all documents that contain or describe an agreement that relates to one or more Oxymorphone ER Products and is an agreement between Respondent and any holder of an NDA, ANDA or 505(b)(2) for any Drug Product;
3. a summary of Respondent's efforts to cease being a party to an agreement that violates Paragraph II.B and copies of all correspondence (including, but not limited to, electronic mail and letters) sent or received by Respondent as part of such efforts;
4. a summary of Respondents efforts to comply with Paragraph II.C and copies of all correspondence (including, but not limited to, electronic mail and letters) sent or received by Respondent as part of such efforts; and
5. Copies of the certifications required by Paragraph III.C and the policies and procedures required by Paragraphs III.D and III.E.

provided that, Respondent does not need to submit any agreements, correspondence or other documents that Respondent submitted to the Commission with a prior verified written report required by this provision.

C. Each compliance report submitted pursuant to this Paragraph shall be verified by a notarized signature or sworn statement of the Chief Executive Officer or other officer or employee of the Respondent specifically authorized to perform this function, or self-verified in the manner set forth in 28 U.S.C. § 1746. Commission Rule 2.41(a), 16 C.F.R. § 2.41(a), requires that the Commission receive an original and two copies of each compliance report. A paper original of each compliance report shall be filed with the Secretary of the Commission and electronic copies shall be transmitted to the Secretary at ElectronicFilings@ftc.gov, and the Compliance Division at bccompliance@ftc.gov.

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

V. Change of Corporate Control

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least 30 days prior to:

1. Any proposed dissolution of Impax Laboratories, Inc.;

2. Any proposed acquisition of, or merger or consolidation involving Impax Laboratories, Inc.; or

3. Any other change in Respondent, including assignment or the creation, sale, or dissolution of subsidiaries, if such change may affect compliance obligations arising out of this Order.

B. Respondent shall submit any notice required under this paragraph electronically to the Secretary of the Commission at ElectronicFilings@ftc.gov and the Compliance Division at bccompliance@ftc.gov.

VI. Access Provisions

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

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

B. To interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

VII. Termination

IT IS FURTHER ORDERED that this Order shall terminate 20 years from the date it is issued.

ORDERED:

_____
D. Michael Chappell
Chief Administrative Law Judge

Date: _____, 2018

Appendix 2

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

In the Matter of	)	
	)	Docket No. 9373
Impax Laboratories, Inc., a corporation.	)	

[PROPOSED] ORDER ~~FOR PERMANENT INJUNCTION~~

I. Definitions

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

A. "Commission" means the United States Federal Trade Commission.

B. "Impax" or "Respondent" means Impax Laboratories, Inc., its directors, officers, employees, agents, representatives, successors (including any combination of Impax Laboratories, Inc. and Amneal Pharmaceuticals LLC), and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Impax Pharmaceuticals, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

C. "505(b)(2) Application" means an application filed with the United States Food and Drug Administration pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b)(2).

D. "ANDA" means an Abbreviated New Drug Application filed with the United States Food and Drug Administration pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j).

E. "Authorized Generic" means a Drug Product that is manufactured pursuant to an NDA and Marketed in the United States under a name other than the proprietary name identified in the NDA.

F. "Brand/Generic Settlement" means any agreement or understanding that settles a Patent Infringement Claim in or affecting Commerce in the United States.

G. "Brand/Generic Settlement Agreement" means a written agreement that settles a Patent Infringement Claim in or affecting Commerce in the United States.

H. "Branded Subject Drug Product" means a Subject Drug Product marketed, sold, or distributed in the United States under the proprietary name identified in the NDA for the Subject Drug Product.

I. "Commerce" has the same definition as it has in 15 U.S.C. § 44.

J. "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 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.

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. Patents held by, or licensed to, an NDA Holder.

W. "Payment by the NDA Holder to the Generic Filer" means a transfer of value by the NDA Holder to the Generic Filer (including, but not limited to, a No-AG Commitment, money, goods, or services), regardless of whether the Generic Filer purportedly transfers value in return, where such transfer is either (i) expressly contingent on entering a Brand/Generic Settlement Agreement, or (ii) agreed to during the 90 days period starting 45 days before executing a Brand/Generic Settlement Agreement and ending 45 days after executing a Brand/Generic Settlement Agreement. The following, however, are not Payment by the NDA Holder to the Generic Filer:

1. compensation for the NDA Holder's saved future litigation expenses, but only if the total compensation the NDA Holder agrees to provide to the Generic Filer during the 90 day period starting 45 days before and ending 45 days after executing the Brand/Generic Settlement Agreement does not exceed a maximum limit, which is initially set at $7,000,000 and shall be increased (or decreased) as of January 1 of each year by an amount equal to the percentage increase (or decrease) from the previous year in the annual average Producer Price Index for Legal Services (Series Id. PCU5411—5411--) published by the Bureau of Labor Statistics of the United States Department of Labor or its successor;

2. the right to Market, as of an agreed upon Generic Entry Date, Generic Product(s) in the United States under an ANDA or 505(b)(2) Application (i) that is controlled by the Generic Filer and was not transferred to the Generic Filer by the NDA Holder or (ii) to which the Generic Filer has a license from a party other than the NDA Holder;

3. provisions to facilitate, by means other than the transfer of goods or money, the Generic Filer's ability to secure or maintain final regulatory approval, or commence or continue the Marketing, of a Generic Product, 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 to~~shall not enter any agreement that prevents, restricts, or in any way disincentivizes competition between Oxymorphone ER Products~~, including but not limited to the First Amendment to the 2010 Settlement and License Agreement~~.

~~B.~~

~~C. The First Amendment to the 2010 Settlement and License Agreement is null and void and Respondent shall relinquish all rights to any Refund Payment under Paragraph 10(c) of the Agreement and shall return any Refund Payment received. Respondent shall further take whatever action is necessary to render the ruling in this Paragraph of the Order a Final Nullity Decision under the First Amendment to the 2010 Settlement and License Agreement.~~

~~D. Within sixty (60) days after the date this Order is issued, Respondent shall take whatever action is necessary to vacate, amend, or nullify any agreement to which it is a party that prevents, restricts, or in any way disincentivizes competition between Oxymorphone ER Products.~~

C. [redacted]

III. Compliance Program

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

A. Designation and retention of an antitrust compliance officer or director to supervise the design, maintenance, and operation of the program;

B. Training regarding Respondent's obligations under this Order and the Antitrust Laws for Executive and General Counsel Staff within 30 days after this Order becomes final and at least annually thereafter;

C. Certification by each Executive and General Counsel Staff member and each that she or he has received the training required in Paragraph III.C;

D. Policies and procedures for employees and representatives of Respondents to ask questions about, and report violations of, this Order and the Antitrust Laws confidentially and without fear of retaliation of any kind;

E. Policies and procedures for disciplining employees and representatives of Respondents for failure to comply with this Order and the Antitrust Laws; and

F. The retention of documents and records sufficient to record Respondents' compliance with its obligations under this Paragraph III of this Order, including but not limited to records showing that employees and representatives of Respondents have received all trainings required under this Order during the preceding two years.

IV. Reporting Requirements

IT IS FURTHER ORDERED that

A. Respondent shall file a verified written report to the Commission ("compliance report"):

1. 90 days after the date this Order is issued; and
2. One year after the date this Order is issued, and annually for the next 19 years on the anniversary of that date, and
3. At such other times as the Commission may require.

B. In each compliance report, Respondent shall describe the manner and form in which Respondent intends to comply, is complying, and has complied with this Order, including by submitting:

1. a copy of any additional agreement with a party to a Brand/Generic Settlement to which Respondent is a signatory if (i) the relevant Brand/Generic Settlement Agreement includes an agreement by the Generic Filer not to research, develop, manufacture, Market or sell the Subject Drug Product for any period of time, and (ii) the relevant additional agreement is entered within a year of executing the Brand/Generic Settlement Agreement;
2. copies of all documents that contain or describe an agreement that relates to one or more Oxymorphone ER Products and is an agreement between Respondent and any holder of an NDA, ANDA or 505(b)(2) for any Drug Product;
3. a summary of Respondent's efforts to cease being a party to an agreement that violates Paragraph II.B and copies of all correspondence (including, but not limited to, electronic mail and letters) sent or received by Respondent as part of such efforts;
4. a summary of Respondents efforts to comply with Paragraph II.C and copies of all correspondence (including, but not limited to, electronic mail and letters) sent or received by Respondent as part of such efforts; and

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

provided that, Respondent does not need to submit any agreements, correspondence or other documents that Respondent submitted to the Commission with a prior verified written report required by this provision.

C. Each compliance report submitted pursuant to this Paragraph shall be verified by a notarized signature or sworn statement of the Chief Executive Officer or other officer or employee of the Respondent specifically authorized to perform this function, or self-verified in the manner set forth in 28 U.S.C. § 1746. Commission Rule 2.41(a), 16 C.F.R. § 2.41(a), requires that the Commission receive an original and two copies of each compliance report. A paper original of each compliance report shall be filed with the Secretary of the Commission and electronic copies shall be transmitted to the Secretary at ElectronicFilings@ftc.gov, and the Compliance Division at bccompliance@ftc.gov.

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

V. Change of Corporate Control

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least 30 days prior to:

1. Any proposed dissolution of Impax Laboratories, Inc.;
2. Any proposed acquisition of, or merger or consolidation involving Impax Laboratories, Inc.; or
3. Any other change in Respondent, including assignment or the creation, sale, or dissolution of subsidiaries, if such change may affect compliance obligations arising out of this Order.

B. Respondent shall submit any notice required under this paragraph electronically to the Secretary of the Commission at ElectronicFilings@ftc.gov and the Compliance Division at bccompliance@ftc.gov.

VI. Access Provisions

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, upon written request and five days' notice to the relevant Respondent, made to its principal place of business as identified in this Order, registered office of its United States subsidiary, or its headquarters office, the notified

Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

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

B. To interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

VII. Termination

IT IS FURTHER ORDERED that this Order shall terminate 20 years from the date it is issued.

ORDERED:

_____
D. Michael Chappell
Chief Administrative Law Judge

Date: _____, 2018

CERTIFICATE OF SERVICE

I hereby certify that on February 14, 2018, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

Donald S. Clark
Secretary
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-113
Washington, DC 20580
ElectronicFilings@ftc.gov

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Ave., NW, Rm. H-110
Washington, DC 20580

I also certify that I delivered via electronic mail a copy of the foregoing document to:

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Counsel for Respondent Impax Laboratories, Inc.

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