PUBLIC

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

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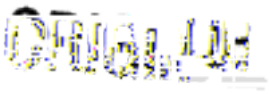
In the Matter of:

IMPAX LABORATORIES, INC.,

a corporation.

Docket No. 9373



RESPONDENT IMPAX LABORATORIES, INC.'S REPLY TO COMPLAINT COUNSEL'S POST-TRIAL BRIEF

Edward D. Hassi
Michael E. Antalics
O'MELVENY & MYERS LLP
1625 Eye Street, NW
Washington, DC 20006
Telephone: (202) 383-5300
Facsimile: (202) 383-5414

[Additional Counsel on Signature Page]

Counsel for Impax Laboratories

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INTRODUCTION

On the first day of trial, this Court asked whether Complaint Counsel cares about "what actually happened" in the "real world." (Court, Tr. 73.) Complaint Counsel's post-trial brief answers that question with a resounding ***NO***. Despite paying lip service to the rule of reason, Complaint Counsel offers no evidence that the Settlement & License Agreement (the "SLA") or the Development & Co-promotion Agreement (the "DCA") actually harmed competition or left consumers worse off than they otherwise would have been. Nor does Complaint Counsel dispute that the SLA allowed Impax to sell generic Opana ER on a sustained basis, free from patent risk, earlier than could have been achieved through litigation. In fact, Complaint Counsel concedes that Impax's sales have "result[ed] in dramatic cost savings to consumers."[1] It just thinks this Court should ignore that and other consumer benefits.

Complaint Counsel may not like it, but antitrust law requires the parties and this Court to examine "actual market realities."

1. Complaint Counsel advocates a legal standard that bears no resemblance to the rule of reason. In *FTC v. Actavis Inc.*, 133 S. Ct. 2223 (2013), the Supreme Court held that patent settlements that include a "large and unjustified" reverse payment are subject to antitrust scrutiny under the traditional rule of reason. *Id.* at 2237–38. The Court rejected the FTC's argument that courts may presume anticompetitive effects from the existence of such a payment, holding instead that "the FTC must prove its case as in other rule-of-reason cases." *Id.* at 2237.

Complaint Counsel whistles past *Actavis*, advocating that a "large" payment is *prima facie* evidence of anticompetitive effects. (CC PTB at 21–22.) Complaint Counsel further argues that if the defendant cannot "justify" the payment as "legitimate consideration," the settlement violates the antitrust laws. (*Id.* at 28, 60.) On this view, any settlement that includes a "large and unjustified" payment—as defined only by Complaint Counsel—is condemned.

Notably absent from this analysis is any consideration of actual anticompetitive effects or procompetitive benefits—the hallmark of the rule of reason. To accept Complaint Counsel's argument that a court may presume antitrust illegality from the payment itself is to ignore not only *Actavis*, but the Commission's ruling in this proceeding that "anticompetitive effects should not be presumed from the mere presence of a reverse payment." Opinion and Order of the Commission at 8, *In re Impax Labs., Inc.*, Dkt. 9373 (F.T.C. Oct. 27, 2017) [hereinafter "Comm'n Decision"] (citing *Actavis*, 133 S. Ct. at 2237).

Complaint Counsel may dress up old arguments in new clothing, but underneath, they advocate for a stark *per se* framework. This Court should not permit Complaint Counsel to relitigate an issue the Supreme Court has already laid to rest.

2. Complaint Counsel has not shown that Impax received a "large" or "unjustified" reverse payment. A reverse-payment settlement does not carry a "risk" of anticompetitive

harm—and thus does not even trigger rule of reason scrutiny—unless the payment is both "large and unjustified." *Actavis*, 133 S. Ct. at 2237; *see Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC*, No. 15-cv-6549 (CM), 2016 WL 4992690, at *13 (S.D.N.Y. Sept. 13, 2016). While Complaint Counsel concedes its burden of proving a "large" payment (CC PTB at 21–22, 28), it offers no evidence that the SLA's alleged payment terms (*i.e.*, the "Endo Credit" and "No-AG" provisions) conveyed a "large" value to Impax in June 2010. It fails entirely to account for these terms' uncertain and contingent nature, and instead relies on a handful of cherry-picked and inflated "examples" of potential payment outcomes. These self-serving figures are no substitute for a probability-weighted expected value—which Complaint Counsel and its experts did not even attempt to calculate.

Likewise, Complaint Counsel does not point to any evidence that the DCA, with its $10 million payment, was anything other than "fair value" for Endo's profit-sharing rights. *See Actavis*, 133 S. Ct. at 2236 ("fair value" payments for services are justified). It quibbles with Endo's negotiation process, Endo's due diligence, and the way Endo structured the agreement, but at no point values the benefits Endo stood to receive under the deal. Without that, this Court cannot find that Impax received a "large and unjustified" payment under the DCA.

3. Complaint Counsel cannot account for real-world evidence that Opana ER competed against other long-acting opioids ("LAOs") in the relevant market. Complaint Counsel's brief confirms it has no response to documentary, testimonial, and economic evidence showing that Opana ER competed against other LAOs. Complaint Counsel devotes less than a ***single*** page to formularies—the means by which insurers promote price competition among drug companies. And Complaint Counsel completely ignores the University of Pittsburgh Medical Center ("UPMC") study, which empirically demonstrates that consumers switch between LAOs

in response to changes in relative prices. While Complaint Counsel insists that LAO makers competed "primarily" through product differentiation (*e.g.*, CC PTB at 54, 57), it never substantiates that claim. It simply turns a blind eye to swaths of business documents, witness testimony, and economic analysis showing that Endo and other LAO makers competed ***on price*** at the payor, patient, and prescriber levels. This Court should not do likewise.

Rather than respond substantively to Dr. Addanki's

ER on a sustained basis any earlier than January 2013 if it had not agreed to the SLA. (Resp't Impax Labs., Inc.'s Post-trial Br. at 100–126, *In re Impax Labs., Inc.*, Dkt. 9373 (F.T.C. Dec. 20, 2017) [hereinafter "Impax PTB"].) Complaint Counsel offers no rebuttal to this evidence, other than to incant that the SLA eliminated some hypothetical "risk" of competition. (CC PTB at 45.) But speculative "risks" carry no weight under the rule of reason.

5. Complaint Counsel does not dispute that the SLA had procompetitive effects that benefited consumers. For all its rhetorical hand-waving, Complaint Counsel never disputes what may be the most important market reality in this case: the SLA is the ***only*** reason consumers have had uninterrupted access to a low-priced generic version of Opana ER for the last five years. Without the SLA, there is no plausible circumstance—and Complaint Counsel

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As Impax stated in its opening brief, this is not a close case. Conclusory assertions of hypothetical harm do not satisfy Complaint Counsel's burden under the rule of reason, and certainly cannot overwhelm the indisputable—and undisputed—reality that the SLA promoted

However, Complaint Counsel ***does not actually apply*** this "well-established three-step burden shifting framework." Drawing chiefly from a single district court decision—which may not even be good law[2]—Complaint Counsel instead follows an alternative analysis:

- ***First***, Complaint Counsel moves the goalposts, insisting that it need only show some amorphous and unquantifiable "harm to the competitive process" rather than "actual anticompetitive effects" to satisfy its initial burden. (CC PTB at 21–22, 24.) According to Complaint Counsel, proof of "market power and evidence of a large reverse payment" is sufficient to make out a *prima facie* case. (*Id.* at 24, 28 (quoting *Cephalon*, 88 F. Supp. 3d at 416).)
- ***Second***, Complaint Counsel says that evidence of market power and a large payment shifts the burden to Impax to show that the alleged reverse payment—rather than the challenged "restraint"—is justified. (*Id.* at 28.) Complaint Counsel insists that a payment is unjustified unless it represents "saved litigation costs, compensation for services, or some other legitimate consideration." (*Id.*) Complaint Counsel further argues that this Court should ignore evidence that the settlement benefited consumers. (*See id.* at 67–71.)

[2] Complaint Counsel relies heavily on *King Drug Co. of Florence, Inc. v. Cephalon, Inc.* ("*Cephalon*"), 88 F. Supp. 3d 402 (E.D. Pa. 2015). (*See* CC PTB at 23–24, 27–29, 36.) In *Cephalon*, the court began with the observation that "[t]he specific contours of the rule of reason analysis to be applied under *Actavis* are not . . . well-defined," and from there, fashioned its own framework. *See* 88 F. Supp. 3d at 412–21. Later that year, however, the Third Circuit made clear in *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*

- ***Finally***, at no point does Complaint Counsel identify or analyze any less restrictive alternative, as required under the third step of the rule of reason. *O'Bannon v. NCAA*, 802 F.3d 1049, 1074 (9th Cir. 2015).

As its post-trial brief lays bare, Complaint Counsel is pushing for a radical departure from the traditional rule of reason. Because Complaint Counsel's proposed framework ***neither*** requires proof of actual anticompetitive harm ***nor*** permits Impax to proffer evidence of procompetitive effects, it spurns what the Supreme Court has identified as the rule of reason's "central principle": that the inquiry should "focus[] directly on the challenged restraint's impact on competitive conditions."

illegal *per se* without inquiry into the harm it has actually caused.”). Complaint Counsel’s

approach, proof of a settlement with a large and unjustified payment that causes delay merely shifts the burden to the defendant to "offer legitimate justifications and come forward with evidence that the challenged settlement is in fact procompetitive." *Id.* at 869–70. As in any rule of reason case, "[t]he ultimate burden throughout rests with the plaintiff to show that [the] challenged settlement is anticompetitive." *Id.* at 871 (citing *Bert G. Gianelli Distrib. Co. v. Beck & Co.*, 172 Cal. App. 3d 1020, 1048 (Ct. App. 1985)).

Numerous district and appellate courts have likewise concluded that proof of a settlement with a "large and unjustified" reverse payment may trigger antitrust scrutiny, but does not answer the ultimate rule of reason question.[6] As one of those courts noted, to hold otherwise "would compel antitrust scrutiny of a settlement regardless of whether its terms could reasonably be construed as a large and unjustified reverse payment," which would "ignore the limiting principles set forth in [*Actavis*], and subject virtually ***any*** settlement to antitrust scrutiny—a result the [Supreme] Court could not have intended." *Actos*, 2015 WL 5610752, at *14.

Complaint Counsel's conflation of the initial "large and unjustified" payment inquiry with the rule of reason competitive effects analysis infects its entire case. This Court must reject Complaint Counsel's thinly veiled *per se* standard and apply the traditional rule of reason.

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[6] *See, e.g.*, *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 251–52 (3d Cir. 2017), *petition for cert. filed*, No. 17-771 (U.S. Nov. 20, 2017) (only after plaintiffs have "'allege[d] facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment under *Actavis*'" may plaintiffs "proceed to prove their allegations under the traditional rule-of-reason analysis") (quoting *Loestrin I*, 814 F.3d at 552; *Sergeants Benevolent Ass'n*, 2016 WL 4992690, at *13 (large, unjustified reverse payment "trigger[s] antitrust concern" under *Actavis*); *In re Actos End Payor Antitrust Litig.*, No. 13-CV-9244 (RA), 2015 WL 5610752, at *11, *14 (S.D.N.Y. Sept. 22, 2015), *aff'd in part and vacated in part on other grounds*, 848 F.3d 89 (2d Cir. 2017) (same); *United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1065–66 (N.D. Cal. 2014) (large and unjustified reverse payment "raise[s] antitrust concerns"; "only after finding such a payment in the settlement may courts engage in the traditional rule of reason analysis").

B. Complaint Counsel Was Required to Prove That Impax Received a "Large and Unjustified" Payment Under the Challenged Agreements.

As the foregoing authorities make clear, an alleged reverse-payment settlement does not raise antitrust concern unless the payment is "both 'large and unjustified.'" *Lipitor*, 868 F.3d at 251 (quoting *Actavis*, 133 S. Ct. at 2237). These are discrete requirements. *Id.*

1. Complaint Counsel's Proposed Definition of "Large" Is Untenable.

Complaint Counsel concedes it must prove that Impax received a "large reverse payment." (CC PTB at 24, 28.) As the term suggests, Complaint Counsel must come forward with evidence that allows this Court to "assess the value of the [alleged] payment." *Loestrin I*,

Complaint Counsel's second prong—that the payment must be "significant enough to induce a generic challenger to abandon its patent claim" (CC PTB at 36)—proves too much. In ***every*** reverse-payment settlement case, the plaintiff can point to the settlement's existence as proof that the payment was sufficient to induce the generic company to withdraw its patent challenge, for if the generic company had ***not*** "abandon[ed] its patent claim," there would be no settlement to challenge. A requirement that is satisfied in every case is meaningless. *See In re Eldercare Props. Ltd.*, 568 F.3d 506, 524 (5th Cir. 2009) (O'Connor, J., retired) ("That argument proves too much; it would apply in every case.").

2. Complaint Counsel Bears the Burden of Showing That Any Alleged

services), there is no risk of anticompetitive harm and no basis for applying antitrust scrutiny. Under Complaint Counsel's view, however, a plaintiff would be able to shift the rule of reason burden to the defendant merely by showing a "large" reverse payment. ***That*** is tantamount to a "quick look" analysis, which places the onus on the defendant to offer justifications for its conduct before any evidence of anticompetitive effects has been proffered.[7] *See Deutscher Tennis Bund v. ATP Tour, Inc.*, 610 F.3d 820, 831 (3d Cir. 2010) ("Under 'quick look' analysis, the competitive harm is presumed, and the defendant must promulgate some competitive justification for the restraint.") (quotation omitted); *Major League Baseball Props., Inc. v. Salvino, Inc.*, 420 F. Supp. 2d 212, 220 (S.D.N.Y. 2005), *aff'd*, 542 F.3d 290 (2d Cir. 2008) ("Under a quick look analysis, the plaintiff is relieved of its initial burden of showing that the challenged restraints have an adverse effect on competition.") (quotation omitted). Unsurprisingly, this is exactly what the FTC advocated for in *Actavis*—unsuccessfully.[8]

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Complaint Counsel admits it must ***plead*** an unjustified payment, but insists that it need not ***prove*** one. (CC PTB at 30.) This is nonsensical. Complaint Counsel bears the burden of both pleading ***and*** proving each element of its *prima facie* case. *See* Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 1405a (rev. ed. 2017) ("The plaintiff bears the burden of, first, alleging,

summary judgment.").[9] In order to subject the SLA to rule of reason scrutiny, Complaint Counsel was required to "prove by the applicable standard at trial that the settlement included a large and unjustified reverse payment." *In re Aggrenox Antitrust Litig.* ("*Aggrenox II*"), No. 3:14-md-2516 (SRU), 2015 WL 4459607, at *10 (D. Conn. July 21, 2015); *see In re Aggrenox Antitrust Litig.* ("*Aggrenox I*"), 94 F. Supp. 3d 224, 240 (D. Conn. 2015) (plaintiff must "ultimately prove . . . that a large and otherwise unjustified reverse-payment was made as part of the settlement").

C. Complaint Counsel Was Required to Prove That Endo Possessed Monopoly Power in a Properly Defined Relevant Market.

Complaint Counsel concedes, as it must, that it was required to prove that Endo

D. Complaint Counsel Was Required to Prove That the Challenged Agreements Actually Harmed Competition.

Assuming Complaint Counsel could demonstrate that Impax received a "large and unjustified" payment and that Endo possessed monopoly power, it was then required to prove that "the challenged agreements had the effect of injuring competition." *In re Schering-Plough Corp.* ("*Schering I*"), No. 9297, 2002 WL 1488085, at *88 (F.T.C. June 27, 2002); *see In re*

competition would have occurred earlier." 133 F. Supp. 3d at 756. Though the Third Circuit's affirmance largely centered on antitrust injury, the court held that because "there was ***no delay*** associated with the 300 mg product," "the analysis in *Actavis*

competition. *See, e.g.*, *Rambus Inc. v. FTC*, 522 F.3d 456, 463–67 (D.C. Cir. 2008) (dismissing antitrust claim where there was "insufficient evidence" that alternative technology would have been adopted but for defendant's alleged conduct); *Engine Specialties, Inc. v. Bombardier Ltd.*, 605 F.2d 1, 7–11 (1st Cir. 1979) ("It must be shown . . . that the potential competitor . . . had the necessary desire, intent, and capability to enter the market.").

Finally, Complaint Counsel asserts that in *Microsoft*, the D.C. Circuit "explained that proving a rule of reason violation does not 'turn on a plaintiff's ability or inability to reconstruct the hypothetical marketplace absent a defendant's anticompetitive conduct.'" (CC PTB at 27 (quoting *Microsoft*, 253 F.3d at 79).) That is just wrong. The quoted language does not even come from the D.C. Circuit's discussion of the rule of reason, but rather from its enumeration of the causation requirements in a monopoly maintenance claim. *See Microsoft*, 253 F.3d at 78–80.[11] Complaint Counsel blithely ignores the D.C. Circuit's actual discussion of the rule of reason, in which the court held that the government was required to "show that Microsoft's conduct unreasonably restrained competition," and that "[m]eeting that burden 'involves an inquiry into the ***actual effect***' of Microsoft's conduct on competition in the [relevant] market." 253 F.3d at 95 (quoting *Jefferson Par.*, 466 U.S. at 95) (emphasis added).

In the end, Complaint Counsel is asking this Court to presume anticompetitive effects on the basis of a "large" payment (CC PT at 23–24, 28), contrary to *Actavis* and the Commission's ruling in this very case. *See* Comm'n Decision at 8 (citing *Actavis*, 133 S. Ct. at 2237). This Court should hold Complaint Counsel to its burden of showing that the settlement had an actual adverse effect on competition in the relevant market.

[11] The *Microsoft* court made clear that to support a monopoly maintenance claim, the government must prove that the defendant's conduct had an "anti

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As Impax has already explained,[12] a payment is ***not*** a restraint. To "restrain" means to "bind." *Bd. of Trade of City of Chi. v. United States*, 246 U.S. 231, 244 (1918). A "restraint of trade" is something that restricts competition. *Antitrust Law* ¶ 1502. More precisely, it refers to a reduction in output. *See id.* ("an anticompetitive reduction in output, which is one that is capable of producing a price increase, . . . is the most appropriate meaning of an antitrust restraint").

A payment does not, by itself, have ***any*** effect on competition—and certainly is not a "reduction in output." *Id.* In the reverse-payment settlement context, the "restraint" is the ***settlement***, which is what "bind[s]" the settling parties, *Bd. of Trade*, 246 U.S. at 244, and "imped[es] the due course of trade," *Standard Oil Co. of N.J. v. United States*, 221 U.S. 1, 55 (1911); *see also NCAA v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 98 (1984) (practices that "limit[ed] members' freedom" were "restraint of trade"). Courts routinely treat the alleged reverse-payment settlement, rather than the payment itself, as the challenged "restraint."[13] Indeed, the *Actavis* Court recognized that the concern is not payments *per se*, but the ***agreement to stay out of the market*** that large and unjustified reverse payments may procure.[14]

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[12] (*See, e.g.*, Impax PTB at 131–32; Resp't Impax Labs., Inc.'s Pretrial Br. at 80–81, *In re Impax Labs., Inc.*, Dkt. 9373 (F.T.C. Oct. 17, 2017).)

[13] *See, e.g.*, *Lipitor*, 868 F.3d 245 (plaintiffs "challeng[ed] the settlement agreement as an unlawful restraint of trade."); *Loestrin I*, 814 F.3d at 542 ("They contend that these agreements constitute illegal restraints on trade."); *Wellbutrin*, 133 F. Supp. 3d at 752 (holding that "settlements . . . are without question agreements in restraint of trade"); *In re Androgel Antitrust Litig. (No. II)*, No. 1:09-MD-2084-TWT, 2014 WL 1600331, at *8 (N.D. Ga. Apr. 21, 2014) ("This logic indicates that the 'source . . . of the anticompetitive restraint at issue' is the parties' reverse payment agreement itself.") (quoting *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 499 (1988)).

[14] *See, e.g.*, *Actavis*, 133 S. Ct. at 2227 (reverse-payment agreement is one that "require[s] . . . the claimed infringer, not to produce the patented product" in return for "many millions of dollars"); *id.* at 2229–30 (generics allegedly violated FTC Act by "agreeing 'to share in Solvay's monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years'"); *id.* at 2231 ("the plaintiff agreed to pay the defendants many millions of dollars to stay out of its market"); *id.* at 2233 (under reverse-payment agreements, "a party with no claim for damages . . . walks away with money

Complaint Counsel focuses myopically on the Supreme Court's statement that the defendant is entitled to put on evidence of "legitimate justifications," "explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason." (CC PTB at 28, 68, 70 (quoting *Actavis*, 133 S. Ct. at 2236).) Even assuming the "challenged term" refers specifically to the payment (which is not entirely evident), nowhere did the Court say that any procompetitive justifications must be solely attributable to the payment. The Court merely indicated that the defendant is permitted to "show[] the lawfulness of that term under the rule of reason." *Actavis*, 133 S. Ct. at 2236. And while a "large and unjustified" payment may raise antitrust suspicion, courts assess competitive effects with reference to the settlement ***as a whole***. *See, e.g.*, *Loestrin II*, 261 F. Supp. 3d at 330–31; *Wellbutrin*, 133 F. Supp. 3d at 753–54; *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 752 (E.D. Pa. 2014). As the *Cipro* Court explained, once the plaintiff proves a large and unjustified payment that resulted in an agreement to delay generic entry, the defendant is entitled to show that "***the challenged settlement*** is in fact procompetitive." 348 P.3d at 869–70 (emphasis added).

F. Complaint Counsel Was Required to Show That a Substantially Less Restrictive Alternative Was Feasible.

A plaintiff may rebut a defendant's procompetitive justifications by demonstrating that the challenged restraint was "not reasonably necessary" to achieve those benefits, *United States v. Brown Univ.*, 5 F.3d 658, 669 (3d Cir. 1993), or that the "legitimate objectives can be achieved in a substantially less restrictive manner," *O'Bannon*, 802 F.3d at 1070 (quoting *Tanaka v. Univ. of S. Cal.*, 252 F.3d 1059, 1063 (9th Cir. 2001)). It is not enough to suggest, without evidence, that the parties might have reached some hypothetical alternative settlement that would have

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simply so it will stay away from the patentee's market"); *id.* at 2234 ("payment in return for staying out of the market [] simply keeps prices at patentee-set levels."); *id.* at 2237 ("paying the challenger to stay out [of the market]" risks antitrust liability).

1. Complaint Counsel Did Not Even A

either Endo or Impax placed any particular value on the Endo Credit or No-AG provisions when

n.22 (D. Mass. 2013)).) Impax does not assert that the No-AG and Endo Credit provisions

outcomes "under various circumstances." (CC PTB at 38–39; *see* FOF ¶ 649; Noll, Tr. 1613.) Citing these "examples," Complaint Counsel claims that the No-AG and Endo Credit terms ranged in value from $16.5 million to more than $62 million "under any reasonable scenario." (CC PTB at 37.) This band-aid cannot cure the fatal defect in Complaint Counsel's case.

Complaint Counsel has no basis for asserting that these "examples" are any more "reasonable" than the potential outcomes that Dr. Noll excluded, since ***none*** of the examples listed in Complaint Counsel's brief or in Dr. Noll's report is probability-weighted. (FOF ¶¶ 648–49; *see* Noll, Tr. 1613 ("I didn't attach probabilities to those."); Noll, Tr. 1650–51 ("I did not calculate the probability of any of these [scenarios] or any of the others that are in the report.").) Lacking cogent analysis, Complaint Counsel may not simply declare some outcomes more "reasonable" than others. *See Camaj v. Holder*

chance,[20] when in fact, the evidence indicates that Endo was planning a "late switch" strategy. (FOF ¶¶ 209, 636–38; RX-094.0003.) Indeed, it only makes sense that a rational actor like Endo "would manage that transition [to reformulated Opana ER] to minimize its patient loss and to minimize whatever payments it was going to make." (Addanki, Tr. 2355.) Complaint Counsel never explains ***why*** Endo would buck its incentives and deliberately introduce reformulated Opana ER so early as to guarantee a material payment liability under the Endo Credit.

Nor does the evidence bear out Complaint Counsel's assertion that Endo "did not plan to wait until the end of 2012 to introduce its reformulated [Opana

after Opana ER hit the shelves, and years before Endo filed its NDA for reformulated Opana ER. (CX2578-002, -009.) It is not clear why this "evidence" should trump post-settlement documents showing that Endo was actually planning a late switch.

To make matters worse, Complaint Counsel's curated "examples" of potential payment outcomes are indefensible. For instance, Complaint Counsel does not even apply a discount rate to account for the time value of money—something Dr. Noll ***did*** do. (CC PTB at 38–39.) Thus, while Complaint Counsel says the No-AG was worth "at least $16.5 million" (CC PTB at 38), it does not mention that at the time of the settlement, the present value of that "example" would have been just $11 million, according to its own expert. (CCF ¶ 471.) Deducting saved litigation costs from $11 million leaves just a few million dollars in surplus "payment." Given the realities of the pharmaceutical industry, one can hardly describe a few million dollars as "large." (*Cf.* Court, Tr. 51 ("ten million is nothing").)

Likewise, Complaint Counsel's assertion that the "smallest possible" Endo Credit payment was $62 million is pure fiction. (CC PTB at 39.) Dr. Noll conjured up that figure ***without*** referencing the SLA's Endo Credit formula, using a methodology that does not pass the smell test.[22] Even worse, the $62 million "estimate" assumes ***zero*** sales of original Opana ER in

[22] Rather than relying on the Endo Credit formula, Dr. Noll estimated that Opana ER sales in the third quarter of 2010 were "approximately 62 percent of actual peak sales in 2011," and then apparently mm φ K, m φ pK, p m M!¯ æo h fict ', A 62 per# l Ç D Ey t p tales in £ the ! h p ¾

the fourth quarter of 2012. (Reply FOF ¶ 470.)[23] If Endo sold any original Opana ER in that quarter, as it in fact planned to,[24] then any Endo Credit payment would necessarily be ***much*** less than $62 million. (Reply FOF ¶ 470.) For instance, if Endo's fourth quarter 2012 sales of original Opana ER were 49.9% of peak sales, then, assuming (as Dr. Noll did) that Opana ER sales peaked in the third quarter of 2010, the Endo Credit payment would have been roughly $100,000—about ***0.16%*** of Complaint Counsel's $62 million figure. (Reply FOF ¶ 470.)

Without a defensible valuation of the No-AG and Endo Credit terms, Complaint Counsel cannot meet its burden of proving that Impax received a "large" reverse payment under the SLA. Phony "examples" and *ipse dixit* cannot compensate for that failure of proof.

3. Complaint Counsel's "Inducement" Test Does Not Establish That Impax Received a Large Payment Under the SLA.

Complaint Counsel next claims the "payment" to Impax under the SLA was "large" because it "induce[d]" Impax to drop its patent challenge. (CC PTB at 36–37.) As noted, this "test" proves too much. Section I.B.1, *supra*. But Complaint Counsel's argument deteriorates even further under the facts of this case. Complaint Counsel points to the ultimate Endo Credit payment in 2013 as evidence that "the payment Impax received was sufficiently large to induce it to drop its patent challenge." (CC PTB at 37.) But how could the ultimate amount of the Endo Credit, which was unknown, unevaluated, and unforeseen in June 2010, have "induced" Impax

[23] In its proposed findings of fact, Complaint Counsel repeats the falsehood that if Opana ER sales "dropped just enough to trigger the Endo Credit, then the Endo Credit payment to Impax would be worth approximately $62 million to Impax in 2013." (CCF ¶ 470.) However, ***none*** of its "supporting" evidence backs up the claim that $62 million is "the smallest possible payment . . . if the Endo Credit were triggered." (CC PTB at 39; *see* Reply FOF ¶ 470.)

[24] (FOF ¶¶ 636–37; *see* CX4017 (Levin, Dep. 131–32, 143–44, 148–49) (testifying that Endo's original plan was to transition to reformulated Opana ER in late 2012, and that original Opana ER sales were not expected to be zero in the fourth quarter of 2012); RX-094.0006 (according to Endo accounting memo dated April 2012, "prior to March [2012] it would have been reasonable to assume that prescriptions of old formulation would have occurred in Q4 2012").)

to drop its patent case? Impax never tried to estimate the Endo Credit's value at the time of settlement. (FOF ¶¶ 581, 583–84; *see* Mengler, Tr. 582; CX4038 (Engle, Dep. 187–88); Noll, Tr. 1649.) There is no evidence that Endo expected to make a payment or that Impax expected to receive one. (FOF ¶¶ 581–92.) If anything, it was the license that allowed Impax to sell generic Opana ER before the patents-in-suit expired, and to continue selling generic Opana ER despite any later-acquired patents, that "induced" Impax to drop its patent challenge.

B. The SLA Did Not Convey an "Unjustified" Payment to Impax.

Though Complaint Counsel bears the burden of establishing that Impax received a "large ***and*** unjustified" reverse payment, *supra* Section I.B.2, Impax put on unrebutted evidence that any alleged payment under the SLA could not have been "unjustified."[25]

In *Actavis*, the Supreme Court emphasized that a reverse payment gives ris

185, 187.) It worked in tandem with the SLA's contingent royalty provision—a potential "Impax Credit" (Court, Tr. 614), under which Impax would pay Endo a hefty royalty if Endo grew the market for original Opana ER. (FOF ¶¶ 195–97.)

Complaint Counsel quibbles that the contingent royalty provision could not have served as a "carrot" because it was "something Endo proposed in its initial term sheet on May 26, 2010." (CC PTB at 66.) False. Endo initially proposed a ***non-contingent*** royalty. (Reply FOF ¶ 1058; *see* CX2616 (May 26, 2010 Guy Donatiello email to Chris Mengler stating: "The royalty rate from Impax to Endo during the exclusivity (35%) should have no trigger. . . . The Agreement should be for a 35% royalty for all sales regardless of the size of the market.").) The very next day, Impax counter-proposed a contingent royalty. (Reply FOF ¶ 1058; *see* RX-318 (May 27, 2010 Chris Mengler email to Alan Levin stating: "Generic profit sharing: if most recent 4 months prior to launch is less than 150M, no royalty to Endo. If greater than 150M and less than 175M, 10% profit split; if greater than 175M, 15% profit split.").) Impax was successful in negotiating a contingency as part of the final settlement. (FOF ¶¶ 195–98.)

Complaint Counsel next says it is "wholly implausible" that the Endo Credit and royalty terms would deter Endo from switching to reformulated Opana ER, since any payment to Impax would be smaller than the "hundreds of millions of dollars" Endo might make from switching the market. (CC PTB at 66–67.) This begs the question: what exactly was Impax supposed to do? The SLA negotiations were a give and take, and Endo unsurprisingly sought terms that would minimize any potential liability under the Endo Credit. (Reply FOF ¶ 466; Cuca, Tr. 639–40.) Complaint Counsel's implicit position—that the Endo Credit was "unjustified" because it ended up being ***insufficiently large*** to deter Endo's product switch—is too clever by half.

Finally, Complaint Counsel asserts that Impax's "carrot and stick" justification is "not legally cognizable," because Impax's attempt to deter Endo from switching to a reformulated product "that the market might prefer" was itself "anticompetitive." (CC PTB at 67.) Complaint Counsel is speaking out of both sides of its mouth. In the federal court predecessor to this litigation, the FTC alleged that Endo's switch to reformulated Opana ER "harmed consumers." (Compl. ¶ 163, *FTC v. Endo Pharm. Inc.*, No. 16-cv-1440 (PSD) (E.D. Pa. Mar. 30, 2016), ECF No. 1.) The fact that the FDA has since asked Endo to withdraw reformulated Opana ER from the market vindicates Impax's position that Endo's switch was not motivated by safety concerns. (FOF ¶ 258; *see* FOF ¶¶ 222–23 (Impax responded to Endo's citizen petition with scientific evidence that original Opana ER was not withdrawn for safety or efficacy reasons).)

The unrebutted evidence shows that the SLA's Endo Credit and No-AG provisions were not "unjustified" payments for delay.

C. The DCA Did Not Convey a "Large" or "Unjustified" Payment to Impax.

Complaint Counsel concedes that an alleged reverse payment is "justified" if it reflects "'compensation for other services that the generic has promised to perform.'" (CC PTB at 28 (quoting *Actavis*, 133 S. Ct. at 2236).) At trial, ***Impax proved just that***. Though it was is not Impax's burden to do so, *supra* Section I.B.2, Impax presented compelling evidence that the DCA payment terms were justified as fair compensation for the profit-sharing rights the DCA granted Endo in return. (*See* FOF ¶¶ 420–76; Impax PTB at 42–46.) Even if it were not part of Complaint Counsel's *prima facie* case to prove an "unjustified" payment (and it is), it would still have to rebut Impax's evidence of justification by showing that the DCA payments "exceeded the value of litigation costs or other products or services."

its overall burden in this step of the rule-of-reason analysis.") (emphasis added). Complaint Counsel has not even ***addressed*** the evidence Impax has offered.

Instead, Complaint Counsel suggests that this Court should eschew any fair-value-for-services inquiry. According to Complaint Counsel, its criticisms of Endo's negotiations, Endo's diligence, and the manner in which Endo structured the DCA "***preclude[]*** Impax from justifying the $10 million payment under the DCA as merely 'compensation for services Impax has agreed to perform.'" (CC PTB at 64 (quoting *Actavis*, 133 S. Ct. at 2236) (emphasis added).) In other words, when confronted with evidence that the DCA payment was "justified," Complaint Counsel runs from the "large and unjustified" payment inquiry altogether.

Insisting that this Court ignore inconvenient evidence is a familiar tune for Complaint Counsel,[26] but it is not the law. The record evidence shows that the DCA was a *bona fide* business deal, and that Endo's DCA payment was justified as fair value consideration.

1. Complaint Counsel's Proposed Approach to Analyzing the DCA Conf valult this

indicators of subjective intent obviate analysis of whether the payment was "fair value" for services. *Actavis*, 133 S. Ct. at 2236. To the contrary, Complaint Counsel's own authorities address this issue head on—and reject Complaint Counsel's approach. *See, e.g.*, *Aggrenox I*, 94 F. Supp. 3d at 243 (cited in CC PTB at 25, 34 n.20, 70) ("Even if the payments exceed avoided litigation costs, the *Actavis* factors—the size of the payment[,] . . . their independence from other services for which they might be fair consideration, and any other convincing justification—still matter."). "Antitrust implications for a reverse payment only arise if the payment is ***separate from compensation for the fair market value of other products and services bargained for in the settlement***, as well as the potential litigation costs that the settlement effectively saves." *K-Dur*, 2016 WL 755623, at *12 (emphasis added).[27] The law is clear: Complaint Counsel must rebut Impax's strong showing that the DCA payments were fair value for the profit-sharing rights Endo receiv

3. Neither Party Intended the DCA as Compensation for Delay.

Even assuming the appropriate inquiry under *Actavis* centered on subjective intentions, the record does not bear out the nefarious purposes Complaint Counsel imputes to Endo and Impax. Endo's contemporaneous business documents,

(FOF ¶¶ 425–63; *e.g.*, CX1209; RX-080.) Endo witness testimony corroborates this assessment. (FOF ¶¶ 425–63; *e.g.*, Cobuzzi, Tr. 2536–62, 2622–29.) Complaint Counsel does not explain why its strained attempts to infer ill intent should trump ***direct*** evidence of Endo's desire to invest in a potentially lucrative pharmaceutical collaboration.

Complaint Counsel mainly relies on evidence that, in its view, shows that the DCA was not a "standalone agreement." (CC PTB at 61.) This is meaningless. Complaint Counsel would have to show that the DCA payment was "large and unjustified" even if the SLA and DCA ***were a single agreement***. *K-Dur*, 2016 WL 755623, at *12; *supra* note 27. In any case, none of the evidence cited in its brief substantiates the alleged causal connection between the agreements.

a. *Negotiation Teams and Timing.*

Complaint Counsel cites documents and testimony showing that the SLA and DCA were negotiated together, by some of the same Endo and Impax team members, and on the same timetable. (CC PTB at 61.) That Endo negotiated the two deals simultaneously does not establish that the parties would not have executed one without the other. Nor does the SLA's cross-reference to the DCA suggest that the SLA induced the parties to sign the DCA. (FOF ¶¶ 348–50; *see* Koch, Tr. 313–14 (Impax assessed DCA and SLA as standalone agreements); CX4017 (Levin, Dep. 157–58) (SLA and DCA "were stand-alone legal documents"); CX4031

To support its argument, Complaint Counsel asserts that "Endo and Impax never discussed business development

Complaint Counsel leaves out other details that further undermine its spin. After rejecting a collaboration on IPX-066, Impax proposed a deal with different terms and licensing rights, including a ***different upfront payment***. (FOF ¶ 328; Reply FOF ¶¶ 1082, 1115; RX-318.) In fact, a $10 million upfront payment did not reappear until June 2, 2010, when Chris Mengler indicated that the proposal then on the table included a $10 million upfront payment as well as an option for Endo to purchase IPX-203, retain profits from 10% of all sales (not just those generated by non-neurologists), or retain 100% of profits from sales generated by non-neurologists, all with no license fee to Impax. (Reply FOF ¶ 1082; CX0406.)

c. *Parties' Internal Documents.*

While Complaint Counsel purports to discern Impax's and Endo's intent from "internal

that matter) what the bullet point meant. (*See*

This is not the first time counsel for the FTC has played this card. In *FTC v. AbbVie Inc.*, 107 F. Supp. 3d 428 (E.D. Pa. 2015), the FTC alleged that the defendants had entered into a business deal that was "unusually favorable" to the generic company. *Id.* at 434. It characterized the deal as different from what is "customary in such situations" and "particularly suspect." *Id.* at 436. The court dismissed the FTC's reverse-payment claims on a pleading motion, holding that, even if the brand company "signed a bad deal for itself and a good deal for [the generic]," this would not make it an actionable reverse-payment agreement. *Id.*

Likewise, as discussed in Impax's opening brief, Complaint Counsel in *Schering-Plough* challenged the respondents' "side deal," alleging that the parties' diligence was "strikingly superficial relative to industry standards." *Schering I*, 2002 WL 1488085, at *93, *95; (*see* Impax PTB at 47–48.) This Court held, and the Eleventh Circuit affirmed, that expert testimony regarding what was usual for the industry did not demonstrate that the agreement was anything other than "a bona fide side deal for fair value." *Schering I*, 2002 WL 1488085, at *93–95; *see Schering-Plough Corp. v. FTC* ("*Schering II*"), 402 F.3d 1056, 1068–71 (11th Cir. 2005).

Through Dr. Geltosky's opinions, Complaint Counsel insinuates that the DCA was a not a legitimate collaboration—and thus that Endo and Impax intended it as a payment for delay. But Dr. Geltosky himself refused to testify that the DCA was not *bona fide*. (FOF ¶¶ 515–18; *see* Geltosky, Tr. 1125–28.) Dr. Geltosky reviewed all the DCA documents cited in Complaint Counsel's brief, and yet offered no opinion regarding the merits of the deal, or even whether Endo exercised sound business judgment in signing it. (FOF ¶¶ 516–17; Geltosky, Tr. 1125–26.) For all Complaint Counsel's eyebrow-raising, the DCA cannot be condemned as an "unjustified" payment for delay merely because [redacted] (Geltosky, Tr. 1103, 1113–14; *see* FOF ¶¶ 501–14.)

4. Dr. Geltosky's Opinions Are Unreliable.

Even if Dr. Geltosky's opinions were relevant to determining whether the DCA payment was "large" or "unjustified," they are not reliable. Dr. Geltosky's opinions regarding "usual" industry practices are based "primarily" on his personal experiences. (Geltosky, Tr. 1128; *see* Reply FOF ¶¶ 1103, 1136.) But there is no one-size-fits-all approach to pharmaceutical collaborations (Reply FOF ¶ 1111; Cobuzzi, Tr. 2543), and Dr. Geltosky lacks any significant experience with deals similar to the one at issue here. (Reply FOF ¶¶ 1103, 1136.)

Dr. Geltosky admitted that he has been involved in only a "handful" of deals involving a discovery-stage asset, as IPX-203 was in 2010. (FOF ¶ 550; Geltosky, Tr. 1144–45.) He has virtually no relevant experience at a mid-sized pharmaceutical company like Endo. (FOF ¶¶ 552–54; Reply FOF ¶¶ 1103, 1136; Geltosky, Tr. 1141–43, 1177.) In all but a few of the deals Dr. Geltosky has worked on, the party investing in the asset was a behemoth. (FOF ¶ 553; Reply FOF ¶¶ 1103, 1136; Geltosky, Tr. 1141, 1160, 1180.) Those companies have annual sales and research and development budgets exponentially larger than Endo's. (FOF ¶ 553; Reply FOF ¶ 1103.) As Dr. Geltosky admitted at trial, he cannot speak to how mid-sized pharmaceutical companies approach the evaluation of discovery-stage product candidates. (FOF ¶ 554; Reply FOF ¶ 1103; Geltosky, Tr. 1143; *see also* Cobuzzi, Tr. 2626–27.)

Dr. Geltosky also held himself out as an expert on "what Endo documents mean"—despite the fact that he has never worked at or consulted for Endo, and was not offered as an expert on this topic. (Geltosky, Tr. 1121, 1058; *see* FOF ¶¶ 537–39, 542–44, 560–62; Reply FOF ¶ 1102.) In this capacity, he drew conclusions from a set of documents that Complaint Counsel curated for him, in some instances basing his opinion on a single document.[29] (FOF ¶¶

[29] For example, Dr. Geltosky's conclusion that Endo did not follow its ordinary business development practices in diligencing the DCA derives from his review of ***one*** Endo document

Geltosky Opinion Identified by Complaint Counsel	**What the Record Evidence Actually Says**
"4) Endo conducted only a few days of limited diligence on IPX-203 in order to 'check the box,' even though the industry standard and Endo's documented process is to perform weeks of rigorous due diligence on a potential development opportunity." (CC PTB at 64.)	Endo as a company, and specific members of the diligence team (Robert Cobuzzi and Kevin Pong), had expertise in and had previously done work involving carbidopa-levadopa Parkinson's disease treatments. (FOF ¶¶ 387–88, 416–18.) Dr. Cobuzzi testified that in light of this expertise and experience, as well as the information Impax had provided, he felt he had sufficient time to assess the DCA and conclude it presented a lucrative opportunity for Endo. (FOF ¶ 419.) Dr. Cobuzzi also indicated that due diligence never proceeds in a "perfect" sequence. (FOF ¶¶ 412–13.)
"5) Endo used information about IPX-066 as a 'surrogate' for evaluating IPX-203 even though IPX-203's success hinged on it being 'spectacularly better' than IPX-066." (CC PTB at 64.)	Dr. Cobuzzi testified that he uses comparator drug information "all the time," and that it is "much easier" to evaluate a candidate with this information. (FOF ¶¶ 406, 409.)[30] Dr. Cobuzzi and subject matter experts on his team determined IPX-066 was an appropriate comparator in assessing IPX-203. (FOF ¶ 401.) Given his team's familiarity with the area, Dr. Cobuzzi viewed this model as sufficient to allow him to reach his conclusion that the deal made financial sense for Endo. (FOF ¶¶ 397–405, 419–24, 547–49.) The Endo team viewed IPX-203 as likely to succeed in offering a Parkinson's treatment superior to other carbidopa levodopa treatments. (FOF ¶¶ 439–52, 464.)

[30] Dr. Geltosky himself admitted that information on IPX-066 was relevant to assessing "key variables" related to the DCA, and that use of benchmark drug information is generally appropriate. (FOF ¶¶ 407, 563–64.)

Geltosky Opinion Identified by Complaint Counsel	What the Record Evidence Actually Says
"6) Endo's financial valuation of the DCA relied on assumptions taken from IPX-066 that were inaccurate for IPX-203 and did not take into account any of the substantial development risks IPX-203 faced." (CC	

superior to any other; that there is no discernible population of patients for whom Opana ER is the only or best option; and that switching among LAOs is routine. (FOF ¶¶ 723–25, 729–45; *see, e.g.*

All of this evidence leads to one conclusion: Opana ER competed in a relevant market that included many LAOs. (FOF ¶¶ 693–97.) Because Endo's share of that market never even approached 10%, it could not have possessed monopoly power. (FOF ¶¶ 1002–09.)

B. Complaint Counsel's Attempted Criticisms of Dr. Addanki's Monopoly Power Analysis Are Unavailing.

Complaint Counsel tries to poke holes in Dr. Addanki's analysis of the relevant market and Endo's alleged monopoly power, but none of its criticisms holds up.

1. Dr. Addanki Does Not "Misunderstand" the Monopoly Power Inquiry.

Complaint Counsel starts from the premise that Dr. Addanki "misunderstands" the monopoly power inquiry. (CC PTB at 56.) According to Complaint Counsel, "[m]uch of Dr. Addanki's conclusion regarding market power stems from his use of the term 'market power' to mean the ability to set price above marginal cost ***as a result of anticompetitive conduct***." (CC PTB at 56.) This assertion is nothing short of baffling. Complaint Counsel's ostensible "support" is limited to two paragraphs in Dr. Noll's rebuttal report, which relate ***solely*** to the Lerner Index—not to Dr. Addanki's broader analysis. (*See* CCF ¶ 957 (citing CX5004 (Noll Rebuttal Rep. ¶¶ 115–16)).) In those paragraphs, Dr. Noll addr

"normal market outcome" in many industries, including the pharmaceutical industry. (FOF ¶¶ 677, 681; Noll, Tr. 1415–16.) These admissions only ***confirm*** Dr. Addanki's statement that pricing above marginal cost does not show monopoly power, and hence cannot satisfy the monopoly power requirement in an antitrust rule of reason case. Complaint Counsel's attempt to construe this undisputed point as evidence of some "misunderstanding" gets nowhere.

2. There Is Substantial Evidence of Economic Substitution Among Long-Acting Opioids.

Complaint Counsel next claims that "Dr. Addanki incorrectly equates therapeutic, or functional, interchangeability with economic interchangeability." (CC PTB at 57.) In its telling, Dr. Addanki's analysis showed that LAOs "work in generally simi

Dr. Addanki's analysis of competition at the payor level is compelling proof that LAOs belong to a single product market. Reflecting the "fear . . . of formularies" that this Court observed at trial (Court, Tr. 2143), Complaint Counsel simply refuses to engage with the reality that formularies provide direct evidence of ***economic*** substitution. (FOF ¶¶ 854, 876–77; *see* Addanki, Tr. 2225–26 ("The second thing you can infer [from competition for formulary placement] is that economic substitutability is actually happening."); RX-547 (Addanki Rep. ¶ 44 ("[F]ormulary structures can—and, as I show below, do in this case—provide useful insights about economic substitutability among pharmaceuticals.").)[33] All said, Complaint Counsel devotes less than a ***single page*** in its brief to discussing formularies. (CC PTB at 58.)

Formularies are the means by which payors "promote competition among prescription pharmaceutical suppliers and control costs." (Addanki, Tr. 2217; *see* FOF ¶¶ 818–20.) Pharmaceutical companies compete on the basis of price—in the form of discounts and rebates, which lower the net prices insurers pay for drugs—to secure favorable placement on insurers' formularies. (FOF ¶¶ 818–31.) Formularies thus embody ***two*** forms of price competition: first, drug companies compete on price to secure favorable positioning; and second, if a company is successful in winning favorable formulary placement, its products are made available to patients at a lower out-of-pocket price (in the form of a copay). (FOF ¶¶ 59–63, 67–75, 828.)

Indeed, the very idea of a formulary is ***founded*** on economic substitution. Lowering patients' out-of-pocket costs for certain medications, but not others, drives patients to the favored drugs. (FOF ¶ 828.) As Dr. Addanki noted, "if the insurers didn't think they could actually

[33] (*See also* RX-547 (Addanki Rep. ¶ 57) ("[T]he willingness of a drug benefit plan to vary the relative positioning of products in a given category underscores that the plan regards the products as ***economic substitutes***.") (emphasis added); Addanki, Tr. 2232–33 ("So what you've got going on is you've got ***substitution going on in response to price competition***, which is, of course,

drive volume by adjusting their formularies, . . . the insurers wouldn't bother." (Addanki, Tr. 2226; *see* FOF ¶ 828; Reply FOF ¶¶ 944–45, 949.) The antitrust agencies recognize this dynamic. *See* Fed. Trade Comm'n & U.S. Dep't of Justice, *Improving Health Care: A Dose of Competition*, Ch. 7 at 11–12 (July 2004) ("Through a formulary, the [pharmacy benefits manager ('PBM')] controls the price that health plans and enrollees pay and may influence the use of various drugs and the mix of drugs dispensed. . . . Greater formulary compliance allows the PBMs to negotiate with the pharmaceutical manufacturer for better prices, because formulary compliance is an indication of the ability of the PBM to steer enrollees to various drugs.").

Endo's business documents affirm that "managed care access is id c ÿ ! on iz

multiple products," LAO makers had to "create a financial position for the payer" that justified favorable formulary placement. (FOF ¶ 821 (quoting Bingol, Tr. 1325).)

Impax has shown that changes in relative price—as embodied in formulary changes—***do*** induce switching among LAOs, thus demonstrating cross-elasticity of demand. (FOF ¶¶ 731, 750–72); *see Du Pont*, 351 U.S. at 400 ("An element for consideration as to cross-elasticity of demand between products is the responsiveness of the sales of o

see FOF ¶¶ 899–914.) The existence of these program further establishes that LAOs were economic substitutes, since, as Dr. Addanki testified, we do not see this kind of

theory is inconsistent with business documents showing that Endo competed for formulary placement ***on the basis of price***. Sections III.A and III.B.2, *supra*.[36] Complaint Counsel does not cite a single document suggesting that Endo or any other LAO maker sought to obtain favorable formulary placement through "product differentiation."[37] *V(SeQGCLUEHTFK.LaVEB;HC6aJVH¶8supra@1ORVHPà* 944.) "Conclusory allegations, speculation, and unsubstantiated assertions are not evidence." *Olabisiomotosho v. City of Houston*, 185 F.3d 521, 525 (5th Cir. 1999).

Complaint Counsel's theory also cannot explain Dr. Addanki's finding that "individual formularies change the relative positions of [LAO] products over time." (RX-547 (Addanki Rep. ¶ 76); *see* FOF ¶¶ 869–75.) If an insurer were persuaded to favor a particular LAO on the basis of its differentiated qualities, one would not expect to see consistent "churn" on that insurer's formulary. (Reply FOF ¶¶ 943–49.) Complaint Counsel would apparently have this Court believe (again, without any supporting evidence) that product differentiation leads individual insurers to constantly change their minds about which LAO is superior. The trends identified by Dr. Addanki are far more consistent with price competition producing different "winners" and "losers" over time—a reality that is borne out in Endo's business records. (Reply FOF ¶¶ 943–49; RX-547 (Addanki Rep. ¶¶ 72–76); *see* FOF ¶¶ 836–60.)

Finally, Complaint Counsel repeats Dr. Noll's criticism that Dr. Addanki's MMIT analysis excludes generic LAOs. (CC PTB at 58.) As Dr. Addanki explained at trial, the purpose of this particular analysis was to assess the degree of competition among LAOs for which an AB-rated generic was ***not*** available—*i.e0026088c0000300538not?ORELpàA00VE@08@SàV)2)$SHpàA0$ppàE60EPààE@R*

this Court anything new about competition among LAOs, because it is undisputed that generic drugs usually end up on favorable formulary tiers. (Reply FOF ¶¶ 946–50; Addanki, Tr. 2313–15.) Of course, if Dr. Addanki were to add generic LAOs to his MMIT analysis, "all we'd be doing is adding another layer or another bar here or another few bars there"; it would not change the story about the degree to which Opana ER competed against other LAOs for which a generic was not available during the time period studied, such as OxyContin, Avinza, MS Contin, and Exalgo. (Addanki, Tr. 2314; *see* Reply FOF ¶¶ 946–50.)

In other words, Complaint Counsel misses the point of the MMIT study, which was but one component of Dr. Addanki's monopoly power analysis. Complaint Counsel also does not seem to realize that even if the relevant market were strictly limited to the branded LAOs that Dr. Addanki included in the MMIT analysis, Opana ER's market share would still be miniscule.[38] Finally, Complaint Counsel overlooks the fact that the UPMC study ***did*** include generic LAOs. (Reply FOF ¶ 654; RX-087.) When UPMC changed its formularies to favor Opana ER and various generic LAOs over branded OxyContin, generic Morphine Sulfate ER and generic Fentanyl patch each saw an uptick in prescriptions. (Reply FOF

4. Ordinary Course Business Documents Reflect Price Competition Among LAO Makers.

Complaint Counsel next asserts that Endo's internal business documents "overwhelmingly focus on ***differentiating*** Opana ER from other LAOs based on its unique characteristics—not competing with them on price." (CC PTB at 57.) Complaint Counsel elides the fact that that its "supporting" evidence is limited to a handful of documents discussing Endo's ***promotional*** activities. (Reply FOF ¶¶ 940–42; *see* CCF ¶¶ 940–42.) Documents that discuss price competition at the payor and patient levels may be unfavorable to Complaint Counsel's case, but Complaint Counsel cannot simply sweep them under the rug.

The reality is that Endo's business documents ***do*** discuss price competition. As described in Impax's opening brief, for example, in an April 2012 internal analysis, [redacted] (Impax PTB at 95; CX3206-002; *see* FOF ¶ 850.) [redacted] (CX3206-002; *see* FOF ¶ 850.) Endo expected that many payors would "see the price differential as sufficient incentive to utilize Opana ER and make the prescribing formulary change." (CX2606-002; *see* FOF ¶ 850; Reply FOF ¶ 919.) Complaint Counsel has no excuse for overlooking this document, given that Dr. Noll cites it in his report. (*See* CX5000 (Noll Rep. ¶ 149).)

Similarly, in an April 9, 2013 "Business Review" for Opana ER, Endo directly compared Opana ER's pricing to that of two other LAOs, OxyContin and Nucynta ER. (Reply FOF ¶ 940; RX-073.0002 (Slide 72).) Endo indicated that it sought to draw market share from competitors through "Pricing and Contracting Effectiveness," citing the "UPMC model" as an example by which Endo was able to "block Oxycontin." (Reply FOF ¶ 940; RX-073.0002 (Slide 30)). Indeed, Endo reported that the "Advantaged Formulary Status vs. OxyContin" showed the

"greatest" shifts in share from OxyContin to Opana ER. (Reply FOF ¶ 940; RX-073.0002 (Slide 33)). Endo specifically analyzed how Opana ER's formulary coverage measured up to that of OxyContin and Nucynta ER. (Reply FOF ¶ 940; RX-073.0002 (Slide 8).)

Endo and its rivals also discussed one another's copay programs, by which they competed on price at the patient level. (FOF ¶¶ 899–915.) [redacted] (FOF ¶¶ 904–06 (quoting RX-028.0011).) [redacted] (FOF ¶ 912; *see, e.g.*, RX-445.0015 [redacted].) [redacted] (FOF ¶ 911; RX-448.0020.) These documents are highly probative of market definition. *See FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1080 (D.D.C. 1997) (relying on evidence that Staples and Office Depot "price check[ed] the other office superstores" in defining relevant market as sale of office supplies through office superstores). And yet Complaint Counsel pretends this evidence does not exist.

Even when it came to promotion, LAO makers were not wholly concerned with product differentiation; economic substitution still loomed large. In 2009, Endo noted that prescribers cited Opana ER's lack of formulary coverage as its "most negative aspect." (CX1106-009; *see* FOF ¶ 837.) Endo competed aggressively for formulary placement in ensuing years, winning a number of victories. Section III.B.2, *supra*; (FOF ¶¶ 840–52.) It then informed prescribers of

"OPANA ER formulary access" through marketing. (RX-16.0002 at 97; *see* FOF ¶ 897.) Endo specifically targeted prescribers that were known to "switch from Oxycontin or [Morphine Sulfate ER] to OPANA ER." (RX-023.0002.) [redacted] (RX-445.0021–22; *see* FOF ¶ 897.) And Dr. Michna confirmed that formulary status often figures into LAO makers' promotional efforts. (FOF ¶ 898; CX4046 (Michna, Dep. 148–49).) To suggest, as Complaint Counsel does, that Endo's promotional documents focus solely on product differentiation is to ignore what the evidence actually says.

Moreover, the notion that product differentiation efforts show that LAOs did not compete on price is false. (Impax PTB at 95–96.) Complaint Counsel apparently does not appreciate that the need to engage in promotion was in part driven by the recognition that LAOs "***are not very differentiated***." (FOF ¶ 999 (quoting RX-023.0002) (emphasis added).) "[N]onprice competition is too widespread to indicate power." *Antitrust Law* ¶ 520c.

5. Complaint Counsel's Invocation of the "Cellophane Fallacy" Is Meaningless.

Rather than engage with evidence showing that LAOs are economic substitutes, Complaint Counsel attempts to write it off as an example of the "cellophane fallacy."[39] (CC PTB at 59.) Setting aside the fact that this fallacy is named for a criticism of the Supreme Court's *Du Pont* decision, which remains good law,[40] Complaint Counsel does nothing to

[39] Impax notes that in *Schering-Plough*, Complaint Counsel also (unsuccessfully) charged that Dr. Addanki and the respondent had committed the cellophane fallacy. (*See* Compl. Counsel's Reply Br. at 53–54, *In re Schering-Plough Corp.*, Dkt. 9297 (F.T.C. May 14, 2002).)

[40] As this Court has observed, "[r]elying on *du Pont*, courts have found the 'reasonable interchangeability' standard to be the essential test for ascertaining the relevant product market." *N.C. Bd. of Dental*, 152 F.T.C. at 161.

explain why real-world evidence of price-induced switching is an instance of the fallacy rather than genuine evidence of an LAO market. (*Id.*; *see* Reply FOF ¶ 930–33.)

By Complaint Counsel's logic, an antitrust plaintiff can simply shout "cellophane fallacy" to discount ***any*** real-world evidence of switching among products. Contrary to Complaint Counsel's argument, however, the antitrust agencies recognize that evidence of "how customers have shifted purchases in the past in response to relative changes in price or other terms and conditions" is probative of the relevant market. U.S. Dep't of Justice & Fed. Trade Comm'n, *Horizontal Merger Guidelines* § 4.1.3 (2010).

The sole case Complaint Counsel cites in this regard, *United States v. Eastman Kodak Co.*, 853 F. Supp. 1454 (W.D.N.Y. 1994), *aff'd*, 63 F.3d 95 (2d Cir. 1995), only further underscores why its "cellophane fallacy" argument does not hold water. Like Complaint Counsel here, the government in *Kodak* accused the defendants' expert of committing the cellophane fallacy. *Id.* at 1469–70. The court disagreed. Whereas the purportedly competing products in *Du Pont* "were not particularly good substitutes for cellophane," the various brands of photographic film at issue in *Kodak* were of comparable quality and "compet[ed] for the same customers." *Id.* at 1470. The existence of "subtle quality differences" among the products did not render them each markets unto themselves. *Id.* at 1470 & n.9.

So too here. Despite minor chemical differences, LAOs treat the same conditions, are used interchangeably by physicians, and compete for the same customers. (FOF ¶¶ 698–710, 720–28, 940–59, 970.) In fact, LAOs are ***viewed by the market participants themselves*** as direct competitors. (FOF ¶¶ 788–814.) Market participants are "presumed to have accurate perceptions of economic realities." *1-800 Contacts*, at 124–25 (quotation omitted).

* * *

In short, Complaint Counsel's attempts to undermine Dr. Addanki's analysis of the relevant market and monopoly power fall flat.

C. Complaint Counsel Cannot Run from the Commission's Conclusion That Opana ER Competed in the Long-Acting Opioid Market.

Impax is not alone in the position that Opana ER competed against other LAOs in the relevant market. In 2009, just one year before the SLA was signed, the Commission itself reached the same conclusion in reviewing a proposed merger between King Pharmaceuticals and Alpharma. (*See* Compl. ¶¶ 1, 11, *In re King Pharm., Inc. & Alpharma Inc.*, No. C-4246 (F.T.C. Feb. 2, 2009)); King Pharm., Inc. and Alpharma Inc. Agreement Containing Consent Order to Aid Public Comment, 74 Fed. Reg. 295, 296 (Jan. 5, 2009).

Apparently lacking any cogent response to the Commission's findings, Complaint Counsel resorts to misrepresentation. Complaint Counsel insists that, in fact, the Commission in *King Pharmaceuticals* alleged a relevant market consisting only of "'oral long-acting morphine

As the Commission stated in its analysis published in the Federal Register, the proposed acquisition threatened to eliminate competition "in the market for oral long acting opioid analgesics ('oral LAOs')." 74 Fed. Reg. at 296. The Commission specifically stated that "***Endo***

(D.D.C. 2000) (rejecting both parties' expert analyses as "not persuasive"; relying on "[t]he views of Swedish Match and National competitors, statements by loose leaf distributors, and internal documents of Swedish Match and National" to determine the relevant market). And here, the "business reality"—as demonstrated by evidence from companies that compete in the market—is that LAOs competed on price at every level of the pharmaceutical industry. (*See* Impax PTB at 75–91); Section III.B.4, *supra*. This evidence is unrebutted.

Even if generic versions of original Opana ER ***were*** more successful than other generic LAOs in stealing share from Endo's reformulated Opana ER, as Complaint Counsel contends, that does not mean the relevant market is limited to Opana ER. (Reply FOF ¶ 935.) It only makes sense that generic versions of Opana ER would have a more pronounced impact on branded Opana ER sales, particularly given that Actavis' generic Opana ER benefited from AB-rated substitution and Impax specifically marketed its generic product to physicians who prescribed branded Opana ER.[41] (FOF ¶¶ 158, 229–31; Reply FOF ¶ 935; *see* RX-394.) Complaint Counsel repeatedly states that generic and branded versions of Opana ER are "close" or "uniquely close" substitutes (*see, e.g.*, CC PTB at 48, 49 n.26, 51, 52), but that argument misses the mark. The question is not whether Opana ER and other LAOs are "uniquely close" substitutes—the question is whether they are "***reasonable*** substitutes, even though the products themselves are not entirely the same." *FTC v. Sysco Corp.*, 113 F. Supp. 3d 1, 25 (D.D.C. 2015) (emphasis added) (citing *Cardinal Health*, 12 F. Supp. 2d at 46; *Staples*, 970 F. Supp. at 1074). To belong to the same market, products need only be "roughly equivalent to one another for the

[41] Actavis and Impax are the only companies that have sold generic Opana ER. (*See* FOF ¶¶ 116–17, 257.) Actavis no longer sells the drug due to the injunctions that resulted from Endo's follow-on patent suits. (FOF ¶¶ 251–56.)

use to which [they are] put." *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 436–37 (3d Cir. 1997).

Within a relevant market comprised of "reasonable" substitutes, some products may be "closer" substitutes than others. Pepsi and Coke are obviously "close" substitutes, but they still compete against other soft drinks. *See Green Country Food Mkt., Inc. v. Bottling Grp., LLC*, 371 F.3d 1275, 1282–83 (10th Cir. 2004) (rejecting argument that "Pepsi branded products constitute a market distinct from other soft drink products"); *Barq's, Inc. v. Barq's Beverages, Inc.*, 677 F. Supp. 449, 454–55 (E.D. La. 1987) (rejecting proposed market that was limited to root beer, and holing that the relevant market was "all soft drinks"). By the same token, even ***if*** branded and generic versions of Opana ER share certain "unique" qualities that make them particularly "close" substitutes, "these subtle differences [from other LAOs] . . . do not mean that other [LAOs] are not a reasonable substitute for [Opana ER]." *Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co.*, Civ. No. 12-3824, 2015 WL 1736957, at *10 (E.D. Pa. Apr. 16, 2015), *aff'd*, 838 F.3d 421 (3d Cir. 2016) (holding that the relevant market was not limited to branded and generic Doryx, but included other oral tetracyclines).[42]

[42] Impax acknowledges that it mistakenly cited *FTC v. Swedish Match* for the proposition that non-chemically identical products may belong to the same market so long as they are reasonably interchangeable. (Impax Post-trial Br. at 74 n.24); *cf. Swedish Match*, 131 F. Supp. 2d at 156–65 (determining that while loose leaf and moist snuff tobacco might belong to a "broader market" of "smokeless tobacco," the relevant market was limited to loose leaf tobacco, for which moist snuff tobacco was not economically substitutable). But that proposition—that the relevant market inquiry hinges on reasonable interchangeability, ***not*** on chemical identity—remains unassailable. *See Du Pont*, 351 U.S. at 393 ("there are certain differences in the formulae for soft drinks but one can hardly say that each one is an illegal monopoly").

In any event, *Swedish Match* only further demonstrates why the relevant market here is ***not*** limited to Opana ER products. There, the court affirmed that "determination of the relevant product market is 'a matter of business reality . . . of how the market is perceived by those who strive for profit in it.'" 131 F. Supp. 2d at 159 (quoting *Cardinal Health*, 12 F. Supp. 2d at 46). Rejecting the parties' expert economic analyses as "not persuasive," *id.* at 161, the court instead relied on "[t]he views of Swedish Match and National competitors, statements by loose leaf

This Court is "not required to accept uncritically" Dr. Noll's cursory observations about Opana ER sales trends. *It's My Party, Inc. v. Live Nation, Inc.*, 811 F.3d 676, 683 (4th Cir. 2016). Business realities show that Opana ER and other LAOs were economic substitutes. *See id.* ("No party can expect to gerrymander its way to an antitrust victory without due regard for market realities.") (citing *E.I. Du Pont de Nemours & Co. v. Kolon Indus., Inc.*, 637 F.3d 435, 442 (4th Cir. 2011)).

2. Complaint Counsel Failed to Prove That Switching Costs Are High.

were any, were not so high as to make switching between LAOs impractical. (FOF ¶¶ 778–84; Reply FOF ¶¶ 661–64.)

Complaint Counsel never estimated or quantified the alleged "switching costs." (FOF ¶ 986.) As Dr. Noll admitted, he made no such attempt; he merely "identified" the supposed costs. (FOF ¶ 986; Noll, Tr. 1553–54.) Nor does Complaint Counsel substantiate the claim that switching between LAOs is a "lengthy procedure." (CC PTB at 53.) Its "supporting" evidence, described in Paragraph 663 of Complaint Counsel's proposed findings of fact, says ***nothing*** about how long switching takes. (CCF ¶ 663; *see* Reply FOF ¶¶ 663–64.)[43] This failure of proof precludes Complaint Counsel from relying on amorphous claims about "switching costs" as evidence of its alleged relevant market. *See SMS Sys. Maint. Servs., Inc. v. Dig. Equip. Corp.*, 188 F.3d 11, 20 (1st Cir. 1999) ("SMS has not proffered significantly probative evidence sufficient to create a fact question as to whether this alleged switching cost is material"); *Brokerage Concepts, Inc. v. U.S. Healthcare, Inc.*, 140 F.3d 494, 515 (3d Cir. 1998) ("we find no evidence suggesting that U.S. Healthcare members who wish to switch HMOs face switching costs significant enough to constitute a lock in"); *Commercial Data Servers*, 262 F. Supp. 2d at 68–69 (rejecting plaintiff's proposed relevant market where plaintiff's expert "did not try to identify any S/390 customers who wanted to leave the S/390 platform but were unable to migrate due to high switching costs, or to quantify how many such customers there might be").

[43] In a similar vein, Complaint Counsel falsely states that "Dr. Michna agreed that small price changes are unlikely to cause [him] to switch a patient from one opioid to another." (CC PTB at 53.) Dr. Michna merely stated that he did not monitor day-to-day fluctuations in LAO prices. (Reply FOF ¶ 667; *see* CCF ¶¶ 565, 667; CX4046 (Michna, Dep. 149).) But as Dr. Michna explained, he ***is*** aware of changes in formulary tiering, and has switched hundreds of patients among LAOs in recent years due to such changes. (Reply FOF ¶ 667; CX4046 (Michna, Dep. 149); RX-549 (Michna Rep. ¶ 23).)

profile" did not delineate a relevant market because "[i]nterchangeability is defined by rough equivalence, not perfect correspondence"). And the fact that Opana ER may not work effectively for ***individual*** patients is neither here nor there. *See SMS Sys.*, 188 F.3d at 20 ("[t]estimony of unbearable switching costs by a mere handful of . . . customers" did not warrant single-product market); *Mylan*, 2015 WL 1736957, at *8, *10 (the fact that "acne treatment is 'highly individualized'" and that there might be "patients for whom Doryx is a preferred treatment" did not militate in favor of Doryx-only market). Since there is no discernible population of patients for whom Opana ER is the only or best option—a fact both medical experts agreed upon—it would be impossible for Endo to price-discriminate against any such patients. (FOF ¶¶ 928, 939; Michna, Tr. 2169; CX4041 (Savage, Dep. 38); CX4039 (Noll, Dep. 171–72) ("[Endo] wouldn't be able to price-discriminate among patients on the basis of their conditions.")); *see Horizontal Merger Guidelines* §§ 3, 4.1.4 (markets defined by "targeted customers" must be based on "observable characteristics").

Because Complaint Counsel has not shown that any alleged switching costs were high, its arguments on this point do nothing to establish that Endo possessed monopoly power.

3. Internal Doou

Complaint Counsel yet again parrots Dr. Noll's line that Endo's documents "do not refer to pricing of any other LAOs" (CC PTB at 54), but repeating that mantra does not make it any

4. The Fact That Some Courts Have Found Single-Drug Markets Does Not Dictate the Relevant Market in This Case.

Complaint Counsel points out that some courts have found relevant markets that were limited to a branded pharmaceutical product and its AB-rated generics. (CC PTB at 48–51.) Unsurprisingly, this selection omits the many cases in which courts have found relevant markets consisting of multiple pharmaceutical products.[46]

Complaint Counsel places particular emphasis on a recent district court decision involving the drug Lidoderm. (CC PTB at 50 (discussing *United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA, Inc.*, No. 14-md-02521-WHO, — F. Supp. 3d —, 2017 WL 5068533 (N.D. Cal. Nov. 3, 2017).) But that case just goes to show why the relevant market here is ***not*** limited to Opana ER. Unlike LAOs, which are broadly indicated for the treatment of chronic pain, Lidoderm is indicated only to treat "postherpetic neuralgia," though it can be prescribed to treat other conditions. 2017 WL 5068533, at *16. The defendants there nonetheless proposed an "essentially unlimited market for pain relief products," including opioids, anticonvulsants, antidepressants, muscle relaxants, non-steroidal anti-inflammatory

[46] *See, e.g.*, *Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 435–38 (3d Cir. 2016) (relevant market consisted of oral tetracyclines generally); *SmithKline Beecham Corp. v. Abbott Labs.*, No. C 07-5702 CW, 2014 WL 6664226, at *3 (N.D. Cal. Nov. 24, 2014) (evidence presented at trial was sufficient to establish multi-product market for "protease inhibitors"); *Bayer Schera Pharma AG v. Sandoz, Inc.*, No. 08 Civ. 03710 (PGG), 2010 WL 1222012, at *2–6 (S.D.N.Y. Mar. 29, 2010) (rejecting alleged single-API markets as "implausibly narrow"); *Schering I*, 2002 WL 1488085, at *73–78 (relevant market consisted of "all oral potassium supplements"; rejecting Complaint Counsel's allegation of single-product market); *In re Warner-Lambert Co.*, 87 F.T.C. 812, 915–18 (1976) (relevant submarket included branded and unbranded thyroid products); *see also In re Asacol Antitrust Litig.*, No. 15-cv-12730-DJC, — F.R.D. —, 2017 WL 5196381, at *27–30 (D. Mass. Nov. 9, 2017) (finding genuine issue as to whether relevant market was limited to Asacol 400mg and its AB-rated generics, or included "all oral 5-ASA treatments"); *Safeway Inc. v. Abbott Labs.*, 761 F. Supp. 2d 874, 888–89 (N.D. Cal. 2011) (genuine issue as to whether broad multi-drug or narrow multi-drug relevant market was appropriate); *Meijer, Inc. v. Barr Pharm., Inc.*, 572 F. Supp. 2d 38, 56–62 (D.D.C. 2008) (genuine issue as to whether relevant market was limited to brand and generic versions of specific contraceptive, or included variety of oral contraceptives).

drugs, and topical anesthetics. *Id.* at *1, *17. While the court rejected the defendants' vast market definition, it acknowledged that in pharmaceutical cases, courts "have limited the market to similar classes of drugs," *id.* at *18—just as the relevant market here is limited to LAOs. (*Cf.* Compl. ¶ 27, *In re Impax Labs., Inc.*, Dkt. 9373 (F.T.C. Jan. 19, 2017) ("Opioids are one of the world's oldest known classes of drugs, and they have long been used to relieve pain.").)

The defendants in *United Food* argued that "therapeutic equivalency" was sufficient to identify the contours of a market, and "essentially ignor[ed] c Ŏ ɹ n I Ɲ Ȯ

E. Complaint Counsel Failed to Carry Its Burden of Proving That Endo Possessed Monopoly Power.

Because Complaint Counsel failed to establish that the relevant market is limited to Opana ER, it cannot maintain that Endo possessed monopoly power in the relevant market. *N.C. Bd. of Dental*, 152 F.T.C. at 160. Endo's share of the actual relevant market—the market for LAOs—never even reached 10%. (FOF ¶ 1002; RX-547 (Addanki Rep., Ex.10).) That is insufficient to support an antitrust rule of reason claim. *Vollrath*, 9 F.3d at 1461.

Complaint Counsel half-heartedly resorts to various "direct" methods of proving monopoly power (CC PTB at 47–48, 55–56), but these are no more availing.

Ability to Exclude Competitors. In a single throw-away line, Complaint Counsel points to the fact that "Endo was able to exclude numerous generic firms as a result of its patents and by triggering the 30-month regulatory Hatch-Waxman stay" as ostensible evidence of Endo's monopoly power. (CC PTB at 55.) But the Supreme Court has rejected the "'patent equals market power' presumption." *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 44 (2006); (*see* Impax PTB at 97–98.) Endo's ability to trigger the 30-month stay by bringing a patent suit under the Hatch-Waxman Act is equally meaningless, since ***every*** holder of an Orange Book-listed patent can do the same when it receives a Paragraph IV certification. *See* 35 U.S.C. § 271(e)(2)(A); 21 U.S.C. § 355(j)(5)(B)(iii).

Price-Cost Margins. Arguing that Endo had a "high" price-cost margin, Complaint Counsel repeats the claim that "the Lerner Index for Opana ER shows that Endo had market power."[47] (CC PTB at 55.) It insists that in a highly competitive market, "the Lerner Index will be at or near zero." (*Id.*) Dr. Noll himself undermined these assertions at trial. He testified—on ***direct*** examination—that a high Lerner Index "doesn't necessarily mean" that a firm has

[47] A "Lerner Index" measures a supplier's markup of price over marginal cost. (FOF ¶ 673.)

monopoly power. (FOF ¶ 677; Noll, Tr. 1415; *see* Reply FOF ¶¶ 882–96.) Dr. Noll explained that in industries with "high fixed costs and low marginal costs," ***including the pharmaceutical industry***, a high Lerner Index is a "normal market outcome." (FOF ¶ 681; Noll, Tr. 1416; *see* Reply FOF ¶¶ 882–96.) Thus, even if Endo had a "high" Lerner Index, that is not evidence of monopoly power. (FOF ¶¶ 676–84; Reply FOF ¶¶ 882–96; *see* Noll, Tr. 1416 ("whether there's monopoly profit or not you don't know").) Complaint Counsel would have to show that Endo had an "abnormally high" price-cost margin ***and*** that it restricted output. *Mylan*, 838 F.3d at 434. Complaint Counsel has proven neither. *See id.* (plaintiffs failed to show that defendants' 83% margin was "abnormally high").[48]

Price Differentials. Complaint Counsel points out that the launch of generic Opana ER "result[ed] in dramatic cost savings to consumers" because Impax priced its product below Endo's reformulated Opana ER. (CC PTB at 47.) It goes on to argue that if Endo did not have monopoly power, "competition from existing products already would have driven down its Opana ER prices and profits to the competitive level." (*Id.* at 48.) This argument fails because, as just discussed, Complaint Counsel has not shown that Endo's prices or profits were

[48] If Endo had been exercising monopoly power to restrict output, then we should have seen an expansion in overall output when Impax launched generic Opana ER in January 2013. (FOF ¶ 664; Addanki, Tr. 2348–50.) But when Impax entered, there was ***no*** increase in prescriptions of branded and generic Opana ER, indicating that Endo had not been restricting output. (FOF ¶ 668; Addanki, Tr. 2350; RX-547 (Addanki Rep. ¶ 96, Ex. 12).)

Dr. Noll's claim that output in the fourth quarter of 2013 was 7% higher than in the fourth quarter of 2012 is based on quantities of Opana ER distributed to pharmacies, rather than actual quantities dispensed to consumers. (Reply FOF ¶ 964; CX5004 (Noll Reuttal Rep. ¶ 87).) Dr. Addanki's metric (actual prescriptions) is the more appropriate measure of output, since it measures actual consumption. (Reply FOF ¶ 964; CX4044 (Addanki, Dep. 162–63)); *see Major League Baseball*, 542 F.3d at 318–19 ("output" measured by consumption of MLBP licenses). If Endo were restricting output below consumer demand so as to maintain supracompetitive prices, then Impax's introduction of generic Opana ER should have caused an increase in product dispensed to (and consumed by) patients. (FOF ¶¶ 661–71; RX-547 (Addanki Rep. ¶ 96); CX4044 (Addanki, Dep. 71–72).) There was no such increase. (FOF ¶ 668.)

supracompetitive. (FOF ¶ 676; Noll, Tr. 1416.) In any event, price differences do not prove monopoly power. *See Twin City Sportservice, Inc. v. Charles O. Finley & Co.*, 512 F.2d 1264, 1274 (9th Cir. 1975) ("the scope of the relevant market is not governed by the presence of a price differential between competing products"). To hold otherwise "would render most brand name pharmaceutical companies as *per se* monopolists prior to generic entry." *In re Remeron Direct*

1488085, at *88 ("In a rule of reason case, Complaint Counsel must prove that the challenged agreements had the effect of injuring competition.").

The closest Complaint Counsel comes to addressing actual competitive effects is its contention that the SLA "eliminated the risk that Impax ***might*** have launched earlier than 2013." (CC PTB at 45 (emphasis added).) But Complaint Counsel does not muster up any evidence that, but for the settlement, Impax ***could have or would have*** launched generic Opana ER on a sustained basis prior to January 1, 2013. *See Sergeants Benevolent Ass'n*, 2016 WL 4992690, at *15 (plaintiffs must show "that the settlement agreements did, in fact, delay generic entry"); *McWane*, 2014 WL 556261, at *32–37 (where Complaint Counsel alleged that challenged agreement "eliminate[d] the risk of competition," ruling for respondents on the ground that the allegedly excluded competitor was not "reasonably probable" to enter the market in the absence of the agreement). Without more, the alleged elimination of some unparticularized, hypothetical risk of competition does not establish a rule of reason violation. *See Schering II*, 402 F.3d at 1072 ("the anticompetitive effect cannot be hypothetical or presumed") (citing *Cal. Dental*, 526 U.S. at 763 n.3);

date before 2013. (FOF ¶¶ 138–39; *see* Mengler, Tr. 565–67 (Endo was "adamant about 2013 and not getting anything into 2012" and "was certainly digging in their heels with that date"); Koch, Tr. 239 (Impax "met complete resistance to the concept of an earlier launch date").) Complaint Counsel does not contest this evidence. (*Cf.* Noll, Tr. 1599–1600 ("Impax's attempt to get an earlier date met with complete resistance.").) Nor does it contend that Impax and Endo could have or would have reached some hypothetical alternative settlement with an earlier entry date, were the alleged "payment" terms taken off the table. (CC PTB at 44–45; *see* FOF ¶¶ 1458–59, 1506 (neither Dr. Noll nor Dr. Bazerman could say that some alternative settlement was possible); FOF ¶¶ 1458–65, 1488–92, 1503–20, 1565–74 (no evidence or basis for assuming that a hypothetical alternative settlement was possible).) Indeed, as Complaint Counsel ***admits***, Impax asked for a simple entry date-only settlement, and Endo flatly refused. (CC PTB at 45; *see* FOF ¶¶ 133–35, 1508; Snowden, Tr. 370–75; CX4032 (Snowden, Dep. 96–99).)

Since Impax could not force Endo to accede to an earlier entry date, it was left with only two options: **(1)** negotiate a settlement with the earliest 2013 date it could secure, with protections in place to protect its ability to sell generic Opana ER on a robust and sustained basis, as it actually did; or **(2)** continue litigating against Endo and risk being enjoined from selling generic Opana ER. Complaint Counsel has done nothing to show that continued litigation would have permitted Impax to sell Opana ER on a sustained basis any earlier than January 2013.

1. Complaint Counsel Has Not Shown That Impax Would Have Launched Generic Opana ER At-Risk.

Complaint Counsel argues, as an initial matter, that "[t]he evidence does not support Î

Impax to show it would not have thrown caution to the wind and launched at-risk. Devoting just one paragraph to this argument, Complaint Counsel does ***nothing*** to address the evidence that Impax's activities were consistent with routine planning procedures that it follows for every product in its pipeline. (FOF ¶¶ 1239–1314; *see* Impax PTB at 115–26.) Complaint Counsel simply engages in unfounded innuendo, disregarding (and misrepresenting) the actual record.

Complaint Counsel first says Impax had "manufactured a large portion of its 'launch inventory build'" (CC PTB at 45), but that is not true. The ***only*** batches of generic Opana ER that Impax manufactured were for process validation—an FDA-required step that Impax must perform for all products, and which need not be repeated once it is successfully completed. (FOF ¶¶ 1257–61, 1302–06; Reply FOF ¶ 192; CX4010 (Mengler, IHT 71–72).) The "launch inventory build" refers to the amount of product that Impax has to manufacture, over and above the process validation batches, to support a full launch. (FOF ¶ 1252; *see* Camargo, Tr. 967–68.) And the undisputed evidence shows that Impax ***never began*** the launch inventory build. (FOF ¶¶ 1316–17; *see* Camargo, Tr. 1016, 1020; RX-186.0004; CX2898.)

Complaint Counsel also says Impax "had the API on hand to manufacture the remainder" of the launch build (CC PTB at 45), but again, the facts do not bear that out. At the time of the settlement, Impax did not have sufficient quota from the DEA to purchase all the API it would need to support a full launch. (Reply FOF ¶ 181; *see* FOF ¶ 1298 (Impax had to reduce launch inventory build from 12 batches to eight batches due to insufficient quota).) Complaint Counsel also omits the fact that Impax was later able to use what API it did have on hand to support the January 2013 launch of generic Opana ER. (FOF ¶¶ 1313–14; Camargo, Tr. 1022.)

And it is overly simplistic to say, as Complaint Counsel does, that "[t]he only remaining step was to seek formal authorization from the Board" to launch at-risk. (CC PTB at 45–46; *see*

FOF ¶¶ 1222–34.) Before Impax could pursue an at-risk launch of generic Opana ER, the following steps would have had to take place, at minimum: **(1)** senior management would have to decide to recommend an at-risk launch to the Board of Directors; **(2)** several members of senior management would have to make a "very formal presentation" to the Board; **(3)** senior management would have to respond to inquiries from the Board, which might necessitate the appointment of a special Board committee; **(4)** Mr. Koch would have to draft a resolution seeking the Board's vote; **(5)** the full Board would have to vote on whether to authorize the proposed at-risk launch; and **(6)** the vote and resolution would have to be recorded in the Board's minute book. (FOF ¶¶ 1179–1205; Impax PTB at 119–20.) ***None of this happened in the case of generic Opana ER.*** (FOF ¶¶ 1206–38; Impax PTB at 120–21.)

All told, Complaint Counsel presents no evidence that Impax was seriously considering an at-risk launch, or that Impax would have launched at-risk absent settlement. More importantly, Complaint Counsel ignores the real-world consequences of launching at-risk, which negate any suggestion that an at-risk launch would have benefited consumers to a greater extent than the SLA. Launching without a license would have risked a preliminary injunction, forcing Impax to withdraw from the marketplace. (FOF ¶¶ 1142, 1210–11; Snowden, Tr. 503–06.) And of course, if Impax's sales were enjoined, Impax would lose the benefit of its hard-earned 180-day exclusivity period. (FOF ¶¶ 1142, 1210–11; Figg, Tr. 1920, 1923; Noll, Tr. 1606; Addanki, Tr. 2380–81; Hoxie, Tr. 2778–80.) Complaint Counsel cannot argue with a straight face that any sales made during a brief at-ris

Launching without a license means risking lost profits damages—which can be trebled if the infringing sales are deemed willful. (FOF ¶¶ 1130–32.) Since generic drugs sell at a fraction of the branded drug's price, lost profit damages will ***always*** exceed the generic company's net revenues—potentially by many multiples. (FOF ¶¶ 1135–39.) Because of this, an at-risk launch could imperil Impax's very existence as a going concern. (FOF ¶ 1137; Koch, Tr. 287.)

Complaint Counsel has no answer to these realities. It offers neither evidence nor argument that Impax would have disregarded these severe risks and launched generic Opana ER without a license—or that consumers would have been better off in that scenario than they have been in the real world. (FOF ¶¶ 1363–69; RX-547 (Addanki Rep. ¶¶ 138–42, 155–57).)

2. Regardless of Litigation Outcomes, Continued Litigation Would Not Have Permitted Impax to Launch Generic Opana ER Without Risk Any Earlier Than January 2013.

And of course, the story would not have stopped there. In addition to the '482 patent, Impax would have had to deal with the two additional patents Endo obtained in 2012 (the '122 and '216 patents). (JX-003-006 (¶¶ 37–38).) And then the '737 and '779 patents in 2014. (JX-001-013 (¶¶ 59–60).) Regardless of litigation outcomes, Impax would have been tied up in litigation against Endo until well beyond January 2013—just as other generic companies have been. (FOF ¶¶ 1094–1105; Figg, Tr. 1951; *see* Addanki, Tr. 2360, 2363–64, 2376–79 (testifying that "in the but-for world . . . Endo and Impax would have been embroiled in litigation for years to come after that settlement").)

Absent settlement with Endo, there is no realistic scenario in which Impax could have launched generic Opana ER free from patent risk before January 2013. None. Because of this, Complaint Counsel cannot contend—and certainly has not shown—that the SLA harmed competition. Under the rule of reason, Impax is entitled to judgment. *See Cal. Dental Ass'n v. FTC*, 224 F.3d 942, 958 (9th Cir. 2000) ("Under rule-of-reason analysis, then, because CDA's advertising restrictions do not harm consumer welfare, there is no antitrust violation. In other words, the FTC has failed to demonstrate substantial evidence of net anticompetitive effect.").

B. Impax Has Offered Substantial, Unrebutted Evidence That the Settlement Was Procompetitive.

Complaint Counsel's failure to present evidence of actual anticompetitive effects is dispositive of this case. But even if Complaint Counsel had satisfied its initial burden under the rule of reason, its case would still fail, because Impax has presented unrebutted evidence that the SLA increased competition and benefited consumers. *See Toscano v. PGA Tour, Inc.*, 201 F. Supp. 2d 1106, 1123 (E.D. Cal. 2002) (granting summary judgment where plaintiff "fail[ed] to rebut the fact that there [were] procompetitive justifications"

As the Commission noted, this case is different from *Actavis* because it "involves patents beyond those in litigation at the time of the Settlement Agreement, and a provision of that agreement allowed generic entry notwithstanding the potential that such patents might issue." Comm'n Decision at 12. Whereas other generic companies have been permanently enjoined from selling generic Opana ER until 2029, Impax has been providing the product to consumers for the past five years. (FOF ¶¶ 256–57.) In fact, Impax is currently the ***only*** supplier of any version of Opana ER—all thanks to the SLA. (FOF ¶ 264; JX-003-008 (¶ 59).)

Impax could never have achieved this outcome had it not settled with Endo. Section IV.A, *supra*. Because the SLA expedited and safeguarded Impax's ability to launch generic Opana ER, it promoted competition and benefited consumers. These indisputable procompetitive benefits easily satisfy Impax's burden under the rule of reason. *See NCAA*, 468 U.S. at 102 (actions that "enable[] a product to be marketed which might otherwise be unavailable . . . widen consumer choice . . . and hence can be viewed as procompetitive."); *Law v. NCAA*, 134 F.3d 1020, 1023 (10th Cir. 1998) ("making a new product available" and "widening consumers choice" are procompetitive benefits); *AbbVie Inc.*, 107 F. Supp. 3d at 437 (agreement that "facilitate[ed] Teva's ability to compete in the cholesterol drug market [was] good for the consumer" and procompetitive under *Actavis*); *Wellbutrin*, 133 F. Supp. 3d at 760 ("ensuring consistent supply of product . . . to consumers" is a procompetitive justification).

Wellbutrin is instructive. There, the defendants raised as a procompetitive justification the fact that the generic companies (Anchen/Teva) procured, as part of a settlement with GlaxoSmithKline (GSK), a sublicense to a patent (owned by Andrx) that was not at issue in the original patent suit. 133 F. Supp. 3d at 737, 747, 759. Teva had insisted on the sublicense on the ground that it "needed 'the full freedom to operate' without concern over [a] patent infringement

claim by Andrx." *Id.* at 747. The court held that the sublicense was a cognizable procompetitive justification for the settlement, since it "eliminat[ed] an independent and substantial hurdle to generic entry" and removed "the possibility that Andrx could prevent generic Wellbutrin XL from being marketed for the 15 years remaining on its patent." *Id.* at 758–59.

So too here. Impax was aware that Endo was "banking on" its pending patent applications (FOF ¶ 147; RX-398.0001), and that if those patents issued, they would be an "independent and substantial hurdle to generic entry." *Wellbutrin*, 133 F. Supp. 3d at 759. And so Impax negotiated for a license to both existing ***and*** future patents, which would guarantee it the "freedom to operate." (FOF ¶¶ 145–57; CX4026 (Nguyen, Dep. 155–58).) The SLA thus eliminated the possibility that Endo could prevent Impax from selling generic Opana ER until Endo's existing and any later-issued patents would expire. Consumers have reaped the benefits of earlier and sustained access to low-priced generic Opana ER. This is procompetitive.

1. Complaint Counsel Does Not Deny That the Settlement—the "Restraint" at Issue—Has

$10 million DCA payment—did not restrain competition. Complaint Counsel appears to concede as much, noting that "the payment on its own does not technically 'restrain' Impax's entry." (CC PTB at 69.) But this is not a technicality; this is the sum and substance of the rule of reason. *See Bd. of Trade*, 246 U.S. at 238 ("The true test of legality is whether the ***restraint*** imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition.") (emphasis added); 15 U.S.C. § 1 (prohibiting ***agreements "in restraint of trade"***) (emphasis added).

In a reverse-payment case, the relevant restraint is the settlement itself, which governs whether and when the generic company can enter the market. Section I.E, *supra*. As the California Supreme Court held in *Cipro*, "[o]nce a plaintiff has made out a *prima facie* case that a reverse payment patent settlement has anticompetitive effects," the burden shifts to "the defendants to offer legitimate justifications and ***come forward with evidence that the challenged settlement is in fact procompetitive***." 348 P.3d at 869–70 (emphasis added). While Complaint Counsel did not make out a *prima facie* case of anticompetitive effects, Impax provided overwhelming evidence that the settlement was procompetitive. The consumer benefits flowed directly from the "restraint"—the settlement—which "was negotiated as a whole, agreed to as a whole, and went into effect as a whole." *Wellbutrin*, 133 F. Supp. 3d at 754.

The flaw in equating the reverse payment to the challenged restraint is evident from the face of Complaint Counsel's post-trial brief. Complaint Counsel suggests that the alleged payment terms were not necessary or responsible for the SLA's procompetitive benefits, since "Impax surely did not need to be paid to accept the broad license," and "Endo certainly would have been willing to give ***less***, i.e., just the license and not the payment," "in exchange for the January 1, 2013 entry date." (CC PTB at 69.) But this hypothetical settlement—one with a

January 1, 2013 entry date and the broad patent license, but with no alleged payment terms—***is no less restrictive of competition than the actual SLA***. In other words, Complaint Counsel's own hypothetical merely underscores that the alleged payments are not "restraints."

Complaint Counsel's own cases demonstrate the distinction between paym

restraint was anticompetitive. *See id.* at 686–87 ("as a result of the Board's action . . . numerous non-dentist teeth whitening providers in North Carolina stopped offering teeth whitening services"). The Fourth Circuit and Supreme Court affirmed. *See N.C. Bd. of Dental Exam'rs v. FTC*, 717 F.3d 359, 374–75 (4th Cir. 2013), *aff'd*, 135 S. Ct. 1101 (2015).

In *1-800 Contacts*, this Court also relied on evidence of "actual," post-restraint effects in finding a violation of the antitrust laws. *1-800 Contacts*, at 151–56. For example, this Court found that "the Challenged Agreements were effective in restricting advertisements from competitors in response to a search for 1-800 Contacts' trademark terms," which led to increases in "sales for 1-800 Contacts, the higher-priced competitor." *Id.* at 154–55. This real-world evidence of "actual anticompetitive effects" was bolstered by two experts' economic modeling of the but-for world, which demonstrated that consumers "more likely than not" paid higher prices as a result of the respondents' conduct. *Id.* at 156–60. As *1-800 Contacts* underscores, there is no basis for turning a blind eye to actual, post-settlement competitive effects.[52]

To support its nonsensical argument, Complaint Counsel erects another strawman, mischaracterizing Impax's position as being that the SLA's procompetitive character hinges on the subsequent patent rulings upholding Endo's patents. (CC PTB at 71.) That is emphatically not true. Impax has already demonstrated that ***regardless*** of the whether Impax or Endo prevailed in the original litigation, or in any subsequent litigation, it would not have been able to sell generic Opana ER without patent risk before January 2013. Section IV.A.2, *supra*; (Impax

[52] As Impax has previously shown, the few cases Complaint Counsel cites for the idea that the rule of reason ignores post-restraint effects all trace back, directly or indirectly, to two cases—neither of which actually supports Complaint Counsel's position. (*See* Resp't Impax Labs., Inc.'s Opp. to Compl. Counsel's Mot. for Partial Summ. Dec. at 16–17,

PTB at 106–12.) If anything, the later patent rulings only confirm Impax's wisdom in negotiating the SLA, which has been a major boon for consumers.[53]

* * *

Impax has proven through substantial unrebutted evidence that the SLA resulted in significant procompetitive effects.

C. Complaint Counsel Has Not Attempted to Show That a Less Restrictive Alternative Was Possible.

Complaint Counsel does not attempt to rebut Impax's showing of procompetitive justifications. In fact, Complaint Counsel's post-trial brief does not even address less restrictive alternatives. (*See* CC PTB at 71.) This alone warrants judgment for Impax. *See N. Am. Soccer League*, 2017 WL 5125771, at *15, *19–21 (no likelihood of success where defendant proffered evidence of procompetitive effects, and plaintiff failed to "provide some alternative to the [challenged restraint] that offer[ed] the same procompetitive benefits . . . 'without significantly increased cost'") (quoting *O'Bannon*, 802 F.3d at 1074).[54]

It is Complaint Counsel's burden to "make a strong evidentiary showing" that a "substantially less restrictive alternative" was "viable." *O'Bannon*, 802 F.3d at 1074. At no point has Complaint Counsel even ***attempted*** to articulate a specific, less restrictive alternative

[53] Complaint Counsel's suggestion that it is "unworkable" to "focus on how events unfolded" after the settlement (CC PTB at 67) ignores the fact that courts do this all the time. Where potential anticompetitive effects never actually materialize, courts enter judgment for defendants. *See, e.g.*, *Top Mkts., Inc. v. Quality Mkts., Inc.*, 142 F.3d 90, 96–97 (2d Cir. 1998) (affirming summary judgment where plaintiff "failed to show any adverse effect on competition as a whole," despite evidence of "***potentially*** higher prices"); *Mineabea Co. v. Papst*, 444 F. Supp. 2d 68, 219 (D.D.C. 2006) (judgment for defendants when, "even if Papst had intended to cause anticompetitive effects,

that it contends was feasible under the circumstances. In fact, Complaint Counsel has not shown that Impax and Endo were capable of reaching ***any*** alternative settlement.

Complaint Counsel cannot simply assume, without evidence, that some hypothetical alternative settlement with an earlier entry date was feasible here. In some cases, a "pure" entry date settlement is not possible at all. (FOF ¶¶ 1565–74; RX-547 (Addanki Rep. ¶¶ 115–24).) These include situations in which **(1)** the parties have divergent views on the likely outcome of the patent case; **(2)** there is asymmetric information regarding future demand for the branded drug; and **(3)** the brand company is planning to introduce a reformulated product. (FOF ¶¶ 1565–74; RX-547 (Addanki Rep. ¶¶ 115–24)

(2) a prohibition on "entering into or being party to" any agreement that "in any way disincentivizes competition between Oxymorphone ER Products"; and **(3)** a specific order nullifying the "First Amendment to the 2010 Settlement and License Agreement" (the "2017 Settlement"). (Compl. Counsel's Proposed Order ("CC PO") § II.) Complaint Counsel also asks this Court to impose a compliance program and reporting requirements. (*Id.* §§ III, IV.) Complaint Counsel proposes that these measures remain in effect for 20 years. (*Id.* § VII.)

"[C]omplaint counsel bears the burden of showing the need for injunctive relief." *TRW, Inc. v. FTC*, 647 F.2d 942, 954 (9th Cir. 1981).[55] Antitrust remedies "should be tailored to fit the wrong creating the occasion for the remedy," *Microsoft*, 253 F.3d at 107, going "no further than is reasonably necessary to correct the evil and preserve the rights of competitors and public," *FTC v. Royal Milling Co.*, 288 U.S. 212, 217 (1933). Each remedy must be "as specific as possible, not only in the core of its relief, but in its outward limits, so that parties may know[ ] their duties and unintended contempts may not occur." *Int'l Salt Co. v. United States*, 332 U.S. 392, 400 (1947).

Complaint Counsel falls far short of these standards. Even if Complaint Counsel had proven that Impax violated the antitrust laws—and it has not—it furnishes no basis for imposing a prospective remedy. But even assuming some forward-looking remedy were appropriate, that would in no way justify the far-reaching and needlessly broad restrictions Complaint Counsel now seeks. Nor would it validate Complaint Counsel's newfound attack on Impax's 2017

[55] Complaint Counsel's citation to *TRW* appears to confuse the standard for overcoming "mootness" and with the standard for justifying a prospective remedy. (*See* CC PTB at 74 (citing *TRW*, 647 F.2d at 953).) Overcoming mootness is a more lenient standard than that for justifying prospective relief. *See TRW*, 647 F.2d at 954 ("The legal standard governing our review of the need for prospective relief is whether 'there exists some cognizable danger of

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settlement with Endo, which Complaint Counsel has never investigated or formally challenged in any proceeding. This Court should reject Complaint Counsel's overreach.

A. Complaint Counsel Failed to Prove a Cognizable Danger That Impax Will Enter into Anticompetitive Reverse-Payment Settlements.

Before this Court can impose any prospective remedy, Complaint Counsel must show that Impax presents a "cognizable danger" of repeating the condemned conduct—here, a patent settlement that includes a "large and unjustified" reverse payment. *W.T. Grant*, 345 U.S. at 633. This must be grounded in record fact. *See id.* at 634–35 (affirming denial of relief where there was no evidence of a "significant threat of future violation"); *TRW*

would be hard-pressed to find a single generic pharmaceutical company that is ***not*** routinely engaged in patent litigation.

Third, Complaint Counsel says "Impax has powerful incentives to resolve one or more of these patent litigations with a reverse payment." (*Id.*) But ***every*** pharmaceutical has these incentives, because they are built into the system. *See Actavis*, 133 S. Ct. at 2227–29, 2235 (explaining why Hatch-Waxman Act creates incentives for reverse-payment settlements). As Dr. Noll testified at trial, "there's almost always a potential for a [reverse-payment] deal between the brand name firm and the generic firm." (Noll, Tr. 1433.) The existence of "incentives" that apply industrywide cannot establish a cognizable danger of recurrence.

Fourth, Complaint Counsel alleges that Impax's current CEO testified that he would "always" seek a No-AG provision. (CC PTB at 74.) This is misleading at best. Mr. Bisaro testified (long before he joined Impax) that, in his understanding, there was "not supposed to [be] an AG" under Hatch-Waxman, and that he would "always try to maintain that, wherever possible." (CX4000 (Bisaro, IHT at 33–34).) In other words, Mr. Bisaro expressed his understanding that the Hatch-Waxman Act was not designed to allow AGs in the first place—a not unreasonable position[56]—and that he preferred to maintain that market dynamic.

[56] When the AG phenomenon arose, it was not clear whether launching an AG violated the Hatch-Waxman Act's 180-day exclusivity period for first filers. *Cf. Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 53–55 (D.C. Cir. 2005) (determining, ultimately, that Hatch-Waxman does not bar AGs). Former FTC Chairman Jon Leibowitz suggested that launching an AG was itself anticompetitive.

"whether the infraction is an 'isolated occurrence" are key to the "cognizable danger" inquiry. *SEC v. Cavanagh*, 155 F.3d 129, 135 (2d Cir. 1998). In the *Cavanagh* case, the court held that the defendant's "general lack of concern for the seriousness of the charges" and "history of securities law violations" warranted injunctive relief. *Id.* at 135–36. Impax, in contrast, has never been found liable of an antitrust violation, either before or after the SLA. *See W.T. Grant*, 345 U.S. at 635 (fact that "[n]one of the corporations appeared to have engaged in more than one alleged violation" weighed against injunctive relief); *see also FTC v. Nat'l Lead Co.*, 352 U.S. 419, 429 (1957) (limiting remedy despite finding that the "chief beneficiary [of the unlawful conduct] had been previously adjudged a violator of the antitrust laws"). Even the settlement at issue in this case was lawful under prevailing law when it was signed.[57]

B. The Specific Remedies Sought by Complaint Counsel Are Overbroad.

Complaint Counsel may only seek remedies that have a "reasonable relation to the unlawful practice." *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 613 (1946); *see* 15 U.S.C. § 45(b) (where violation is found, Commission may order respondent to "cease and desist from using ***such method of competition or such act or practice***.") (emphasis added). Here, the alleged "unlawful practice" is limited to a reverse-payment settlement agreement. (*See* Compl. ¶ 1 ("This action challenges an anticompetitive reverse-payment agreement . . .").) Despite this action's narrow ambit, Complaint Counsel now seeks remedies that it does not even contend to be "reasonably related" to anticompetitive reverse-payment settlements. This Court should not indulge Complaint Counsel's unjustified requests. At most, any remedial order should be limited to a prohibition on anticompetitive reverse-payment settlements.[58]

1. Complaint Counsel's Request That No Future Settlement Include "Value" Flowing from the Brand Company to Impax Is Needlessly Overbroad.

In Section II(A) of the Proposed Order, Complaint Counsel seeks to prohibit Impax from entering any settlement in which a brand company makes "any Payment" to Impax. (CC PO § II(A).) This is the closest Complaint Counsel comes to articulating a reasonable remedy, and yet it still sweeps too broadly. For one, the term "payment" is defined to include any "transfer of value." (*Id.* § 1(W).) It is difficult to conceive of an agreement that would ***not*** run afoul of this prohibition, given that every contract necessarily entails consideration—*i.e.*, a "transfer of value"—flowing in both directions. *See AbbVie*, 107 F. Supp. 3d at 436 ("something of value invariably flows both ways as a result of any contract."); *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J.) ("But ***any*** settlement agreement can

[58] As previously explained, even this prospective remedy would require proof of a "cognizable danger" of future violations. Section V.A, *supra*.

be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement.").

Complaint Counsel does not stop there. It would prohibit any brand-to-generic "transfer of value . . .

2. Complaint Counsel's Requested Prohibition on Agreements That "Disincentivize" Competition Among Opana ER Products Is Improper.

Complaint Counsel next seeks to prevent Impax from entering any agreement that "prevents, restricts, or in any way disincentivizes competition between Oxymorphone ER Products." (CC PO § II(B).) This remedy should be stricken for the following reasons.

First, Section II(B) bears no "reasonable relation to the unlawful practice" at issue—an alleged reverse-payment settlement. *Siegel*, 327 U.S. at 613. Complaint Counsel seemingly concedes the disconnect; it admits that the remedy does not even target similar conduct. (*See* CC PTB at 75 ("this injunction is not limited to the same or similar conduct").) Complaint Counsel instead ties the proposed relief to the ***product*** (Opana ER). It cites no legal authority for this novel remedy. Nor could it. The Supreme Court has made clear that the remedy must relate to the challenged ***practice***. *See Nat'l Lead*, 352 U.S. at 428 ("[T]he courts will not interfere except where the remedy selected has no reasonable relation to the ***unlawful practices*** found to exist.") (emphasis added); *Siegel*, 327 U.S. at 611 ("The Commission has wide discretion in its choice of a remedy deemed adequate to cope with the ***unlawful practices***.") (emphasis added).

Complaint Counsel's reliance on *Massachusetts v. Microsoft*, 373 F.3d 1199 (D.C. Cir. 2004), is misguided. (CC PTB at 75.) In that case, the D.C. Circuit explicitly recognized that "the resulting relief ***must*** represent a reasonable method of eliminating the consequences of the illegal ***conduct***." *Massachusetts*, 373 F.3d at 1216 (emphasis added) (quotation and alteration omitted).[60] Complaint Counsel has not made any argument or factual showing as to why the alleged unlawful practice in issue—a reverse-payment settlement—gives it carte blanche to seek a prohibition on "any agreement" that may affect Opana ER products.

[60] In fact, the D.C. Circuit affirmed the district court's rejection of some proposed relief, even though it related directly to the product at issue. 373 F.3d at 1216–22.

Second, Section II(B)'s language is hopelessly vague. Where an "order's prohibitions are not sufficiently 'clear and precise in order that they may be understood by those against whom they are directed,'" the prohibition should be stricken. *Removatron Int'l Corp. v. FTC*, 884 F.2d 1489, 1499 (1st Cir. 1989) (quoting

conduct . . . the stronger the proof that is needed to justify the remedy." *In re Rambus, Inc.*, Dkt. 9302, 2007 WL 431524, at *5 (F.T.C. Feb. 5, 2007). Here, there is total discord between the extremity of the requested remedy and the nonexistent evidentiary basis for seeking it.

Perversely, nullifying the 2017 Settlement could reduce competition and harm consumers. Dissolving the agreement would immediately throw the status of Impax's patent license—which has ensured an uninterrupted supply of generic Opana ER for five years and counting—into flux, potentially reigniting the litigation that gave rise to the settlement in the first place. Complaint Counsel is not ignorant of this consequence. If Complaint Counsel is to be believed, abrogation the 2017 Settlement could precipitate Impax's exit from the marketplace. (*See* CCF ¶ 1430 ("If the parties had not settled, Impax could have been . . . required to withdraw its Original Opana ER from the market.").) Nowhere does Complaint Counsel articulate why it thinks this is a desirable outcome.

At most, Complaint Counsel hints that nullification of the 2017 Settlement would open the door to Endo reintroducing original Opana ER. This is pure fantasy. As Endo explains in its opposition to Complaint Counsel's proposed relief,[61] it has certified to the FDA that it considers original Opana ER ***unsafe***. (Intervenor Endo Pharm., Inc.'s Opp. to Compl. Counsel's Findings & Proposed Relief at 13, *In re Impax Labs., Inc.*, Dkt. 9373 (F.T.C. Jan. 16, 2018) [hereinafter "Endo Opp."]; *see* FOF ¶¶ 222, 225; CX3203-037 (representing to FDA that continued sale of original Opana ER "would allow abuse or diversion to continue," putting consumers at risk of "potentially lethal dose[s] of oxymorphone").) Any suggestion that Endo might now reintroduce a product it previously condemned in public regulatory filings is "absurd." (Endo Opp. at 13.) To put it bluntly, that ship has sailed.

[61] Impax adopts and incorporates by reference the arguments made by Endo in its January 16, 2018 Opposition where applicable.

Complaint Counsel's attempt to abrogate the 2017 Settlement without conducting any investigation or discovery, without adducing any record evidence, and without bringing any formal challenge to it, violates Impax's due process rights. Because Complaint Counsel did not put Impax on notice that it intended to invalidate the settlement until ***after the trial***, it has circumvented the entire investigatory and Part III process—thereby depriving Impax of the opportunity to develop evidence and expert testimony to refute Complaint Counsel's new allegations. (*Cf. id.* at 11–14.) That is unlawful. *See Murphy Oil Corp. v. Fed. Power Comm'n*, 431 F.2d 805, 813 (8th Cir. 1970) ("The parties to a proceeding before an administrative agency such as the Commission are entitled to: first, due notice as to the nature and scope of the contemplated inquiry; second, an opportunity to be heard and present evidence; and third, a full hearing in conformity with the fundamental concepts of fairness. A departure from these minimal requirements is a denial of procedural due process.") (quoting *Shell Oil Co. v. Fed. Power Comm'n*, 334 F.2d 1002, 1012 (3d Cir. 1964)).

4. Other Provisions of Complaint Counsel's Proposed Order Are Also Overbroad and Unnecessary.

The remaining provisions in Complaint Counsel's Proposed Order are problematic as well. At minimum, they should be modified as follows:

First, Complaint Counsel does not explain why the reporting requirements in Section IV(B) should sweep so broadly, requiring the production of potentially voluminous communications with third parties. (CC PO § IV(B).) At the very least, subsections (B)(2) through B(4) should be stricken.

Second, Section VII should be modified so that the Order terminates after 10 years from the date of issuance instead of 20 years. (*Id.* § VII.) The Commission found that a 10-year term was sufficient in its settlement with Endo, which involved the exact same conduct. (*See*

Dated: February 7, 2018 By:

CERTIFICATE OF SERVICE

I hereby certify that on February 7, 2018, I filed the foregoing document 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, D.C. 20580
ElectronicFilings@ftc.gov

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

I also certify that I caused a copy of the foregoing to be served upon the following individuals by electronic mail:

Markus Meier
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington, DC 20580
Telephone: 202-326-3759
Email: mmeier@ftc.gov

Bradley Albert
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington, DC 20580
Telephone: 202-326-3759
Email: balbert@ftc.gov

Daniel Butrymowicz
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington, DC 20580
Telephone: 202-326-3759
Email: dbutrymowicz@ftc.gov

Nicholas Leefer
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington, DC 20580

Telephone: 202-326-3759
Email: nleefer@ftc.gov

Synda Mark
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington, DC 20580
Telephone: 202-326-3759
Email: smark@ftc.gov

Maren Schmidt
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington, DC 20580
Telephone: 202-326-3759
Email: mschmidt@ftc.gov

Eric Sprague
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington, DC 20580
Telephone: 202-326-3759
Email: esprague@ftc.gov

Jamie Towey
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington, DC 20580
Telephone: 202-326-3759
Email: jtowey@ftc.gov

Chuck Loughlin
Federal Trade Commission
600 Pennsylvania Ave, NW
Washington, DC 20580
Telephone: 202-326-3759
Email: cloughlin@ftc.gov

DATED: February 7, 2018

/s/ *Benjamin J. Hendricks*
Benjamin J. Hendricks

CERTIFICATE FOR ELECTRONIC FILING

I hereby 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.

DATED: February 7, 2018

/s/ *Benjamin J. Hendricks*
Benjamin J. Hendricks

Notice of Electronic Service

I hereby certify that on February 13, 2018, I filed an electronic copy of the foregoing RESPONDENT IMPAX LABORATORIES, INC.'S REPLY TO COMPLAINT COUNSEL'S POST-TRIAL BRIEF, RESPONDENT IMPAX LABORATORIES, INC.'S REPLIES TO COMPLAINT COUNSEL'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW, with:

D. Michael Chappell
Chief Administrative Law Judge
600 Pennsylvania Ave., NW
Suite 110
Washington, DC, 20580

Donald Clark
600 Pennsylvania Ave., NW
Suite 172
Washington, DC, 20580

I hereby certify that on February 13, 2018, I served via E-Service an electronic copy of the foregoing RESPONDENT IMPAX LABORATORIES, INC.'S REPLY TO COMPLAINT COUNSEL'S POST-TRIAL BRIEF, RESPONDENT IMPAX LABORATORIES, INC.'S REPLIES TO COMPLAINT COUNSEL'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW, upon:

Bradley Albert
Attorney
Federal Trade Commission
balbert@ftc.gov
Complaint

Daniel Butrymowicz
Attorney
Federal Trade Commission
dbutrymowicz@ftc.gov
Complaint

Nicholas Leefer
Attorney
Federal Trade Commission
nleefer@ftc.gov
Complaint

Synda Mark
Attorney
Federal Trade Commission
smark@ftc.gov
Complaint

Maren Schmidt
Attorney
Federal Trade Commission
mschmidt@ftc.gov
Complaint

Eric Sprague
Attorney
Federal Trade Commission
esprague@ftc.gov
Complaint

Jamie Towey
Attorney
Federal Trade Commission
jtowey@ftc.gov
Complaint

Chuck Loughlin
Attorney
Federal Trade Commission
cloughlin@ftc.gov
Complaint

Alpa D. Davis
Attorney
Federal Trade Commission
adavis6@ftc.gov
Complaint

Lauren Peay
Attorney
Federal Trade Commission
lpeay@ftc.gov
Complaint

James H. Weingarten
Attorney
Federal Trade Commission
jweingarten@ftc.gov
Complaint

Edward D. Hassi
O'Melveny & Myers, LLP
ehassi@omm.com
Respondent

Michael E. Antalics
O'Melveny & Myers, LLP
mantalics@omm.com
Respondent

Benjamin J. Hendricks
O'Melveny & Myers, LLP
bhendricks@omm.com
Respondent

Eileen M. Brogan
O'Melveny & Myers, LLP
ebrogan@omm.com
Respondent

Anna Fabish
O'Melveny & Myers, LLP
afabish@omm.com
Respondent

Stephen McIntyre
O'Melveny & Myers, LLP
smcintyre@omm.com
Respondent

Rebecca Weinstein
Attorney
Federal Trade Commission
rweinstein@ftc.gov
Complaint

Garth Huston
torney
Federal Trade Commission

Complaint