UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Joseph J. Simons, Chairman**
Maureen K. Ohlhausen
Noah Joshua Phillips
Rohit Chopra
Rebecca Kelly Slaughter

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

COMPLAINT COUNSEL'S REPLY TO RESPONDENT IMPAX LABORATORIES, LLC'S ANSWERING BRIEF

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Dated: September 12, 2018

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CCF	Complaint Counsel's Proposed Findings of Fact
CCRF	Complaint Counsel's Reply Findings of Fact
RCRF	Respondent's Reply Findings of Fact
ID	Initial Decision
F. or FF.	Initial Decision Findings of Fact
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Generic competition benefits consumers by making available a lower-cost alternative to the branded product. Impax, however, sought and accepted a large reverse payment from Endo in exchange for its agreement *not* to compete with a generic version of Opana ER for 2½ years. The Initial Decision correctly found that this agreement had anticompetitive effects because it protected Endo's monopoly from the risk of generic competition. Impax does not seriously dispute this conclusion.

The central question presented by this appeal is whether Impax satisfied its burden under the second step of the rule of reason to justify this anticompetitive restraint. Impax offers two reasons why it has. Neither has merit.

First, Impax says that it may justify the payment to prevent the risk of competition by pointing to any procompetitive provision in the broader settlement. It therefore relies on purported procompetitive benefits from the settlement's freedom-to-operate license. But under the rule of reason, Impax can satisfy its burden only by showing that its *anticompetitive conduct* "promote[d] a sufficiently pro-competitive objective." Impax concedes that it has not done so. It makes no effort to show how the payment to avoid the risk of competition furthered any procompetitive benefits from the freedom-to-operate license, and makes no claim that it needed to be paid to accept a license that benefited it.

Second, Impax argues that the settlement as a whole is the anticompetitive "restraint," and thus any procompetitive provision in the overall agreement may justify it. But the Supreme Court has identified "the specific restraint at issue" in a reverse-payment case as the payment by the patentee to "purchase. . . the exclusive right to sell its product" until the agreed-upon entry date, not the overall patent litigation settlement. Impax must show how the inclusion of that restraint—as opposed to other terms in the broader agreement—furthers a procompetitive

objective. Impax's failure to do so ends the rule-of-reason inquiry and establishes an antitrust violation.

The Commission should also reject the Initial Decision's balancing analysis. The Initial Decision mistakenly assumed that the relevant anticompetitive harm is the extent of "actual delay" in generic entry, rather than the elimination of the risk of competition that occurred when the agreement was entered. It then weighed that redefined harm against purported benefits resulting from unpredictable events occurring years after the settlement. Impax repeats both mistakes in its brief. But *Actavis* and courts interpreting it make clear that the anticompetitive harm from a reverse-payment agreement is the elimination of the *risk* of competition through sharing monopoly profits, not "actual delay." And a legal regime that allows the legality of an agreement to change over time based on subsequent events is unworkable.

Impax's cross appeal of the Initial Decision's finding that Endo had market power should also be rejected. Complaint Counsel provided an unchallenged analysis by its economic expert showing that Opana ER exhibited cross elasticity only with its generic equivalent and not with any other type of long acting opioid. Impax offers no reason to doubt this analysis and no evidence of cross elasticity between Opana ER and non-oxymorphone ER drugs. Indeed, Impax does not refute that generic oxymorphone ER entered the market at a lower price and took substantial sales from branded Opana ER—something that could not have occurred if competition with other long-acting opioids had already constrained the price to a competitive level.

Finally, Complaint Counsel's proposed order is properly tailored to prevent Impax from reprising its anticompetitive conduct without any undue burden on Impax's legitimate business activities. Impax's attacks on those provisions ignore both the order's limiting language and the

governing law. Its bolder claim that the Commission cannot order *any* remedy for its illegal conduct ignores the record evidence and the Commission's remedial authority to protect and restore competition.

ARGUMENT

I. Impax must show that the use of a payment to restrain generic competition furthered any claimed procompetitive benefit

At the rule of reason's second step, a defendant must "show that the challenged conduct promotes a sufficiently pro-competitive objective." *United States v. Brown Univ.*, 5 F.3d 658, 669 (3d Cir. 1993). But Impax repeatedly declines to explain how accepting a payment to avoid the risk of competition promoted its freedom-to-operate license. Instead, it claims that it "need not prove a link" between the anticompetitive restraint and its proffered justifications under the rule of reason. Opp. 19-21. Alternately, it argues that the relevant "restraint" is not the payment to avoid the risk of competition until January 2013, but rather the entire SLA, and it can therefore rely on any procompetitive feature in that document. Opp. 15-21. Both arguments are wrong.

A. An antitrust defendant has the burden to establish the requisite connection between the challenged restraint and any claimed procompetitive benefit

As the leading treatise explains, under the rule of reason, defendants have "the burden of coming forward with allegations and evidence that the justifications claimed are legitimate in principle and are *actually promoted significantly by the restraint*." Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶1511c (3d and 4th eds. 2010-2017) ("Areeda") (emphasis added); *see also id.* ¶1505a (under the rule of reason, "[a]n allegedly legitimate objective is, of course,

entirely immaterial unless it is served by the challenged restraint").[1] Indeed, the Supreme Court has long rejected proffered justifications where the restraint was "not even arguably tailored to serve such an interest." *NCAA v. Board of Regents*, 468 U.S. 85, 117-18 (1984). That is because the purpose of the rule of reason is "to distinguish between restraints with anticompetitive effect that are harmful to the consumer and restraints stimulating competition that are in the consumer's best interest." *Ohio v. American Express Co.*, 138 S. Ct. 2274, 2284 (2018) (internal quotation marks omitted). If an anticompetitive restraint does not itself stimulate competition, it is not justified.

Actavis makes this point directly: it states that the rule-of-reason analysis requires a defendant to show that "legitimate justifications are present, thereby explaining the presence of the *challenged term* and showing the lawfulness of *that term* under the rule of reason." *FTC v. Actavis, Inc.*, 570 U.S. 136, 156 (2013) (emphasis added); *see also King Drug Co. v. Smithkline Beecham Corp.*, 791 F.3d 388, 412 (3d Cir. 2015) ("*Lamictal*") (defendant must "show that the *challenged conduct* promotes a sufficiently pro-competitive objective" (emphasis added)). The "challenged term" in *Actavis* was the payment to avoid the risk of competition. *Actavis*, 570 U.S. at 156. Thus, Impax must show that the payment to avoid the risk of competition furthered any alleged procompetitive benefit.

Commission precedent similarly requires a defendant to "articulate the specific link between the challenged restraint and the purported justification." *In re Polygram Holding, Inc.*, 136 F.T.C. 310, 347 (July 24, 2003), *aff'd*, 416 F.3d 29 (D.C. Cir. 2005). Impax attempts to

[1] Impax contends that it is "the *plaintiff's* burden to establish the absence of any connection by demonstrating that the challenged restraint is not reasonably necessary to achieve the stated benefits." Opp. 19. This argument confuses steps two and three of the rule-of-reason analysis. Moreover, even if it were Complaint Counsel's burden to show a lack of connection, we have amply done so. CCAB 20-21.

distinguish *Polygram* because it applied a "quick look" analysis rather than the full rule of reason. But the quick look analysis simply abbreviates the *plaintiff's* burden under the rule of reason; it does not change the defendant's burden to show that the challenged conduct promotes a procompetitive objective. *See California Dental Ass'n v. FTC*, 526 U.S. 756, 779-80 (1999) ("*CDA*") (in rule-of-reason, quick look, and per se analyses, "the essential inquiry remains the same—whether or not the challenged restraint enhances competition"); *Deutscher Tennis Bund v. ATP Tour, Inc.*, 610 F.3d 820, 830-31 (3d Cir. 2010) (under quick look, "competitive harm is presumed, and the defendant must promulgate some competitive justification for the restraint" (internal quotation marks omitted)).

Impax erroneously claims that the Supreme Court's recent decision in *American Express* supports its view that "procompetitive benefits arising from factors other than" the challenged restraint can be considered. Opp. 20. It does not. The Court expressly acknowledged the established principle that a defendant must "show a procompetitive rationale for *the restraint*." 138 S. Ct. at 2284 (emphasis added). *American Express* did not need to consider whether the defendant had met that burden, because it found that plaintiffs failed to meet their initial burden to prove anticompetitive effects. *Id.* at 2290 ("[P]laintiffs have not satisfied the first step of the rule of reason.").

Impax similarly misrepresents the *Actavis* district court's recent summary judgment opinion. Opp. 20. That opinion did not hold that defendants could "justify the settlements as procompetitive because they allowed generic entry earlier than the patent would have allowed." Opp. 20 (quoting *In re Androgel Antitrust Litig. (No. II)*, 2018 WL 2984873, at *11 (N.D. Ga. June 14, 2018). To the contrary, it held that defendants had to "justify the *payments* as being procompetitive" (*id.* at *11 (emphasis added)), and expressly stated that defendants "may *not*

justify the payments on the grounds that the patent was valid and infringed because such an argument is irrelevant." *Id.* at *12 (emphasis added).

B. The relevant restraint is the use of the payment to prevent generic competition—not the SLA as a whole

Alternatively, Impax asserts that the restraint is not the reverse payment, but the written settlement agreement as a whole, and thus any part of the SLA can be offered as a procompetitive benefit. Opp. 13, 15-16.[2] But Complaint Counsel does not claim that the payment itself is a "restraint." The payment is significant because it distinguishes a potentially problematic settlement from a traditional settlement. Absent a reverse payment, as *Actavis* made clear, there is generally no antitrust concern with a settlement that allows "the generic manufacturer to enter the patentee's market prior to the patent's expiration." 570 U.S. at 158. But the restraint is not the payment itself; it is the payment in conjunction with a restriction on the generic's ability to compete. As *Actavis* explained, "the specific restraint at issue" in a reverse-payment case is a payment by the patentee to "purchase . . . the exclusive right to sell its product" until the agreed-upon entry date. *Id*. at 153-54; *see also* ID 99 ("The restraint in a reverse payment settlement agreement is . . . the use of the payment to restrain potential generic competition."). Impax must therefore justify the payment to eliminate the risk of competition.

Actavis is consistent with a long line of Supreme Court precedent identifying the challenged "restraint" as the allegedly anticompetitive provisions of a broader agreement and requiring the defendant to show that the inclusion of those provisions promoted a procompetitive

[2] Impax also contends that the Commission must consider the SLA as a whole because the freedom-to-operate license "was integral to both the settlement and the resulting competitive effects." Opp. 2 (stating Impax would not have settled without the license). But asking whether a *procompetitive* provision was necessary to the broader undertaking misses the point of the justification analysis. The question is whether the restraint (payment to eliminate the risk of competition) furthered the asserted procompetitive objective.

benefit.[3] In *Nat'l Soc'y of Prof'l Eng'rs v. United States*, the challenged restraint was a specific section of a much broader code of ethics. 435 U.S. 679, 683-84 (1978). The Court did not "evaluate[] all aspects of the 'canon of ethics,'" as Impax asserts. Opp. 18. It focused narrowly on Section 11(c), which banned competitive bidding, and found that provision unlawful because it did not further any procompetitive objectives. 435 U.S. at 683-84 & nn.3-5.

Similarly, in *CDA*, the Supreme Court identified the restraint as the specific application of one particular section in the association's broader ethics code—even though member dentists agreed to abide by the entire code. 526 U.S. at 760-61. The Supreme Court did not consider other portions of the ethics code, or even other procompetitive applications of Section 10 itself. *Id.* at 772, 778. Most recently, in *American Express*, the Supreme Court identified the relevant restraint as Amex's antisteering provisions, even though those provisions were discrete terms in Amex's broader merchant contracts. *See* 138 S. Ct. at 2290 (holding that "Amex's antisteering provisions do not unreasonably restrain trade").[4]

The Commission has held similarly. In the *Realcomp* matter, the restraint Impax describes as "three separately adopted policies" (Opp. 18) was actually three specific rules contained in the expansive "Rules and Regulations" governing member participation in Realcomp's multiple listing service (MLS). *See* Initial Decision, *In re Realcomp II, Ltd.*, 2007

[3] Impax misunderstands (Opp. 14) Areeda's statement that the "the content of the restraint is the sum total of everything that the parties have 'agreed' about *and* that is alleged to injure competition." Areeda ¶1504d (emphasis added). Consistent with longstanding Supreme Court precedent, the "restraint" only includes those things the parties have agreed to that are alleged to harm competition.

[4] Impax claims that the Court's anticompetitive-effects analysis examined Amex's general business model separately from the antisteering provisions. Opp. 19-21. Not so. The Court focused specifically on competitive effects flowing from the antisteering provisions. *See American Express*, 138 S. Ct. at 2288-89. The Court discussed Amex's business model of charging higher fees and providing additional rewards because that model *required* the antisteering provisions to be viable. *See id.* at 2282-83.

WL 4465486, at FF.150-56, 168, 356-360 (F.T.C. Dec. 10, 2007). The Commission treated the three challenged rules as the relevant restraint—not the overall MLS Rules and Regulations. *See In re Realcomp II Ltd.*, 2007 WL 6936319, at *5, *12-13 (F.T.C. Oct. 30, 2009). And in finding those restraints to be unlawful, the Commission did not credit the procompetitive benefits of the MLS as a whole because the specific restraint did not further those benefits. *Id.* at *29. The Sixth Circuit affirmed. *Realcomp II, Ltd. v. FTC*, 635 F.3d 815, 826-27 (6th Cir. 2011) ("[T]he challenged restraint is an internal rule within an MLS regarding its distribution of certain types of real-estate listings to the public.").

Impax's other citations are similarly misplaced. Then-Judge Sotomayor's concurrence in *Major League Baseball Props., Inc. v. Salvino, Inc.*, 542 F.3d 290 (2d Cir. 2008), does not indicate that "in every other rule-of-reason case, agreements are evaluated as a whole." Opp. 16. Rather, Justice Sotomayor explained that, under the ancillary restraint doctrine, a challenged restraint is *not* evaluated as part of a broader joint venture *unless* it is "reasonably necessary to achieve any of the efficiency-enhancing purposes of a joint venture." *Salvino*, 542 F.3d at 338-39. The same principle applies here. Because Impax has not shown (and, indeed, never argued) that it needed to be paid to accept the settlement terms it claims were procompetitive, the payment to avoid the risk of competition must be assessed independently of those other terms. *See* CCAB 17.

The post-*Actavis* district court cases Impax cites also do not support its argument. Opp. 18-19. These cases simply explain that, in determining whether a reverse payment is "large," the court should assess all relevant payments, even if spread across multiple documents. *See In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 330-38 (D.R.I. 2017) (payments contained in two different written agreements considered together); *In re Niaspan Antitrust Litig.*, 42 F.

Supp. 3d 735, 752 (E.D. Pa. 2014) (separate payments considered together to determine if reverse payment was "large"); *In re Aggrenox Antitrust Litig.*, 94. F. Supp. 3d 224, 243 (D. Conn. 2015).

Impax also cites a decision from the Eastern District of Pennsylvania to support its position that a settlement must be evaluated as a whole. Opp. 17 (citing *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 753-74 (E.D. Pa. 2015)). But that district court's analysis cannot survive a later decision by the Third Circuit in *In re Lipitor Antitrust Litig.*, 868 F.3d 231 (3d Cir. 2017). In *Lipitor*, defendants argued on a motion to dismiss that a supply agreement and resolution of separate litigation rendered their overall settlement agreement procompetitive. The Court of Appeals rejected that argument, stating that "defendants have the burden of justifying the rather large reverse payment here, and they offer no reason why those other elements of the settlement agreement do so." *Id.* at 256-57.

C. Complaint Counsel's focus on the payment to prevent the risk of competition is not "gerrymandering"

Left without legal support for its arguments, Impax contends that Complaint Counsel's focus on certain provisions of the SLA as the payment to avoid the risk of competition amounts to "gerrymandering." Impax seems to suggest that Complaint Counsel intentionally excluded the freedom-to-operate license from its challenge in order to prevent Impax from relying on the license as a procompetitive benefit. Opp. 16.

But Complaint Counsel is not "gerrymandering" anything; the freedom-to-operate license is not a "payment" within the meaning of *Actavis.* A reverse payment is problematic because it represents a sharing of the brand's monopoly profits. *Actavis*, 570 U.S. at 154. Unlike the No-AG provision, Endo Credit, and DCA payment, the freedom-to-operate license did not transfer to Impax "a share of [Endo's] monopoly profits that would otherwise be lost in the competitive

market." *Id.* at 154. It only provided value when Impax actually *competed* with Endo. Its value thus came from *eroding* Endo's monopoly, not preserving it.

Of course, Impax could rely on the procompetitive benefits from the freedom-to-operate license if it showed how the payment to eliminate the risk of competition served to promote those benefits. Impax has repeatedly declined to do so.

D. Impax's approach would effectively swallow *Actavis* and other rule-of-reason precedent

As Complaint Counsel's opening brief explained, the provisions Impax relies on as procompetitive benefits—an entry date before patent expiration and a license to patents beyond those in suit—are common terms in reverse-payment settlements. If those two terms can justify the anticompetitive reverse payment in this case, they could justify an anticompetitive reverse payment in any future settlement. *See* CCAB 21-23. Indeed, if an antitrust defendant could justify anticompetitive terms in an agreement simply by pointing to procompetitive terms in the same contract, the defendants in *Nat'l Soc'y of Prof'l Eng'rs* could have defended their ban on competitive bidding—contained in a single section of the society's ethics code—by referencing other parts of the ethics code that promoted competition. *See* 435 U.S. at 692-96. And the defendants in *Realcomp* likely would have escaped liability because the three challenged rules were part of a broader set of rules supporting a service the Commission acknowledged was "efficiency-enhancing." *See* 2007 WL 6936319, at *29. Impax's approach would thus eviscerate *Actavis* and Section 1, and must be rejected.

Impax argues that the Commission should not be concerned with such future implications because the Initial Decision merely assessed "case-specific facts" regarding the settlement's "actual effect on competition" after Impax entered in January 2013. Opp. 22-23. But if the freedom-to-operate license only counts as a procompetitive benefit due to unpredictable

developments years down the road, the result would be an antitrust regime fraught with uncertainty for the industry, courts, and antitrust law enforcers. CCAB 28. By contrast, if, as Impax suggests elsewhere in its brief (*see* Opp. 30-31), subsequent events are not essential to the finding of countervailing benefits, then the ALJ's approach would provide an easy way to evade *Actavis* by including a freedom-to-operate provision in the settlement agreement. CCAB 21-23. Either way, the Initial Decision's conclusion on this point is untenable.

II. The payment to avoid the risk of competition was not reasonably necessary to obtain Impax's claimed procompetitive benefits

Impax failed to prove that the large reverse payment to prevent the risk of competition promoted any legitimate procompetitive objective. *See* Pt. I, *supra*. That failure ends the rule-of-reason inquiry and obviates the need for any further analysis. Nonetheless, Complaint Counsel has also demonstrated that the payment was not reasonably necessary to achieve Impax's asserted procompetitive benefits because Endo certainly would have provided (and Impax could have accepted) the same license without a large payment. *See* CCAB 25-26. Correspondingly, Complaint Counsel showed that the procompetitive benefits of the freedom-to-operate license could have been achieved in a specific less-restrictive way: settling with Endo without the large payment to prevent the risk of competition. Indeed, the Supreme Court expressly identified this less restrictive alternative:

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

Actavis, 570 U.S. at 158 (emphasis added).

Impax does not dispute that it could have obtained the same freedom-to-operate license without accepting a large payment. Instead, it contends that such a no-payment settlement is not

"less restrictive of competition" because Complaint Counsel did not prove that it would have resulted in an earlier entry date for Impax. Opp. 25. This misunderstands the concept of a less restrictive alternative.

A less restrictive alternative is one that eliminates the restraint and still provides the asserted procompetitive benefits. *See NCAA*, 468 U.S. at 117 (distinguishing "[t]he specific restraints on football telecasts that are challenged in this case" from NCAA rules tailored to achieve legitimate objective of competitive balance among amateur athletic teams). To show a less restrictive alternative, Complaint Counsel need not reconstruct the hypothetical but-for world and identify a specific earlier entry date to which the parties would have agreed absent the payment. A large reverse payment harms the competitive process by distorting the bargaining process that ordinarily would protect consumer interests. CCAB 29. It can be expected to induce the generic to agree to an entry date "that is later than it would have otherwise accepted." *Lamictal*, 791 F.3d at 405; *see also* F.446 ("[I]t is unlikely that a patent holder would agree by a settlement to pay an alleged infringer anything more than saved litigation costs, only to obtain entry on the date the alleged infringer would have accepted anyway."). A settlement without a large reverse payment eliminates this harm to the competitive process and can be expected to yield an entry date that approximates "the expected level of competition that would have obtained had the parties litigated." *In re Cipro Cases I & II*, 348 P.3d 845, 865 (Cal. 2015). A no-payment settlement, therefore, is less restrictive of competition while still allowing Impax to obtain a freedom-to-operate license.

Indeed, the evidence here demonstrates that Endo was willing to trade money for its preferred 2013 entry date. Each time Impax sought an earlier entry date, Endo responded with more money. For example, Impax sought an acceleration trigger that would move up Impax's

entry date if branded Opana ER sales dropped below a certain level. Endo rejected the possibility of earlier entry, but agreed to additional payments through the Endo Credit. (FF.137-39, 147-54). Impax claims this evidence shows that the "proffered [no-payment] alternative has been tried but failed." Opp. 26. It shows the opposite: both parties found it preferable to share the monopoly profits preserved by avoiding competition.

A no-payment settlement also would be "less restrictive of competition" because it would extinguish Endo's promise not to compete with an authorized generic version of Opana ER during Impax's 180-day exclusivity period. Prior to its settlement, Endo had been planning to introduce an authorized generic to recoup some of the large losses in Opana ER sales that would result from generic competition. (F.108). Competition from an Endo AG would lead to lower prices for consumers. (CCF ¶¶397-98). The No-AG agreement, however, precluded such price-reducing competition, guaranteeing "a generic monopoly instead of a generic duopoly." *Lamictal*, 791 F.3d at 405. By freeing Endo from its No-AG commitment, a no-payment settlement would have permitted immediate additional generic competition upon Impax's entry.

III. The Initial Decision also erred in weighing competitive effects

Because Impax failed to show the requisite link between its anticompetitive conduct and its purported procompetitive objectives, this case should never have reached the balancing stage. But the ALJ's balancing analysis is also wrong because it departed from *Actavis's* teaching that "the relevant anticompetitive harm" in a reverse-payment case is preventing the risk of competition, 570 U.S. at 157, and weighed procompetitive benefits based on unlikely subsequent events. As a result, the ALJ focused on the wrong question and ignored that certain harm from preventing potential generic competition for 2½ years outweighed the speculative benefits of the freedom-to-operate license. CCAB 26-33.

A. Impax misreads *Actavis*

A central teaching of *Actavis* is that "the relevant anticompetitive harm" in a reverse-payment case is that potential competitors "prevent the risk of competition" by settling patent litigation with an agreement that "maintain[s] and [] share[s] patent-generated monopoly profits." 570 U.S. at 157. The Initial Decision's balancing inquiry instead viewed the relevant harm as actual "delayed generic competition." ID 100, 147. Impax defends this approach by misreading *Actavis* and lower court interpretations.

First, Impax argues that *Actavis*'s definition of the "relevant anticompetitive harm" merely "explain[s] why reverse-payment settlements are not immune from antitrust scrutiny." Opp. 36. But the Court had already reaffirmed that patent settlements are subject to antitrust scrutiny in an earlier section of the opinion. *See* 570 U.S. at 149-50. The Court discussed the relevant anticompetitive harm to explain why the antitrust analysis does not require assessment of the patent's validity and infringement. *Id.* at 157-58. And that highlights Impax's problem: if Impax were correct that proving an anticompetitive effect requires the plaintiff to demonstrate that the generic would have entered on an earlier date absent the agreement, then a plaintiff would need to prove what would have happened in the patent case. The Court, however, said multiple times that such an inquiry was "normally not necessary." *Id*. at 157; *see also Androgel*, 2018 WL 2984873, at *12.

Second, Impax finds no support for its "actual delay" requirement in the lower court decisions it cites. Opp. 36. In *Lamictal*, the term "payment for delay" (which *Actavis* did not use) was explicit shorthand for "payment to prevent the risk of competition." 791 F.3d at 412. Indeed, *Lamictal* explained that "the antitrust problem" in *Actavis* "was that, as the Court inferred, entry *might* have been earlier, and/or the risk of competition not eliminated, had the reverse payment not been tendered." *Id*. at 408 (emphasis added).

Likewise, *Cipro* does not require proof that entry actually would have occurred earlier. *Cipro* used the word "delay" as shorthand for a restriction on entry. 348 P.3d at 865 ("If the settlement contains no component of delay and permits the generic to enter the market and compete fully and immediately, there is no restraint of trade and no potential for antitrust concern."). Indeed, *Cipro* concluded that the challenged reverse-payment agreement could be anticompetitive even though the relevant patent in that case had been found valid and infringed in subsequent litigation. *Id*. at 870.[5]

Notably, Impax ignores the First Circuit's post-*Actavis* decision, *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34 (1st Cir. 2016), which directly contradicts Impax's contention that establishing a violation in reverse-payment cases requires proof of actual delay. Agreeing with an FTC amicus brief, *Nexium* explained that the question of whether a generic "would have launched . . . earlier" is *not* part of assessing "the existence of an antitrust violation," but instead part of a private plaintiff's required showing of injury. *Id*. at 60. Thus, despite the *Nexium* jury's finding that "some antitrust violation resulted" from the defendants' agreement, the court agreed that the "plaintiffs failed to establish an antitrust injury that entitled them to monetary relief" because the generic drug manufacturer would not "have launched a generic earlier" than the settlement date. *Id*. Here, it is undisputed that Complaint Counsel need

[5] The reference to "no delay" in *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 163 (3d Cir. 2017), addressed a product that had entered the market immediately upon FDA approval. *In re K-Dur Antitrust Litig.*, 2016 WL 755623, at *12-13 (D.N.J. Feb. 5 2016), adopted the *Cipro* framework and equated "delayed entry" with "a limit on the generic challenger's entry." *In re Aggrenox Antitrust Litig.*, 2015 WL 4459607 (D. Conn. July 21, 2015), addressed the causation of injury-in-fact requirement for private plaintiffs.

not show injury-in-fact.[6] Accordingly, Complaint Counsel need not show that a generic would have launched earlier.

B. *American Express* does not contradict or limit *Actavis*

Impax also errs when it suggests that *American Express* conflicts with *Actavis* regarding the relevant harm in a reverse-payment case. Opp. 32. As *American Express* itself explains, proof of "actual detrimental effects" on competition, "such as reduced output, increased prices, or decreased quality in the relevant market," is one way to prove the requisite anticompetitive effect, but not the only way. *See id.* at 2284 (describing alternative methods); *see also FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 462 (1986) ("*IFD*") (condemning challenged restraint that harmed the competitive process "even absent proof that it resulted in higher prices"). The *American Express* "plaintiffs stake[d] their entire case on proving Amex's agreements increase merchant fees." 138 S. Ct. at 2287; *see also id.* at 2224-85 & n.6. Their failure to prove increased prices or reduced output in the relevant market (credit-card transactions) was thus fatal for them. But *Actavis* makes clear that a reverse-payment agreement has an anticompetitive effect if it shares monopoly profits to prevent even a small risk of competition. *See* 570 U.S. at 157. That is what the Initial Decision found here. ID 7.

Moreover, as *Actavis* reiterated, rule-of-reason analysis is a "sliding scale" and "the quality of proof required should vary with the circumstances." 570 U.S. at 159 (internal quotation marks omitted). The circumstances presented here are distinctly different from those in *American Express,* which addressed a vertical restraint involving "two-sided transaction platforms" with strong "indirect network effects." 138 S. Ct. at 2285-87 & n.9. This case

[6] Impax's attempt to draw a distinction between antitrust injury and injury-in-fact (Opp.32-33) is irrelevant. Complaint Counsel does not need to prove either to establish an antitrust violation.

involves a *horizontal* restraint between a patentee and its generic challenger to avoid competing in exchange for a sharing of the resulting monopoly profits.

While *American Express* was careful to distinguish horizontal agreements from vertical restraints (s*ee id.* at 2285 n.7), Impax obscures this distinction, invoking *In re McWane, Inc.*, 2014 WL 556261 (F.T.C. Jan. 30, 2014). Opp. 35. But in *McWane,* the Commission determined that the challenged agreement was a vertical restraint between a supplier and its distributor—and noted that "[c]ourts typically accord less scrutiny to vertical restraints than to horizontal restraints." *Id.* at *35-36. By contrast, there is no serious dispute that this case involves a horizontal restraint. Impax had filed with the FDA to market a generic version of Opana ER in competition with Endo. (CCF ¶¶94, 99-101). It was challenging Endo's patent and taking active steps to be in a position to launch upon board approval. (CCF ¶¶106-110, 127-213). Impax offers no reason why a sophisticated pharmaceutical company like Endo would pay Impax to prevent a nonexistent risk of competition and to accelerate generic competition to one of its most important products.

C. The Initial Decision's reliance on post-settlement events was error

The Initial Decision correctly concluded that Impax accepted a large and unjustified reverse payment from Endo, "the purpose and effect of which was to induce Impax to give up its patent challenge and agree not to launch a generic Opana ER until January 2013." ID 6-7. At the balancing stage, however, the ALJ redefined the relevant harm as "actual delay" and then improperly balanced that recast harm against post-settlement benefits arising from the "freedom-to-operate" license. ID 147-48. As a result, its conclusion rested on a series of then-unpredictable events occurring years after the settlement. ID 156-58. Defending the Initial Decision's approach, Impax contends that "[t]here is no temporal limitation on rule-of-reason analysis." Opp. 28-31. To be sure, post-agreement evidence can sometimes shed light on the likely

competitive effects of the underlying conduct. For example, Impax cites cases that consider post-agreement evidence to determine whether there were "actual detrimental effects" that obviated the need to prove market power.[7]

But in cases challenging an agreement to prevent the *risk* of competition, courts focus on the market—and the risk—as it existed at the time of that conduct. *Cipro*, 348 P.3d at 870 ("Agreements must be assessed as of the time they are made").[8] As *Cipro* explained, "[j]ust as later invalidation of a patent does not prove an agreement when made was anticompetitive, later evidence of validity will not automatically demonstrate an agreement was procompetitive." *Id.* (citations omitted). In this case, the facts about the subsequently-issued patents shed no light on the competitive effects of the agreement at the time it was made, when "[n]obody knew . . . whether those patents were going to issue." CCF ¶1396. Yet the issuance and enforcement of the subsequent patents was essential to the ALJ's conclusion that the SLA was procompetitive. ID 157. Nothing in antitrust jurisprudence supports an approach where the finding of a violation hinges on unpredictable later developments and liability could fluctuate as events unfold over

[7] *Compare IFD*, 476 U.S. at 460-61 (no need for market power inquiry given evidence of "actual detrimental effects"), *with American Express*, 138 S. Ct. at 2287 (no anticompetitive effects proven where plaintiffs "stake[d] their entire case" on direct evidence that Amex's agreements increased merchant fees); *see also In re N. Carolina Bd. of Dental Examiners*, 152 F.T.C. 640, 686 (2011) (finding actual detrimental effect in addition to proof of market definition and power).

[8] *See United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (en banc) (asking whether Java and Navigator were competitive threats "at the time Microsoft engaged in the conduct at issue"); *Apotex, Inc. v. Cephalon, Inc.*, 255 F. Supp. 3d 604, 611 (E.D. Pa. 2017) (post-settlement ruling not relevant to competitive effects given "*ex ante* framework mandated by the *Actavis* rule of reason analysis").

time. Indeed, Impax offers no reason to doubt that the result of its approach would be uncertainty for the industry, courts, and antitrust law enforcers. Opp. 28.[9]

Finally, Impax disputes that the Initial Decision's balancing approach applies any "bright line tests" or engages in a "simple mathematical exercise." Opp. 37. But that is exactly what it does. At the end of the balancing analysis, the Initial Decision states that "[e]ven if it is assumed that Impax would have entered the market as early as June 2010, and that the settlement therefore delayed generic entry (and extended Endo's patent monopoly) *for two and a half years*," the procompetitive benefits still outweigh the harm because the SLA "allowed uninterrupted and continuous access to generic Opana ER for more than *five years*." ID 157-58 (emphasis added). This flawed balancing—relying on the fact that "five" is greater than "two and a half"—would legitimize many naked payments to eliminate the risk of competition, and must be rejected.

IV. The Commission should correct the additional issues identified by Complaint Counsel

A. The $10 million DCA payment was made to avoid the risk of competition, not for the value of IPX-203

As Complaint Counsel showed in its opening brief, the "basic reason" for the $10 million upfront DCA payment was to "avoid[] the risk of competition."[10] CCAB 36-39. Impax has provided no reason to find otherwise.

First, Impax is wrong that Complaint Counsel is trying to impose liability on Impax based on Endo's "subjective motivation for entering the DCA." Opp. 58. Under *Actavis*, the key

[9] Impax errs when it states "the Commission has already ruled that the facts regarding [the subsequently-acquired patents] . . . are relevant to balancing anticompetitive harms and procompetitive benefits." Opp. 24 (internal quotations omitted). The Commission expressly declined to decide such questions without a full record and briefing. SD Op. 12, 13.

[10] *Androgel*, 2018 WL 2984873, at *11.

factual question focuses not on Endo's subjective motivation, but whether the "basic reason" for the payment was to obtain the profit-sharing rights in IPX-203 or to secure Impax's agreement not to enter before 2013. *Actavis*, 570 U.S. at 158. Impax certainly had no illusions about why Endo was paying it: it described the $10 million payment as [redacted] (CCF ¶1084).

Second, contrary to Impax's assertion (Opp. 58), Complaint Counsel's pharmaceutical collaborations expert, Dr. John Geltosky, offered many opinions "about the merits" of the DCA. Dr. Geltosky testified that the $10 million payment was unusually large for an early stage deal (CCF ¶¶1219-28); Endo's evaluation lacked the rigor typical in the industry and took a fraction of the time it would usually take (CCF ¶¶1131-90); Endo's financial analysis was seriously flawed and did not provide an accurate valuation of the deal (CCF ¶¶1191-1218); and, given the high risks and uncertainty associated with an early stage project, the DCA terms were inconsistent with the usual and expected industry practice. (CCF ¶¶1219-1245). Impax's real complaint is that Dr. Geltosky did not offer a dollar value for the DCA or explicitly opine on the soundness of Endo's business judgment, but that is not a basis to ignore his opinions. *See* CCAB 34-36.

Third, Impax misrepresents the value of what Endo received under the DCA. [redacted]

[redacted]

Outside an agreement preventing generic entry, Endo had no interest in IPX-203.

B. The Commission should clarify that establishing a *prima facie* case does not require the plaintiff to rebut the defendant's proffered justifications

The Initial Decision departed from the established rule-of-reason burden-shifting framework by treating Impax's proffered justifications for the reverse-payment agreement as an element of Complaint Counsel's *prima facie* case. CCAB 39-41. Impax tries to defend this approach by claiming *Actavis* makes proof of a large and unjustified payment a "threshold requirement," to avoid the purported antitrust immunity that would otherwise attach. Opp. 60. But as discussed above, this immunity argument misreads *Actavis*. *See* Part III, *supra*.

Impax's reliance on *Cipro* and *K-Dur*, is likewise unpersuasive. Without explanation, these cases treat two specific potential justifications as part of the plaintiff's *prima facie* case and would require the defendant to proffer evidence at that stage. *See Cipro*, 348 P.3d at 865-67; *In re K-Dur*, 2016 WL 755623, at *12-14. But the rule of reason places defendant's justification burden at the second step. As the Initial Decision demonstrates, departing from that established structure invites consideration of additional types of justifications in the *prima facie* case. *See* ID 118-19 (addressing Impax's "carrot and stick" justification). The Commission should reject that approach and clarify that in a reverse-payment case, the plaintiff proves its *prima facie* case by showing that: (1) the branded drug company agreed to make a "large" payment to the generic; (2) the generic agreed to a limit on entry into the market; and (3) the branded drug company possessed market power at the time of the agreement.

C. Professor Noll's *ex ante* valuation of the No-AG/Endo Credit payment was well founded

At the time Endo and Impax entered the settlement agreement, the value of the No-AG/Endo Credit payment depended on a single uncertain factor: what would happen to sales of

original Opana ER between June 2010 and the last quarter of 2012. Thus, Professor Noll calculated the payment's value in four scenarios: (1) sales remained flat; (2) sales grew; (3) sales fell, but not enough to trigger the Endo Credit; and (4) Endo switched the market to reformulated Opana ER and sales fell essentially to zero. *See* CCAB 42. Impax complains that Professor Noll did not analyze other plausible scenarios. Opp. 61. But the only alternative scenario Impax proposes—a perfectly timed and hastily completed reformulation switch—the ALJ specifically rejected as implausible. ID 111.

Impax's other criticism of Professor Noll is similarly unfounded. Impax faults Professor Noll for not calculating a specific expected value (Opp. 61), but Impax's own economic expert agreed that such a calculation is not "in any practical sense doable" (CCF ¶479). Nor did Complaint Counsel fail to "account for the time value of money." Opp. 61. Impax acknowledges in the next sentence that Complaint Counsel's Findings of Fact provided the 2010 present values of Professor Noll's figures—all of which were large as compared to saved litigation costs. Opp. 61; (CCF ¶¶467-72).

V. Endo possessed market power in a properly defined market for oxymorphone ER

At the time it made its large reverse payment to Impax, Endo had market power in a properly defined market for oxymorphone ER. The evidence demonstrates that, although other long-acting opioids (LAOs) can sometimes be used to treat the same conditions as oxymorphone ER, those products exhibited little cross elasticity of demand with branded or generic Opana ER and are therefore outside the relevant market. Impax has failed to refute this critical point. In a market limited to oxymorphone ER products, Impax cannot seriously dispute that Endo had market power.

A. Oxymorphone ER is the proper market in which to assess Impax's conduct

Defining a relevant market is not an end in itself. The purpose is to assess the likely competitive effects of the conduct at issue. *See U.S. Healthcare, Inc. v. Healthsource, Inc.*, 986 F.2d 589, 598 (1st Cir. 1993) (in defining the market, a key question is "*why* we are doing so: that is, what is the antitrust question in this case that market definition aims to answer?"). The market inquiry in this case seeks to determine whether the challenged reverse-payment agreement, which eliminated the risk of generic competition for over two years, was anticompetitive. Here, as in many cases, "the anticompetitive effects of exclusion [of generic products] cannot be seriously debated." *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1311 n.27 (11th Cir. 2003).

1. Products are only in the same market if they exhibit significant cross elasticity of demand

Market definition requires identifying "the market participants and competitive pressures that restrain an individual firm's ability to raise prices or restrict output." *Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 496 (2d Cir. 2004). Impax argues that other LAOs must be included in the relevant market as Opana ER because they can be prescribed to treat many of the same conditions. Opp. 45. But market definition involves more than simply identifying functional substitutes. *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962) (functional substitutability provides only "[t]he outer boundaries of a product market"). "[T]he circle must be drawn narrowly to exclude any other product to which, within reasonable variations in price, only a limited number of buyers will turn." *Times-Picayune Pub. Co. v. United States*, 345 U.S. 594, 612 n.31 (1953).

Thus, the traditional market definition inquiry turns on whether products are *economic* substitutes, meaning they demonstrate "significant positive cross-elasticity of demand."

SmithKline Corp. v. Eli Lilly & Co., 575 F.2d 1056, 1063-64 (3d Cir. 1978).[11] Cross elasticity "measures the responsiveness of the demand for one product to changes in the price of a different product." *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 438 n.6 (3d Cir. 1997). If cross elasticity between two products is high, "[a] slight increase in price" of one "will result in a large drop in demand as customers begin to use the substitute product." *Rosefielde v. Falcon Jet Corp.*, 701 F. Supp. 1053, 1067 n.23 (D.N.J. 1988). Thus, neither firm can "raise price[s] above the competitive level without losing so many sales so rapidly that the price increase is unprofitable and must be rescinded." *Midwestern Mach. Co., Inc. v. Nw. Airlines, Inc.*, 392 F.3d 265, 274 (8th Cir. 2004) (quoting William A. Landes & Richard A. Posner, Market Power in Antitrust Cases, 94 Harv. L. Rev. 937 (1981)). Conversely, if cross elasticity between two products is low, a slight increase in price of one will not cause sufficient sales to shift to the other. Products with low cross elasticity thus are in separate markets. In the pharmaceutical context, courts routinely exclude therapeutically similar drugs from the relevant market when they do not exhibit significant cross elasticity.[12]

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[11] *See also Telecor Commc'ns, Inc. v. Sw Bell Tel. Co.*, 305 F.3d 1124, 1131 (10th Cir. 2002) (reasonable interchangeability "may be measured by, and is substantially synonymous with, cross-elasticity"); *United States v. Archer-Daniels-Midland Co.*, 866 F.2d 242, 248 (8th Cir. 1988) (functionally interchangeable sweeteners in separate markets because "a small change in the price of [one] would have little or no effect on demand for [the other]").

[12] *See, e.g. SmithKline*, 575 F.2d at 1064 (cephalosporin antibiotics not in same relevant market as other antibiotics despite "a certain degree of interchangeability" because they did not demonstrate "significant cross-elasticity of demand"); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2018 WL 563144, at *8 (D. Mass. Jan. 25, 2018) ("Even in the pharmaceutical market [] cross-elasticity must be demonstrated between products to establish a market definition that includes them."); *United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA*, 296 F. Supp. 3d 1142, 1176 (N. D. Cal. 2017) ("*Lidoderm*"); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 388 (D. Mass. 2013); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1319 n.40 (S.D. Fla. 2005); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 522 (E.D.N.Y. 2005).

2. The evidence shows significant cross elasticity between branded and generic oxymorphone ER

The evidence shows there was significant cross elasticity between branded Opana ER and generic oxymorphone ER. (CCRF ¶¶981-82). Indeed, it is clear that both parties viewed the branded and generic versions of Opana ER as *uniquely* close economic substitutes. Endo and Impax both expected generic oxymorphone ER to enter at a lower price and take significant sales from Opana ER. (CCF ¶¶585-627). Endo's internal business projections and sworn court testimony show that it believed the launch of generic oxymorphone ER would lead to irreversible price erosion for the oxymorphone ER market and significant volume and revenue loss for Opana ER. (CCF ¶¶245, 603, 605, 610-13, 616-26).

The actual impact of generic entry largely confirmed Endo and Impax's expectations. When Impax launched generic oxymorphone ER in 2013, [redacted] Endo's reformulated Opana ER. (CCF ¶636 (*in camera*)). [redacted] (CCF ¶¶636 (*in camera*), 909). Competition from Impax resulted in substantial savings for consumers who switched to Impax's lower-cost product. (CCF ¶¶636-37). Indeed, despite not being automatically substitutable for reformulated Opana ER, generic oxymorphone ER captured [redacted]. (CCF ¶630 (*in camera*)).

These facts show that competition from generic oxymorphone ER mattered to consumers. It lowered the price of oxymorphone ER, took substantial sales from branded Opana ER, and saved consumers money. If Opana ER were already facing robust competition from existing LAO products before generic oxymorphone ER entry, those other LAOs already would have competed down Opana ER's price and sales long before generic oxymorphone ER entered the market, and Impax's entry would have had little additional effect. *See In re Aggrenox Antitrust*

Litig., 199 F. Supp. 3d 662, 667 (D. Conn. 2016) ("[I]f competitive prices were being charged before the patented drug had a generic competitor, then the entry of new competitors would not result in a substantial change in price.").

3. Other LAOs exhibited little cross elasticity with oxymorphone ER products

The evidence also shows that other LAOs based on different molecules were not close economic substitutes for Opana ER and did not meaningfully constrain Endo's prices. (CCF ¶¶670-89, 694-96, 703-07). To assess cross elasticity, Complaint Counsel's economic expert, Professor Roger Noll of Stanford University, empirically analyzed the effect of newly introduced non-oxymorphone LAO products on Opana ER sales. If other LAOs and Opana ER had high cross elasticity of demand, then entry of new LAO products—particularly lower-cost generic versions—would reduce Opana ER sales as consumers switched to the lower-priced product. (CCF ¶672). But Professor Noll found that entry of new LAOs had little to no effect on Opana ER sales. (CCF ¶¶654, 669-716).

Professor Noll also examined whether Impax's generic oxymorphone ER entry affected demand for other LAO products. Once again, Professor Noll found no perceptible evidence that consumers switched from non-oxymorphone LAO drugs to the cheaper generic oxymorphone ER. (CCF ¶¶669-716). Impax's own witnesses confirmed Professor Noll's findings: Impax's marketing director testified that he believed Impax's generic oxymorphone ER took sales *only* from other oxymorphone products. (CCRF ¶¶981-82). Indeed, Impax did not even consider the price of non-oxymorphone LAOs when pricing its generic oxymorphone ER. (CX5000 at 070 (Noll Report) (citing CX4004 (Engle IH Tr. 83-86, 224)); *see also* CCF ¶¶645-53).

In sum, the data do not show a pattern of substitution between Opana ER and these other products, meaning there is low cross elasticity of demand among them. (CCF ¶673). Indeed, according to Endo's own documents, the overall rate of switching between different LAOs is

extremely low—approximately 3%. (CCRF ¶¶747, 749). Any limited competition from other LAOs was insufficient to lower oxymorphone ER's price to a more competitive level. (CCF ¶¶636 (*in camera*), 909).

The medical evidence supports this economic conclusion. Branded Opana ER and generic oxymorphone ER are the only LAOs containing the molecule oxymorphone, which has unique properties. (CCF ¶¶35, 726, 748, 755). Endo itself often touted oxymorphone's "distinct pharmacologic properties compared with most other opioids." (CCF ¶726).[13] Both medical experts agree there are differences among long-acting opioids and that it is important for prescribers to be aware of these differences. (CCF ¶¶504-10, 746-49, 759-60). And it is undisputed that different patients can respond differently to different opioid molecules in terms of effectiveness and side effects. (CCF ¶507). For this reason, opioid treatment requires trial and error to find the best molecule for a specific patient. This medical testimony makes clear that these clinical considerations—not small price changes—drive prescribing patterns. Indeed, Impax's medical expert testified that he would not generally even be aware of an LAO price change unless it was dramatic. (CCF ¶565, CCRF ¶¶894).

Impax's economic expert, Dr. Addanki, has little response to this evidence. He does not dispute the data showing that, unlike other LAOs, the entry of generic oxymorphone ER took substantial sales from Endo's branded product. (CCF ¶¶628-44). Indeed, Dr. Addanki concedes that his own analysis entirely ignored the impact of generic competition because he already "know[s] what's going to happen." (CCF ¶¶909-11, 946-47). Nor does he dispute Professor

[13] *See also* CCF ¶¶730 (Opana ER is a "rapidly growing brand . . . due to the inherent characteristics of the compound . . . ."), 731 ("Opana ER is a product that has inherent characteristics that make it a product that physicians and patients both want to use"), 732 ("what we really focus on in terms of positioning Opana ER in the marketplace is the inherent advantages of the compound itself").

Noll's conclusion that the data show no pattern of substitution between Opana ER and non-oxymorphone LAOs (CCF ¶¶670-716) or demonstrate any meaningful switching between Opana ER and other LAOs in response to price changes. And he does not criticize the medical evidence showing high switching costs to change from Opana ER to other opioids. (CCF ¶986). These facts demonstrate low cross elasticity of demand between Opana ER and other LAOs.

Instead of rebutting Professor Noll's expert analysis, Impax complains that he did not "try to calculate any cross-elasticities of demand" and merely conducted a "visual inspection" of sales trends to assess the relevant market. Opp. 54. But Professor Noll conducted exactly the type of analysis that courts have relied on to assess the relevant product market. *See SmithKline Corp. v. Eli Lilly & Co.*, 427 F. Supp. 1089, 1118-19 (E.D. Pa. 1976); *Ciprofloxacin*, *3*63 F. Supp. 2d at 522-23; *Lidoderm*, 296 F. Supp. 3d at 1174-75. And Impax's own expert agreed that it was not possible to mathematically calculate cross-price elasticities because of data limitations. (CCF ¶655; RX-547 at 0023-24 (¶42 (Addanki Report))). Indeed, as one of the leading antitrust scholars explains, the detailed econometric calculations Impax demands are only necessary "when patterns are not obvious." Areeda ¶562b; *see also McWane*, 2014 WL 556261, at *15 ("Econometric analysis can be a valuable tool for defining the market, but it is only one of several that may be used for that purpose."). The data here show a clear pattern: non-oxymorphone LAOs had no discernible impact on Opana ER. (CCF ¶¶674-716).

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

Impax provides what it claims are examples of economic competition between Opana ER and other LAOs. Opp. 45-49. But none of these examples actually demonstrate that consumers switched between Opana ER and other, non-oxymorphone LAOs in response to a small but significant price difference.

1. Impax provides no evidence of cross elasticity at the patient level

Impax points to evidence that Endo provided patients with coupons or rebates to reduce their insurance copays and argues that Endo would not have done so if it were a monopolist. Opp. 46. But Impax does not identify any evidence that patients switched LAOs as a result of these coupons. Indeed, the undisputed facts show that overall switching between LAOs was extremely low despite this "aggressive" couponing. (CCRF ¶¶747-49). Thus, the fact that Endo provided discounts to patients reveals nothing about cross elasticity, and instead "simply shows that, in order to grow the market for what defendants repeatedly characterize as a unique product, price concessions and rebates for [the product] were necessary." *Lidoderm*, 296 F. Supp. 3d at 1174.

2. Impax provides no evidence of cross elasticity at the prescriber level

Impax highlights the unremarkable fact that Endo marketed Opana ER to physicians. But Endo's promotional activities often touted oxymorphone's "distinct pharmacologic properties compared with most other opioids." (CCF ¶726). Such efforts were intended to convince doctors *not* to substitute other LAOs for Opana ER. (CCRF ¶¶878-98; CCF ¶726-36, 769, 781-83, 790). This kind of advertising tends to *decrease* price competition because it makes products appear *less* interchangeable. *See Solodyn*, 2018 WL 563144, at *8 (promotional materials "emphasiz[ing] the therapeutic differences [the brand product] provided, or its 'clinical efficacy,' rather than benefits [the brand] offered on a price dimension" support finding that other brand products were not included in the market); Lawrence A. Sullivan, et al., The Law of Antitrust: An Integrated Handbook 69 (3d ed. 2015) (product differentiation can be an entry barrier that contributes to market power). Impax also argues that Endo informed doctors about formulary placement, but, as described below, it provides no evidence of cross elasticity at the formulary level either.

3. Impax provides no evidence of cross elasticity at the payor level

Impax notes that LAO manufacturers offered discounts to insurers in exchange for favorable formulary placement. And it highlights a study indicating that patients switched between OxyContin and Opana ER after one regional health plan, UPMC, gave Opana ER a better formulary placement. Opp. 47-48. But Impax's own economic expert testified that he could not say whether changes in formulary placement for Opana ER and other LAOs—including the UPMC change—occurred for price (as opposed to clinical) reasons. (CCF ¶944; CCRF ¶¶763-67, 836). And Impax's anecdotal example of a single formulary change leading to patient switching does not demonstrate switching on any significant level—particularly where the overall rate of switching between all LAOs was only 3%. (CCRF ¶¶747-49).

4. Contemporaneous business documents show that Endo did not focus on price competition with other LAOs

Impax also urges the Commission to "pay close attention" to drugmakers' business documents in deciding the relevant product market. Opp. 48-49. We agree. Impax points to a few examples of business documents that use terms like "LAO market." (Opp. 49). But "the mere fact that a firm may be termed a competitor in the overall marketplace does not necessarily require that it be included in the relevant market for antitrust purposes." *FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1075 (D.D.C. 1997). And a holistic review of Endo's internal documents confirms that they (1) rarely mention the relative price of other LAOs, (2) instead focus on competing through product differentiation (CCF ¶¶721-33, 737-39; CCRF ¶¶878, 882-83), and (3) uniformly recognize that generic oxymorphone ER—but not other LAOs—posed a unique threat to Opana ER's revenues. (CCF ¶¶599-626). Numerous Endo and Impax forecasts showed that the only event that was expected to lower Opana ER revenues, volume, and price was the launch of generic oxymorphone ER. *See* Pt. V.A.2, *supra*; (CCF ¶¶592-98, 603-07, 611, 613,

618, 621); *see also Solodyn*, 2018 WL 563144, at *8 (brand forecasts projecting that only generics version, and not other branded products, were "likely to lower [] prices and capture branded sales" support market definition limited to brand and generic equivalents).

5. Impax misunderstands the Commission's *King Pharmaceuticals* order

Impax erroneously contends that "the Commission identified a market consisting of 'the manufacture and sale of oral LAOs'" in its King Pharmaceuticals, Inc./Alpharma Inc. settlement. Opp. 50 (quoting Complaint ¶12, *In re King Pharm., Inc. & Alpharma, Inc.*, No. C-4246 (F.T.C. Feb. 2, 2009). Not so. The Commission noted that the relevant line of commerce was "*no broader than* the manufacture and sale of oral LAOs," but expressly defined a "*narrower market* for oral long-acting morphine sulfate." *See id.* ¶11 (emphasis added). Indeed, had the Commission defined the market to include all oral LAOs, it would not have required the companies to divest one of their two morphine sulphate products—which combined made up less than 20% of total oral LAO sales. *See* Agreement Containing Consent Order to Aid Public Comment, *In the Matter of King Pharm., Inc. & Alpharma, Inc.*, File No. 081-0240, 74 Fed. Reg. 295, 296 (Jan. 5, 2009). Thus, the King/Alpharma complaint defined the relevant market around a specific LAO (oral long-acting morphine sulfate)—which is exactly what Complaint Counsel urges the Commission to do here.

C. Endo possessed market power in the oxymorphone ER market

Though it disagrees with Complaint Counsel's market definition, Impax does not appear to dispute that, at the time Impax and Endo entered the SLA and DCA, Endo had market power in a market limited to branded and generic oxymorphone ER. At the time of the settlement in 2010, Endo had 100% of the oxymorphone ER market, and the Herfindahl-Hirschman Index was 10,000. (CCF ¶¶830, 840-42). And this power was protected by numerous substantial entry barriers, including the lengthy and expensive FDA licensing process for pharmaceuticals, the

DEA's additional regulations for opioids, Endo's patents, and the exclusionary rights provided by the Hatch-Waxman regulatory structure. (CCF ¶¶843-50).

Additional evidence confirms Endo's market power.

First, although not determinative, Endo's willingness to make a large payment to Impax indicates that it had market power. ID 140. "[A] firm without that power" is not "likely to pay large sums to induce others to stay out of the market." *Actavis*, 570 U.S. at 157; *see also Cipro*, 348 P.3d at 869 ("Logically, a patentee would not pay others to stay out of the market unless it had sufficient market power to recoup its payment through supracompetitive pricing."); *Aggrenox*, 199 F. Supp. 3d at 665 ("[i]t is vanishingly unlikely, however, that a large reverse payment would be made [when a brand cannot sell its drug at supracompetitive prices], which is why a large reverse payment is such a strong indicator of market power"); Areeda ¶520b2 ("Market power can sometimes be inferred from an exclusionary practice that would not be rational for a firm lacking significant power.").[14]

Second, the evidence shows that Impax's generic entry increased the output of oxymorphone ER—[redacted] (CCF ¶¶963-64; CCRF ¶¶667, 669 (*in camera*)). To make its contrary claim, Impax relies on a flawed metric: it looks at three-month moving averages, which do not isolate the output increase in Impax's entry month. (CCF ¶¶963-65; CCRF ¶667). Even using Impax's flawed data, however, generic entry still increased output because it halted an ongoing decline in Opana ER demand. (CCF ¶¶963-65; CCRF ¶¶669).

[14] The cases cited by Impax are not to the contrary. Opp. 44. The *Solodyn* district court noted the "interconnectedness" between the making of a reverse payment and market power. 2018 WL 563144, at *5. And in *Nexium*, the jury was asked whether the defendant had "market power within the relevant market"; nothing prevented it from inferring market power based on the large payment. *See* 842 F.3d at 49-50.

Third, prior to generic entry, Endo was able to maintain a supracompetitive price for Opana ER, and a high price-cost margin, without losing sales. (CCF ¶¶895-96 (*in camera*), 909). But once generic oxymorphone ER entered, Endo could not maintain sales at this supracompetitive price: it lost approximately [redacted] of its market share to Impax's much cheaper product. (CCF ¶¶630, 636 (*in camera*), 909). Impax claims that Endo must have faced competition from other LAOs before generic oxymorphone was available because the [redacted] Opp. 48 (*in camera*). [redacted]. (CCF ¶880; CCRF ¶830). Further, Endo was able to grow Opana ER sales very rapidly during this same period despite the entry of other LAOs, indicating market power. (CCF ¶935; CCRF ¶660).

At bottom, Impax's generic oxymorphone ER was inarguably a far more potent competitive restraint on Endo's Opana ER product than any non-oxymorphone LAO. Preventing the risk that it would compete with Opana ER was anticompetitive.

VI. The Proposed Order is an appropriate exercise of the Commission's remedial authority

Once a violation is found, the Commission has an obligation to order effective relief to protect the public from future violations and to restore competitive conditions to the marketplace. 15 U.S.C. § 45(b). The Commission "has wide discretion" to craft an appropriate remedy. *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 612 (1946). Yet Impax insists that even if the challenged agreement is found to be unlawful, no prospective injunction is warranted. Opp. 62-67. Impax's no-remedy arguments, however, are meritless. Impax can and should be enjoined from entering into additional reverse-payment settlements and from continuing to hamper competition in the oxymorphone ER market. *FTC v. Nat'l Lead Co.*, 352 U.S. 419, 428 (1957) (confirming the Commission's power to issue cease-and-desist orders).

First, Impax incorrectly claims that no relief is appropriate because there is no cognizable danger that it will enter into another reverse-payment agreement. Opp. 62-64. It is well-established that unlawful "past conduct gives rise to an inference of a reasonable expectation of continued violations." *SEC v. Manor Nursing Ctrs., Inc.*, 458 F.2d 1082, 1100 (2d Cir. 1972). Impax's agreement with Endo was a conscious effort to maintain and share monopoly profits at the expense of consumers; Impax has entered into at least one other agreement alleged to include a large, unjustified reverse payment[15]; Impax remains an active player in the pharmaceutical industry and regularly engages in patent infringement litigations[16] and has powerful incentives to resolve patent litigations with reverse payments.[17] Moreover, Impax continues to deny culpability and makes no assurances against engaging in future violations. Where a party "continues to maintain that [its] past conduct was blameless," there is no reason to expect it to desist from that conduct. *SEC v. Cavanagh*, 155 F.3d 129, 135 (2d Cir. 1998); *see also FTC v. Med. Billers Network, Inc.*, 543 F. Supp. 2d 283, 323 (S.D.N.Y. 2008). These factors establish the danger of recurrence and compel Impax to be enjoined.[18]

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[15] *See Solodyn*, 2018 WL 563144. Impax settled the allegations following trial. Reuters, "Impax to pay $35 million to settle part of Soldyn antitrust litigation," Mar. 10, 2018, https://www.reuters.com/article/us-impax-labs-lawsuit/impax-to-pay-35-million-to-settle-part-of-solodyn-antitrust-litigation-idUSKCN1GM0SK; Reuters, "Impax reaches $20 million deal to end trial over generic drug's delay," Mar. 29, 2018, https://www.reuters.com/article/us-impax-labs-lawsuit/impax-reaches-20-million-deal-to-end-trial-over-generic-drugs-delay-idUSKBN1H520X.

[16] CCF ¶¶1473-78.

[17] CCF ¶¶977-82.

[18] In determining the risk of recurrence, factors to consider include: "the defendants' scienter, whether the conduct was isolated or recurrent, whether defendants are positioned to commit future violations, the degree of consumer harm caused by defendants, defendants' recognition of their culpability, and the sincerity of defendants' assurances (if any) against future violations." *Med. Billers Network*, 543 F. Supp. 2d at 323.

Second, Impax is wrong that the order's restriction on entering reverse-payment agreements would "prohibit Impax from entering any settlement in which a brand company makes" any payment and "prevent Impax from purchasing for fair value any services or materials from a brand company." Opp. 64. The order expressly excludes certain forms of value that are unlikely to be a sharing of the patentee's monopoly profits preserved by avoiding competition (and thus anticompetitive), such as patent licenses and the right to market the generic product. Proposed Order I.W. Impax does not explain why these carve-outs are inadequate (Opp. 64), and similar provisions have worked successfully in other FTC injunctions.[19] Nor does the order significantly limit Impax's ability to enter legitimate business transactions. Proposed Order I.W. Impax would remain free to enter any legitimate agreement for goods or services with a brand company so long as that arrangement is not done within 45 days of a patent settlement.

Third, Impax complains that Provision II.C of the proposed order would "strip Impax of its right to enforce a 2017 settlement agreement between Endo and Impax." Opp. 66. But the so-called "right" it wishes to enforce is a new SLA provision sheltering Impax from oxymorphone ER competition. In August 2017, Impax and Endo amended the SLA to resolve a second Endo suit against Impax for breach of contract. (CCF ¶¶1426-27). Under the amendment, Impax [redacted]

[19] *See* Stipulated Order for Permanent Injunction, *FTC v. Endo Pharm. Inc.*, No. 17-cv-312 (doc. 25, Feb. 2, 2017); Stipulated Order for Permanent Injunction, *FTC v. Teikoku Pharma USA, Inc.*, No. 16-cv-1440 (doc. 14, Apr. 7, 2016); Stipulation Order for Permanent Injunction and Equitable Monetary Relief, *FTC v. Cephalon, Inc.*, No. 2:08-cv-2141 (doc. 405, June 17, 2015).

[redacted]. (CCF ¶1428). This provision disincentivizes Endo from competing itself or licensing additional manufacturers.

Throughout this proceeding, Impax has touted the fact that it is the only oxymorphone ER product on the market today. But the fact that the oxymorphone ER monopoly simply changed hands from Endo to Impax does not benefit consumers. Paragraph II.C would help restore competition in the oxymorphone ER market by eliminating the exclusivity requirement as a condition for Impax's royalty obligation. The provision would not affect Impax's other rights under the amendment, including a license to additional Endo patents.

Impax's claim that the provision has "no reasonable relation to the challenged agreement" (Opp. 64) is plainly unfounded as it specifically concerns an amendment to the challenged agreement that continues to suppress competition in the oxymorphone ER market and is appropriate fencing-in relief. *See Nat'l Lead Co.*, 352 U.S. at 431; *Toys "R" Us, Inc. v. FTC*, 221 F.3d 928, 940 (7th Cir. 2000).

Impax's further claim that Paragraph II.C "violates [its] due process rights" (Opp. 67) is similarly without merit. Although the 2017 amendment was executed just two months before trial, the record fully addresses it.[20] Impax offered no response to Complaint Counsel's proposed findings on the 2017 amendment. (RCRF ¶¶1420-29). Complaint Counsel has never made "impromptu allegations" (Opp. 67) that the 2017 amendment itself is a Section 5 violation. But the Commission may prohibit conduct (even if otherwise lawful) if it "represents a reasonable method of eliminating the consequences of the illegal conduct" or preventing its resumption. *Id.*; *see also Nat'l Soc'y of Prof'l Eng'rs*, 435 U.S. at 697-98 (even though a remedy "may impinge upon rights that would otherwise be constitutionally protected[] do[es] not prevent [the court]

[20] *See* CC Pre-Trial Br. 37 n.156; CC Post-Trial Br. 76; CCF ¶¶1420-29.

from remedying the antitrust violation."). The cases cited by Impax are not to the contrary. Opp. 67.

Finally, Impax objects to Paragraph II.B. because it prohibits conduct other than reverse-payment agreements. Opp. 65. But the Commission is not limited to imposing a "simple proscription against the precise conduct previously pursued." *Nat'l Soc'y of Prof'l Eng'rs*, 435 U.S. at 698. "If the Commission is to attain the objectives Congress envisioned . . . it must be allowed effectively to close all roads to the prohibited goals, so that its order may not be by passed with impunity." *FTC v. Ruberoid Co.*, 343 U.S. 470, 473 (1952).

Impax is also incorrect that the use of the terms "prevents," "restricts," and "disincentivizes" are "vague." Not every word in an order needs to be defined. These terms have plain meaning, and the purpose of the provision is clear. It seeks to prohibit Impax from entering agreements with another oxymorphone ER manufacturer or applicant that would suppress oxymorphone ER competition between the two companies. To the extent the Commission wishes to further clarify the provision, this could be easily accomplished with the following language (modifications underlined):

> Paragraph II. B: Respondent shall not enter any agreement <u>with another Oxymorphone ER Manufacturer or Applicant</u> that prevents, restricts, or in any way disincentivizes competition between Oxymorphone ER Products.
>
> Paragraph I Definitions: <u>"Oxymorphone ER Manufacturer or Applicant" means any company that has an Oxymorphone ER NDA or ANDA, has filed an Oxymorphone ER NDA or ANDA, or is preparing to file an Oxymorphone ER NDA or ANDA.</u>

* * *

When Complaint Counsel initially sued Impax in federal district court, Impax argued that "the agency's proper recourse under the FTC Act is to do so through an ***administrative proceeding*** under Section 5(b) of the FTC Act." Defendants' Mem. in Support of Motion to

Dismiss, at 3, *FTC v. Endo Pharm. Inc.*, Case No. 16-cv-01440 (E.D. Pa. July 12, 2016). Now that this case is in an administrative proceeding, Impax wrongly insists that there is no remedy to be had at all. Opp. 62-67. That cannot be right. In 2010, Impax consciously agreed with Endo to maintain and share monopoly profits at the expense of consumers. In 2017, Impax amended that original agreement to once again share and maintain monopoly profits, with Impax now holding the monopoly. Impax continues to deny culpability and makes no assurance against future violations. Impax has the incentive, desire, and opportunity to enter similar agreements in the future. (CCF ¶¶1460-84). The proposed relief is appropriate to prevent Impax from committing future violations and to help restore competition in the oxymorphone ER market.

CONCLUSION

Impax has provided no reason why the Commission should not reverse the Initial Decision and enter Complaint Counsel's proposed order.

Respectfully submitted,

Dated: September 12, 2018

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CERTIFICATE FOR ELECTRONIC FILING

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

September 12, 2018 By: /s/ *Rebecca E. Weinstein*
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