

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 APPEAL OF THE INITIAL DECISION

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STATEMENT OF THE CASE

A. Summary of the Argument

After a 12-day trial, the Administrative Law Judge found that Respondent Impax Laboratories accepted a large and unjustified reverse payment from Endo Pharmaceuticals, “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.” Initial Decision (“ID”) 6-7. Before this agreement, Impax presented a significant threat to Endo’s lucrative Opana ER franchise. Impax was vigorously challenging Endo’s patents in court and preparing for a possible imminent launch. Competition from Impax would have devastated Endo’s Opana ER profits and thwarted its critical franchise-extension strategy. To protect these profits, as the Initial Decision found, Endo agreed to pay Impax at least \$23 million (and potentially much more) in return for Impax’s agreement to stay off the market for 2½ years.

As the Supreme Court made clear in *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013), this type of collusive agreement to prevent the risk of competition and share the resulting monopoly profits is anticompetitive. The Initial Decision recognized as much. But it nonetheless found that this agreement was justified because a different provision in the settlement gave Impax a license to potential future patents Endo might acquire and because—years after the settlement—Endo used later-acquired patents to prevent other companies from selling generic Opana ER. Since Impax’s license allowed it to remain on the market while other companies were enjoined, the ALJ ruled that the “real-world effect” of the settlement as a whole was procompetitive.

In reaching this conclusion, the Initial Decision made three critical errors:

First, though it recognized that the challenged restraint is the use of a reverse payment to restrain potential generic entry, the Initial Decision did not require Impax to show that this

restraint plausibly furthered its claimed procompetitive benefits. Contravening decades of rule-of-reason precedent, the Initial Decision instead allowed Impax to rely on asserted benefits flowing from *other* provisions in the overall Opana ER settlement agreement.

Second, Complaint Counsel showed that the payment to eliminate the risk of competition was not reasonably necessary for Impax to obtain the license to future patents. Both the license and the payment were benefits flowing to Impax, and basic logic shows that Endo would have been willing to provide (and Impax could have accepted) the license without the payment. Impax has never argued otherwise. The Initial Decision, however, rejected this logic, holding that Complaint Counsel had to offer more proof that, absent the payment, an alternative settlement would still have contained a license to future patents.

Third, despite the lack of any valid justification, the Initial Decision proceeded to a balancing exercise that rests impermissibly on hindsight. Ignoring the need to assess the antitrust legality of agreements as of the time entered, the Initial Decision held that unpredictable events occurring years after the settlement can retroactively justify anticompetitive harm that occurred at the time of the agreement. It compounded this error by dismissing the anticompetitive harm from this reverse payment—which kept Impax off the market for the vast majority of the remaining term of the litigated patents—as “largely theoretical.” But the certain harm from preventing potential generic competition for 2½ years easily outweighs the speculative benefit from a license to future patents that may or may not even issue.

In addition, Complaint Counsel asks the Commission to correct three errors that did not affect the outcome of this case, but have significant implications for other reverse-payment challenges. First, in holding that the \$10 million upfront payment Impax received pursuant to a simultaneous development deal was justified, the Initial Decision failed to assess, as *Actavis*

instructs, “the basic reason” for that payment. 570 U.S. at 158. As a result, it dismissed substantial evidence that Endo would never have made an unconditional \$10 million payment for the deal absent its desire to secure Impax’s agreement not to compete with its generic Opana ER product. Second, the Initial Decision erroneously required Complaint Counsel to disprove Impax’s proffered justifications for the payments as part of Complaint Counsel’s *prima facie* case. Third, the Initial Decision incorrectly dismissed an economic analysis of the *ex ante* value of the payment provisions in the settlement agreement because it provided a range of the plausible values, rather than a precise expected value calculation that Impax’s own expert agreed was impossible to perform.

B. Background

As *Actavis* explains, reverse-payment agreements arise under the “unique regulatory framework” governing generic drug entry, known as the Hatch-Waxman Act. *Id.* at 155-56. The Act streamlined the process for generic drug approval under Abbreviated New Drug Applications (“ANDAs”) and established provisions to encourage generic applicants to challenge patents they believe are invalid or not infringed. Such challenges begin with a “paragraph IV certification.” The first generic applicant to submit a paragraph IV certification challenging the brand’s patents is eligible for 180 days of market exclusivity. The FDA may not approve any other generic applications until this exclusivity period expires or is forfeited. The Act also gives the brand-name drug manufacturer an automatic 30-month stay of FDA approval if it sues promptly when it disagrees with a paragraph IV certification. *Id.* at 142-44.

These features of the Hatch-Waxman Act have unintentionally led to reverse-payment patent settlements in which the brand-name drug manufacturer uses “its monopoly profits to avoid the risk of patent invalidation or a finding of non-infringement.” *Id.* at 156. In a settlement with no reverse payment, an agreement setting a generic entry date is presumably a traditional

compromise of competing claims, reflecting the parties' assessments of the likely risks and rewards of continuing litigation. But payment from the patent holder in return for the generic's agreement to "stay away from the patentee's market" is "something quite different." *Id.* at 152.

The reverse payment effectively transforms rivals with opposing interests into partners in an arrangement that preserves the pool of brand profits:

[S]ettlement on the terms said by the FTC to be at issue here— payment in return for staying out of the market simply keeps prices at patentee-set levels . . . while dividing that return between the challenged patentee and the patent challenger. The patentee and the challenger gain; the consumer loses.

Id. at 154. *Actavis* thus teaches that reverse-payment agreements raise a core antitrust concern: that the competitive process that serves consumers' interests will be subverted because a potential competitor finds it more profitable to share in the incumbent's monopoly profits than to compete. The agreement "to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market" is "the very anticompetitive consequence that underlies the claim of antitrust unlawfulness." *Id.* at 157.

C. Facts

Impax posed a critical threat to Endo's Opana ER franchise

In May 2010, Endo and Impax were preparing for a patent infringement trial relating to one of Endo's flagship products, Opana ER. (F.72). Opana ER is an extended-release formulation of oxymorphone, an opioid approved to treat pain. (FF.41-46). Impax was the first of several generic drug manufacturers to file an ANDA for the five most popular dosages of Opana ER with paragraph IV certifications. (F.173). It received tentative FDA approval on May 13, 2010 and expected final approval on June 14, 2010—in the middle of the patent trial. (FF.64-66, 72).

Impax represented a significant threat to Endo's Opana ER franchise. Although the patents Endo asserted were set to expire in 2013, Endo predicted generic entry as early as July 2010. (CCF ¶¶53, 61). And even if Impax "wait[ed] for the appeal to play out" so that it could launch risk-free, Endo projected Impax's launch would "likely happen around June of [2011]." (CCF ¶¶370, 372).

For its part, Impax had been working hard to be launch-ready as early as June 2010. (CCF ¶¶127-213). Successfully launching generic Opana ER in 2010 was a "Company Key Goal," and Impax consistently forecasted a launch as early as June 2010 or, alternatively, after a Federal Circuit decision in mid-2011. (CCF ¶¶130, 148, 158). After Impax received tentative approval, senior management updated the "current assumption" for generic Opana ER to "At-Risk Launch in 2010" and alerted the board of directors that it might seek at-risk launch approval. (CCF ¶¶139, 145-46). Thus, the risk to Endo was real. And Endo forecasted generic competition would erode branded Opana ER sales by 70% within six months. (F.97).

To protect its profits, Endo planned to launch a "Tamper Resistant Formulation" of Opana ER. (FF.96-109). Moving the market to this reformulated version prior to generic launch could avoid the dramatic losses resulting from generic entry. (FF.97-98).¹ But the success of Endo's reformulation strategy hinged on introducing, and transitioning patients to, reformulated Opana ER *before* Impax's generic entry. (FF.99-106). If successful, Endo expected peak annual sales of about \$200 million; if not, peak annual sales would be only \$10 million. (F.99). Thus, Endo's "Priority #1" for reformulated Opana ER was to "Beat Generics by 1 Year." (F.99).

¹ Impax's generic Opana ER would not be therapeutically equivalent ("AB-rated") to Endo's reformulated Opana ER and, therefore, could not be automatically substituted for the brand at the pharmacy. (FF.14, 29, 200).

By May 2010, however, Endo had not yet sought FDA approval for reformulated Opana ER. (F.105). Endo predicted it would take up to 10 months to get FDA approval and six to nine additional months to convert the market to the reformulated product. (FF.105-06). In short, Endo needed more time to implement its plan. Thus, upon learning of Impax's tentative FDA approval, Endo reopened settlement negotiations with Impax. (FF.119-22; CCF ¶¶219, 225-26). From the outset, Endo sought to keep Impax off the market until 2013 in exchange for compensation. (CCF ¶227).

Impax wanted protection from an Endo authorized generic

As the first generic filer with paragraph IV certifications for the most frequently prescribed dosages of Opana ER, Impax was eligible for Hatch-Waxman's 180-day exclusivity period. (F.174). But this exclusivity would not prevent Endo from launching an authorized generic ("AG"). An AG is essentially the brand-name drug, but marketed and priced as a generic. (F.175). Impax viewed competition from an Endo AG during this valuable exclusivity period as a significant threat to its bottom line. (FF.179-81). Competition from an AG further drives down generic prices and takes significant sales from the generic first filer, reducing the first filer's exclusivity-period revenues by, on average, 40 to 52%. (CCF ¶¶397-98). Endo estimated that it would recoup as much as \$25 million of lost revenues through AG sales during this period (CCF ¶¶84, 399) and was actively preparing to launch an AG upon Impax's entry. (F.108).

Given the impact of AG competition, Impax's top executives discussed internally the desirability of obtaining Endo's agreement not to launch an AG (a "No-AG") during Impax's exclusivity period. (F.121). Impax calculated that a No-AG provision would be worth \$23-\$33 million in additional profits. (FF.179-81, 193). Although Impax's generics president was hesitant about settling with a later entry date, he deemed a settlement with later entry and a No-AG promise from Endo to be a "different story. I'd love that!!!!" (CCF ¶224).

Impax agreed to stay off the market until January 2013 in exchange for a large reverse payment

Endo initially offered Impax a March 10, 2013 entry date, a No-AG provision, and a \$10 million upfront cash payment, ostensibly as part of a side agreement relating to a Parkinson's drug Impax was developing. (FF.131, 294).

Impax was concerned, however, that a 2013 entry date would allow Endo to shift the market to a reformulated product before Impax's generic entry. (FF.139-43, 148). A successful Endo reformulation strategy would essentially eliminate the original Opana ER market, which, in turn, would "subvert the value of the deal." (FF.204-05). Impax would lose not only the benefit of the No-AG provision, but also the value of the first-filer exclusivity period itself. (CCF ¶¶420-21). To address this concern, Impax proposed an entry acceleration trigger that would permit it to market generic Opana ER immediately if sales of Endo's original Opana ER product fell to a specified level. (FF.137-39; CCF ¶424).

Endo rejected this proposal, but sweetened the reverse payment: Endo offered a "make whole" payment, called the "Endo Credit," that would "back-up" the value of the No-AG provision if Endo reformulated Opana ER. (FF.147-54, 197, 211-15). As Impax's chief negotiator described it, the goal was to "come up with a number that [Impax] would have made . . . if [it] had a generic in that six-month period." (CCF ¶255). This protection was "super, super important" to Impax; "something that didn't protect us from the downside was . . . a deal-breaker." (F.208).

With that issue resolved, Impax and Endo reached an agreement in principle on the terms of the Settlement and License Agreement ("SLA"): (1) a January 1, 2013, entry date (eight months before expiration of the two asserted patents); (2) the No-AG provision; and (3) the Endo

Credit. (F.154; CCF ¶298). During the next three days, the parties exchanged drafts and finalized language. (FF.160-65).

After reaching an agreement in principle, and two days before the settlement was finalized, Impax asked Endo for protection against future patents that Endo might obtain. (FF.169, 244-45). Although Impax regularly sought a “freedom-to-operate” provision in patent settlements (F.565), to that point the negotiations had only involved a license to Endo’s then-existing Opana ER patents. (FF.134, 166). Endo agreed to change the license. (F.170).

As part of the settlement negotiations, Endo and Impax also negotiated a development and co-promotion agreement (“DCA”) relating to a potential treatment for Parkinson’s disease. (F.123; CCF ¶¶232-39, 285-312). From the outset, Endo offered Impax a \$10 million upfront cash payment. (F.294). Endo never wavered from that promise, even after Impax insisted the deal cover an unformulated, untested concept in the earliest phase of development rather than the late-stage drug that Endo expected. (FF.247, 295-98, 303, 314-15).

The parties executed the SLA and DCA on June 7, 2010. (FF.244-45). The settlement protected Opana ER from generic competition until January 1, 2013. (F.124). Because Impax was the first filer for the most popular dosages of Opana ER, no other company could launch a generic version of those dosages until Impax’s exclusivity period expired. (F.449). Endo’s payments thus provided “a clear path (until January 2013) to establish [reformulated Opana ER] demand.” (CCF ¶440).

Post-settlement events

Endo’s reformulation strategy ultimately succeeded. Endo introduced reformulated Opana ER in March 2012 and had effectively eliminated all original Opana ER sales by the time Impax entered in January 2013. (FF.110, 230). As a result, Endo was obligated to pay Impax \$102 million under the Endo Credit. (FF.229, 236-37).

Endo obtained additional patents claiming Opana ER beginning in late 2012 and started asserting them against other generic drug manufacturers. (FF.575-83). In 2015 and 2016, some of these patents were upheld and prevented other companies from marketing generic Opana ER. (FF.578, 585-87).

Despite obtaining the license to future patents, Impax did not avoid further litigation. In May 2016, Endo sued Impax for breach of the settlement agreement, contending that Impax had violated its obligation to negotiate a royalty for the later-acquired patents. (CCF ¶1421). Endo also claimed infringement of these patents. (CCF ¶1421).

In July 2017, Endo announced that it would comply with an FDA request that it voluntarily withdraw reformulated Opana ER from the market. (CCF ¶1429; F.111). Shortly thereafter, Endo and Impax settled the breach of contract suit [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Proceedings below

The Commission's January 2017 complaint charges that Impax agreed not to compete with Endo's Opana ER for 2½ years in return for a share of Endo's monopoly profits.² It further alleges that this agreement did not further any legitimate, procompetitive objective.

Following a three-week trial, Chief Administrative Law Judge D. Michael Chappell issued an initial decision on May 11, 2018. He found that Endo agreed to make a large reverse payment to Impax, "the purpose and effect of which was to induce Impax to give up its patent

² Endo settled with the Commission regarding Opana ER and another product. *See* Stipulated Order for Permanent Injunction, *FTC v. Endo Pharm. Inc.*, No. 17-cv-312 (N.D. Cal. Feb. 2, 2017).

challenge and agree not to launch generic Opana ER until January 2013.” ID 6-7. But the ALJ ruled that the settlement agreement as a whole was procompetitive because it provided a license enabling Impax to sell its generic product even when Endo subsequently acquired additional patents and successfully enforced them against other generic drug companies. ID 7, 144-46, 157-58.

The ALJ’s rule-of-reason analysis acknowledged that the relevant anticompetitive harm in a reverse-payment case is the branded drug firm’s use of a large payment to prevent the risk of competition. ID 100. He then assessed the No-AG’s value as of the settlement date, looking to contemporaneous evidence reflecting Impax’s profit expectations as the sole generic seller for six months. ID 104-06. He concluded that the No-AG was worth \$23-\$33 million in additional profits. ID 106. He also determined that the Endo Credit was designed to “backstop” the value of the No-AG in case of an Endo reformulation. ID 107-10, 114. As a result, he deemed it unnecessary to estimate a separate monetary value for the Endo Credit. The ALJ concluded that the size of the No-AG/Endo Credit reverse payment was large relative to the estimated saved litigation costs. ID 114-15.

The ALJ also found that at the time of settlement Endo had a monopoly in the relevant market for oxymorphone ER. ID 139-141; (FF.90-95).³ Though Opana ER is one of a number of long-acting opioids, the ALJ observed that generic drugs are uniquely close competitors to their branded counterparts, and a variety of record evidence concerning the effect of entry of generic Opana ER confirmed that conclusion. (FF.26-32, 41, 97, 108, 171-94). The ALJ also noted the Supreme Court’s observation that a firm without market power is unlikely to make a large

³ The ALJ expressed uncertainty about whether *Actavis* requires a finding of market power. ID 139. We believe it does.

payment to induce a generic to stay off the market. ID 139-40 (quoting *Actavis*, 570 U.S. at 157). Although not mentioned by the ALJ, the record also contains extensive additional evidence confirming Endo's monopoly power. (CCF ¶¶498-965).

As part of Complaint Counsel's *prima facie* case, the ALJ also considered and rejected Impax's attempts to justify the No-AG and Endo Credit provisions. ID 116-19. The ALJ explained that the entry date's movement from March 2013 to January 2013 was "not significant," given the negotiation evidence as a whole. ID 118. And the ALJ rejected Impax's claim that the Endo Credit was part of a "carrot and stick" strategy to deter Endo from moving the market to reformulated Opana ER as unsupported by the evidence and economically implausible. ID 118-19. The ALJ therefore found that the evidence "readily supports the conclusion" that the No-AG and Endo Credit provisions were "compensation to Impax for giving up its patent challenge and committing not to launch a generic Opana ER until January 2013." ID 117. Use of this large payment to prevent the risk of competition established the relevant anticompetitive effect under *Actavis*. ID 89, 100.

With regard to the DCA, however, the ALJ ruled that the evidence failed to prove Endo's \$10 million upfront cash payment was to induce Impax to stay off the market. The ALJ held that "[f]or purposes of justification, the issue is whether the payment was fair value for what was received." ID 137. The ALJ dismissed the extensive evidence showing that the terms and timing of the DCA were closely intertwined with the settlement agreement. ID 135. He also declined to credit the testimony of a pharmaceutical industry expert who explained that the DCA terms, and Endo's abbreviated deal evaluation, were so contrary to basic industry norms that it was implausible that Endo (or any other sophisticated drug company) would have paid \$10 million upfront for the DCA. ID 135-38; (*see also* CCF ¶¶1220-26). The ALJ dismissed this opinion

because the expert had not calculated the DCA's net present value to Endo at the time of the settlement. ID 137-38.

Having found a *prima facie* case of competitive harm, the ALJ turned to the second step of the rule-of-reason framework, where “the burden shifts to the defendant to prove procompetitive justifications for the challenged restraint.” ID 91. The ALJ explained that the challenged restraint in a reverse-payment case is “the use of the payment to restrain potential generic competition.” ID 99. But despite the well-established principle that, at this second step, the antitrust defendant's burden is “to show that the restraint in fact serves a legitimate objective,” (Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 1504b (3d and 4th Eds. 2010-2017) (“Areeda”)), the ALJ did not require Impax to make such a showing.

Instead, relying on post-settlement events, the ALJ concluded that the SLA as a whole had procompetitive benefits because of the license to future patents. ID 141-46 (describing Endo's acquisition of patents more than two years after the settlement; subsequent court rulings in 2015 and 2016 upholding some of these patents; Endo's withdrawal of its original Opana ER product; and its 2017 withdrawal of reformulated Opana ER at the FDA's request). He concluded that the “real-world effect” of the SLA's provision covering future patents is that “there is a product on the market and available to consumers today that would not be there had Impax not had the foresight to negotiate licenses to future patents.” ID 146.

The ALJ then undertook to balance the harms and benefits of the settlement agreement as a whole. His balancing analysis again focused on events occurring years after the June 2010 settlement. ID 7, 156-58. In light of these subsequent events, he found the “real world procompetitive benefits” of the SLA were “substantial.” ID 157.

In addition, while the ALJ’s earlier analysis recognized that “the relevant anticompetitive harm” in a reverse-payment case is the patentee’s use of monopoly profits to prevent the *risk* of competition (ID 89), at the balancing stage, he recast the harm as the extent of “delayed generic competition.” ID 100, 147. He deemed this harm “largely theoretical” and credited trial testimony by Impax’s executives and patent law expert that Impax was unlikely to have entered before 2013. ID 148-56. The ALJ ultimately ruled that any possible harm from Impax’s agreement to stay off the market for 2½ years in return for Endo’s payment is “far outweighed by the more than five years of uninterrupted and continuous access to generic Opana ER.” ID 157-58.

QUESTION PRESENTED

The ALJ held that Impax and Endo agreed to settle patent litigation using a large reverse payment, “the purpose and effect of which was to induce Impax to give up its patent challenge and agree not to launch a generic Opana ER until January 2013.” ID 7.

The question presented is whether, under established rule-of-reason principles, this reverse-payment agreement was nonetheless justified where Impax: (1) proffered no evidence that the payment to eliminate the risk of competition furthered any legitimate, procompetitive objective; and (2) relied on asserted countervailing benefits arising years after the agreement from a different provision of the settlement.

ARGUMENT

I. Impax failed to satisfy its burden to justify the challenged agreement

Actavis defines the “relevant anticompetitive harm” in a reverse-payment case as payment “to prevent the risk of competition.” 570 U.S. at 157. The Initial Decision found that “Endo provided Impax with a reverse payment, the purpose and effect of which was to induce Impax to give up its patent challenge and agree not to launch a generic Opana ER until January

2013.” ID 7, 138. The ALJ further determined that the payment—a No-AG provision secured by the Endo Credit and worth approximately \$23 to \$33 million—was large and that Endo had market power. ID 138-41. Under the rule of reason, this proof of competitive harm shifted the burden to Impax to “show that the restraint in fact serves a legitimate objective.” Areeda ¶ 1504(b); *see also King Drug Co. v. Smithkline Beecham Corp.*, 791 F.3d 388, 412 (3d Cir. 2015) (“*Lamictal*”).

The Initial Decision, however, held that the justification inquiry in a reverse-payment case does not require such a showing. Although it correctly recognized that “[t]he restraint in a reverse payment settlement agreement is . . . the use of the payment to restrain potential generic competition” (ID 99), it did not require Impax to show that the use of the payment promoted Impax’s claimed procompetitive objectives. Instead, the Initial Decision ruled that “procompetitive benefits arising in connection with the settlement agreement as a whole are properly considered as part of a well-structured rule of reason”—regardless of whether the payment to eliminate the risk of competition served those benefits. ID 141. This was error.

Nothing in *Actavis* or subsequent cases warrants abandoning the longstanding principle that a defendant can justify its anticompetitive conduct only by showing that the conduct furthered its procompetitive objective. Here, Impax has not done so. Eliminating this requirement would make it easy for drug companies to pay generic rivals not to compete without violating the antitrust laws. Moreover, under *Actavis*, when parties agree to share monopoly profits and preserve the brand’s monopoly until a date of their choosing, the fact that they might enable competition *after* that date cannot justify their conduct.

A. To justify anticompetitive conduct, a defendant must show the conduct furthered a claimed procompetitive objective

As the Commission observed in *In re Polygram Holding, Inc.*, to establish a procompetitive justification for its anticompetitive conduct, a defendant must “articulate the specific link between the challenged restraint and the purported justification.” 136 F.T.C. 310, 347 (July 24, 2003), *aff’d*, 416 F.3d 29 (D.C. Cir. 2005). Indeed, “[a]n allegedly legitimate objective is, of course, entirely immaterial unless it is served by the challenged restraint.” Areeda ¶ 1505a. The logic of this principle is straightforward: “If the defendants have a procompetitive justification, it must have been a motivating factor for the restraint, and the defendants should be able to establish it rather easily.” Herbert Hovenkamp, *The Rule of Reason*, 70 Fla. L. Rev. 81, 107 (2018). Thus, well-established rule-of-reason precedent requires a defendant to show that the challenged conduct furthered a legitimate, procompetitive objective. When defendants fail to establish the requisite link, courts reject the justification even if the proffered benefits are otherwise legitimate.

For example, in *NCAA v. Board of Regents*, 468 U.S. 85 (1984), the NCAA sought to justify its restrictions on football telecasts on the basis that they promoted amateurism. The Supreme Court accepted that promoting amateurism was a legitimate procompetitive objective, but rejected NCAA’s justification because the “specific restraints on football telecasts” were “not even arguably tailored to serve such an interest.” *Id.* at 117-18. Similarly, in *North Texas Specialty Physicians v. FTC*, 528 F.3d 346 (5th Cir. 2008), the defendant sought to justify its anticompetitive pricing activities for its primary, fee-for-service payor contracts on the basis that this conduct promoted “spillover” efficiencies by attracting providers who participated in NTSP’s other, risk-based contract. *Id.* at 368. Affirming the Commission, the Fifth Circuit assumed that these “spillover” benefits were legitimate, but held they did not justify the

challenged conduct because “NTSP has no theory as to how its proffered procompetitive effects . . . result from or are in any way connected to” the anticompetitive pricing practices being challenged. *Id.* at 368-70.

The ALJ appeared to ignore this well-established requirement because the challenged restraint is contained in a broader agreement. But a defendant’s obligation to connect the challenged restraint to the claimed procompetitive objective applies equally in that context. In *NCAA*, the challenged restraints on football telecasts were part of a broader set of rules agreed to by member colleges. The Supreme Court noted that it was “reasonable to assume that most of the regulatory controls of the NCAA are justifiable means of fostering competition among amateur athletic teams and therefore procompetitive.” 468 U.S. at 117. But the Court focused narrowly on whether the challenged restrictions on football telecasts promoted this procompetitive objective. *Id.* at 117-20. In *National Society of Professional Engineers v. United States*, 435 U.S. 679 (1978), the challenged restraint was a single provision in the defendant’s code of ethics, which barred members from discussing fees with prospective clients until after they had been hired. *Id.* at 682-83. The Supreme Court did not consider procompetitive benefits flowing from the ethics code as a whole; instead, it focused on whether the specific challenged provision served a legitimate objective. *Id.*; see also *FTC v. Ind. Fed’n of Dentists*, 476 U.S. 447 (1986) (considering only whether the challenged restraint, not the broader “work rule” as a whole, furthered a procompetitive objective).

The Commission took the same approach in *In re Realcomp II, Ltd.*, 2007 WL 6936319, at *13 (F.T.C. Oct. 30, 2009). The challenged restraint was an “internal rule within an MLS

[multiple listing service].” *Realcomp II, Ltd. v. FTC*, 635 F.3d 815, 826 (6th Cir. 2011).⁴ The Commission acknowledged that Realcomp’s overall operation of the MLS was efficiency enhancing. *Realcomp*, 2007 WL 6936319, at *29. But it still found the challenged restrictions unjustified because those provisions did not “allow Realcomp or its members to ‘increase output, or improve product quality, service or innovation.’” *Id.* at *30 (quoting *Polygram*, 136 F.T.C. at 346). The Sixth Circuit affirmed the Commission’s analysis. *Realcomp*, 635 F.3d at 834-36.

This principle is also reflected in the ancillary restraint doctrine, which requires a defendant to show that the ancillary restraint was a necessary part of a procompetitive agreement. *See Major League Baseball Props., Inc. v. Salvino, Inc.*, 542 F.3d 290, 338-39 & n.6 (2d Cir. 2008) (Sotomayor, J., concurring in the judgment); *Polk Bros., Inc. v. Forest City Enters., Inc.*, 776 F.2d 185, 189 (7th Cir. 1985). “[U]nder established precedent, a restraint is only ancillary if it is necessary to achieve otherwise unattainable procompetitive benefits.” *In re Sulfuric Acid Antitrust Litig.*, 743 F. Supp. 2d 827, 872 (N.D. Ill. 2010). When the restraint is not plausibly necessary to achieve the claimed benefits of an agreement, the benefits are not considered. *See Blackburn v. Sweeney*, 53 F.3d 825, 828 (7th Cir. 1995) (condemning reciprocal agreement not to advertise in each other’s territory because restraint was not ancillary to the procompetitive dissolution of the partnership).

Applying these traditional antitrust principles, *Actavis* makes clear that, to be justified, the inclusion of a reverse payment must serve a legitimate, procompetitive objective beyond the general benefits of the settlement. The Court contrasted “settlement on terms permitting the patent challenger to enter the market before the patent expires”—which is generally

⁴ The challenged rule was contained in a broad set of rules and regulations that governed member participation in the MLS. *See Initial Decision, In re Realcomp II, Ltd.*, 2007 WL 4465486, at FF.150-56, 168, 356-60 (F.T.C. Dec. 10, 2007).

procompetitive—with “settlement on the terms said by the FTC to be at issue here—payment in return for staying out of the market.” 570 U.S. at 154. The Court further explained that a defendant in a reverse-payment case may show “that legitimate justifications are present, thereby explaining the presence of the *challenged term* [payment in return for staying out of the market] and showing the lawfulness of *that term* under the rule of reason.” *Id.* at 156 (emphasis added); *see also id.* at 158 (“[O]ne who makes such a payment may be unable to explain and to justify it.”). On remand, the *Actavis* district court held that defendants have the burden “to justify the payments as being procompetitive.” *In re Androgel Antitrust Litig.*, 2018 WL 2984873, at *11 (N.D. Ga. June 14, 2018); *see also Lamictal*, 791 F.3d at 412 (to establish a justification, the defendant must “show that the challenged conduct promotes a sufficiently pro-competitive objective”); *King Drug Co. v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 414 (E.D. Pa. 2015) (at justification stage of rule of reason, “defendants are given the opportunity to show that the payment was justified by a procompetitive objective”).

The Commission’s 2016 amicus brief to the Third Circuit in the *Wellbutrin* litigation articulated this same principle. It explained that the district court had erred by failing to require a connection between the defendants’ claimed procompetitive justifications and the use of the large reverse payment (a No-AG commitment) to induce Teva to agree to stay off the market:

The court relied on a number of provisions in the settlement that might assist Teva’s getting the generic product to market. But the antitrust question is not whether there are benefits to certain provisions in the abstract. It is whether the benefits are attributable to the restraint—in this case the payment.

Brief of FTC as Amicus Curiae in Support of No Party at 23, *In re Wellbutrin XL Antitrust Litig.*, Nos. 15-3559, 15-3591, 15-3681, 15-3682 (3d Cir. Mar. 11, 2016).⁵ Like the *Wellbutrin* district court, the ALJ erred when he relied on benefits from other settlement provisions (the provisions providing protection from potential future patents) that might assist Impax in selling its generic, but did not require any showing that the payment to stay out of the market promoted those benefits.

The Initial Decision erroneously cited *Actavis* to support its departure from traditional rule-of-reason analysis. It stated that *Actavis* “expressly identified ‘redeeming virtues’ of a patent settlement as among the ‘traditional antitrust factors’ that can be considered in evaluating antitrust legality.” ID 99. But *Actavis* merely stated that “traditional antitrust factors” (including “redeeming virtues”) were relevant to evaluating antitrust claims involving patents; the Court never suggested that, in a reverse-payment case, those redeeming virtues could be unmoored from the restraint—the use of a payment to prevent the risk of competition. 570 U.S. at 148-49. The Initial Decision also cited *In re Cipro Cases I & II*, 348 P.3d 845 (Cal. 2015), but *Cipro* did not abandon the traditional inquiry into the connection between the challenged restraint and the asserted procompetitive objective. On the contrary, *Cipro* concluded that a plaintiff will prevail if it “eliminate[s] the possibility that litigation costs or other products or services could explain the consideration” and “dispel[s] each additional justification the defendants put forward to

⁵ On appeal, the Third Circuit affirmed the district court solely on the ground that plaintiffs failed to show the requisite injury-in-fact to establish standing. *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 163-65 (3d Cir. 2017).

explain the consideration.” *Id.* at 871. The “consideration,” of course, is the large reverse payment.⁶

Consistent with these principles, the Commission should only consider procompetitive benefits of the settlement if Impax has shown that the challenged restraint—payment to induce it to stay out of the market—furthered those benefits.

B. Impax provided no evidence that the payment to eliminate the risk of competition furthered its asserted procompetitive objectives

Impax has not attempted to show that the payment to eliminate the risk of competition (rather than the settlement generally) furthered any procompetitive objectives. To the contrary, both logic and the factual record demonstrate that Impax could have obtained the asserted procompetitive benefits— a license to additional patents and entry in January 2013—without also accepting any payment from Endo.

First, both the payment and the future patents license were benefits flowing to Impax. Impax surely did not need to be paid to accept a license that benefited it. Similarly, because Endo was willing to give both the large payment and the license to Impax, it certainly would have been willing to give *less* (i.e., just the license and not the payment). Thus, the payment could not have had the purpose or effect of helping Impax obtain the future patent license.

The ALJ’s findings confirm this straightforward logic. Impax was aware of Endo’s pending patent applications as early as February 2010. (F.167; CCF ¶1412). Yet Impax’s settlement negotiations with Endo were driven by the No-AG provision, the “make whole”

⁶ The Initial Decision also cites *In re K-Dur Antitrust Litig.*, 2016 WL 755623, at *13 (D.N.J. Feb. 25, 2016) and *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 737 (E.D. Pa. 2015). The cited portion of *K-Dur*, however, simply quotes *Cipro*. And, as noted above, the *Wellbutrin* district court erred when it treated a sublicense to a third-party patent as a procompetitive justification without requiring a showing of how the payment served to achieve that benefit.

provision, the DCA, and the entry date. (FF.131-56, 159). Impax did not seek a license to potential future Opana ER patents until June 5—two days before the settlement was executed. (F.169). There is no evidence that the late addition of the future patents license bore any relation to the parties' agreement on payment provisions designed to compensate Impax for staying off the market until 2013.

Second, the payment to eliminate the risk of competition was not necessary for Impax to obtain entry in January 2013. Since Endo was willing to agree to a January 2013 date and make a large payment to Impax, it certainly would have agreed to the same date without making a payment. Had Impax's goal been to obtain a January 2013 entry date, it could easily have done so without receiving a payment from Endo.

The evidence shows that “the purpose and effect” of Endo's large payment “was to induce Impax to give up its patent challenge.” ID 7, 138. The only reasonable explanation for the payment is that it was necessary to prevent Impax from demanding an entry date before January 2013, or from refusing to settle at all. Indeed, the ALJ found that Impax accepted the payment as compensation for *staying out* of the market and not competing when it otherwise might have done so. Impax thus cannot plausibly suggest that Endo's large payment was intended to induce it to accept a license to *promote* generic competition. Courts have long rejected justifications where, as here, the evidence shows they are “merely an excuse to cover up different and anticompetitive reasons.” *McWane, Inc. v. FTC*, 783 F.3d 814, 841-42 (11th Cir. 2015) (internal quotation marks omitted); *see also Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 484 (1992).

C. The Initial Decision's approach would provide a simple roadmap to evade *Actavis*

Accepting justifications based on general settlement benefits that are not plausibly attributable to the presence of a payment to eliminate the risk of competition would have

significant implications for future reverse-payment enforcement. So-called “freedom-to-operate” provisions in various forms are common features in Hatch-Waxman patent settlement agreements. (See CCF ¶1411; CX5007 at 9-11 (Hoxie Report) (explaining that patent challengers normally seek a license to all potentially relevant patents and applications to ensure “freedom to operate”)). As the Initial Decision noted, “Impax would regularly seek a broad patent license” and was “very firm” about always obtaining one. (F.565).

If such common settlement provisions can justify a collusive agreement to preserve and share a brand’s monopoly profits, then there is a simple roadmap for drug companies to use anticompetitive reverse-payment agreements and still pass antitrust muster. The brand company could offer a large payment (even a naked cash payment) to induce the generic to abandon its patent claims. The purpose and effect of this payment may well be to preserve the brand’s monopoly and eliminate the possibility of generic competition for a period of time. But, to justify this restraint under the Initial Decision’s approach, the brand company need only allow generic entry some time before patent expiration and provide a common freedom-to-operate license.

Indeed, if the mere presence in the SLA of the January 2013 entry date and a freedom-to-operate license in the SLA can provide a procompetitive justification for the reverse-payment agreement in this case, there is no limiting principle that would distinguish any other settlement that contained similar terms. This approach would effectively resurrect, in a new form, the scope of the patent test the Supreme Court rejected in *Actavis*. Under that rule, a brand could legally make a large payment to the generic as long as it let the generic enter the market on or before its patents’ expiration dates. See *Actavis*, 570 U.S. at 146.⁷ *Actavis* established that a “reverse

⁷ The scope-of-the-patent test recognized that antitrust liability might still attach if the brand obtained its patent through fraud or enforced it through a sham infringement lawsuit.

payment was not immunized, of course, simply because of that early-entry ‘license.’” *Lamictal*, 791 F.3d at 406-07. But the Initial Decision’s approach would create a new rule that entry before patent expiration—coupled with an ordinary freedom-to-operate license—effectively immunizes an otherwise anticompetitive reverse-payment agreement. Drug companies would be able to use reverse payments without fear of antitrust liability.

D. *Actavis* forecloses the argument that an entry date chosen as a result of a collusive reverse-payment agreement benefits consumers

The Initial Decision found that Impax had to be induced to accept entry in 2013 with a payment of more than \$20 million. ID 117 (finding that the No-AG provision on its own “was not sufficient to induce Impax to settle the patent litigation and agree to the March 2013 entry date proposed by Endo”). But the ALJ then accepted Impax’s contention that Endo’s anticompetitive purchasing of that entry date was justified by competition after that date.⁸ This ultimately amounts to holding that Impax should receive procompetitive credit for its collusive agreement with Endo to allow generic competition on—but not before—January 1, 2013. *Actavis* makes clear, however, that using a reverse payment to share the monopoly profits before an agreed-upon generic entry date is an antitrust *harm*, not a procompetitive benefit. Indeed, as the ALJ found, the payment was meant to induce Impax to take a *later* entry date—not facilitate generic competition.

Actavis recognized a fundamental distinction between patent settlements based on a compromise entry date and settlements that contain a reverse payment. As the Supreme Court made clear, there is generally no antitrust concern when parties settle “by allowing the generic manufacturer to enter the patentee’s market prior to the patent’s expiration, without the patentee

⁸ The sole procompetitive benefit the Initial Decision found from the freedom-to-operate license was that it supported competition after January 2013.

paying the challenger to stay out prior to that point.” 570 U.S. at 158. Because the brand and generic have opposing incentives, such a settlement can be presumed to represent a compromise that reflects their expectations about the outcome of the patent suit:

Absent payment, one can accept an agreement to postpone market entry as a fair approximation of the expected level of competition that would have obtained had the parties litigated; absent payment, any delay in entry may be attributed to the effective strength of the challenged patent, rather than the settlement agreement.

Cipro, 348 P.3d at 865.

The inclusion of a payment changes this dynamic: Settlement with a “payment in return for staying out of the market [] simply keeps prices at patentee-set levels . . . while dividing that return between the challenged patentee and the patent challenger.” *Actavis*, 570 U.S. at 154. When this occurs, “[t]he patentee and the challenger gain; the consumer loses.” *Id.* That is because such a payment tends to induce the generic to stay out of the market longer than it otherwise would be willing to, and to share the brand’s monopoly profits rather than compete them away.⁹

Impax’s argument that enabling generic competition after January 2013 is a procompetitive benefit thus amounts to a frontal assault on the antitrust foundations of *Actavis*. Endo and Impax did not select the date Endo purchased with the No-AG/Endo Credit because it was better for consumers; they chose it because it was better for them. Having arrived at a

⁹ (*See* F.446 (“[I]t is unlikely that a patent holder would agree by a settlement to pay an alleged patent infringer anything more than saved litigation costs, only to obtain entry on the date the alleged infringer would have entered anyway.”)); *see also Lamictal*, 791 F.3d at 405 (“[W]hen the parties’ settlement includes a no-AG agreement, the generic also presumably agrees to an early entry date that is later than it would have otherwise accepted.”); *Cipro*, 348 P.3d at 867 (if brand was not obtaining “exclusion beyond the point that would have resulted, on average, from simply litigating the case to its conclusion,” it “would have had little incentive to settle at such a high price”).

January 2013 entry date through a collusive agreement to preserve and share Endo's monopoly profits, Impax cannot now argue that this entry date benefitted consumers. *Actavis* holds the opposite: when a patentee and a challenger agree to an entry date as a result of sharing monopoly profits, "[t]he patentee and the challenger gain; the consumer loses." 570 U.S. at 154.

II. Complaint Counsel showed that the payment to stay out of the market was not reasonably necessary to obtain Impax's asserted procompetitive benefits

At the third stage of the rule of reason, Complaint Counsel may prevail by showing that a payment to stay out of the market was not reasonably necessary for Impax to achieve the stated objectives. ID 95; *see also Lamictal*, 791 F.3d at 412. The Initial Decision ruled that Complaint Counsel had failed to meet this burden because we "fail[ed] to demonstrate that such hypothetical settlement [without a payment] could have, or would have, included the broad patent license." ID 147. This was error.

Impax's asserted procompetitive objective was to obtain the earliest possible entry and a freedom-to-operate license. Impax "could have" obtained both in a settlement that did not include a large payment to eliminate the risk of competition. *See Actavis*, 570 U.S. at 158 (parties "may . . . 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"). The evidence shows that Endo was willing to trade money for its preferred 2013 entry date. Basic common sense thus dictates that Endo would have been willing to agree to the same (or earlier) date and the freedom-to-operate license without having to make a large payment to Impax. Indeed, Impax has never argued (let alone offered evidence) that it could not have achieved its claimed objectives without insisting on the payment.

Requiring additional proof from Complaint Counsel would create "an almost impossible standard." *In re Solodyn Antitrust Litig.*, 2018 WL 563144, at *21 (D. Mass. Jan. 25, 2018). It is

neither meaningful nor surprising that Impax and Endo never seriously discussed an alternative settlement without a payment. *See* ID 147 n.35. When defendants are “acting unlawfully to eliminate competition throughout their settlement negotiations, then it is unreasonable to expect a paper trail signifying rational, lawful business choices.” *Solodyn*, 2018 WL 563144, at *21; *see also United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA*, 296 F. Supp. 3d 1142, 1190 (N.D. Cal. 2017) (“[I]t is not surprising that no evidence shows that defendants were contemplating anything other than the actual Settlement.”); *United States v. Microsoft Corp.*, 253 F.3d 34, 79 (D.C. Cir. 2001) (“[N]either plaintiffs nor the court can confidently reconstruct a product’s hypothetical technological development in a world absent the defendant’s exclusionary conduct. To some degree, the defendant is made to suffer the uncertain consequences of its own undesirable conduct.” (internal quotations omitted)).

III. The anticompetitive harm from the certain elimination of competition outweighs any hypothetical benefits of a license to possible future patents

Because Impax’s claimed procompetitive justifications must be rejected, there is no need to balance them against anticompetitive effects. But even under a balancing analysis, the reverse-payment agreement would still be anticompetitive. In concluding otherwise, the Initial Decision made two fundamental errors. First, it measured procompetitive benefits of the settlement agreement based on post-settlement events, ignoring the well-established principle that an agreement’s legality should be judged as of the time it is entered. Second, it measured the anticompetitive effect based on whether Impax actually would have entered earlier, ignoring the Supreme Court’s instruction (and its own earlier conclusion) that the relevant anticompetitive harm is the elimination of the *risk* of competition. This error conflated the necessary showing of antitrust violation with a showing of antitrust *injury*—a burden placed only on private plaintiffs.

Viewed at the time of the settlement, rather than retrospectively, it is clear that the certain elimination of the risk of competition in the oxymorphone ER market for 2½ years outweighs the speculative benefits of a freedom-to-operate license to patents that might never even have issued.

A. At the time of the agreement, Impax’s claimed procompetitive benefits were speculative

It is fundamental that “the reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into.” *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1306 (11th Cir. 2003). “A court must ask whether an agreement promoted enterprise and productivity *at the time it was adopted.*” *Polk Bros.*, 776 F.2d at 185 (emphasis added); *see also Blackburn*, 53 F.3d at 828 (same).¹⁰

But the ALJ did not evaluate the claimed procompetitive benefits of the SLA as of the time of that agreement. In June 2010, as Endo’s attorney later explained, “[n]obody knew whether these [subsequent] patents were going to issue The Patent Office may never have issued the patents.” (CCF ¶ 1396). And any patents that did issue might or might not be upheld in subsequent litigation. Thus, the benefits of the SLA’s freedom-to-operate license were, at the time of the agreement, entirely speculative. The ALJ, however, used hindsight to conclude that the SLA had “actual consumer benefits” that were “substantial” because “there is a product on the market and available to consumers today that would not be there had Impax not had the foresight to negotiate licenses to future patents.” ID 146, 157. This conclusion depends entirely on a series of events occurring years after the settlement, including: (1) Endo’s 2012 acquisition of additional patents; (2) subsequent court rulings in 2015 and 2016 enforcing those patents

¹⁰ The Initial Decision properly applied this principle earlier in the analysis when it concluded that the \$102 million Endo ultimately paid to Impax was “not . . . the proper measure of the value of the Endo Credit, which must be measured as of the date of the settlement.” ID 113.

against other generic companies; (3) Endo's 2012 discontinuation of Original Opana ER; and (4) the FDA's 2017 request that Endo withdraw reformulated Opana ER from the market. ID 7, 143-46, 157-58.

The Initial Decision's focus on post-settlement developments to retroactively justify an anticompetitive agreement not only contradicts established law, but is also unworkable in practice because an agreement's legality could fluctuate over time. This agreement would have been anticompetitive before the first additional Endo patent issued in November 2012, but potentially procompetitive after November 2015 when a district court upheld one of Endo's post-settlement patents. And that determination could change again based on the outcome of any appeal. The uncertainty inherent in the Initial Decision's approach would undermine drug companies' ability to settle patent litigation as well as the ability of courts and enforcement agencies to identify antitrust violations.

B. The certain elimination of the risk of competition was a real anticompetitive harm

Consistent with the central teaching of *Actavis*, the Initial Decision correctly found that "the relevant anticompetitive harm" from a reverse-payment agreement is the elimination of the risk of competition. ID 89; *Actavis*, 570 U.S. at 157-58. It further concluded "that the Endo-Impax Settlement included payment to prevent the risk of competition." ID 100. At the balancing stage, however, it dismissed the anticompetitive harm from this agreement as "largely theoretical" because it found it "unlikely" that, absent the settlement, Impax would have launched generic Opana ER before 2013. ID 156-57. The reverse-payment agreement, however, is anticompetitive because it eliminated the *risk* of entry before January 2013. No one knows whether entry *actually* would have occurred absent the settlement. But a wealth of evidence shows that at the time of the settlement, Impax posed a substantial threat of generic entry.

1. The relevant anticompetitive effect in a reverse-payment case is the elimination of the risk of competition

The rule-of-reason anticompetitive effects inquiry focuses on whether an agreement, by its nature, “promotes competition or . . . suppresses competition.” *Nat’l Soc’y of Prof’l Eng’rs*, 435 U.S. at 691; *see also Cal. Dental Ass’n v. FTC*, 526 U.S. 756, 770-81 (1999) (examining “the principal tendency of a restriction” to interfere with competition). As Judge (now Justice) Breyer explained, “anticompetitive” has a “special meaning” under the antitrust laws, referring “not to actions that merely injure individual competitors, but rather to actions that harm the competitive process.” *Clamp-All Corp. v. Cast Iron Soil Pipe Inst.*, 851 F.2d 478, 486 (1st Cir. 1988) (internal quotations omitted).¹¹

Anticompetitive effects *can* be established by demonstrating an actual increase in price or decrease in output, because those effects reveal the underlying anticompetitive character of the agreement. *See, e.g., Sullivan v. Nat’l Football League*, 34 F.3d 1091, 1097 (1st Cir. 1994). But that is not the only way to prove antitrust harm. The Supreme Court also has condemned restraints because they “impede[d] the ordinary give and take of the market place,” *Nat’l Soc’y of Prof’l Eng’rs*, 435 U.S. at 692, or were “likely enough to disrupt the proper functioning of the price-setting mechanism of the market . . . even absent proof that [they] resulted in higher prices.” *Ind. Fed’n of Dentists*, 476 U.S. at 461-62.

The use of a large reverse payment to eliminate the risk of competition harms the competitive process by distorting the bargaining process that ordinarily would protect consumer interests. *Actavis*, 570 U.S. at 153-54; *see also supra* Part I.B. Antitrust law “does not condone

¹¹ *See also Microsoft*, 253 F.3d at 58 (equating “anticompetitive effect” with harm to “the competitive process” (emphasis in original)); *Interface Grp., Inc. v. Mass. Port Auth.*, 816 F.2d 9, 10 (1st Cir. 1987) (same); *Fishman v. Estate of Wirtz*, 807 F.2d 520, 536 (7th Cir. 1986) (same).

the purchase of protection from *uncertain* competition any more than it condones the elimination of *actual* competition.” Areeda ¶ 2030b (emphasis added); *see also Cipro*, 348 P.3d at 863 (“[T]hese principles extend into the patent arena to prohibit a patentee’s purchase of a potential competitor’s consent to stay out of the market.”). As the *Actavis* district court explained on remand, “the Supreme Court made clear in *Actavis* that avoiding even the possibility of competition, however small, is itself an antitrust violation.” *Androgel*, 2018 WL 2984873, at *9. Thus, an agreement to share monopoly profits to avoid generic competition is anticompetitive regardless of whether the generic would have otherwise entered earlier. *See Actavis*, 570 U.S. at 157.¹²

The Initial Decision’s focus on whether Impax actually would have entered before January 2013 confuses proof of antitrust violation with proof of actual injury from that violation. But these are “distinct matters that must be shown independently.” *In re Nexium Antitrust Litig.*, 842 F.3d 34, 60 (1st Cir. 2016). To establish standing under the Clayton Act, a private plaintiff must prove actual harm with some showing that the cheaper generic product would have come to market earlier absent the settlement. *See, e.g., Wellbutrin*, 868 F.3d at 163-65; *Nexium*, 842 F.3d at 60. But a government antitrust enforcer can prove an antitrust violation even where there is no “actual” injury. *See Nexium*, 842 F.3d at 60 (confirming jury’s finding of an antitrust violation even though jury found the generic *would not* have launched earlier but for the agreement); *Androgel*, 2018 WL 2984873, at *10 (rejecting defendants’ argument that FTC must show the

¹² The Initial Decision’s contrary approach relies largely on a misreading of *Cipro*. *Cipro* did not require an examination of when entry would have occurred as “[e]very restraint of trade condemned for suppressing market entry involves uncertainties about the extent to which competition would have come to pass.” 348 P.3d at 864. Instead, the court explained, the antitrust laws forbid agreements “eliminating the risk of competition—the competitive market that ‘might have been.’” *Id.* at 864-65 (quotation marks omitted).

challenged agreements “*actually* delayed entry” and holding that “FTC only needs to prove that the Defendants entered into the settlements in order to avoid the risk of a competitive market” (emphasis in original)). This distinction between private parties and government enforcers reflects policy: while the interest of a private plaintiff is to “remediate an injury,” the interest of the government is “to prevent and restrain violations of the antitrust laws along with the attendant social costs such violations can cause.” *Nexium*, 842 F.3d at 60 (quoting Brief of Amicus Curiae FTC in Support of No Party at 9-10, *In re Nexium Antitrust Litig.*, Nos. 15-2005, 15-2006, 15-2007 (1st Cir. Mar. 10, 2016)).

2. Impax posed a real risk of generic entry prior to January 2013

As the ALJ correctly held, “the evidence proves that the Endo-Impax Settlement included payment to prevent the risk of competition.” ID 156. Endo would not have paid to prevent competition from Impax if Impax did not pose a real threat of competing before January 2013.

Indeed, Impax had strong financial incentives to launch its generic product “as early as possible” to prevent Endo from destroying Impax’s market opportunity with a reformulated product. (CCF ¶¶121-26). Successfully launching oxymorphone ER in 2010 was a “key” Impax goal, and Impax consistently forecasted a launch as early as June 2010. (CCF ¶¶127-30, 137, 148-67, 188). Impax’s generics president had informed the Board of Directors that oxymorphone ER “was a good candidate for an at-risk launch” and presented a June 2010 at-risk launch as the “Current Assumption” in May 2010 board materials. (CCF ¶¶139, 145-47). Impax invested significant resources preparing for a June 2010 launch, including obtaining additional quota from the DEA, manufacturing product for launch, and getting customer commitments to purchase the product upon launch. (CCF ¶¶168-213). Absent the settlement, Impax would have been “ready to launch [on the] same day” as ANDA approval in June 2010. (CCF ¶204). Following the settlement, Impax was forced to discard approximately \$1.4 million in manufactured

oxymorphone ER product and was left with more than \$1.6 million in oxymorphone API with a 2011 expiration date. (CCF ¶¶208-12).

Impax might also have been able to enter risk-free before 2013 even if it waited until an appellate decision in the patent case. In that scenario, Endo believed that Impax's launch would "likely happen around June [2011]." (CCF ¶¶65, 370). Impax had the same expectation, modeling a mid-2011 entry date as a "base case" scenario. (CCF ¶¶166, 592, 597). Impax's patent expert predicted an appellate decision in November 2011. (CCF ¶1377).

The Initial Decision largely ignored this evidence. Instead, it made much of the fact that Impax's management never sought board authorization for an at-risk launch and that Impax could have faced potentially significant damages liability if it launched. ID 150-54. But the question is not whether Impax necessarily would have launched in the absence of the settlement; that is an *injury* question. Instead, to establish an antitrust violation, the questions are whether Impax posed a competitive risk to Endo and whether Endo made a large payment to avoid that risk. The answer to both questions is yes.

C. The Initial Decision's balancing approach would legitimize many naked payments to eliminate the risk of competition

The Initial Decision's weighing analysis gets things exactly backwards. The record shows a certain and significant anticompetitive harm: the elimination of the risk of competition from Impax for 2½ years—the vast majority of the remaining term for Endo's asserted patents. In comparison, the procompetitive benefit of a license to possible future patents (if counted at all) was "largely theoretical" at the time of the settlement. The parties did not know whether any subsequent patents would even issue, let alone whether they would be effective in blocking Impax's generic. The balancing is thus straightforward: a certain harm outweighs a speculative benefit.

But there is a more fundamental problem with the Initial Decision’s “balancing” approach. The Initial Decision simply looked at whether the length of time Impax was permitted to be on the market prior to expiration of the licensed patents exceeded the length of time Impax agreed to stay off the market. ID 141-48, 156-58. This approach would automatically bless any agreement that allows generic entry for more than 50% of the remaining life of the last possible expiring patent (whether asserted or not), even if the brand used a large, unjustified (even naked) reverse payment. The scope-of-the-patent test *Actavis* rejected would be replaced by a “51%-of-the-remaining-patent-life” test. *See Actavis*, 570 U.S. at 147-48. And if parties could measure the benefit based on a license to potential future patents with an uncertain (but far away) expiration date, there may be no realistic limit to how long they can agree to restrain entry. Indeed, the agreement in this case kept Impax out of the market for about 79% of the remaining life of the patents asserted in the patent litigation.¹³ But the ALJ nonetheless found the agreement procompetitive because it allowed Impax to enter before expiration of patents that Endo obtained years later. Such a result cannot stand under *Actavis*.

IV. The Commission should correct other aspects of the Initial Decision

A. The \$10 million upfront payment under the DCA was not justified by the profit-sharing rights Endo received

Actavis teaches that, in assessing a reverse payment, “the relevant antitrust question” is: what is “the basic reason” for the payment?

Although the parties may have reasons to prefer settlements that include reverse payments, the relevant antitrust question is: What are those reasons? If the basic reason is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of

¹³ The agreement prevented Impax from entering for 30 months (from June 2010 until January 2013) and permitted entry only eight months prior to expiration of patents at issue. (CCF ¶¶1311-12).

some other justification, the antitrust laws are likely to forbid the arrangement.

570 U.S. at 158. A payment may merely reflect “compensation for other services that the generic has promised to perform”; if so, “there is not the same concern that a patentee is using its monopoly profits to avoid of the risk of patent invalidation or a finding of noninfringement.” *Id.* at 156. Thus, the “fair value for services” inquiry focuses on the “basic reason” for the payment: Did the brand company make the payment as compensation for goods or services it received, or did it make the payment to “induce the generic challenger to abandon its claim with a share of its monopoly profits”? *Id.* at 154.

The Initial Decision, however, failed to assess the “basic reason” for Endo’s \$10 million upfront payment under the DCA. While this error did not alter the Initial Decision’s conclusion that Endo made a large, unjustified payment to Impax, the Commission should clarify the proper justification analysis for reverse payments that take the form of side business transactions. Such side deals are a common form of compensation and will likely arise in future cases. The evidence in this case shows that the “basic reason” for Endo’s \$10 million DCA payment was to induce Impax to stay off the market.

1. The relevant antitrust inquiry focuses on the basic reason for the payment

Rather than examine the “basic reason” for Endo’s \$10 million payment, the ALJ focused on whether the DCA was “a good deal for Endo.” ID 132. By focusing on the wrong question, the ALJ erroneously rejected much of the relevant evidence concerning the reason for Endo’s payment. For example, Complaint Counsel presented testimony from Dr. John Geltosky, an expert in pharmaceutical business development with over 35 years of experience. Dr. Geltosky testified that the negotiation, due diligence, strategic fit, and payment terms of the DCA were inconsistent with Endo’s and the industry’s usual approach. (CCF ¶¶1085-1255). This testimony

supported Complaint Counsel’s position that Endo was not paying for the benefits of this deal, but rather to induce Impax to stay out of the market. The ALJ, however, disregarded this testimony because Dr. Geltosky failed to offer an opinion on the “actual value of the DCA,” which, in his view, “incurably undermine[d]” Dr. Geltosky’s opinions. ID 137-38.

Actavis, though, does not require establishing a precise financial value, or determining that the side deal was a sham. Instead, a court should assess the basic reason for the payment based on the totality of the circumstances. Lower courts applying *Actavis* have followed this approach. Most recently, on remand in *Actavis*, the district court framed the question at summary judgment as whether a reasonable factfinder could conclude that the side deal was “entered into for the purpose of avoiding the risk of competition.” *Androgel*, 2018 WL 2984873, at *11. It found “comparative valuations of services are not necessary” to prove that a payment is large and unjustified. *Id.* Instead, the court looked to expert opinion that the side deal was inconsistent with industry practice and evidence that the parties agreed to the reverse payment before negotiating the specifics of the services to be provided. *Id.*

In *Nexium*, the district court reached a similar conclusion. Notwithstanding the “lack of fair market value evidence,” the court held there was sufficient evidence to conclude that a contemporaneous business arrangement was an unjustified reverse payment. *In re Nexium Antitrust Litig.*, 42 F. Supp. 3d 231, 264 (D. Mass. 2014) (explaining that the arrangement was highly lucrative, negotiated in conjunction with the settlement and formally extraneous to the patent litigation). Similarly, in *Cephalon*, the court found that evidence that the “payments exceed fair value for goods and services” was not necessary to support a finding of an unjustified payment. 88 F. Supp. 3d at 419. Instead, in denying summary judgment, the court pointed to direct and circumstantial evidence relating to the reason for the side deal payments. *Id.* at 419-21

(citing evidence, among other things, that the brand disregarded its own due diligence standards).

Unlike these post-*Actavis* cases, the Initial Decision’s analysis relied extensively on *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005)—a case decided well before *Actavis*—for the proposition that “expert opinion that a process was unusual for the industry” cannot show that a side deal was a “pretext” or was not “justified for fair value.” ID 136. But that reliance merely confirms that the ALJ was asking the wrong question.

As post-*Actavis* cases consistently reflect, the justification inquiry should consider the totality of the circumstances to determine the “basic reason” for the payment. The Commission should therefore clarify that evidence that the negotiations, due diligence, and terms of a side deal payment were inconsistent with industry standards and the brand’s standard practice is highly relevant to this inquiry.

2. The reason for the \$10 million upfront DCA payment was to induce Impax to stay off the market

The evidence in this case shows that: the DCA was negotiated as part of the Opana ER patent litigation settlement (CCF ¶¶1066-84); Endo evaluated the DCA on a “condensed” timeline so that it could be finalized in tandem with the settlement (CCF ¶¶1125-27); Endo was willing to enter into the deal only as part of the settlement negotiations (CCF ¶¶1266-67); and Endo’s paid business consultant had previously ruled out the products at issue in the DCA as worthwhile investments (CCF ¶¶1090-92). The record also shows that Endo offered the same \$10 million upfront payment despite a significant change in the product under discussion (CCF ¶¶232-39, 1082-83), and even though it had never previously made *any* upfront payment for a pre-clinical product (CCF ¶1133). Notwithstanding this evidence, the ALJ ruled that the \$10 million DCA payment was a payment for fair value, relying primarily on testimony from two company executives—Endo’s Dr. Robert Cobuzzi and Impax’s Michael Nestor. (*See* FF.257-61,

335-55, 369-70, 378-409). But this testimony is contradicted by contemporaneous business documents and other record evidence.¹⁴

First, the ALJ credited trial testimony of Dr. Cobuzzi (the executive in charge of Endo’s DCA evaluation) that Endo had adequate time to negotiate and evaluate the DCA. (FF.337-45). But, in contemporaneous documents Dr. Cobuzzi complained that there was “very little time for this evaluation.” (CCF [REDACTED], 290 ([REDACTED])). [REDACTED] The DCA was negotiated from start to finish in only three weeks, far quicker than industry standard (6-12 months) and Endo’s own documented process (“6 months-1 year from initial evaluation to deal close”) (CCF ¶¶1105-06, 1110, 1121-30), with only three days of cursory diligence to “check the box,” instead of its typical “≤ 4 months.” (CCF ¶¶299, 1123). There is no explanation for these unusual time constraints other than the desire to secure Impax’s assent to the 2013 entry date. Indeed, Dr. Cobuzzi conceded that this “short time frame” was driven by the need to complete the DCA at the same time as the settlement. (CCF ¶310).

Second, the ALJ relied heavily on Dr. Cobuzzi’s testimony that the DCA was a good deal for Endo. (FF.346-55); ID 132. But he ignored that this testimony was based largely on a financial analysis that reached a positive result only because it failed to account for any risk that IPX-203 (the ultimate subject of the DCA) might fail in development or might not be commercially successful—even though Impax’s witnesses acknowledged the “fairly low” likelihood that the product would even be approved. (CCF ¶295). [REDACTED]

¹⁴ Where trial testimony is contradicted by contemporaneous documentary evidence, the testimony should be given little weight. *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1948); *see also In re Toys “R” Us, Inc.*, 126 F.T.C. 415, 567 n.39 (1998) (rejecting “self-serving” testimony that was contradicted by contemporaneous documentary evidence).

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

By crediting Dr. Cobuzzi’s testimony that the DCA was a “good deal,” the ALJ ignored these numerous critical flaws in the analysis underlying this testimony.

Third, the ALJ concluded, based solely on Dr. Cobuzzi’s testimony, that the \$10 million upfront payment for the DCA was typical in the pharmaceutical industry. (FF.369-70); ID 132. But Endo has never paid *any* upfront money for any other product in early stage development. (CCRF ¶453). As Dr. Geltosky explained, a deal for a pre-clinical product like IPX-203 would normally involve little if any guaranteed money, but instead would provide increasing milestone payments as the product showed potential in development. (CCF ¶¶1224-26). Yet here, Endo offered to pay \$10 million without even knowing what it was getting in return. (CCRF ¶¶397, 422; CCF ¶1083).

Fourth, the ALJ relied on Mr. Nestor’s testimony about the promising development of a product with the same IPX-203 code name to support his conclusion that the DCA was fair value for Endo’s \$10 million payment. (FF.378-395); ID 129-31. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Indeed, outside the context of the patent settlement, Endo consistently demonstrated that it was not actually interested in Impax’s Parkinson’s disease drugs. (CCF ¶¶1090-92, 1267).

Taken in its entirety, the record shows that Endo agreed to pay \$10 million not to obtain potential profit-sharing rights in IPX-203, but instead to secure Impax’s agreement not to sell generic Opana ER before 2013. Impax described the \$10 million payment as [REDACTED]

[REDACTED] And Endo acknowledged that the DCA “adds significant topline revenue for Opana,” not from IPX-203 itself. (CCF ¶1084).

B. The Commission should clarify that a plaintiff in a reverse-payment case satisfies its *prima facie* burden with proof of a large payment and market power

Rule-of-reason analysis follows a well-established burden-shifting framework: (1) the plaintiff must make a *prima facie* showing of anticompetitive harm; (2) the burden then shifts to the defendant to demonstrate a procompetitive justification for the restraint; and (3) the burden shifts back to the plaintiff to show that the restraint is not reasonably necessary to achieve the procompetitive objective.¹⁵ The Initial Decision correctly found that Complaint Counsel proved an anticompetitive effect and that the “payment conferred to Impax by the no-AG and Endo Credit provisions . . . was unjustified.” ID 116. But it departed from the established rule-of-

¹⁵ See, e.g., *United States v. Brown Univ.*, 5 F.3d 658, 669 (3d Cir. 1993); see also *Cal. Dental Ass’n*, 526 U.S. at 771; *Nat’l Football League*, 34 F.3d at 1097; *Areeda* ¶¶ 1502-11.

reason framework by assessing Impax’s proffered justifications for the reverse payment at the initial stage of the analysis.

Although this approach did not alter the outcome of the first-step analysis, it is unwarranted and unwise, and nothing in *Actavis* endorses it. In any rule-of-reason case, a plaintiff has the initial burden to show that the challenged restraint “has the potential for genuine adverse effects on competition.” *Ind. Fed’n of Dentists*, 476 U.S. at 460-61. *Actavis* concluded that the challenged restraint—use of a large reverse payment to induce the generic patent challenger to stay off the market—has such potential. 570 U.S. at 153-54. The Court explained that a large payment from the brand-drug manufacturer to its would-be generic rival may “provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claims with a share of its monopoly profits that would otherwise be lost in the competitive market.” *Id.* at 154.¹⁶

A defendant may rebut that conclusion by showing some legitimate justification for the reverse payment. *Id.* at 156. But *Actavis* consistently treated “large” and “unjustified” as distinct concepts. Complaint Counsel thus satisfied its initial burden with proof that Endo (1) made a “large” payment to Impax, and (2) possessed monopoly power at the time of settlement—and so had monopoly profits to share with the generic. *See id.* at 154.

The Initial Decision’s framework, however, requires an inquiry into procompetitive justifications in the plaintiff’s *prima facie* case, and then, if the plaintiff dispels those justifications (as Complaint Counsel did here), an additional justification inquiry in the

¹⁶ On remand, the *Actavis* district court, in denying the defendants’ summary judgment motions, observed that evidence of a large payment is “the Supreme Court’s proxy for reaching the ultimate question: whether the agreement was entered into for the purpose of avoiding the risk of competition.” *Androgel*, 2018 WL 2984873, at *11; *see also Cephalon*, 88 F. Supp. 3d at 416.

defendant's case. Contrary to the ALJ's supposition, however, *Actavis* did not make proving the absence of a justification for the payment "an element of proving anticompetitive effects." ID 115. The passage the ALJ cites for this proposition simply explains why the presence of a reverse payment is not subject to "quick look" analysis. *See Actavis*, 570 U.S. at 159. Nothing in this passage or elsewhere in *Actavis* authorizes the Initial Decision's departure from standard rule-of-reason analysis.

To the contrary, *Actavis* explicitly held that "the FTC must prove its case as in other rule of reason cases." *Id.* Indeed, it expressly instructed that "[a]n antitrust defendant may show in an antitrust proceeding that legitimate justifications are present, thereby explaining the challenged term and showing the lawfulness of that term under the rule of reason." *Id.* at 156. The Commission should hold that this traditional framework is fully applicable in reverse-payment cases.¹⁷

C. The Commission should credit the economic analysis of the *ex ante* value of the No-AG/Endo Credit payment

The Initial Decision correctly found, based on Impax's contemporaneous projections, that the No-AG provision was worth \$23 to \$33 million to Impax and that the purpose of the Endo Credit was to make Impax whole if Endo transitioned the market to a reformulated Opana ER. (F.193). But it rejected evidence from Complaint Counsel's economic expert, Professor Roger Noll, assessing the *ex ante* value of these payment provisions, stating that he had not sufficiently explained his calculations. ID 111. Although rejection of Professor Noll's analysis did not alter

¹⁷ The Initial Decision cites two cases that incorporate a (more limited) justification inquiry into the plaintiff's *prima facie* case. Both are clear, though, that the defendant bears the burden to come forward with evidence of the potential justifications for the payment. *See* ID 116 (citing *Cipro*, 348 P.3d at 871; *K-Dur*, 2016 WL 755623, at *13). The Initial Decision, however, left unclear what evidentiary burden, if any, the defendant bears at step one. The traditional burden-shifting framework incorporates well-established principles to guide courts on such matters.

the conclusion that Endo made a large payment to Impax to eliminate the risk of competition, the Commission should clarify that Professor Noll's calculations should have been considered. Economic analyses are likely to play an important role in future cases because reverse payments increasingly involve more complex forms of non-cash compensation.

From an *ex ante* perspective, the ultimate size of the combined No-AG/Endo Credit payment depended critically on an uncertain factor: original Opana ER's eventual sales in the last quarter of 2012. Professor Noll therefore calculated the range of the payment's potential values given plausible changes in original Opana ER sales between June 2010 (the agreement date) and the end of 2012:

- (1) if original Opana ER sales remained flat;
- (2) if original Opana ER sales grew;
- (3) if original Opana ER sales declined, but not enough to trigger the Endo Credit; and
- (4) if original Opana ER sales had essentially disappeared by the time Impax entered.

(CX5000 at 159-60, 169-70 (Noll Report)).¹⁸ Relying on Impax's contemporaneous documents and Opana ER sales data, Professor Noll calculated that the *ex ante* values of the No-AG and Endo Credit provisions under these plausible outcomes ranged from \$16.5 million to at least \$62 million. (CCF ¶¶461-71).

The Initial Decision appears to fault Professor Noll's analysis because he did not calculate a mathematical "expected value" of the payment at the time of the settlement. ID 35,

¹⁸ Impax argued that there was a possibility that both the No-AG and Endo Credit could be worth zero. The Initial Decision found such possibility "implausible." ID 111-12. It was not necessary for Professor Noll to assess the probability of these implausible scenarios. (See CX5004 at 71-72 (Noll Rebuttal Report)).

38. An expected value is the “probability-weighted sum of every conceivable event.” (CCRF ¶1423). But even Impax’s own expert conceded that such a calculation is not “in any practical sense doable.” (CCF ¶479). Indeed, Impax’s expert offered no criticism of Professor Noll’s calculations. (CCF ¶479). Nor did Impax challenge or rebut any of Professor’s Noll’s calculations.

Professor Noll’s calculations are well supported and demonstrate that the *ex ante* value of the No-AG/Endo Credit payment was large under all plausible outcomes. They confirm what Impax’s CFO told investors at that time: that Impax would receive a large payment “almost no matter what happened.” (CCF ¶438). The Commission should clarify that consideration of this expert evidence is appropriate in assessing whether Impax received a large payment from Endo.

V. The Commission should enter Complaint Counsel’s proposed remedial order

The Commission has “wide discretion” in crafting an appropriate remedy. *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 611 (1946). The Supreme Court has emphasized that the Commission “is not limited to prohibiting the illegal practice in the precise form in which it is found to have existed in the past.” *FTC v. Ruberoid Co.*, 343 U.S. 470, 473 (1952).¹⁹ Instead, “those caught violating the Act must expect some fencing in.” *FTC v. Nat’l Lead Co.*, 352 U.S. 419, 431 (1957).²⁰

¹⁹ See also *Nat’l Soc’y of Prof’l Eng’rs*, 435 U.S. at 698 (in fashioning remedy for an antitrust violation, it is “entirely appropriate” to go “beyond a simple proscription against the precise conduct previously pursued”).

²⁰ See also *Nat’l Lead Co.*, 352 U.S. at 428 (a remedy is proper as long as it has a “reasonable relation to the unlawful practices found to exist”); *In re Toys “R” Us, Inc.*, 126 F.T.C. 695, 697 (1998) (fencing-in remedy may reasonably “include such additional provisions as are necessary to preclude the revival of the illegal practices” (internal quotations omitted)).

Complaint Counsel's proposed order has three parts:

First, Paragraph II.A of the proposed order is an injunction to prevent and deter Impax from entering similar reverse-payment agreements in the future. It is modeled on numerous existing Commission orders²¹ and would cover all potential forms of reverse payments, including No-AG commitments and business transactions entered within 45 days of the patent settlement. (Proposed Order, Paragraph I.X). It specifically carves out payments that are unlikely to be anticompetitive, such as saved litigation expenses, acceleration clauses permitting entry when another generic enters, or provisions facilitating the regulatory approval of the generic's product. (Proposed Order, Paragraph I.W). As such, Impax would be free to enter settlements based on a negotiated entry date or other "traditional settlement considerations" that are unlikely to raise competition concerns. *Actavis*, 570 U.S. at 156.

Second, Paragraph II.B would provide protection in the specific market for oxymorphone ER products by barring Impax from "entering any agreement that prevents, restricts, or in any way disincentivizes competition between oxymorphone ER products."²² This provision restricts Impax's ability to enter into future agreements involving extended-release oxymorphone that threaten competition in that market. (Revised Proposed Order, Paragraph II.B). It would not affect existing agreements.

Third, Paragraph II.C addresses a provision in a current agreement between Impax and Endo that disincentivizes competition for oxymorphone ER. In 2017, Endo and Impax resolved

²¹ See Stipulated Order for Permanent Injunction, *FTC v. Endo Pharm. Inc.*, No. 17-cv-312 (N.D. Cal. Feb. 2, 2017); Stipulated Order for Permanent Injunction, *FTC v. Teikoku Pharma USA, Inc.*, No. 16-cv-1440 (E.D. Pa. Apr. 7, 2016); Stipulated Order for Permanent Injunction and Equitable Monetary Relief, *FTC v. Cephalon, Inc.*, No. 08-cv-2141 (E.D. Pa. June 17, 2015).

²² Complaint Counsel revised its proposed order post-trial to avoid any impact on the rights of Intervener Endo Pharmaceuticals. The revised proposed order (attached as Appendix A) modified Paragraphs II.B and II.C.

their post-settlement litigation concerning the SLA's provisions regarding subsequently-acquired patents. (CCF ¶¶1415-30). Under the settlement, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Paragraph II.C thus prevents Impax from enforcing the portion of the agreement that conditions Impax's obligation to pay royalties on the absence of any competing oxymorphone ER product.

CONCLUSION

For the foregoing reasons, Complaint Counsel respectfully requests that the Commission reverse the Initial Decision and enter the Order included in Appendix A.

Respectfully submitted,

Dated: July 10, 2018

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Counsel Supporting the Complaint

Appendix A

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)
)
) Docket No. 9373
Impax Laboratories, Inc.,)
a corporation.)
_____)

[PROPOSED] ORDER FOR PERMANENT INJUNCTION

Upon consideration of all of the evidence on the record in this matter:

I. Definitions

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

- A. "Commission" means the United States Federal Trade Commission.
- B. "Impax" or "Respondent" means Impax Laboratories LLC, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Impax, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. "505(b)(2) Application" means an application filed with the United States Food and Drug Administration pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b)(2).
- D. "ANDA" means an Abbreviated New Drug Application filed with the United States Food and Drug Administration pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j).
- E. "Authorized Generic" means a Drug Product that is manufactured pursuant to an NDA and Marketed in the United States under a name other than the proprietary name identified in the NDA.
- F. "Brand/Generic Settlement" means any agreement or understanding that settles a Patent Infringement Claim in or affecting Commerce in the United States.
- G. "Brand/Generic Settlement Agreement" means a written agreement that settles a Patent Infringement Claim in or affecting Commerce in the United States.

- H. “Branded Subject Drug Product” means a Subject Drug Product marketed, sold, or distributed in the United States under the proprietary name identified in the NDA for the Subject Drug Product.
- I. “Commerce” has the same definition as it has in 15 U.S.C. § 44.
- J. “Control” or “Controlled” means the holding of more than 50% of the common voting stock or ordinary shares in, or the right to appoint more than 50% of the directors of, or any other arrangement resulting in the right to direct the management of, the said corporation, company, partnership, joint venture, or entity.
- K. “Drug Product” means a finished dosage form (e.g., tablet, capsule, solution, or patch), as defined in 21 C.F.R. § 314.3(b), approved under a single NDA, ANDA or 505(b)(2) Application, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.
- L. “Executive and General Counsel Staff” means the Respondent’s Executive Team, including the Chief Executive Officer, the Chief Financial Officer, the General Counsel, the Chief Compliance Officer, Presidents of divisions within Respondent, including the Generics Division and Specialty Pharm Division, and all attorneys in the Respondent’s office of General Counsel.
- M. “First Amendment to the 2010 Settlement and License Agreement” means the Contract Settlement Agreement, including all exhibits thereto, entered as of August 5, 2017, between Impax and Endo Pharmaceuticals Inc. (CX3275).
- N. “Generic Entry Date” means the date in a Brand/Generic Settlement Agreement, whether certain or contingent, on or after which a Generic Filer is authorized by the NDA Holder to begin manufacturing, using, importing, or Marketing the Generic Subject Drug Product.
- O. “Generic Filer” means a party to a Brand/Generic Settlement who controls an ANDA or 505(b)(2) Application for the Subject Drug Product or has the exclusive right under such ANDA or 505(b)(2) Application to distribute the Subject Drug Product.
- P. “Generic Product” means a Drug Product manufactured and/or sold under an ANDA or pursuant to a 505(b)(2) Application.
- Q. “Market,” “Marketed,” or “Marketing” means the promotion, offering for sale, sale, or distribution of a Drug Product.
- R. “NDA” means a New Drug Application filed with the United States Food and Drug Administration pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b), including all changes or supplements thereto that do not result in the submission of a new NDA.
- S. “NDA Holder” means a party to a Brand/Generic Settlement that controls the NDA for the Subject Drug Product or has the exclusive right to distribute the Branded subject Drug Product in the United States.
- T. “No-AG Commitment” means any agreement with, or commitment or license to, the Generic Filer that prohibits, prevents, restricts, requires a delay of, disincentivizes, or

imposes a condition precedent upon the research, development, manufacture, regulatory approval, or Marketing of an Authorized Generic.

- U. “Oxymorphone ER Product” means any extended-release tablet containing oxymorphone that is the subject of an NDA, ANDA, or 505(b)(2) Application.
- V. “Patent Infringement Claim” means any allegation threatened in writing or included in a complaint filed with a court of law that a Generic Product may infringe one or more U.S. Patents held by, or licensed to, an NDA Holder.
- W. “Payment by the NDA Holder to the Generic Filer” means a transfer of value by the NDA Holder to the Generic Filer (including, but not limited to, a No-AG Commitment, money, goods, or services), regardless of whether the Generic Filer purportedly transfers value in return, where such transfer is either (i) expressly contingent on entering a Brand/Generic Settlement Agreement, or (ii) agreed to during the 90 days period starting 45 days before executing a Brand/Generic Settlement Agreement and ending 45 days after executing a Brand/Generic Settlement Agreement. The following, however, are not Payment by the NDA Holder to the Generic Filer:
 - 1. compensation for the NDA Holder’s saved future litigation expenses, but only if the total compensation the NDA Holder agrees to provide to the Generic Filer during the 90 day period starting 45 days before and ending 45 days after executing the Brand/Generic Settlement Agreement does not exceed a maximum limit, which is initially set at \$7,000,000 and shall be increased (or decreased) as of January 1 of each year by an amount equal to the percentage increase (or decrease) from the previous year in the annual average Producer Price Index for Legal Services (Series Id. PCU5411—5411--) published by the Bureau of Labor Statistics of the United States Department of Labor or its successor;
 - 2. the right to Market, as of an agreed upon Generic Entry Date, Generic Product(s) in the United States under an ANDA or 505(b)(2) Application (i) that is controlled by the Generic Filer and was not transferred to the Generic Filer by the NDA Holder or (ii) to which the Generic Filer has a license from a party other than the NDA Holder;
 - 3. provisions to facilitate, by means other than the transfer of goods or money, the Generic Filer’s ability to secure or maintain final regulatory approval, or commence or continue the Marketing, of a Generic Product, by, inter alia, providing covenants, waivers, permissions, releases, dismissals of claims, and/or authorizations;
 - 4. waiver or a limitation of a claim for damages based on prior Marketing of the Generic Subject Drug Product, but only if the NDA Holder and the Generic Filer do not agree, and have not agreed, to another Brand/Generic Settlement for a different Drug Product during the 90 day period starting and 45 days before and ending 45 days after the execution of the Brand/Generic Settlement; and
 - 5. a continuation or renewal of a pre-existing agreement between an NDA Holder and a Generic Filer but only if: (i) the pre-existing agreement was entered into at least 90 days before the relevant Brand/Generic Settlement Agreement, (ii) the terms of the renewal or continuation, including the duration and the financial

terms, are substantially similar to those in the pre-existing agreement, and (iii) entering into the continuation or renewal is not expressly contingent on agreement to a Brand/Generic Settlement.

- X. “Subject Drug Product” means the Drug Product for which one or more Patent Infringement Claims are settled under a given Brand/Generic Settlement. For purposes of this Order, the Drug Product of the NDA Holder and the Generic Filer to the same Brand/Generic Settlement shall be considered to be the same Subject Drug Product.
- Y. “U.S. Patent” means any patent issued by the United States Patent and Trademark Office, including all divisions, reissues, continuations, continuations-in-part, modifications, or extensions thereof.

II. Prohibited Agreements

IT IS FURTHER ORDERED that:

- A. Respondent is prohibited from entering into any Brand/Generic Settlement that includes:
 - 1. (i) a No-AG Commitment and (ii) an agreement by the Generic Filer not to research, develop, manufacture, distribute, Market, or sell the Subject Drug Product for any period of time; or
 - 2. (i) any Payment by the NDA Holder to the Generic Filer and (ii) an agreement by the Generic Filer not to research, develop, manufacture, distribute, Market, or sell the Subject Drug Product for any period of time.
- B. Respondent is prohibited from entering into or being party to any agreement that prevents, restricts, or in any way disincentivizes competition between Oxymorphone ER Products, including but not limited to the First Amendment to the 2010 Settlement and License Agreement.
- C. The First Amendment to the 2010 Settlement and License Agreement is null and void and Respondent shall relinquish all rights to any Refund Payment under Paragraph 10(c) of the Agreement and shall return any Refund Payment received. Respondent shall further take whatever action is necessary to render the ruling in this Paragraph of the Order a Final Nullity Decision under the First Amendment to the 2010 Settlement and License Agreement.
- D. Within sixty (60) days after the date this Order is issued, Respondent shall take whatever action is necessary to vacate, amend, or nullify any agreement to which it is a party that prevents, restricts, or in any way disincentivizes competition between Oxymorphone ER Products.

III. Compliance Program

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

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

IV. Reporting Requirements

IT IS FURTHER ORDERED that

- A. Respondent shall file a verified written report to the Commission ("compliance report"):
 - 1. 90 days after the date this Order is issued; and
 - 2. One year after the date this Order is issued, and annually for the next 19 years on the anniversary of that date, and
 - 3. At such other times as the Commission may require.
- B. In each compliance report, Respondent shall describe the manner and form in which Respondent intends to comply, is complying, and has complied with this Order, including by submitting:
 - 1. a copy of any additional agreement with a party to a Brand/Generic Settlement to which Respondent is a signatory if (i) the relevant Brand/Generic Settlement Agreement includes an agreement by the Generic Filer not to research, develop, manufacture, Market or sell the Subject Drug Product for any period of time, and (ii) the relevant additional agreement is entered within a year of executing the Brand/Generic Settlement Agreement;
 - 2. copies of all documents that contain or describe an agreement that relates to one or more Oxymorphone ER Products and is an agreement between Respondent and any holder of an NDA, ANDA or 505(b)(2) for any Drug Product;
 - 3. a summary of Respondent's efforts to cease being a party to an agreement that violates Paragraph II.B and copies of all correspondence (including, but not

limited to, electronic mail and letters) sent or received by Respondent as part of such efforts;

4. a summary of Respondents efforts to comply with Paragraph II.C and copies of all correspondence (including, but not limited to, electronic mail and letters) sent or received by Respondent as part of such efforts; and
5. Copies of the certifications required by Paragraph III.C and the policies and procedures required by Paragraphs III.D and III.E.

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

- C. Each compliance report submitted pursuant to this Paragraph shall be verified by a notarized signature or sworn statement of the Chief Executive Officer or other officer or employee of the Respondent specifically authorized to perform this function, or self-verified in the manner set forth in 28 U.S.C. § 1746. Commission Rule 2.41(a), 16 C.F.R. § 2.41(a), requires that the Commission receive an original and two copies of each compliance report. A paper original of each compliance report shall be filed with the Secretary of the Commission and electronic copies shall be transmitted to the Secretary at ElectronicFilings@ftc.gov, and the Compliance Division at bccompliance@ftc.gov.
- D. This Order does not alter the reporting requirements of Respondent pursuant to Section 1112 of the Medicare Prescriptions Drug, Improvement, and Modernization Act of 2003.

V. Change of Corporate Control

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

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

VI. Access Provisions

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

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

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

VII. Termination

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

ORDERED By the Commission:

Donald S. Clark
Secretary

Date: _____, 2018

CERTIFICATE OF SERVICE

I hereby certify that on July 10, 2018, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

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

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

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

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Counsel for Respondent Impax Laboratories, Inc.

July 10, 2018

By: /s/ Rebecca E. Weinstein
Rebecca E. Weinstein
Counsel Supporting the Complaint

CERTIFICATE FOR ELECTRONIC FILING

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

July 10, 2018

By: /s/ Rebecca E. Weinstein
Rebecca E. Weinstein

Notice of Electronic Service

I hereby certify that on July 10, 2018, I filed an electronic copy of the foregoing Complaint Counsel's Appeal of the Initial Decision, 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 July 10, 2018, I served via E-Service an electronic copy of the foregoing Complaint Counsel's Appeal of the Initial Decision, upon:

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I hereby certify that on July 10, 2018, I served via other means, as provided in 4.4(b) of the foregoing Complaint Counsel's Appeal of the Initial Decision, upon:

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Complaint

Rebecca Weinstein
Attorney