PUBLIC

ORIGINAL

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

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

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KEY IMPAX AND ENDO PERSONNEL

Impax

1. **Carole Ben-Maimon**: Ms. Ben-Maimon is the former President of Impax's Generic Division. She assumed that role in fall 2011 after Mr. Mengler departed Impax in the second half of 2010.

2. **Joe Camargo**: Mr. Camargo is Impax's former Vice President of Manufacturing & Materials Management. Mr. Camargo was responsible for overall supply chain activities for Impax's generic oxymorphone ER product.

3. T**odd Engle**: Mr. Engle is Impax's Vice President of Sales and Marketing for its generics division. From 2010 to 2014, Mr. Engle was Impax's Senior Director of Sales Operations for generics. He had responsibility for readying Impax's generic oxymorphone ER for market from a sales perspective.

4. **Art Koch**: Mr. Koch is Impax's former Executive Vice President and Chief Financial Officer. In early June 2010, Mr. Koch assumed the role of Impax's chief negotiator of the Development and Co-Promotion Agreement and the Settlement and License Agreement with Endo. Mr. Koch signed both the Development and Co-Promotion Agreement and the Settlement and License Agreement on behalf of Impax.

5. **Chuck Hildenbrand**: Mr. Hildenbrand is Impax's former Senior Vice President of Operations. Mr. Hildenbrand had ultimate operations responsibility for Impax's preparations to be ready to potentially launch generic oxymorphone ER at risk in 2010.

6. **Larry Hsu**: Dr. Hsu is the founder and former President and CEO of Impax. Dr. Hsu had ultimate authority over whether Impax would settle with Endo and, if so, on what terms Impax would accept.

7. **Chris Mengler**: Mr. Mengler is the former President of Impax's Generics Division. Mr. Mengler was Impax's lead negotiator of a settlement with Endo until early June 2010.

8. **Michael Nestor**: Mr. Nestor is Impax's President of Impax's Branded Division.

9. **Bryan Reasons**: Mr. Reasons is Impax's Chief Financial Officer.

10. **Ted Smolenski**: Mr. Smolenski is Impax's former Senior Director of Portfolio Management and Strategy. Mr. Smolenski managed strategy and forecasting for Impax's generic portfolio from project initiation through launch, including for generic oxymorphone ER. Mr. Smolenski provided assistance during the settlement negotiations with Endo.

11. **Meg Snowden**: Ms. Snowden is Impax's Vice President of Intellectual Property.

Endo

12. **Demir Bingol**: Mr. Bingol is Endo's former Senior Director, Oral Pain Solutions Group. Until leaving the company in June 2011, Mr. Bingol had responsibility for the Opana ER franchise, including preparing for a potential at-risk generic launch by Impax and planning for the switch to a reformulated version of the product.

13. **Robert Cobuzzi**: Dr. Cobuzzi is President of Endo Ventures Ltd. Previously, he was Senior Vice President of Corporate Development for Endo. Dr. Cobuzzi was responsible for Endo's evaluation of the Development and Co-Promotion Agreement.

14. **Roberto Cuca**: Mr. Cuca is Endo's former Treasurer and Senior Vice President of Finance. Mr. Cuca assisted in Endo's negotiation of the Impax-Endo Settlement & License Agreement by analyzing key terms, including the Endo Credit and the licensed generic entry date, from a financial perspective.

15. **Guy Donatiello**: Mr. Donatiello is Endo's Senior Vice President of Intellectual Property. Along with Mr. Levin, Mr. Donatiello represented Endo in the settlement negotiations with Impax.

16. **Alan Levin**: Mr. Levin is Endo's former Executive Vice President and Chief Financial Officer. Mr. Levin was Endo's chief negotiator of the Development and Co-Promotion Agreement and the Settlement and License Agreement with Impax.

INTRODUCTION

This case is about an anticompetitive reverse-payment agreement between Respondent Impax Laboratories, Inc. and Endo Pharmaceuticals Inc. The agreement eliminated the risk of lower-cost generic competition to Opana ER, one of Endo's biggest products. In May 2010, with trial on Endo's patent infringement claims less than a month away, Impax received tentative FDA approval for its generic version of Opana ER. Endo understood that Impax could receive final approval in mid-June 2010, and enter any time after that. The prospect of generic competition to one of its biggest products was a "worst case scenario" for Endo. Endo expected it would destroy Opana ER's sales in as little as three months. It would also ruin Endo's plan to protect its Opana ER franchise by launching a reformulated version; Endo knew that if Impax entered with its generic before Endo could shift patients to a reformulated product, its reformulation strategy would fail.

Faced with this generic threat, Endo paid Impax *not* to launch its generic version of Opana ER. Impax agreed to stay out of the market for two and half years, until January 1, 2013. In exchange, Endo agreed that it would not compete with its own generic version of Opana ER during Impax's 180-day exclusivity period—a valuable promise that Impax expected would nearly double its profits during that period. But Impax became concerned that Endo would execute a reformulation strategy and destroy the market for original Opana ER before Impax's 2013 entry date. If that happened, Impax would lose not only the benefit of the No-AG agreement, but also the value of the first-filer exclusivity period itself. So Impax demanded an "insurance" provision that would "correct for the lost value of the market" if Opana ER sales declined before Impax's generic entry date. Endo agreed and ended up paying Impax $102 million under this provision, called the "Endo Credit." Endo also agreed to pay Impax $10

million in cash immediately for potential future rights to an unformulated and highly uncertain drug compound Impax was considering developing.

In *FTC v. Actavis*, 133 S. Ct. 2223, the Supreme Court held that such large "reverse payments" can violate the antitrust laws. The Court explained that a large reverse payment "suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness." *Id*. at 2236. That is what happened here. Endo's large payment turned Impax from a would-be rival into a partner in Endo's oxymorphone ER monopoly. As the Court concluded, with such a reverse payment, the "patentee and the challenger gain; the consumer loses." *Id*. at 2235.

In defense of its reverse-payment agreement, Impax offers essentially three arguments. First, it claims Complaint Counsel must prove that, absent the challenged agreement, generic entry actually would have occurred before January 2013. Impax's "actual delay" argument confuses the government's required showing of an antitrust *violation* with a private plaintiff's additional requirement to show actual *injury*. In this case, Complaint Counsel satisfied its burden to show anticompetitive effects by proving that the agreement harmed the competitive process by inducing Impax to agree to stay off the market for two and half years in exchange for a share of Endo's monopoly profits.

Second, Impax argues that the $112 million payment it received under this settlement should be ignored because there was some undefined, theoretical possibility that it might have received no value from either the No-AG provision or the Endo Credit. But this argument is inconsistent with the overwhelming weight of record evidence. At the time of the agreement, Impax viewed these provisions as having substantial value. Impax's primary negotiator said he

would "love" a No-AG provision, viewed the Endo Credit insurance as "super, super important" to Impax's willingness to accept the settlement, and dismissed the theoretical possibility of a zero payment scenario as "so unlikely it wasn't worth worrying about." Indeed, Impax's then-CFO informed investors that the combination of the No-AG and Endo Credit ensured that Impax would realize value from the settlement "almost no matter what happens." And these provisions worked just as intended: Impax did not enter until January 2013, and, because Original Opana ER sales declined before then, Impax got a $102 million "make-whole payment" under the Endo Credit.

Finally, Impax insists that it should win this case because it now markets the only Opana ER product available to consumers. But Impax is still unable to explain how the *payment* it received—the No-AG/Endo Credit and the upfront development deal cash—contributed to this outcome. Impax offers neither evidence nor logic that can explain why it would need to be paid to accept the license to future patents that the settlement provided.

The fundamental fatal flaw in Impax's entire defense is that it simply provides no convincing explanation for the payment provisions it secured. Impax insists that without the challenged settlement, it would not have entered the market until after January 1, 2013. But Impax's argument effectively asks this Court to conclude that Endo agreed to pay Impax large sums—ultimately $112 million—to *accelerate* generic competition to one of its most important products. In the end, the reverse payment is exactly what it appears to be and what the record evidence confirms it to be: an unlawful sharing of Endo's monopoly profits to avoid the risk of competition.

I. Industry Background

Antitrust inquiries "must always be attuned to the particular structure and circumstances of the industry at issue." *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540

U.S. 398, 411 (2004) ("*Trinko*"). The distinctive features of the pharmaceutical industry provide the context for assessing the agreement challenged in this case.

A. The Hatch-Waxman Act

Generic drug entry into the market is governed by the provisions of the law commonly referred to as the "Hatch-Waxman Act." (CCF ¶ 6).[1] The Act sought to facilitate entry of lower-cost, generic drugs by streamlining the FDA approval process for such drugs. In particular, generic drug manufacturers can submit an "Abbreviated New Drug Application" (ANDA). (CCF ¶ 8). The ANDA allows the generic to rely on the brand's safety and efficacy data and show, among other things, bioequivalence to an already-approved branded drug. (CCF ¶ 8); *see also Actavis*, 133 S. Ct. at 2228.[2]

Congress established special rights and procedures that apply when a company seeks to market its generic product before expiration of the brand's patents. Such a generic applicant must: (1) certify to the FDA that the brand's patent is invalid or not infringed by the generic product (known as a "Paragraph IV certification"); and (2) notify the patent holder of the certification. (CCF ¶ 11). If the patent holder files suit within 45 days, the FDA cannot approve the generic for 30 months—unless, before then, the patent expires or is judicially determined to be invalid, unenforceable, or not infringed. (CCF ¶ 12); *see also Actavis*, 133 S. Ct. at 2228. If this 30-month stay expires and the generic patent challenger obtains final FDA approval before the patent litigation concludes, the patent holder must either persuade the court to grant a

[1] Drug Price Competition and Patent Term Restoration Act of 1984, Pub Law 98-417, 98 Stat 1585 (1984) (codified at various sections of Titles 15, 21, 28, and 35 of the U.S. Code). Congress enacted further amendments to the generic drug approval process in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat 2066 (2003).

[2] To show bioequivalence, the ANDA filer must show that its product has the same active ingredient and performance as its brand-name counterpart. (CCF ¶¶ 8-9).

preliminary injunction or else face the possibility that the generic will launch its product "at-risk." (CCF ¶¶ 119-20).

The Hatch-Waxman framework "provides a special incentive" to encourage patent challenges: It grants the first company to file a Paragraph IV ANDA a period of 180-day market exclusivity, beginning on the first day of its commercial marketing. (CCF ¶ 14); *see also Actavis*, 133 S. Ct. at 2228-29. The FDA may not grant final approval to any subsequent ANDA filer until the first filer's exclusivity period expires or is forfeited. (CCF ¶ 14). *See also Actavis*, 133 S. Ct. at 2229. The "vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period." *Actavis*, 133 S. Ct. at 2229. (citation omitted); *see also* (CCF ¶ 15).

Although the 180-day exclusivity period enables the first-filer to sell its product without competition from other generic companies, it does not prevent the brand-name drug manufacturer from selling its own "authorized generic." (CCF ¶ 27).[3] An authorized generic or "AG" is essentially the brand name drug sold without the trademark or brand name. (CCF ¶ 27). Brand-name companies often introduce AGs to recoup some of the large losses they face once generic entry begins. (CCF ¶ 28). Entry of an authorized generic reduces the first-filer's revenues during the 180-day exclusivity period by an average of 40 to 52 percent. (CCF ¶ 29). This effect on the first filer's revenues arises for two reasons. First, an authorized generic takes a significant share of sales from the first filer. (CCF ¶ 29). Second, competition from an authorized generic drives down generic prices. (CCF ¶ 29).

[3] *See, e.g.*, *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51, 54-55 (D.C. Cir. 2005).

B. The Economics of Generic Drug Competition

Generic drugs are unique sources of competition for their brand-name drug counterparts. State legislatures throughout the country have enacted laws that permit (and sometimes require) a pharmacist to substitute a therapeutically equivalent generic drug (known as an "AB-rated" drug) for the brand, unless a physician directs or the patient requests otherwise. (CCF ¶¶ 16, 21-22).[4]

Generic entry generally has an enormous impact on sales of the brand-name drug. The first generic version of a given drug on the market is priced, on average, nearly 15 percent lower than the brand-name drug. (CCF ¶ 24). Because of automatic substitution at the pharmacy, a brand-name drug typically expects to lose about 90 percent of its market share (by unit sales) to its generic competitors. (CCF ¶¶ 28, 68, 70). After additional generic competitors enter, generic prices drop by as much as 85 percent or more from the original brand's price. (CCF ¶ 24). As a result, competition from generic drugs saves consumers billions of dollars annually. (CCF ¶ 25).[5]

C. The Economics of Reverse Payment Agreements and No-AG Commitments

The disparity in price between brand-name and generic drugs means that a brand company loses much more from generic competition than the generic company gains. As a result, both the brand and generic drug manufacturer have an incentive to preserve the monopoly (through the generic's agreement to stay out of the market) and share the resulting monopoly

[4] To obtain an "AB rating" from the FDA, the drug product must be both "pharmaceutically equivalent" (e.g., contains the same active pharmaceutical ingredient as the branded drug and has the same dosage and form) and have been proven to be "bioequivalent" (i.e., to exhibit a similar rate and extent of absorption as the brand product). That FDA determination typically triggers state automatic-substitution laws. *See New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 645 (2d Cir. 2015). All states and the District of Columbia have such laws. *Id.* at 644-45.

[5] *See also* U.S. Gov't Accountability Office, *Report No. GAO-12-371R, Savings from Generic Drug Use* 9-11 (2012), http://www.gao.gov/assets/590/588064.pdf (discussing studies).

profits.[6] Such an agreement keeps prices at monopoly levels and benefits both companies. The brand company can often afford to pay the generic more than the generic would have earned if it entered the market, while still retaining far more profits than it could otherwise expect if generic entry occurred. *Actavis*, 133 S. Ct. at 2235.

The form in which brand companies can share monopoly profits with their potential generic competitors need not be a straight cash payment.[7] Among other things, brands and generics can also use a so-called "No-AG" agreement, in which the branded firm promises the generic patent challenger that it will not launch an authorized generic during the generic's 180-day exclusivity period.[8] In effect, the brand cedes all generic sales to the first filer generic during that period, allowing the generic to earn more sales and at higher prices. Thus, with a No-AG commitment, the first-filer's revenue will approximately double compared to what the first-filer would have made had it faced AG competition. (CCF ¶ 32).

II. Summary of Facts

A. Endo's Opana ER franchise was critical to its business

Opana ER is an extended-release formulation of oxymorphone used to treat chronic pain. (CCF ¶¶ 35-36). Oxymorphone has been available for decades, but Opana ER offers longer-lasting pain relief than previous, immediate-release versions of the drug. (CCF ¶¶ 34-35).

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[6] *See, e.g.*, C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 Colum. L. Rev. 629, 635-36 (2009).

[7] *See, e.g.*, Michael A. Carrier, *Solving the Drug Settlement Problem: The Legislative Approach*, 41 Rutgers L. J. 83, 98 (2009).

[8] *See* Federal Trade Commission, *Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Overview of Agreements filed in FY 2012* (2013) (showing increase in No-AG commitments).

In addition to Opana ER, there are a number of other long-acting opioid products ("LAOs"). Opana ER, however, "is the only long-acting opioid that contains oxymorphone, a molecule with distinct pharmacologic properties compared with most other opioids." (CCF ¶ 726). As Endo's own documents reflect, these pharmacologic distinctions can be clinically significant in treating individual patients.

The unique features of Opana ER made it very lucrative for Endo. After launching in 2006, it quickly became a critical product for the company. (CCF ¶¶ 37, 39). By 2009, Opana ER annual sales were $172 million—approximately 12% of Endo's total annual revenues. (CCF ¶ 39). By 2010, "Endo . . . was really a company based on two products . . . Lidoderm and Opana." (CCF ¶ 33).

As early as 2007, however, Endo was concerned that it would soon face competition from much cheaper generic versions of Opana ER. (CCF ¶¶ 73-74). Endo's first patent covering Opana ER was set to expire in 2008. (CCF ¶ 50). The patents Endo asserted against Impax in its first patent suit were set to expire in 2013, (CCF ¶¶ 53, 107), but Endo projected that generic Opana ER might launch as early mid-2010. (CCF ¶ 58). Such generic entry was a "worst case scenario" for Endo. (CCF ¶ 68). Endo expected that generic competition would erode brand volume by 85% within three months. (CCF ¶¶ 70). Thus, Endo's number one priority was to "[b]eat [g]enerics." (CCF ¶ 75). And it had a strategy to do so.

Endo had been working on a new, "Tamper Resistant Formulation" of Opana ER ("Reformulated Opana ER") that it believed would extend the life of its Opana ER franchise. (CCF ¶ 73). Endo expected that generic versions of original Opana ER would not be substitutable for the reformulated version. (CCF ¶¶ 76-77). If it was right, and if it could shift

prescriptions from original Opana ER to the reformulated product, Endo could protect its Opana franchise from generic entry. (CCF ¶ 74).

Endo's reformulation plan, however, hinged on timing. In particular, Endo recognized that the "[m]ost important criteria for maximum asset value" for its reformulated product was to "beat Generics by 1 Year." (CCF ¶ 75). This would provide Endo the time it needed to convince doctors to prescribe Reformulated Opana ER *before* the entry of generic Original Opana ER. (CCF ¶¶ 75, 78-79). Endo projected that if it launched the reformulated version before generic entry, peak annual sales of the reformulated product could reach hundreds of millions of dollars. (CCF ¶ 75). But, if generic entry occurred before the transition, Reformulated Opana ER's peak annual sales could amount to approximately $12 million. (CCF ¶ 75). Because a "smooth" transition would take up to a year, Endo wanted to get Reformulated Opana ER to market as soon as possible. (CCF ¶¶ 78-80). If generic versions of Original Opana ER beat the reformulated product to the market, Endo's entire reformulation strategy would be a failure. (CCF ¶ 75).

B. Impax posed an imminent threat to Endo's Opana ER franchise

By May 2010, Endo faced the threat of imminent generic competition from Impax. Impax was the first ANDA filer for the five most profitable dosages of Opana ER. (CCF ¶¶ 94, 101). Impax had been working hard to put itself in a position to launch by June 14, 2010, the date it expected to get final FDA approval. (CCF ¶¶ 109, 112, 168). Indeed, successfully launching oxymorphone ER in 2010 was a "Company Key Goal" and Impax consistently forecasted a launch at that time. (CCF ¶¶ 127-130, 137).

On May 13, 2010, the FDA tentatively approved Impax's ANDA. (CCF ¶ 61). As a result, Impax began to actively consider launching "at risk"—while Endo's patent suit was still ongoing. (CCF ¶ 131). Impax's executives thought a launch of oxymorphone could be "a great

market opportunity." (CCF ¶ 146). Impax CEO Larry Hsu instructed the President of Impax's generics division to "alert" Impax's Board to a "potential oxymorphine [sic] launch" and stated that "we will have a special Board conference call when we do decide to launch at risk on a later date." (CCF ¶ 139). In May 2010, Impax modeled two possible launch scenarios: either June 2010 (upside) or July 2011 (base). (CCF ¶ 144). No other possible launch date was considered in these forecasts. (CCF ¶ 144).

In fact, in materials presented to the Board of Directors that same month, Impax changed the "Current Assumption[]" for Opana ER from "No launch" to "At-Risk Launch" in 2010. (CCF ¶ 145). Notably, during that same May 25, 2010 Board of Directors meeting, Impax Generics President Chris Mengler "expressed the view that Oxymorphone was a good candidate for an at-risk launch." (CCF ¶¶ 146-47). No one at the meeting disagreed. (CCF ¶ 146). And it was understood that the Executive Committee might "come back to the Board seeking an at-risk launch." (CCF ¶ 146).

By the time of tentative approval in May 2010, Impax was already "going down th[e] road" of manufacturing generic Opana ER. (CCF ¶ 140). Impax had spent significant time and money validating its manufacturing process and manufacturing product. (CCF ¶¶ 192-200). Beginning in early 2009, Impax submitted multiple requests to the Drug Enforcement Administration for quota to purchase raw oxymorphone—a controlled substance—for "commercial manufacturing efforts (validation and launch)." (CCF ¶¶ 176-86). To support these requests, Impax submitted to the DEA detailed forecasts for a June 2010 launch of generic Opana ER and "letters of intent" from potential customers stating that they intended to start buying Impax's generic Opana ER product in June 2010. (CCF ¶¶ 178, 182-86). Impax spent millions of dollars to purchase oxymorphone active pharmaceutical ingredient ("API"). (CCF ¶¶

181, 197). Preparing to launch a first-to-file product like oxymorphone ER required commitment of "an inordinate amount of both labor and plant capacity." (CCF ¶ 172). But, by mid-June 2010, Impax had validated its manufacturing process for oxymorphone ER and manufactured a large portion of its "launch inventory build," including more than $1.3 million worth of inventory in both finished goods and brite stock (which is product bottled, but not yet labeled). (CCF ¶¶ 200, 201, 208). Impax's generic Opana ER was "approved & ready to launch" on short notice. (CCF ¶ 188).

Endo similarly expected Impax to launch generic Opana ER as early as June 2010 and no later than summer 2011. (CCF ¶¶ 61-62). Even if Impax did not launch upon FDA approval in June, Endo expected that "Impax could launch at risk" after the district court's verdict in the patent litigation, which would "likely be rendered in the August/September [2010] time frame." (CCF ¶ 63). Alternatively, if Impax "wait[ed] for the appeal to play out" so that it could launch risk-free, its launch would "likely happen around June of [2011]." (CCF ¶ 370).

Thus, by 2010, Endo expected imminent generic entry. By January 2010, Endo feared its reformulation strategy was in jeopardy, concluding that "the scenario in which we were trying to launch ahead of generics is seeming less likely." (CCF ¶¶ 82). As a result, Endo took specific action to prepare for generic entry. It made plans to launch an authorized generic version of Opana ER "on word/action of first generic competitor." (CCF ¶¶ 85, 400). As one internal document put it: "If Impax launches, Endo will launch its authorized generic." (CCF ¶ 85). By May, Endo had manufactured enough product inventory marked as an AG for an initial launch. (CCF ¶¶ 88-89). By early {[redacted]}

C. Impax and Endo began serious settlement negotiations after Impax received tentative approval

Once it obtained tentative approval on May 13, Impax was "in a position to launch [generic Opana ER] on 6/15/2010"—the day after the 30-month stay was set to expire. (CCF ¶¶ 179, 220). The next day, Impax announced its tentative approval in a press release. (CCF ¶ 221).

This press release spurred Endo to re-open settlement negotiations. (CCF ¶ 225). Going into negotiations, Impax wanted to launch its generic oxymorphone ER "as early as possible." (CCF ¶ 122). Endo, on the other hand, wanted to forestall that launch for as long as possible: "Each month that [Opana ER] generics are delayed beyond June 2010 is worth $20 million in net sales." (CCF ¶ 69). Most importantly, Endo wanted to keep generics off the market long enough that its reformulated TRF product could "launch ahead of" them. (CCF ¶¶ 82, 241-45). At this point, however, the timing of Endo's launch of Reformulated Opana ER was unclear; Endo had not yet submitted the reformulated product to the FDA for approval. (CCF ¶ 243). Thus, Endo needed to postpone entry of generic Opana ER as long as possible.

From the outset of negotiations, Endo offered Impax compensation to agree to stay out of the market until 2013. On May 26, 2010, after a week of discussions, Endo sent Impax two proposed term sheets. (CCF ¶ 228). The first offered Impax an entry date of March 10, 2013 and a No-AG provision during Impax's 180-day exclusivity period. (CCF ¶¶ 228, 230-31). The second offered to pay Impax $10 million cash as part of an agreement relating to a Parkinson's disease drug Impax had under development. (CCF ¶ 237). From this point on, the negotiations focused on refining this two-part compensation approach.

1. The No-AG agreement and the "make good" Endo Credit protection

The No-AG agreement was a key factor in securing Impax's agreement not to launch generic oxymorphone ER until 2013. Indeed, Impax executives were initially hesitant to delay

launch even until January 2011. (CCF ¶ 224). As Impax Generics President Chris Mengler explained, "the cost of Jan '11 is lost/delayed sales – you know what they [s]ay about a bird in the hand . . . ." (CCF ¶ 224). But when Impax CEO Larry Hsu proposed "settl[ing] with Endo for January 2011 launch with *No AG*," Mr. Mengler agreed that would be a "different story. I'd love that!!!!" (CCF ¶ 224).

Before Endo proposed the No-AG agreement, Impax fully expected that it would face an Endo AG and that its sales would suffer dramatically as a result. Impax consistently forecasted competition from an AG during its 180-day exclusivity period. (CCF ¶ 409). And Impax recognized that competition from an Endo AG would result in lost market share, a lower price, and would cut its profits in half for its first six months. (CCF ¶¶ 410-15). Endo's No-AG promise assured Impax that this would not happen.

Despite securing the No-AG agreement, Impax was concerned about Endo's insistence on an entry date in 2013. Impax feared that Endo had a "strategy to reduce the [Opana ER] market" in advance of January 2013. (CCF ¶¶ 246-50, 256). Impax understood that a successful Endo reformulation strategy "would have led to the elimination of the Opana ER market," which, in turn, would "subvert the value of the deal." (CCF ¶ 248). If that happened, Impax would lose not only the benefit of the No-AG agreement, but also the value of the first-filer exclusivity period itself. (CCF ¶ 248). Impax thus sought a provision to protect itself from this potential market degradation. (CCF ¶ 250).

Initially, Impax sought to protect itself through an "acceleration trigger" provision that would move up Impax's entry date if branded Opana ER sales dropped below a certain level. (CCF ¶¶ 251-52). On May 27, Mr. Mengler responded to Endo's term sheet by proposing a January 1, 2013 launch date, a No-AG provision, and "certain acceleration triggers, including

market degradation to any alternate product." (CCF ¶ 251). Impax had obtained similar provisions in other settlements. (CCF ¶ 252). Endo, however, "fiercely" opposed this accelerated entry approach. (CCF ¶ 253). Endo negotiators insisted such a provision was unnecessary because "they had no interest in moving the market and they weren't planning to." (CCF ¶ 253).

Impax did not believe this, so on June 1, Endo sweetened the pot. Endo proposed a provision specifying that if sales of Opana ER declined by more than **{ }** before Impax entered, Impax "would be entitled to a 'make good' payment." (CCF ¶ 254). As Impax's chief negotiator, Mr. Mengler, described it, the purpose of this provision was to "come up with a number that we would have made . . . if we had a generic in that six-month period." (CCF ¶ 255). Then, if the market was degraded, "you're going to pay me what I would have made anyway." (CCF ¶ 253). The provision's drafter, Endo executive Roberto Cuca, offered a similar account: "If sales of Opana ER had decreased," the provision would "kind of fix that . . .by making a true-up payment to Impax." (CCF ¶ 255). This payment would "correct for the loss in the value of the market that had occurred before the generic entry date." (CCF ¶ 255).

Impax and Endo reached a "handshake agreement" on June 3, 2010 that included a "make whole" payment. (CCF ¶ 257). The resulting provision required Endo to make a cash payment if sales of Opana ER fell more than **{ }** from their peak before Impax was able to enter the market. (CCF ¶ 273). The exact payment was based on a mathematical formula intended to approximate the revenues Impax would have expected to make from the No-AG agreement if the market had remained intact. (CCF ¶ 274). During the negotiations, Endo ran the formula with different numbers to make sure that it produced a "sensible result," i.e., that it "insulate[d] Impax from the effect of Endo . . . withdrawing or effectively withdrawing Opana ER from the market ahead of the date on which the parties had agreed that Impax would launch."

(CCF ¶ 258). In return for this market protection provision, Impax "stop[ped] pursuing an earlier launch date." (CCF ¶ 257).

2. The Development and Co-Promotion Agreement

While negotiating the Settlement and License Agreement ("SLA"), Impax and Endo simultaneously negotiated Endo's other compensation offer: a pharmaceutical development agreement that included an immediate $10 million cash payment to Impax. (CCF ¶¶ 232-33, 1068-70). The proposed deal initially focused on a product Impax was developing called "IPX-066," an extended release version of carbidopa levodopa intended to treat Parkinson's disease. (CCF ¶¶ 234, 1115). The parties discussed a structure in which Endo would pay Impax $10 million in cash immediately and would potentially make an additional payment if Impax made further progress in development. (CCF ¶ 237). In return, if the product was ultimately approved, Endo would have a right to share in the commercialization and profits. (CCF ¶¶ 238-39).

Endo was not actively pursuing Parkinson's disease opportunities when it began negotiating with Impax. (CCF ¶¶ 1086-89). Some years earlier, Endo had shifted its focus away from neurology to other areas, such as urology, endocrinology, and oncology products. (CCF ¶ 1087). In fact, in 2008, a consultant hired by Endo had excluded Impax's carbidopa levodopa product as a recommended prospect for Endo because the market was already highly genericized. (CCF ¶¶ 1090-92). Not surprisingly, then, Endo's corporate development group—the division responsible for finding and evaluating potential development opportunities—did not seek out IPX-066. (CCF ¶ 1095). Instead, Endo's Chief Financial Officer, Alan Levin, who was negotiating the Opana settlement, informed Endo's head of development, Dr. Robert Cobuzzi, about the IPX-066 opportunity. (CCF ¶ 1095). Mr. Levin gave Dr. Cobuzzi about a week to assess IPX-066. (CCF ¶¶ 1125-27).

Over the next week, Impax provided Endo with information about IPX-066. (CCF ¶¶ 235-36). Endo's corporate development group reviewed this information and began creating a written assessment. (CCF ¶¶ 286-87). {[redacted]}

After reviewing the IPX-066 information, Endo sent Impax a draft term sheet. (CCF ¶ 237). It proposed a $10 million upfront payment and a potential $5 million milestone payment in exchange for profit-sharing rights in IPX-066. (CCF ¶¶ 237-38). The next day, however, Impax "yanked [IPX-066] out from under" Endo. (CCF ¶ 1129). On May 27, 2010, Impax's chief negotiator Chris Mengler replaced IPX-066 in the discussions with a different, unspecified product "designate[d] as 066a" that Impax would "name . . . at signing." (CCF ¶ 294). On June 2, despite knowing only that "066a" was intended to be a follow-on product to IPX-066, Endo offered Impax the same financial terms it had offered for IPX-066—an upfront $10 million payment upon signing and a $5 million milestone payment. (CCF ¶¶ 296-99, 1083). On June 3, Impax and Endo reached an agreement in principle on the terms of the settlement. (CCF ¶ 257).

The next day, June 4, Impax informed Endo that 066a was "IPX-203," a product "similar to IPX066 in that it is carbidopa + levodopa with the differences being that they will use an esterified version of levodopa." (CCF ¶¶ 295, 306). But, unlike IPX-066, which was in the last

stage of clinical development, (CCF ¶ 234), IPX-203 was merely a concept, and had "not yet been formulated." (CCF ¶¶ 295, 1162). The parties thus "really had no idea as to the success" of IPX-203 because the "probability of success with any drug at this point in development is fairly low." (CCF ¶ 295).

Prior to June 4, Endo had no specific information about IPX-203. (CCF ¶¶ 306-07). After June 4, Endo reviewed only minimal information about IPX-203, and instead used the earlier information about IPX-066 as a surrogate. (CCF ¶¶ 307, 1162). It prepared a written evaluation keeping many of the same assumptions from IPX-066. (CCF ¶ 1203). Even though the IPX-203 opportunity was less attractive than IPX-066, the total payment Endo offered to Impax increased over the next few days. (CCF ¶¶ 301-03).

D. Late in the negotiations, Impax proposed an alternative settlement with an earlier entry date and no additional provisions

On June 4, after the major terms for the settlement and development deal had been reached, Impax made a new proposal: instead of the framework currently on the table—the 2013 entry date, No-AG, Endo Credit, and DCA—they "drop[] all of that discussion" and enter "a simple settlement agreement with the Actavis entry date" of July 2011. (CCF ¶ 276). Impax's proposal followed the structure (and entry date) Endo had reached in a previous Opana ER settlement with another generic filer, Actavis. (CCF ¶ 66). Endo was unmoved: Alan Levin insisted on a license agreement "on terms he had negotiated with Chris Mengler" and "refused to entertain any discussion around an earlier license date." (CCF ¶ 277). At this point, the parties resumed negotiating an agreement under the earlier framework, and Mr. Koch negotiated for "better terms on the co-promote deal." (CCF ¶ 278).

E. Impax eventually sought a license to future patents

The June 4 draft of the SLA—which was based on the parties' agreement in principle on all major terms—provided a license to Impax only for the three patents then listed as covering Opana ER. (CCF ¶ 281). On June 5, Impax proposed broadening the license to include "any patents and patent applications owned or licensed by Endo . . . that cover or could potentially cover" Impax's generic oxymorphone ER. (CCF ¶ 280). Impax regularly sought this type of broad license in its patent settlements. (CCF ¶¶ 282-83). Ultimately, the SLA included a license to patent applications and future patents, but the SLA also required Impax and Endo to "negotiate in good faith an amendment to the terms of the License" for any patent that was issued as a result of an application pending at the time of the agreement. (CCF ¶ 284).

F. The Endo settlement eliminated the risk of competition to Opana ER until January 1, 2013

Impax and Endo executed the SLA and a Development and Co-Promotion Agreement ("DCA") late on June 7, 2010. (CCF ¶ 314). Endo, however, did not want to release the signature pages until it had signed a separate settlement with Sandoz, another generic manufacturer seeking to market generic Opana ER. (CCF ¶¶ 315-16). Endo settled with Sandoz on June 8, and the parties then released the escrowed SLA and DCA. (CCF ¶ 317).

The SLA provided:

- A license for Impax to launch generic Opana ER on January 1, 2013. (CCF ¶ 332-34).
- An agreement from Endo that it would not launch or authorize an AG during the first 180 days Impax was on the market. (CCF ¶¶ 322-23).
- The "Endo Credit" provision, which provided that, if Endo's sales of its original Opana ER product fell below 50% of their peak, Endo would make a cash payment to Impax. The dollar value of the payment was based on a formula designed to approximate Impax's expected profits as the only seller of a generic version of Opana ER for six months assuming Endo had not reformulated the product. (CCF ¶¶ 325-27).

The final terms of the DCA specified that Impax would work to develop "an extended release, orally administered product containing a combination of levodopa-ester and carbidopa" for the treatment of Parkinson's disease. (CCF ¶ 1232). The parties understood that the DCA referred to IPX-203. (CCF ¶ 306). Under the DCA, Endo agreed to pay Impax $10 million upfront and up to $30 million in milestone payments if Impax completed certain steps in the development process. (CCF ¶¶ 302-03). Endo received the right to ultimately promote the product—if developed—to non-neurologists and retain a share of the revenues from those prescriptions. (CCF ¶¶ 296-97, 1238). On June 24, Endo wired the non-refundable $10 million upfront payment to Impax. (CCF ¶ 320).

Because Impax was the first filer for the most popular dosages of Opana ER, no other company could launch a generic version of those doses until Impax's 180-day exclusivity period expired. (CCF ¶¶ 392-93). Thus, the settlement essentially guaranteed that Endo would face no competition to Opana ER before January 1, 2013, (CCF ¶¶ 378-87), and gave Endo "a clear path (until January 2013) to establish [Reformulated Opana ER] demand." (CCF ¶ 440). Meanwhile, Impax destroyed over $1.3 million worth of generic oxymorphone ER that it had manufactured to prepare for a possible generic launch. (CCF ¶¶ 208-12).

G. Endo transitioned the Opana ER market to a reformulated version of Opana ER before Impax could launch

Endo introduced its Reformulated Opana ER in early 2012 and aggressively transitioned patients to the new version. (CCF ¶¶ 439-40). By January 1, 2013, Endo had effectively eliminated all sales of Original Opana ER. (CCF ¶ 441). As a result, the Endo Credit was triggered and Endo tendered Impax a cash payment of $102 million. (CCF ¶¶ 441-44). Despite Endo's market degradation efforts, Impax launched generic Opana ER in January 2013 and ultimately captured nearly **{ }** of all oxymorphone ER prescriptions. (CCF ¶¶ 630-42, 841)

The growth of Impax's sales of generic oxymorphone ER came from sales of Endo's branded product, not from any other opioid product. (CCF ¶¶ 652-53).

H. Endo terminated the DCA after the subject product failed

{[redacted]}

{[redacted]}

ARGUMENT

I. The Rule of Reason Framework

FTC v. Actavis held that reverse-payment patent settlements are subject to antitrust scrutiny under the rule of reason. Application of the rule of reason follows a well-established three-step burden shifting framework: (1) the plaintiff bears the initial burden to make a *prima facie* showing of an anticompetitive effect; (2) if the plaintiff makes that showing, the burden shifts to the defendant to demonstrate a procompetitive justification for the restraint; and (3) if the defendant establishes such a justification, the burden shifts back to the plaintiff to show that the restraint is not reasonably necessary to achieve the procompetitive objective.[9]

Actavis emphasized that when applying the rule of reason, "[t]here is always something of a sliding scale in appraising reasonableness" and that "the quality of proof required should vary with the circumstances." 133 S. Ct. at 2237-38 (quotations omitted). In *Actavis*, of course, the relevant circumstances involved a reverse-payment settlement between branded and generic pharmaceutical companies. The same is true here.

A. Complaint counsel satisfies its initial burden with proof that the brand induced the generic to stay off the market with a share of its monopoly profits

Antitrust law rests on the premise that the competitive process will maximize consumer welfare, yielding the best combination of price, quality, and efficiency. As Judge (now Justice) Breyer observed nearly three decades ago: "Anticompetitive" has "a special meaning" under the antitrust laws, referring to "actions that harm the competitive process." *Clamp-All Corp. v. Cast*

[9] *See, e.g.*, *Sullivan v. Nat'l Football League*, 34 F.3d 1091, 1097 (1st Cir. 1994); *United States v. Brown Univ.*, 5 F.3d 658, 669 (3d Cir. 1993); *In the Matter of 1-800 Contacts, Inc.*, No. 9372, at 120 (Initial Decision, Oct. 27, 2017) ("*1-800 Contacts*"). *See also* 7 Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 1504b (3rd and 4th Eds. 2010-2017) ("Areeda").

Iron Soil Pipe Inst., 851 F.2d 478, 486 (1st Cir. 1988) (internal quotation marks omitted).[10] Under *Actavis*, a plaintiff makes a *prima facie* showing of competitive harm by proving that the agreement harms the competitive process and that the defendant has sufficient market power to inflict such harm. Such a showing shifts the burden to the defendant to justify the challenged conduct.[11]

1. A large reverse payment that prevents the risk of competition harms the competitive process

In *Actavis*, the Supreme Court explained that when a branded drug firm settles Hatch-Waxman patent litigation with a large reverse payment, there is concern that the brand is using "its monopoly profits to avoid the risk of patent invalidation or a finding of non-infringement." *Actavis*, 133 S. Ct. at 2236. Such a large reverse payment "suggests that the payment's objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness." *Id*. Indeed, "even a small risk of [patent] invalidity" cannot justify a large payment where the payment "seeks to prevent the risk of competition." *Id*.

As *Actavis* recognizes, a large payment harms the competitive process because it distorts the bargaining process that ordinarily would be expected to protect consumer interests. In the context of a Hatch-Waxman patent litigation settlement, the brand firm seeks to prevent competition for as long as possible. Conversely, the generic company seeks to enter as soon as

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[10] *See also United States v. Microsoft Corp.*, 253 F.3d 34, 58 (D.C. Cir. 2001) (*en banc*) (equating "anticompetitive effect" with harm to "the competitive *process*") (emphasis in original); *Interface Grp., Inc. v. Massachusetts 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).

[11] *See, e.g., 1-800 Contacts* at 120 (collecting cases).

possible. Thus, in the absence of a payment, the bargaining process would be expected to result in a generic entry date that roughly corresponds to the parties' joint assessment of the likely outcome of the patent litigation.

But, as the Court explained, a payment in return for the generic's agreement to "stay away from the patentee's market" is "something quite different." *Id.* at 2233. The payment "in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims, but would lose if the patent litigation were to continue and the patent were held valid or not infringed." *Id*. at 2234. The payment thus transforms rivals with opposing interests into partners who will both benefit from an arrangement that preserves and extends the pool of brand profits. The former rivals "maintain supracompetitive prices to be shared among the patentee and the challenger rather than face *what might have been* a competitive market." *Id.* at 2236 (emphasis added). This sharing of monopoly profits to eliminate "the risk of competition" is the anticompetitive consequence that "underlies the claim of antitrust unlawfulness." *Id.*

Actavis thus teaches that reverse-payment agreements raise the core concern of antitrust law—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 compete those profits away. Such collusion is "the supreme evil of antitrust."[12] Indeed, it is well-settled that a monopolist may not pay a potential competitor to stay out of the market: antitrust law "does not condone the purchase of protection from uncertain competition any more than it condones the elimination of actual competition." 12 Areeda at ¶ 2030b.

Given these principles, courts applying *Actavis* have held that a plaintiff satisfies its "initial burden" under the rule of reason by "establishing anticompetitive effects through market

[12] *See Trinko*, 540 U.S. at 408.

power and evidence of a large reverse payment." *King Drug Co. of Florence, Inc., v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 416 (E.D. Pa. 2015) ("*Cephalon*").[13] Complaint Counsel need not "demonstrat[e] actual anticompetitive effects, such as reduction of output, increase in price, and deterioration in quality of goods or services." *Id.* at 414.

2. The relevant anticompetitive harm is payment to eliminate the risk of competition, not "actual delay"

The Supreme Court emphasized that proving anticompetitive effects does not require litigating the underlying claims of patent validity or infringement, "the virtues or vices of the patent system," or consideration of "every possible pro-defense theory." *Actavis,* 133 S. Ct. at 2237.

Instead, the inquiry turns on the basic factual question whether the patent holder paid a generic challenger to drop its patent challenge and stay off the market:

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

Id. (emphasis added). To answer this question, the antitrust analysis focuses on the payment made by the patent holder, specifically "its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." *Id.*

Impax's argument that the anticompetitive effect inquiry requires Complaint Counsel to show "actual" delayed generic entry misconstrues both *Actavis* and general rule-of-reason

[13] *See also King Drug Co. of Florence, Inc. v. Smithkine Beecham Corp.*, 791 F.3d 388, 412 (3d Cir. 2015) ("*Lamictal*") ("to prove anticompetitive effects," plaintiff must prove "payment to prevent the risk of competition").

principles. Under Impax's theory, Complaint Counsel must prove that Impax's generic version of Opana ER would have entered the market before January 2013 in the absence of the challenged reverse-payment agreement. But the relevant anticompetitive effect under *Actavis* is that potential competitors settle patent litigation with an agreement that "maintain[s] and share[s] patent-generated monopoly profits" and thereby prevents "the risk of competition." 133 S. Ct. at 2236-37. In other words, the reverse-payment settlement harms competition because it interferes with the competitive process.

Nowhere does *Actavis* suggest that plaintiffs must go further and prove that the agreement prevented (or "delayed") actual generic entry that otherwise would have occurred. Indeed, the Court expressly stated that the Federal Trade Commission did *not* have to prove what would have happened in the patent case absent the settlement. *See id*. at 2237. Instead, the Court made clear that eliminating the *risk* of patent invalidation or a finding of noninfringement—"even a small risk"—cannot justify an otherwise unexplained large payment. *Id.* at 2236.

Courts interpreting *Actavis* have confirmed this. For example, the Third Circuit explained in *Lamictal* that "the antitrust problem [in *Actavis*] was that, as the Court inferred, entry might have been earlier, and/or the risk of competition not eliminated, had the reverse payment not been tendered." 791 F.3d at 408. *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224 (D. Conn. 2015), likewise concluded that under *Actavis*, "the "salient question is not whether the fully-litigated patent would ultimately be found valid or invalid" but "whether the settlement included a large and unjustified reverse payment leading to the inference of profit-sharing to avoid the risk of competition." *Id.* at 241.

The California Supreme Court in *In re Cipro Cases I & II*, 348 P.3d 845 (Cal. 2015), discussed the economic logic underlying *Actavis*'s concern with reverse payments. *Id*. at 863-64.

A settlement without a reverse payment would "replicate the expected level of competition; the period of exclusion would reflect the patent's strength." *Id*. at 864. In contrast, "a settlement that delayed entry still longer would extend the elimination of competition beyond what the patent's strength warranted." *Id*. Contrary to Impax's theory, this does not mean the antitrust inquiry requires courts to assess patent strength and calculate "delay." As *Cipro* explains, a court can "identify" whether parties' settlement agreement "eliminates competition beyond the point at which competition would have been expected in the absence of the agreement" by assessing whether the agreement restricts the generic's entry in exchange for a large and unjustified payment. *Id*. at 865-69.

In effect, Impax's insistence that Complaint Counsel prove that generic Opana ER would have entered sooner absent the settlement confuses proof of an antitrust violation with proof of actual injury from that violation. But these are "distinct matters that must be shown independently." *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 60 (1st Cir. 2016) (quoting *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 344 (1990)). A private plaintiff must show "actual harm" because it must prove an injury-in-fact to have standing under the Clayton Act. *See Nexium*, 842 F.3d at 60 ("[P]rivate plaintiffs derive their authority to sue from Section 4 or Section 16 of the Clayton Act and must therefore satisfy the additional evidentiary burdens that those provisions impose."). But a government antitrust enforcer, such as the FTC, can prove an antitrust violation under the rule of reason even absent proof of "actual injury." *Id.* This distinction 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." *Id.*

The D.C. Circuit reached a similar conclusion in the *Microsoft* monopolization case. *Microsoft*, 253 F.3d at 79. The *en banc* decision explained that proving a rule of reason violation does not "turn on a plaintiff's ability or inability to reconstruct the hypothetical marketplace absent a defendant's anticompetitive conduct" because "neither plaintiffs nor the court can confidently reconstruct a product's hypothetical . . . development in a world absent the defendant's exclusionary conduct." *Id.* (citing 3 Areeda at ¶ 651c). Instead, to establish a violation, the government need only show that "as a general matter the [defendant's conduct] is the type of conduct that is reasonably capable of contributing significantly to a defendant's continued monopoly power," viewed "at the time [the defendant] engaged in the anticompetitive conduct." *Id.* An agreement to "maintain and share monopoly profits"—like the reverse-payment settlement in this case—is by definition conduct that is "reasonably capable of contributing significantly to [the brand's] continued monopoly power." *See id.*

Finally, Impax errs when it suggests that anything less than proof of "actual delay" would amount to the presumption of illegality that *Actavis* rejected. Complaint Counsel must prove market power and a large reverse payment to satisfy its *prima facie* case. The "main difference between the burden-shifting analysis under the 'quick look' approach and the rule of reason is that under the former the plaintiff's case does not ordinarily include proof of power or anticompetitive effects." 11 Areeda at ¶ 1914d. Thus, the *Cephalon* court explained, "[t]he burden-shifting framework I have adopted does not qualify as a quick-look approach because the plaintiff still maintains the initial burden—establishing anticompetitive effects through market power and evidence of a large reverse payment." 88 F. Supp. 3d at 416. Complaint Counsel follows the same rule of reason approach here.

B. Proof of a large reverse payment and market power shifts the burden to the defendant to justify the payment

Once a plaintiff demonstrates a large payment and market power, the burden shifts to the defendant to present a legitimate, cognizable justification for the reverse payment: "An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason." *Actavis*, 133 S. Ct. at 2236 (citations omitted).[14] The burden to justify the payment falls on the antitrust defendant because "[t]he defendant, being the author of the restraints, is in a better position to explain why they are profitable and in consumers' best interests." 7 Areeda at ¶ 1505. In a reverse-payment case, the defendant may justify the payment as amounting to "no more than a rough approximation of the litigation expenses saved through the settlement" or reflecting "compensation for other services that the generic has promised to perform." *Actavis*, 133 S. Ct. at 2236. The Supreme Court also stated that there "may be other justifications," but did not identify any. *Id*.

If the defendant cannot justify the reverse payment as representing saved litigation costs, compensation for services, or some other legitimate consideration, then the "unexplained" payment "likely seeks to prevent the risk of competition," and "the antitrust laws are likely to forbid the arrangement." *Id*. at 2236-37.

If the defendant establishes a procompetitive justification for the payment, the burden shifts back to the plaintiff to show that the challenged payment is not "reasonably necessary" to

[14] *See also Lamictal*, 791 F.3d at 412; *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704, 718 (N.D. Ill. 2016) ("The burden is on the defendant to 'show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.'" (quoting *Actavis*, 133 S. Ct. at 2236)); *Cephalon*, 88 F. Supp. 3d at 415-16.

achieve the stated objective.[15] If the plaintiff makes such a showing, the challenged conduct is condemned; if it fails to do so, the court then must weigh procompetitive effects against the harm to competition. 7 Areeda at ¶ 1511c.

Impax has incorrectly asserted that *Actavis* imposes an initial burden on the plaintiff to prove that the challenged payment is unjustified. According to Impax, under *Actavis* a reverse-payment settlement "is not subject to antitrust scrutiny"—in other words, it is immune from antitrust law—unless the plaintiff first proves the generic received a large and unjustified payment. Thus, under Impax's approach, a plaintiff must negate any potential justifications before a court can even begin to analyze the agreement under the rule of reason.

That argument directly contradicts the clear statement in *Actavis* that the defendant (not the plaintiff) is the one required to explain and justify the large payment. 133 S. Ct. at 2236 ("An antitrust *defendant* may show . . . that legitimate justifications are present . . . ."); *id*. at 2237 ("one who makes such a payment may be unable to explain and justify it"). As this language makes clear, the justification inquiry is *part* of the rule-of-reason burden-shifting analysis, not a threshold test to determine whether to apply the rule of reason.

Cephalon squarely rejected the same "threshold" burden argument that Impax makes here. 88 F. Supp. 3d at 405, 412-416. Denying defendants' motion for summary judgment, the court explained in detail that *Actavis* does not create a threshold burden on plaintiffs to prove that a reverse payment is unjustified. Instead, the plaintiff's initial burden is to "establish[] anticompetitive effects through market power and evidence of a large reverse payment." *Id*. at 416. If that initial burden is satisfied, "whether or not the reverse payment is unjustified or

[15] *See, e.g.*, *Cephalon*, 88 F. Supp. 3d at 416 (quoting *Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 75 (3d Cir. 2010)).

unexplained is examined under the standard rule of reason burden-shifting framework, with the *defendant* bearing the burden of providing evidence that the reverse payment is justified by procompetitive considerations." *Id.* (emphasis added).

Impax's argument to the contrary confuses a plaintiff's burden at the *pleading* stage with its burden of proof at the *evidentiary* stage. This distinction was addressed in *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 251-52 (3d Cir. 2017). There, the Third Circuit explained that, to survive a motion to dismiss, "plaintiffs must allege facts sufficient to support the legal conclusion that the settlement agreement involves a large and unjustified reverse payment." *Id*. at 251-52. But at the evidentiary stage, "[t]he Supreme Court clearly placed the onus of explaining or justifying a large reverse payment on *antitrust defendants*." *Id*. at 256-57 (emphasis in original); *see also Lamictal*, 791 F.3d at 411-12 (plaintiff must allege large and unjustified payment, but at proof stage, defendant has the burden to "show that legitimate justifications are present" (internal quotations omitted)).

C. *Actavis* applies to agreements entered before the Supreme Court's decision

The legal standards the Supreme Court adopted in *Actavis* apply to agreements entered before the decision was issued.[16] As the Supreme Court explained in *Harper v. Va. Dep't of Taxation*: "When this Court applies a rule of federal law to the parties before it, that rule is the controlling interpretation of federal law and must be given full retroactive effect in all cases still open on direct review and *as to all events regardless of whether such events predate or postdate our announcement of the rule*." 509 U.S. 86, 97 (1993) (emphasis added).

In *Actavis*, the Supreme Court applied a rule of federal law to the parties before it. The decision therefore must be given "full retroactive effect." *See also Actavis*, 133 S. Ct. at 2238

[16] *See* Tr. 3063 (directing both parties to address this issue in post-trial briefs).

(remanding for further proceedings consistent with the opinion). Following that principle, numerous courts have applied *Actavis* to agreements entered before the Supreme Court's 2013 decision. *See, e.g., In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538 (1st Cir. 2016) (agreement entered in 2009); *Lamictal*, 791 F.3d at 411-12 (agreement entered in 2005); *United Food and Commercial Workers Local 1776 & Participating Emp'rs Health and Welfare Fund v. Teikoku Pharma USA Inc*., 74 F. Supp. 3d 1052 (N.D. Cal. 2014) (agreement entered in 2012).[17]

II. The Prima Facie Case: Endo Shared Its Monopoly Profits with Impax To Avoid the Risk of Competition

Impax received a large reverse payment from Endo to abandon its patent challenge and stay off the market until 2013. First, the SLA's No-AG provision guaranteed that Impax's generic oxymorphone ER product would be the sole generic version of Opana ER available to consumers during Impax's 180-day exclusivity period. Courts have consistently held that No-AG provisions constitute a form of payment under *Actavis*. But Endo and Impax did one better. They further agreed to insure the value of the No-AG provision through the "Endo Credit." Under this provision, Endo would pay Impax in cash if the market for Original Opana ER shrank (for example, if Endo launched a Reformulated Opana ER product) thereby reducing the value of the

[17] In any event, it is incorrect to suggest that Impax and Endo had "no basis" to "believe that the SLA violated antitrust laws so long as it complied with the scope-of-the patent test." Figg Rept ¶ 74. In 2010, courts of appeals' views on reverse-payment settlements were not uniform. *Compare Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005) *and In re Tamoxifen Citrate Antitrust Litig*., 466 F.3d 187 (2d Cir. 2006), *with In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003) *and Andrx Pharm. Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001). The Third Circuit, where the Endo/Impax patent case was litigated, had not expressed a view until 2012, when it rejected the scope of the patent test. *In re K-Dur Antitrust Litig.*, 686 F.3d 197 (3d Cir. 2012), *vacated, Merck & Co. v. La. Wholesale Drug Co.*, 133 S. Ct. 2849 (2013). In 2013, *Actavis* clarified the proper application of existing antitrust law to reverse-payment settlements. And, of course, it is settled law that a plaintiff in a civil antitrust case is not required to prove that the defendant knew its conduct was unlawful. *United States* v. *U.S. Gypsum Co.*, 438 U.S. 422, 436 n.13 (1978).

No-AG provision. As Impax's then-CFO explained to investors, the combination of the No-AG and Endo Credit provisions ensured that Impax would realize value from the agreement "almost no matter what happens." (CCF ¶ 438). If Opana ER sales held steady or increased, Impax would get its expected compensation from the No-AG provision; if the Opana ER sales declined, Impax would get a payment under the Endo Credit. Ultimately, Endo paid $102 million in cash to Impax pursuant to the terms of the Endo Credit provision. The other component of the reverse payment was the $10 million in cash Endo paid to Impax under the terms of the DCA.

A. Impax accepted a payment from Endo to stay off the market until 2013

1. No-AG agreements are a form of payment subject to antitrust scrutiny

The core antitrust concern with a reverse-payment agreement is that the brand firm is "using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement." *Actavis*, 133 S. Ct. at 2236. This concern is not "limited to reverse payments of cash." *Lamictal*, 791 F.3d at 403. It also attaches "to other forms of reverse payment that induce the generic to abandon a patent challenge, which unreasonably eliminates competition at the expense of consumers." *Loestrin*, 814 F.3d at 550. One such payment form is a No-AG agreement. Because No-AG agreements are likely to present the same type of problems as reverse-payments of cash, numerous courts have held that they may constitute large reverse-payments subject to antitrust scrutiny. *See Lamictal*, 791 F.3d at 403; *Loestrin*, 814 F.3d at 550.

A No-AG agreement has substantial monetary value to a first-filer generic firm. The first generic company to file a substantially complete ANDA with a Paragraph IV certification enjoys a 180-day period of exclusivity during which "no other generic can compete with the brand-name drug." *Actavis*, 133 S. Ct. at 2229.[18] (*See also* CCF ¶¶ 390-91). This exclusivity period

[18] *See* 21 U.S.C. § 355(j)(5)(B)(iv).

may be worth "several hundred million dollars" to the first filer. *Id*. at 2235. (*See also* CCF ¶¶ 14-15, 393-94, 404).[19] The exclusivity period, however, does not prevent the brand firm from introducing an AG to stem the losses that result from generic competition. *Lamictal*, 791 F.3d at 405 ("[L]aunching an authorized generic would seem to be economically rational for the brand.").

The first-filer generic company faces two financial effects from AG competition during its 180-day exclusivity period. First, the AG takes a significant share of generic sales from the first-filer. (CCF ¶¶ 28-31). Second, competition between the first-filer generic and the AG drives down generic prices. (CCF ¶ 404). These two effects reduce the first-filer generic's revenues during the 180-day exclusivity period by "40 to 52 percent on average." (CCF ¶ 398; *see also* CCF ¶ 29). These effects are well-known in the pharmaceutical industry. (CCF ¶ 32).

Given these effects, a generic company enjoys substantial benefits from a No-AG agreement; indeed, a generic's revenue will approximately double if there is no AG. (CCF ¶¶ 32, 398). In this case, Impax recognized that competition from an Endo AG would result in lost market share and a lower price and would cut in half Impax's profits during the 180-day exclusivity period. (CCF ¶¶ 404, 409, 411-15). Impax's contemporaneous forecasts show that it expected to make as much as $23 to $33 million more in profit during the first six months if it did not face competition from an authorized generic. (CCF ¶¶ 413-14).

For its part, Endo estimated in 2010 that it could recoup about $25 million in lost sales by selling an authorized generic. (CCF ¶ 998). Giving up this lucrative option would be economically irrational unless Endo received something of greater value in return.

[19] This 180-day exclusivity period can be forfeited as provided under the Hatch–Waxman Act. 21 U.S.C. § 355(j)(5)(D). Impax never forfeited its 180-day exclusivity period. (Snowden, Tr. 484).

Because a No-AG agreement can represent a large transfer of value from the patent holder to the alleged patent infringer, multiple courts have found that a No-AG agreement is a form of reverse payment. As the Third Circuit explained in *Lamictal*¸ by ceding all generic sales during the exclusivity period to the first filer, "[t]he no-AG agreement transfers the profits the patentee would have made from its authorized generic to the settling generic—plus potentially more, in the form of higher prices, because there will now be a generic monopoly instead of a generic duopoly." 791 F.3d at 405. Like other reverse payments, a No-AG agreement may "'provide strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market.'" *Id.* (quoting *Actavis*, 133 S. Ct. at 2235).[20] The "anticompetitive consequence" of this form of reverse payment may be just as harmful as a cash payment because with a No-AG Agreement, the generic "presumably agrees to an early entry date that is later than it would have otherwise accepted." *Lamictal*, 791 F.3d at 405.

2. The No-AG provision here was even more valuable because it was insured by the Endo Credit

The Endo Credit insured the value of Endo's No-AG commitment to Impax. As discussed above, Impax suspected that Endo planned to introduce a reformulated version of Opana ER for which Impax's generic oxymorphone ER product could not be automatically substituted. (CCF

[20] *See also Nexium*, 842 F.3d at 42; *Lamictal*, 791 F.3d at 403 ("[A] no-AG agreement, when it represents an unexplained large transfer of value from the patent holder to the alleged infringer, may be subject to antitrust scrutiny under the rule of reason."); *In re Androgel Antitrust Litig. (No. II)*, No. 1:09-CV-955-TWT, 2017 WL 2404941, at *3 (N.D. Ga. June 2, 2017) ("[N]o-AG agreements clearly hold significant value to the parties involved, and could serve as an alternative to cash-only reverse payment agreements . . . ."); *Aggrenox*, 94 F. Supp. 3d at 243 ("A settlement agreement may be very simple or tremendously complex, and it may involve all manner of consideration; and if, when viewed holistically, it effects a large and unexplained net transfer of value from the patent-holder to the alleged patent-infringer, it may fairly be called a reverse-payment settlement.").

¶¶ 246-48, 418-21). *See also* Section I, above. This would have a devastating impact on Impax's generic sales. As Mr. Mengler, the president of Impax's generic division in 2010, explained, "the way generic drugs are sold is by having a substitute, and if there's no substitute, I get nothing." (CCF ¶¶ 354, 421). Thus, if Impax agreed not to launch its product until 2013, and Endo successfully converted the market to Reformulated Opana ER before Impax launched, then the value of both the No-AG provision and Impax's 180-day exclusivity would be substantially diminished. (CCF ¶¶ 420-23, 427-31).

Impax insisted on downside protection for this possibility before it would accept a 2013 entry date. (CCF ¶¶ 249-75). According to Mr. Mengler, obtaining such protection was "super, super important." (CCF ¶¶ 427, 434). "[S]omething that didn't protect [Impax] from the downside was . . . a deal-breaker" in the settlement negotiations. (CCF ¶¶ 250, 434). The mechanism for protecting Impax from that downside was the Endo Credit. (CCF ¶¶ 428-30). If sales of Original Opana ER fell to less than 50% of their peak before Impax's January 2013 entry, then Endo would be obligated to make a payment to Impax. (CCF ¶¶ 273, 326, 433). The payment amount was based on a mathematical formula designed to approximate Impax's expected profits from the No-AG provision, i.e. Impax's expected profits from selling generic oxymorphone ER during Impax's 180-day exclusivity period without competition from an authorized generic. (CCF ¶¶ 274-75). The Endo Credit payment would, therefore, "correct for the loss in the value of the market that had occurred before the generic entry date." (CCF ¶ 435).

The Endo Credit's value—like the value of any insurance policy—was contingent on certain events occurring, but it nonetheless had substantial value to Impax. Together with the No-AG provision, the Endo Credit provided Impax with "a reasonable outcome almost no matter what happens." (CCF ¶ 438). Impax would realize value from either the No-AG provision or the

Endo Credit—or both. As Impax's current CFO agreed: "[I]f the market for Opana ER did not decline, the value of the No-AG provision would be higher, but if the market did decline, Impax would get a payment under the Endo [C]redit." (CCF ¶ 438). The Endo Credit "insurance" policy protected Impax from a drop in the value of the No-AG provision, thus conveying even more value to Impax. (CCF ¶ 325).

In the end, the Endo Credit worked just as intended. After Endo launched Reformulated Opana ER, sales of Original Opana ER declined substantially, and Endo paid Impax $102 million per the terms of the Endo Credit provision. (CCF ¶¶ 439-44).

3. Endo paid Impax $10 million in cash pursuant to the DCA

Endo also made an upfront, non-refundable cash payment of $10 million to Impax in June 2010 pursuant to the DCA. (CCF ¶¶ 320, 329-31, 445-48). Impax and Endo negotiated the DCA simultaneously with the SLA, expressly incorporated the DCA into the SLA, and executed both agreements on the same day. (CCF ¶¶ 315-17, 1067).

B. Endo's payments to Impax were sufficiently large to cause anticompetitive effects

A reverse payment is "sufficiently large" to cause anticompetitive effects if "it exceeds saved litigation costs" and "was significant enough to induce a generic challenger to abandon its patent claim." *Cephalon*, 88 F. Supp. 3d at 416-17.[21] When Impax settled its patent litigation with Endo, the trial had already begun, so most of the litigation costs had been incurred. (CCF ¶ 455). A conservative estimate of the combined saved litigation costs for both Endo and Impax is

[21] *See also Actavis*, 133 S. Ct. at 2237 ("[T]he likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs . . . ."); *Opana*, 162 F. Supp. 3d at 718 ("A 'large' payment is anything more than the value of the avoided litigation costs plus any other services provided from the generic to the brand manufacturer.").

no more than $5 to $6 million. (CCF ¶¶ 453-58). By itself, Endo's $10 million cash payment under the DCA is greater than these saved litigation costs. (CCF ¶ 460). Impax also received substantial value from the combined No-AG and Endo Credit provisions. (CCF ¶¶ 461-72). Every reasonable estimate of the *ex ante* value of the combined No-AG and Endo Credit provisions exceeded $16 million, and these provisions ultimately resulted in a $102 million cash payment to Impax. (CCF ¶¶ 444, 461-72).

The actual payments from Endo to Impax dwarfed any reasonable estimate of saved litigation costs and ended up being approximately twice as much as Impax expected to make from actually selling its generic product.[22] (CCF ¶¶ 459-60, 472, 493-94). The size of the Endo Credit payment was so large that Impax's CFO believed that it had a substantial impact on Impax's net income. (CCF ¶¶ 495-96). The Endo payment represented about two-thirds of Impax's entire net income for 2013 and was greater than Impax's net income for all of 2012. (CCF ¶¶ 496-97). By any measure, the payment Impax received was sufficiently large to induce it to drop its patent challenge.

1. The value to Impax of the No-AG and Endo Credit ranged from $16.5 million to more than $62 million under any reasonable scenario

The No-AG and Endo Credit worked together to ensure that Impax would receive substantial value from the settlement agreement. If Endo introduced Reformulated Opana ER and thereby reduced the value of sales of Original Opana ER, Impax likely would receive little value from the No-AG provision because the generic market opportunity would be substantially reduced. But Endo would then need to pay Impax pursuant to the Endo Credit provision—as it

[22] *See Actavis*, 133 S. Ct. at 2235 (noting that brand companies sometimes pay a generic challenger "a sum even larger than what the generic would gain in profits if it won the paragraph IV litigation and entered the market").

ultimately did. On the other hand, if Endo did not introduce Reformulated Opana ER or was not able to move customers to it in advance of generic entry, then Impax likely would not receive anything under the Endo Credit. But Impax would receive substantial value from the additional profits realized by not competing with an Endo AG during Impax's exclusivity period. The No-AG agreement and Endo Credit worked together to provide Impax with a "large payment" regardless of what contingency arose. (CCF ¶¶ 435-38, 461-72).

At the time of the settlement, the precise value of the No-AG agreement was uncertain. But if Opana ER sales remained high enough that the Endo Credit was not triggered, then the No-AG provision would be worth at least $16.5 million, and potentially significantly more. (CCF ¶¶ 461-72). Its ultimate value depended on sales of Original Opana ER in January 2013:

- ***Original Opana ER sales increase:*** The value of the No-AG provision would be highest if the sales from Original Opana ER continued to increase between the settlement in June 2010 and Impax's generic entry in January 2013. (CCF ¶ 467). In the real world, sales of Opana ER grew from $240 million in 2010 to $384 million in 2011. (CCF ¶ 415). If sales of Opana ER in 2013 (when Impax entered) equaled its peak just before Endo withdrew Original Opana ER from the market, then the value of the No-AG provision would have been worth approximately $53 million to Impax in 2013. (CCF ¶ 467). Even if Impax were required to pay Endo a royalty under the SLA (in the event that Endo grew the market for Opana ER at an annual rate of 10%), the value to Impax of being the only generic oxymorphone ER seller on the market would always exceed the cost of the royalty. (CCF ¶ 468).

- ***Original Opana ER sales remain flat***. If sales of Original Opana ER merely stayed flat from June 2010 until the date of Impax's entry, the No-AG provision would be worth at least $33 million to Impax in 2013. (CCF ¶ 469).
- ***Original Opana ER sales decline, but the Endo Credit is not triggered***. The value of the No-AG provision would be smallest if Original Opana ER sales declined (presumably because Endo introduced a reformulated version), and the Endo Credit payment was never triggered. Even in this worst-case scenario, however, the value of the No-AG provision would likely be worth approximately $16.5 million in 2013. (CCF ¶ 471).

By contrast, if Original Opana ER sales declined by more than 50% from their peak after the settlement, the No-AG provision would be less valuable, but the Endo Credit would be triggered. (CCF ¶¶ 326, 433). The smallest possible Endo Credit payment (assuming that Opana ER sales peaked at the time of the settlement and declined thereafter) would be approximately $62 million. (CCF ¶ 470).

As it turned out, Opana ER sales continued to grow after the settlement, and Endo ultimately tendered a "make good" payment to Impax of $102 million—approximately twice as much as Impax expected to make from actually selling its product. (CCF ¶¶ 429, 492-97). *See Actavis, 133* S. Ct. at 2235 (noting that brand companies sometimes pay a generic challenger "a sum even larger than what the generic would gain in profits if it won the paragraph IV litigation and entered the market").

2. Impax's argument that the payments it received were not large is factually and legally unsupported

Impax acknowledges that the value of the No-AG and Endo Credit provisions was uncertain at the time of the agreement. Impax further acknowledges that one potential value of

these provisions at the time of the agreement was the $102 million payment Endo actually made to Impax. (CCF ¶ 479). Impax, therefore, concedes that these provisions could—and ultimately did—have significant value to Impax. (CCF ¶ 479).[23]

But Impax contends that this was not a large payment because it was theoretically *possible*, if future events played out in a very specific way, that both the No-AG provision and the Endo Credit provision could yield no value to Impax. Impax makes no attempt to quantify the likelihood of this hypothetical scenario occurring, but its primary negotiator, Chris Mengler, thought it was "so unlikely it wasn't worth worrying about." (CCF ¶ 481). Real world events proved Mr. Mengler correct. Impax's argument that the No-AG and Endo Credit provisions had zero expected value to Impax at the time of agreement simply because there was some theoretical possibility that it might have turned out to be worthless is both legally and factually flawed.

First, the substantial value Impax received from the combination of the No-AG and Endo Credit provisions is no less substantial merely because the precise value was uncertain at the time of the settlement. "[C]ase law confirms that although contingent liabilities technically 'depend[ ] on a future event that may not even occur[ ] to fix either [their] existence or [their] amount,' courts have nevertheless rejected the notion that such liabilities are without any value whatsoever." *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d at 392 n.22 (D. Mass. 2013) (quoting *Freeland v. Enodis Corp.*, 540 F.3d 721, 730 (7th Cir. 2008)) ("*Nexium II*"). Under any reasonable scenario, Impax would realize substantial value from the No-AG provision, the Endo Credit provision, or both. *See* Sections II.A. & II.B.1, above.

[23] Impax's expert, Dr. Addanki, did not criticize how Complaint Counsel's economics expert, Professor Noll, calculated the *ex ante* potential values of the no-AG and Endo Credit provisions. (CCF ¶ 479).

Second, Impax's argument rests on a far-fetched hypothetical scenario that contradicts the contemporaneous evidence. This scenario would require Endo to (1) wait until the fourth quarter of 2012 to launch Reformulated Opana ER—late enough so that Opana ER sales would not drop during the quarter by more than 50% from peak, thereby avoiding triggering the Endo Credit provision and then (2) switch the market from original to Reformulated Opana ER in just a few weeks before Impax launched its generic product in January 2013—fast enough to eliminate the value of the No-AG provision by eliminating any profits Impax might make during its exclusivity period. (CCF ¶ 474).

Endo, however, did not plan to wait until the end of 2012 to introduce its reformulated product. Nor did Endo want to abruptly switch patients from original to Reformulated Opana ER. According to the unrebutted testimony of Endo executives and Endo's own documents, Endo's strategy to maximize the value of its Opana ER franchise was always to launch Reformulated Opana ER as soon as possible *and* "smoothly transition" patients from original to Reformulated Opana ER. (CCF ¶¶ 75-80, 482-87).

Endo knew that it would be harder to transition patients to Reformulated Opana ER if generic oxymorphone ER were already on the market. (CCF ¶¶ 75-80, 482-84, 603-04). Endo's brand manager for Opana ER thus testified that Endo's strategy depended on introducing Reformulated Opana ER "a reasonable amount of time" before generic oxymorphone ER launched. (CCF ¶ 483). Endo's internal forecasts showed that if it launched Reformulated Opana ER before any generic oxymorphone ER products were available, its sales of Reformulated Opana ER would grow. (CCF ¶¶ 75-78, 242-45, 482-84, 605). If Endo waited until after generic oxymorphone ER came to market, then its expected peak sales of Reformulated Opana ER to be dramatically lower. (CCF ¶¶ 75, 244, 483, 605-07).

Endo's strategy also depended on pursuing a smooth transition from original to Reformulated Opana ER that would take at least "months." (CCF ¶¶ 79, 485-87). Endo recognized that physicians are "very careful as they adjust dosages," and planned "for an orderly and phased transition from one product to the other so we made sure we weren't leaving any current patients in a difficult situation." (CCF ¶¶ 79, 487). Endo needed this "orderly and phased transition" to be completed before generic oxymorphone ER entered the market. Indeed, Endo's "Priority #1" for Reformulated Opana ER was "Beat Generics by 1 Year." (CCF ¶ 484). Endo's actual strategy for launching Reformulated Opana ER contradicts Impax's hypothetical scenario in which Endo launched its reformulated product at the last minute and tried to switch patients to the new product in a short period of time. (CCF ¶¶ 482, 485). Indeed, the reformulation of Opana ER—Endo's second-largest product at the time—was a strategically important project designed to extend the life of the Opana franchise. Endo was not willing to risk the success of this project to avoid paying the Endo Credit. (*See* CCF ¶ 477).

Impax itself viewed the No-AG and Endo Credit provisions as having substantial value during the negotiation. Impax's primary negotiator, Mr. Mengler, said that he would "love" a No-AG provision, and testified that the Endo Credit insurance was "super, super important" and a "deal-breaker" for Impax. (CCF ¶¶ 224, 407, 427, 434, 461). Mr. Mengler understood that Endo would need at least "six to nine months" to switch patients from original to Reformulated Opana ER, and thus dismissed the possibility that Endo could game the reformulated launch to substantially reduce the value of the payment. (CCF ¶ 487). Indeed, Mr. Mengler judged the "potential downside scenario" for the settlement payment to be "so unlikely it wasn't worth worrying about" and never raised the issue with other Impax executives. (CCF ¶¶ 480-81). Even the person within Impax who raised this theoretical possibility admitted that his concern was

based purely on "speculation," (not evidence), did no analysis to quantify the likelihood of this scenario occurring, and eventually conceded to Impax's CEO and CFO that it was "probably unlikely." (CCF ¶¶ 475-81).

There is simply no record evidence to suggest that there was any meaningful possibility of both the No-AG and Endo Credit provisions being worthless to Impax. (CCF ¶¶ 482, 489-94). Impax's economist Dr. Addanki nevertheless relies on the unsupported concept of a "later and faster" scenario as the basis for his opinion that "it is possible that the 'No AG' and Endo Credit provisions would have provided zero value to Impax." (CCF ¶¶ 474, 476). For Dr. Addanki to be right—*i.e.*, for the value of something that ended up being worth $102 million to be worthless, Impax's hypothetical "zero value" outcome must not only be possible, but in fact, overwhelmingly likely to occur. (CCF ¶ 488).[24]

In the end, of course, the combination of the No-AG provision and Endo Credit provisions worked exactly as intended and provided significant value to Impax. *See* (CCF ¶¶ 442-45, 451. Endo removed its Original Opana ER product from the market before Impax entered, thereby degrading the market opportunity for Impax's generic product. (CCF ¶¶ 446-47, 836-37). This reduced the value of the No-AG provision and required Endo to tender the "make good" payment under the Endo Credit in the amount of $102,049,199.64. (CCF ¶¶ 436-39, 451).

[24] Professor Noll calculated the likelihood of the combined No-AG/Endo Credit payment having an *ex ante* value less than the $5 million estimate of saved litigation costs. He assumed that the payment had only two possible outcomes: (1) $102 million (the actual value); and (2) zero. Plugging these values into a simple expected value calculation, Professor Noll concluded that there would need to be a 92% probability of the "zero" outcome for the expected value of the payment to be less than $5 million. (CCF ¶ 495).

C. Endo's payment induced Impax to stay out of the market until 2013

1. Impax would not have agreed to a 2013 entry date without the payment

The evidence shows that Endo's large payment induced Impax to accept a settlement with a 2013 entry date.

First, the No-AG agreement was paired with a 2013 entry date from the very outset of negotiations. (CCF ¶¶ 227-28). Endo's first proposed term sheet offered a 2013 entry date and a No-AG promise. (CCF 227-30). All subsequent discussions of a 2013 entry date included a No-AG provision. (CCF ¶¶ 230, 257, 322). As the Third Circuit has explained, "when the parties' settlement includes a no-AG agreement," it also presumably includes an "entry date that is later than [the generic] would have otherwise accepted." *Lamictal*, 791 F.3d at 405. This is borne out in Impax's internal documents: the President of Impax's generics division initially complained internally that later entry would result in "lost/delayed sales," but a settlement with later entry and a "No-AG" was a "different story. I'd love that !!!!" (CCF ¶ 224).

Second, Impax would not have accepted a 2013 entry date without also getting the Endo Credit. Impax was concerned that, if it agreed not to enter until 2013, Endo would launch a reformulated product before then. Impax understood that a successful reformulation strategy "would have led to the elimination of the Opana ER market," which in turn would "subvert the value of the deal." (CCF ¶ 248). Impax thus insisted on protection from this type of market degradation. Initially, Impax proposed an acceleration provision that moved up Impax's entry date if the Opana ER market began to degrade. (CCF ¶¶ 251-52, 424, 1049). But Endo adamantly opposed earlier entry; after all, such entry would jeopardize its ability to switch patients to Reformulated Opana ER. Instead, the parties crafted the Endo Credit to make Impax "whole for the profits that [it] would have otherwise achieved" if the market opportunity had degraded by the time Impax entered in 2013. (CCF ¶¶ 255, 325, 1038). Without the Endo Credit,

a 2013 entry date would have been untenable for Impax. Indeed, Impax's chief negotiator, Mr. Mengler, described the Endo Credit provision as "super, super important" and "a dealbreaker" in the negotiations. (CCF ¶¶ 427, 434). With the Endo Credit, Impax "stop[ped] pursuing an earlier launch date." (CCF ¶ 257).

Third, because the DCA was designed as another form of payment in return for Impax's acquiescence to a 2013 entry date, it was negotiated as part of the settlement. (CCF ¶¶ 115, 1066-84). The parties discussed the DCA only in the context of settlement negotiations, and neither Impax nor Endo proposed entering the DCA independent of the settlement. (CCF ¶¶ 1068-70). After broadly agreeing to a framework including the DCA and a 2013 entry date, Impax suggested dropping the DCA entirely for a 2011 entry date. (CCF ¶ 276). Endo refused and insisted on the later entry date with the business deal—and then sweetened the deal's value to Impax with additional milestone payments. (CCF ¶¶ 277-78, 300-03).

2. The settlement eliminated the risk that Impax might have launched earlier than 2013

Prior to the settlement, Impax could have launched generic Opana ER prior to January 2013 under a variety of different scenarios. At any point after receiving final approval on June 14, 2010, Impax could have launched at risk—i.e., before the patent case was concluded in the Federal Circuit.

The evidence does not support Impax's assertion in this litigation that it would not have launched at risk. By June 2010, Impax had manufactured a large portion of its "launch inventory build." (CCF ¶¶ 196-202). It had the API on hand to manufacture the remainder and could have done so in as little as two weeks. (CCF ¶¶ 191, 197, 199). The President of Impax's generics division had informed the Board of Directors that "oxymorphone was a good candidate for an at-

risk launch." (CCF ¶¶ 146, 341). The only remaining step was to seek formal authorization from the Board, which Impax did not do because of the settlement. (CCF ¶¶ 205, 342-43).

Impax may have been able to enter risk-free before 2013 even if it waited until an appellate decision in the patent case. Endo believed that, if Impax "waited for the appeal to play out," its 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 expert, E. Anthony Figg, predicted an appellate decision in November 2011. (CCF ¶ 1377). To be sure, Impax might have lost the patent case on appeal, or the appeal might have taken longer than expected. But Impax still posed a risk to Endo of earlier generic entry, which the settlement eliminated.

Because Impax was the sole first filer for the five most popular dosages of Opana ER, its agreement to stay out of the market until January 2013 barred all other generic versions of these dosages from entering before that time and until Impax's exclusivity period expired. (CCF ¶¶ 378-82). As a result, the Impax-Endo Settlement Agreement ensured that Endo would face no competition on these five dosages for two-and-a-half years.

D. Endo had market power in the relevant antitrust market for extended-release oxymorphone products

Market power is "the power to control prices or exclude competition." *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956). Defining a relevant market is not an end in itself; rather, "the purpose of the inquiries into market definition and market power" is to determine whether the particular conduct at issue "has the potential for genuine adverse effects on competition." *FTC. v. Ind. Fed'n of Dentists*, 476 U.S. 447, 460 (1986); *see also U.S. Healthcare, Inc. v. Healthsource, Inc.*, 986 F.2d 589, 598 (1st Cir. 1993) ("rational treatment is assisted by remembering to ask, in defining the market, *why* we are doing so: that is, what is the

antitrust question in this case that market definition aims to answer?").[25] In other words, it "provides the context against which to measure the competitive effects of an agreement." *Geneva Pharm. Tech. Corp. v. Barr Labs Inc.*, 386 F.3d 485, 496 (2d Cir. 2004). A firm without market power will not be able to harm competition successfully, and market power thus "distinguishes the antitrust violation from the ordinary business tort." *Kaplan v. Burroughs Corp.*, 611 F.2d 286, 291 (9th Cir. 1979).

The market power inquiry in this case seeks to determine whether the challenged reverse-payment agreement, which eliminated the risk of generic Opana ER entry for over two years, harmed consumers. At the outset, two significant features of this case strongly support that it did.

First, as at least one court has observed, "the anticompetitive effects of [delaying generic entry] cannot be seriously debated." *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1311 n.27 (11th Cir. 2003). Impax's and Endo's documents, the academic literature, and Complaint Counsel's economic expert all confirm that introduction of generic Opana ER was expected to—and ultimately did—result in dramatic cost savings to consumers. The Impax-Endo agreement guaranteed that generic Opana ER would not enter until 2013 and assured that consumers would not enjoy these potential cost savings until then.

Second, the fact that Endo was willing to make a large payment to Impax to prevent the risk of generic entry "provide[s] strong evidence that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market." *Actavis*, 133 S. Ct. at 2235. "A large payment would be an irrational

[25] In antitrust economics, market definition is not an end in itself, but is a tool that is valuable only to the extent that it helps shed light on whether the conduct at issue caused anticompetitive harm by increasing or maintaining market concentration or by enabling a group of independent sellers to engage in effective collusion. (CCF ¶ 512).

act unless the patentee believed that generic production would cut into its profits." *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 262 (D. Mass. 2014) (quotations omitted) ("*Nexium III*"). If Endo had lacked market power, then competition from existing products already would have driven down its Opana ER prices and profits to the competitive level. Endo, therefore, would not expect to benefit from preventing Impax's generic entry and would have no incentive to compensate Impax for not entering. Endo's large payment to Impax was rational because Endo had market power. "Market power can sometimes be inferred from an exclusionary practice that would not be rational for a firm lacking significant power." 2B Areeda at ¶ 520b2.

1. Relevant antitrust markets in the pharmaceutical industry often include only a branded pharmaceutical product and its generic equivalent

"The goal in defining the relevant market is to identify the market participants and competitive pressures that restrain an individual firm's ability to raise prices or restrict output." *Barr Labs.*, 386 F.3d at 496. The Court must identify the products that imposed a competitive constraint on the price of Endo's Opana ER. This does not mean simply identifying products that are to some degree interchangeable with Opana ER. "For every product, substitutes exist. But a relevant market cannot meaningfully encompass that infinite range. The circle must be drawn narrowly to exclude any other product to which, within reasonable variations in price, only a limited number of buyers will turn . . . ." *Times-Picayune Pub. Co. v. United States*, 345 U.S. 594, 612 n.31 (1953). Functional interchangeability between products provides only "[t]he outer boundaries of a product market." *Brown Shoe Co. v. United States,* 370 U.S. 294, 325 (1962).

The relevant antitrust question asks not whether products are functional substitutes, but whether they are economic substitutes. A product is a close economic substitute for Opana ER only if there is high cross-elasticity of demand between the products—*i.e.*, an increase in price

on one product would cause a large number of consumers to switch to the other. *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 437-38 (3d Cir. 1997).[26] If a "small but significant non-transitory increase in price" (SSNIP) of Opana ER would not cause sufficient sales to shift to another product, then the products exhibit low cross-elasticity of demand, and they are not in the same relevant antitrust market. *See, e.g., Babyage.com, Inc. v. Toys "R" Us, Inc.*, 558 F. Supp. 2d 575, 581 (E.D. Pa. 2008).

Different brand-name prescription drugs within the same therapeutic class often are not in the same relevant antitrust market because there is low cross-elasticity of demand between them. (CCF ¶ 573). This is due, at least in part, to the fact that brand-name pharmaceuticals in the same class often use different molecules as their active ingredients. (CCF ¶¶ 556-58, 726, 748). These different molecules may have different features, interactions, or side-effect profiles. (CCF ¶¶ 556-58, 726, 748). This type of product differentiation "tends to be an aggravating factor" that "creates or enlarges market power." Herbert Hovenkamp, Federal Antitrust Policy: The Law of Competition and Its Practice 45-46 (5th ed. 2015). A generic product, on the other hand, has the same active ingredient as its brand counterpart and offers the same features at a much lower price. (CCF ¶¶ 9, 24, 548-50). Such a generic is generally AB-rated to the brand, and pharmacists automatically substitute the generic for the brand. (CCF ¶¶ 9, 16-22). A brand drug

[26] The core underlying fact that economists seek to uncover in defining a relevant market is the cross-elasticity of demand between a reference product and each product that is a plausible close substitute. The cross-elasticity of demand is the percentage change in sales of one product arising from a one percent change in the price of another product. (CCF ¶ 526). If the cross-elasticity of demand between two products is high, an attempt by the producer of one product to increase price will cause a large loss of sales to the other product, assuming that the prices of the other products remain unchanged. (CCF ¶ 527). *See also Olin Corp. v. FTC*, 986 F.2d 1295, 1298 (9th Cir. 1993) (explaining that cross elasticity of demand occurs when "an increase in the price of one product leads to an increase in the demand for another").

will often lose significant sales to its generic competitor, but not to different brand-name pharmaceuticals that potentially treat the same condition.

Numerous courts have found that a brand pharmaceutical was not in the same relevant market as other, functionally interchangeable brand pharmaceuticals. The Northern District of California recently ruled on summary judgment that the relevant antitrust market for Lidoderm, a topical pain patch, was limited to "Lidoderm and its generic equivalents" because "there was no significant cross-elasticity of demand between Lidoderm and any product other than generic Lidoderm." *United Food and Commercial Workers Local 1776 & Participating Emp'rs Health and Welfare Fund v. Teikoku Pharma USA*, --- F. Supp. 3d ---, No. 14-md-02521-WHO, 2017 WL 5068533, at *17, *21 (N.D. Cal. Nov. 3, 2017). The court reached this conclusion despite evidence that the brand "made efforts to convince physicians to prescribe Lidoderm over [] other [branded] drugs." *Id*. at *17.

The idea that a relevant antitrust market is limited to a brand and its generic equivalents has a long pedigree. In 1978, the Third Circuit affirmed a relevant antitrust market that contained only cephalosporin antibiotics and excluded all other antibiotics. *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1064 (3d Cir. 1978). It noted that, "although there is a certain degree of interchangeability among all antibiotics," cephalosporin antibiotics had "unique features" that differentiated them from other antibiotics and had no "significant cross-elasticity of demand" with other antibiotics. *Id.*

Other courts have since reached similar conclusions, excluding from the relevant market other drugs that were functional—but not economic—substitutes. *See Nexium*, 968 F. Supp. 2d at 388 (assuming market limited to branded and generic Nexium, excluding other drugs used to treat heartburn); *In re Terazosin Hydrochloride Antitrust Litig.*, 352 F. Supp. 2d 1279, 1319 n.40

(S.D. Fla. 2005) (market limited to branded and generic hydrochloride, excluding other hypertension drugs); *In re Ciprofloxacin Hydrocholoride Antitrust Litig.*, 363 F. Supp. 2d 514, 522 (E.D.N.Y. 2005) (market limited to ciprofloxacin, excluding other antibiotics in same family); *see also FTC v. Lundbeck, Inc.*, 650 F.3d 1236, 1240-43 (8th Cir. 2011) (affirming that the only two drugs indicated for treating a serious birth defect were in separate product markets).

2. The relevant antitrust market in this case is brand and generic oxymorphone ER products

Although Opana ER is one of numerous LAOs used to treat chronic moderate to severe pain, the evidence confirms that the only close economic substitute for Opana ER was generic oxymorphone ER.

The parties' own expectations show that generic oxymorphone ER was a uniquely close substitute for Opana ER. According to Impax's and Endo's contemporaneous documents, both companies anticipated that generic oxymorphone ER would enter at a lower price than Opana ER and have a dramatic effect on sales of Opana ER. Impax forecasted that its generic oxymorphone ER would be offered at a 45% discount or more to the brand and that it would capture half of Endo's Opana ER sales in the first month. (CCF ¶¶ 585-98). Impax further projected that, within a year, generic oxymorphone ER would have captured 80% to 90% of Endo's Opana ER sales and cost only 5% of the brand price. (CCF ¶¶ 596-98). Endo's projections were similar: it expected to lose 85% of Opana ER sales to generic oxymorphone ER within three months of generic entry. (CCF ¶¶ 610-11). Endo also recognized that generic oxymorphone would take significant sales of Reformulated Opana ER—or constrain its ability to convince consumers to purchase Reformulated Opana ER in the first place. (CCF ¶¶ 245, 603, 605, 617).

Actual events largely confirmed the parties' expectations. In 2013, Impax launched its generic {[redacted]

[redacted]**}** (CCF ¶ 636). Even though Impax's generic product was not automatically substitutable for the Reformulated Opana ER product then on the market, it captured **{**[redacted]**}** of branded Opana ER sales within four years. (CCF ¶ 630). If Opana ER were already facing robust competition from existing LAO products before generic oxymorphone entry, additional competition would not have eroded the sales volume of branded Opana ER products so dramatically. If other LAOs were close economic substitutes to Opana ER, then those other LAOs already would have competed down Opana ER's price and sales long before generic oxymorphone ever entered the market. (CCF ¶¶ 499, 642, 909).

Additional evidence confirms that Impax considered generic oxymorphone ER to be a uniquely close economic substitute for Endo's Opana ER. (CCF ¶ 649). When forecasting sales of generic oxymorphone ER, Impax considered only the market size of Endo's Opana ER, not any other LAO. (CCF ¶¶ 646-48). When Impax considered the price for its generic oxymorphone ER product, Impax referred only to the price of oxymorphone ER products, not the price of any other LAO. (CCF ¶ 652).

The evidence also shows that other LAOs were *not* close economic substitutes with Opana ER and did not meaningfully constrain Endo's prices. Complaint Counsel's economic expert, Professor Noll, empirically evaluated the impact of new LAO entry on the sales of Opana ER. If other LAOs and Opana ER had high cross-elasticity of demand, then entry of new LAO products—particularly lower-cost generic versions of other LAOs—would reduce Opana ER sales as consumers switched to the lower-priced product. (CCF ¶ 672). Professor Noll found that the introduction of new LAO products had little to no effect on Opana ER sales. (CCF ¶¶ 654, 669-73; *see also* CCF ¶¶ 674-716). Professor Noll also evaluated whether entry of lower-cost generic oxymorphone ER affected the demand for other LAO products that Impax contends

should be in the relevant market. Once again, Professor Noll found no perceptible evidence that sales of other LAO drugs shifted in response to changes in the price of oxymorphone ER. (CCF ¶¶ 674-716). The data do not show a pattern of substitution between Opana ER and these other products, meaning that there is low cross-elasticity of demand among them. (CCF ¶ 673). Respondent's economic expert, Dr. Addanki, does not criticize this analysis.

The medical evidence from pain management experts Dr. Seddon Savage and Dr. Edward Michna support this economic conclusion. Both medical experts confirm that patients cannot freely switch between Opana ER and other LAOs in response to changes in price. Different opioid molecules have distinct therapeutic properties, including biological receptors, pharmacokinetic profiles, and adverse side effects or drug interactions. An opioid molecule that works well for one patient may be inappropriate or ineffective for another. (CCF ¶¶ 660, 746-49). Brand Opana ER and generic oxymorphone ER are the only extended-release opioid products that contain the molecule oxymorphone, which has unique properties. (CCF ¶¶ 35, 726, 748, 755).

Even when oxymorphone ER and another LAO might both be medically appropriate for a given patient, switching that patient from one opioid to another is a lengthy procedure that must be monitored by a medical professional to avoid the risk of overdose. (CCF ¶ 663). This creates high switching costs, which deter doctors and patients from switching between opioids in response to a price increase. (CCF ¶ 664). Both Dr. Savage and Dr. Michna agreed that small price changes are unlikely to cause them to switch a patient from one opioid to another. (CCF ¶¶ 565, 665-67). Switching between branded Opana ER and generic oxymorphone ER is more predictable and less difficult because they share the same opioid molecule. (CCF ¶ 755). Endo itself recognized the difficulty of switching patients between Opana ER and other LAOs. (CCF

¶¶ 734-36). In 2012, Endo was faced with the possibility of a supply disruption caused by manufacturing problems. It advised health care professionals about this shortage, and recommended that they "temporarily refrain from starting new patients" on Opana ER "as there is no therapeutically equivalent or pharmaceutically alternative substitute product available" to which patients could switch if the supply of Opana ER ceased. (CCF ¶ 736). This evidence supports the economic analysis showing high cross-elasticity of demand between Opana ER and oxymorphone ER on the one hand, and low cross-elasticity between oxymorphone ER products (brand and generic) and non-oxymorphone LAOs on the other.

Endo's documents further demonstrate that Opana ER primarily competes with other LAOs on the basis of product differentiation, not price. For example, Endo executives repeatedly emphasized the "inherent characteristics of the [Opana ER] compound." (CCF ¶¶ 730-32). In June 2009, when lower-priced generic versions of OxyContin (the most prescribed LAO) became more available, Endo concluded that it could maintain its marketing strategy. (CCF ¶¶ 718-19). As Endo executive Demir Bingol explained, the Opana ER "molecule was still the better fit for different types of patients. Whether there's generic OxyContin or not didn't necessarily change that dynamic." (CCF ¶ 718). Indeed, sales of branded Opana ER continued to grow in 2009 and 2010 despite the entry of other LAOs. (CCF ¶¶ 719-20). Conversely, Endo's internal documents rarely mention relative price with other LAOs as a factor affecting Opana ER sales, and those documents proposing specific Opana ER pricing do not refer to pricing of any other LAOs. (CCF ¶¶ 721-23, 737). In contrast, Endo's pricing of other products, such as Frova, did consider the prices of other drugs in the same "triptan market." (CCF ¶ 738). This evidence further supports the conclusion that Opana ER, unlike Frova, is in a pharmacologic class for which price is not a significant basis of brand-to-brand competition. (CCF ¶ 739).

3. Endo had market power in the market for brand and generic oxymorphone ER

In 2010, Endo had the power to profitably sustain prices for Opana ER above the competitive level and exclude competitors. Professor Noll reached this conclusion based on both indirect and direct evidence. First, Endo's high share of sales in the market for oxymorphone ER and the substantial barriers to entry into that market indirectly show Endo's market power. (CCF ¶¶ 828-52). In 2010, Endo had 100% of the market for oxymorphone ER. (CCF ¶ 830). Even after other oxymorphone ER products entered, Endo has never had less than approximately **{ }** of the market. (CCF ¶ 841). And the market is protected by significant barriers to entry, including patents, regulatory barriers, and loyalty to brand-name drugs. (CCF ¶¶ 843-52). As a result, Endo possessed substantial market power.

Second, Endo's market power is observable directly through its exclusion of competitors and charging of super-competitive prices. (CCF ¶¶ 853-81).. Endo was able to exclude numerous generic firms as a result of its patents and by triggering the 30-month regulatory Hatch-Waxman stay. (CCF ¶¶ 859-63). Internal Endo documents and pricing data show that Endo was able to maintain prices high above its marginal cost for Opana ER without fear of losing sales to other LAOs. (CCF ¶¶ 864-81). Further, the Lerner Index for Opana ER shows that Endo had market power. (CCF ¶¶ 882-96). The Lerner Index is an indicator between zero and one of a product's profitability. (CCF ¶ 883). In a highly competitive market with significant cross-elasticity of demand, the Lerner Index will be at or near zero. (CCF ¶ 884). The Lerner Index for Opana ER, calculated using Endo's average net realized price and marginal cost, was over **{ }**, indicating substantial market power. (CCF ¶ 895). Dr. Addanki did not criticize this calculation. Though a high Lerner Index does not necessarily establish market power, Complaint Counsel's expert

concluded that it supported such a finding in this case based on the structure of the market and the available evidence. (CCF ¶¶ 882-96).

4. Impax misunderstands the market power inquiry

In response to Professor Noll, Impax offers the testimony of Dr. Sumanth Addanki. Dr. Addanki does not criticize Professor Noll's economic analysis of the data. He does not dispute Professor Noll's conclusion that these data show no pattern of substitution between Opana ER and non-oxymorphone LAOs. (CCF ¶¶ 670-716). Nor does he dispute the economic evidence that, unlike other LAOs, the entry of generic Opana ER took substantial sales from Endo's branded product. (CCF ¶¶ 628-44). Dr. Addanki does not demonstrate any meaningful switching between Opana ER and other LAOs in response to price changes. And he does not criticize the medical evidence showing that there are high switching costs to change from Opana ER to other opioids. (CCF ¶¶ 663-64). These facts demonstrate low cross-elasticity of demand between Opana ER and other LAOs. (CCF ¶ 654). Dr. Addanki offers no response.

Nonetheless, Dr. Addanki opines that Opana ER competes in a relevant market that includes all other LAOs. Much of Dr. Addanki's conclusion regarding market power stems from his use of the term "market power" to mean the ability to set price above marginal cost *as a result of anticompetitive conduct*. (CCF ¶ 957). But market power need not flow from anticompetitive conduct. *See Trinko*, 540 U.S. at 407 ("The mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system."). (CCF ¶ 958). And the mere presence of market power does not indicate anticompetitive conduct. (CCF ¶ 958). Market power indicates that if anticompetitive conduct occurs, that conduct will have a significant effect on competition. Here, Impax and Endo engaged in anticompetitive conduct—the reverse payment settlement—that allowed Endo to maintain its market power through improper means. (CCF ¶ 959). That is a

different question from whether Endo had market power in the first place. Dr. Addanki's conflation of those two concepts is a fundamental error.

Dr. Addanki's analysis contains numerous other mistakes that render his opinions unreliable. First, and most fundamentally, Dr. Addanki incorrectly equates therapeutic, or functional, interchangeability with economic interchangeability. (CCF ¶¶ 915-26). He concludes that other LAOs are part of the same relevant market as Opana ER because they work in generally similar ways and can often be used to treat the same conditions. But his analysis stops at identifying functional substitutes. The mere fact that drugs in the same therapeutic class are functionally interchangeable does not establish that they are in the same relevant antitrust market. (CCF ¶¶ 915-18). *See FTC v. Staples, Inc.*, 990 F. Supp. 1066, 1075 (D.D.C. 1997) ("[T]he mere fact that a firm may be termed a competitor in the overall marketplace does not necessarily require that it be included in the relevant product market for antitrust purposes."). Instead, the relevant economic question is whether there is high cross-elasticity of demand between different products—*i.e.*, whether an increase in one product's price will cause customers to switch to another product. (CCF ¶¶ 526-27). Without "significant cross-elasticity of demand," different drugs are not in the same relevant antitrust market even when there is a "certain degree of interchangeability" between them. *SmithKline*, 575 F.2d at 1064.

Second, Dr. Addanki misinterprets Endo's business documents that discuss ways of differentiating Opana ER from other LAOs as evidence other LAOs are close economic substitutes for Opana ER. (CCF ¶¶ 927-39). These documents overwhelmingly focus on *differentiating* Opana ER from other LAOs based on its unique characteristics—not competing with them on price. (CCF ¶ 940-42). Convincing patients and physicians that a drug has differentiated, desirable characteristics builds brand loyalty and makes patients and physicians

less likely to switch to another product in response to a price increase. Such product differentiation undermines, rather than enhances, price competition and acts as a barrier to entry that makes market power more likely. *See* Lawrence A. Sullivan, et al., The Law of Antitrust: An Integrated Handbook 69 (3d ed. 2015) (noting that product differentiation is an entry barrier that can contribute to market power); *FTC v. Tenneco, Inc.*, 433 F. Supp. 105, 111 (D.D.C. 1977) (same); (CCF ¶¶ 724-25).

Third, Dr. Addanki makes a similar error in his analysis of formulary placement for Opana ER and other LAOs. (CCF ¶¶ 943-50). He concludes that placement of LAOs on different insurance plan tiers reflects price competition. (CCF ¶ 943). But Dr. Addanki did not undertake any analysis of prices. (CCF ¶ 944). He cannot conclude that changes in formulary placement were the result of small price changes rather than large price changes. (CCF ¶ 944). Indeed, he cannot conclude that formulary decisions were a function of price competition at all, rather than promotional activity emphasizing product differentiation. (CCF ¶ 944). Because he does not examine whether formulary placement decisions were based on price, Dr. Addanki's review of insurance formularies provides no evidence about the cross-elasticity of demand between Opana ER and other LAOs.

Dr. Addanki's analysis of LAO formulary placement also is flawed because it excludes all generic LAOs. (CCF ¶¶ 946-47). Dr. Addanki acknowledged that a generic will always be placed on a more preferred tier than a brand, yet he excluded this factor from his analysis of formularies. (CCF ¶ 946). By excluding generic drugs—the most important source of competition in this market—Dr. Addanki's formulary analysis significantly overstates the competition between branded products. (CCF ¶ 947).

Finally, even if Opana ER competed to some extent with other LAOs, such limited competition with other products is entirely consistent with the exercise of market power. (CCF ¶¶ 930-33). When a product is priced at a monopoly level, consumers will switch to products that they would not switch to if the price were set at a competitive level. *See United States v. Eastman Kodak Co.*, 853 F. Supp. 1454, 1469 (W.D.N.Y. 1994); 2A Areeda at ¶ 539. It is a basic economic error to assume that functional substitutes are in the same market. This error is so well-known that it has a name: the "cellophane fallacy." (CCF ¶ 931-32). Dr. Addanki's analysis is an example of the cellophane fallacy. (CCF ¶ 933).

Apart from the errors of its expert, Impax also incorrectly asserts that the Commission's consent decree *In the Matter of King Pharmaceuticals, Inc. and Alpharma Inc.*, File No. 081-0240, supports its position that Opana ER and all other LAOs are in the same relevant market. In that decree, the Commission alleged a relevant market for "oral long-acting morphine sulfate" products. *See* Complaint, ¶ 11, Doc. No. C-4246 (Feb. 2, 2009). The Commission expressly acknowledged the availability of other LAOs with "the same mechanisms of action, similar indications, similar dosage forms, and similar dosage frequency" and the existence of a broader market consisting of all LAOs.[27] But despite the presence of these other LAOs, it found reason to believe that a proposed merger of the owners of "the only two competitively significant branded morphine sulfate oral LAOs" would "result in higher prices for branded ER morphine sulfate."[28] It therefore required Alpharma to divest its morphine sulfate LAO product. The relevant market in this case, as in *King Pharmaceuticals*, is the long acting form of the API molecule (here,

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

[28] *Id*.

oxymorphone). *King Pharmaceuticals* is entirely consistent with the relevant market defined by Complaint Counsel.

III. Impax has failed to justify the large payment it received from Endo

Because Complaint Counsel has proven its *prima facie* case, the burden shifts to Impax to justify the reverse payment by showing that it serves to promote some legitimate, procompetitive objective.[29] *Actavis* explained that a defendant may justify a reverse payment by showing that the payment "amount[s] to no more than a rough approximation of the litigation expenses saved through the settlement" or "reflect[s] compensation for other services that the generic has promised to perform." 133 S. Ct. at 2236. In such circumstances, "there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement." *Id.*

Impax cannot justify its large reverse payment on either of these two bases. In addition, Impax has not demonstrated any "other convincing justification," (*Actavis*, 133 S. Ct. at 2237), for the challenged payment.

A. Impax cannot justify its large payment as saved litigation expenses

Impax does not appear to argue that Endo's payments "amount to no more than a rough approximation of the litigation expenses saved through the settlement." *Id.* at 2236. Nor could it. As discussed above, even a generous estimate of the remaining *combined* saved litigation costs from both Endo and Impax is no more than $5 to $6 million. (CCF ¶¶ 452-60). By itself, the $10 million DCA payment significantly exceeds this generous estimate. (CCF ¶ 460).

[29] *See, e.g.*, 7 Areeda at ¶ 1504b (once plaintiff satisfies its burden to show harm to competition, "the burden shifts to the defendant to show that the restraint in fact serves a legitimate objective").

B. Endo's $ 10 million upfront payment under the DCA cannot be explained as a payment for services Impax provided

Although Impax does not contend that either the No-AG agreement or Endo Credit "reflect compensation for other services that the generic has promised to perform," *Actavis*, 133 S. Ct. at 2236, it does claim that the $10 million DCA payment was justified because Endo received profit-sharing rights to a potential future drug product. *See id.* at 2236. The record demonstrates, however, that Endo agreed to the $10 million payment to secure Impax's guarantee that it would stay out of the market until January 2013, not for the product rights. (CCF ¶¶ 321, 446-51, 1066, 1082).

First, the DCA was negotiated as part of the patent litigation settlement discussions, not as a standalone agreement. (CCF ¶¶ 1066-73). The parties' negotiations routinely discussed the terms of the DCA and SLA together. (CCF ¶¶ 1068-69). Indeed, Endo and Impax never discussed business development opportunities outside the context of patent settlement negotiations. (CCF ¶¶ 1069-71, 1079). For Impax, the DCA was primarily negotiated by Generics Division President Chris Mengler, who was also the primary negotiator for the settlement agreement. (CCF ¶¶ 226, 1068-69). Mr. Mengler—the president of the Generics Division—was not typically involved in negotiations for brand drug products like IPX-203, and other Impax employees found his involvement unusual. (CCF ¶ 1069). On the Endo side, the deal was negotiated by Endo's CFO, Alan Levin, who was Endo's lead settlement negotiator. (CCF ¶¶ 1068, 1095). Mr. Levin was not a part of Endo's commercial group, which would normally bring in product development opportunities. (CCF ¶ 1095). Impax and Endo witnesses acknowledged the DCA and SLA were connected. (CCF ¶¶ 1070, 1083-84). In fact, the SLA specifically incorporates the development deal. (CCF ¶ 1067).

Not only were these deals closely linked, but the evidence shows that the DCA needed to be completed before Impax would agree to the SLA (and its 2013 entry date). Endo's commercial group evaluated the DCA on a "condensed" timeline so that it could be finalized in tandem with the settlement. (CCF ¶¶ 1125-27). Indeed, Impax recognized that Endo was "on a tight time table" to complete the DCA "if they wish[ed] to settle prior to June 17." (CCF ¶ 1125). If the DCA were not necessary to secure Impax's assent to the settlement agreement, there is no explanation for these unusual time constraints.

Second, Endo offered the same $10 million upfront payment despite a significant change in the product under discussion. Endo initially offered a $10 million upfront payment for certain rights to IPX-066, a promising late-stage drug. (CCF ¶¶ 232-39). The next day, however, Impax "yanked [IPX-066] out from under" Endo, (CCF ¶¶ 1117, 1129), and instead suggested a deal for an unidentified product it called "066a." (CCF ¶ 292-94). On June 2, 2010, despite having no substantive information about 066a, Endo offered to make the same $10 million upfront payment. (CCF ¶¶ 1082-83). In fact, Endo did not get *any* information about 066a, other than it being a follow-on to IPX-066, until June 4, 2010—two days *after* it offered the $10 million upfront payment. (CCF ¶¶ 299, 1119). And Endo continued to offer that upfront payment after it learned that 066a—also called IPX-203—was an untested, pre-clinical compound that had not even been formulated and entailed far more risk than IPX-066. (CCF ¶¶ 295-97). The fact that Endo's $10 million payment offer never changed even as the expected value of the alleged "services" dropped dramatically demonstrates that the $10 million payment was not made to acquire those services. (CCF ¶¶ 1082, 1209).

Moreover, Endo was willing to enter the DCA despite the fact that, in 2008, Endo's business development consultant had ruled out Impax's carbidopa/levodopa products as

worthwhile collaboration opportunities. (CCF ¶¶ 1090-92). Consistent with its consultant's advice, in 2015 Endo again rejected an opportunity to co-promote Impax's carbidopa/levodopa drug. (CCF ¶¶ 1256-67). By that time, the DCA's proposed formulation of IPX-203 had failed, and Impax sought to amend the agreement to focus on a different type of carbidopa/levodopa compound. (CCF ¶¶ 1257-58, 1260-62). Endo had already made the $10 million upfront payment and would only need to commit to the milestone payments it had already agreed to in the DCA. (CCF ¶ 1267). But outside the context of the Opana ER settlement, Endo declined. (CCF ¶¶ 1256-63). It cited numerous concerns about development risks and about the already highly competitive market for carbidopa/levodopa products—nearly all of which applied equally in 2010 when it agreed to the DCA. (CCF ¶¶ 1264-66).

Third, the DCA was not consistent with Endo's, or the industry's, usual business development practice. Indeed, Endo has never made *any* upfront payment for a license or co-promotion agreement after such limited due diligence. (CCF ¶ 1133). And Dr. John Geltosky, a former pharmaceutical development executive and consultant with 35 years of industry experience, reviewed this agreement and concluded that the negotiations, strategic fit, due diligence, post-agreement conduct, and terms of the DCA were not consistent with the normal practice in the pharmaceutical industry. (CCF ¶¶ 1085-1265). Dr. Geltosky noted many unusual features of the deal:

1) The DCA was negotiated from start to finish in three weeks, far quicker than the industry standard (6-12 months) and Endo's own documented process (4-6 months). (CCF ¶¶ 1103-30).

2) Impax switched the product under discussion from a tested, promising compound to an unknown, far riskier compound shortly before the agreement was signed, but this did not affect the negotiations or financial terms of the DCA. (CCF ¶¶ 1128-86).

3) IPX-203 made little business sense for Endo because it was outside of Endo's target therapeutic areas and would not provide Endo with the near-term revenues it was seeking. (CCF ¶¶ 1085-98; *see also* CCF ¶¶ 1099-1102).

4) Endo conducted only a few days of limited diligence on IPX-203 in order to "check the box," even though the industry standard and Endo's documented process is to perform weeks of rigorous due diligence on a potential development opportunity. (CCF ¶¶ 299, 1132, 1138-39).

5) Endo used information about IPX-066 as a "surrogate" for evaluating IPX-203 even though IPX-203's success hinged on it being "spectacularly better" than IPX-066. (CCF ¶¶ 307, 1157-58, 1162).

6) Endo's financial valuation of the DCA relied on assumptions taken from IPX-066 that were inaccurate for IPX-203 and did not take into account any of the substantial development risks IPX-203 faced. (CCF ¶¶ 1199-1201, 1203, 1205-13).

7) The financial terms of the DCA are "frontloaded"—with an unusually large upfront payment and progressively decreasing milestone payments—whereas early-stage development deals are typically "backloaded" so that the purchaser does not risk as much money up front. (CCF ¶¶ 1220-28).

Finally, the parties' internal documents show that they understood the DCA as a payment for the Opana settlement. A July 2010 Endo Corporate Development Update, approved by senior Endo management, discussed the DCA but made no mention of any benefit to Endo from IPX-203 itself; instead, the document noted that the DCA "adds significant topline revenue *for Opana*." (CCF ¶ 1084) (emphasis added). The only way the DCA added "topline revenue" for Opana is by being part of a settlement that ensured Opana ER would not face generic entry until 2013. (CCF ¶ 1084). Impax had a similar view: it listed the $10 million it received under the DCA as **{** [redacted] **}**

Taken together, this extensive factual record precludes Impax from justifying the $10 million payment under the DCA as merely "compensation for other services that [Impax] has promised to perform." *Actavis*, 133 S. Ct. at 2236.

C. Impax has no "other convincing justification"

Actavis leaves open the possibility that "[t]here may be other justifications" for a reverse payment. *Id*. To establish such a justification, Impax must link any procompetitive benefits it asserts to the "challenged term[s]," i.e., the large payment it received under the settlement. *Id.*

("An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of *the challenged term* . . . ." (emphasis added)). In other words, Impax must prove that the large payment it sought and received from Endo promoted some procompetitive objective.[30]

Impax has offered two purported justifications. First, it attempts to justify the Endo Credit (but not the No-AG agreement or the DCA) as part of a "carrot and stick" mechanism to deter Endo from reformulating its Opana ER product. Second, it argues that the settlement (but not specifically the payment) promoted a procompetitive objective because, as numerous future events are playing out over more than seven years, Impax is now selling the only oxymorphone ER on the market. These justifications, however, are neither cognizable nor supported by the evidence.

1. Impax's "carrot and stick" argument is factually and legally unsupported

Impax seeks to justify the Endo Credit as part of a "carrot and stick" that, combined with the royalty provision, purportedly sought to incentivize Endo to maintain and grow sales of Original Opana ER. According to former Impax CFO Art Koch, the "carrot" was the royalty provision, which called for Impax to pay Endo a 28.5% royalty if Original Opana ER sales increased by a specified percentage before Impax's launch. (CCF ¶ 1055). The "stick" was the Endo Credit. (CCF ¶ 1055). This justification is both factually unsupported and legally untenable.

[30] *See, e.g., United States v. Brown Univ.*, 5 F.3d at 669 ("If a plaintiff meets his initial burden of adducing adequate evidence of market power or actual anti-competitive effects, the burden shifts to the defendant to show that the challenged conduct promotes a sufficiently pro-competitive objective."); 7 Areeda at ¶ 1504b (once plaintiff satisfies its burden to show harm to competition, "the burden shifts to the defendant to show that the restraint in fact serves a legitimate objective").

As a factual matter, the record shows that the Endo Credit was a payment designed to induce Impax to accept a January 1, 2013 entry date. (CCF ¶ 1348). Contemporaneous business documents show that the Endo Credit was intended to provide a "make good" payment that would compensate Impax if the market for Original Opana ER disappeared before Impax's licensed entry date. (CCF ¶¶ 1059-62). Getting such protection before agreeing to the settlement was "super, super important" to Impax; in fact, it was a "deal-breaker." (CCF ¶ 427). And ultimately, the Endo Credit functioned just as it was intended to: when Endo launched its reformulated version of Opana ER and decimated Original Opana ER, it made a cash payment of $102 million to Impax pursuant Endo Credit provision—an amount far below what Endo made in a single year of Reformulated Opana ER sales. (CCF ¶ 1063).

By contrast, not a single contemporaneous Impax business document uses the term "carrot and stick," or even hints that the purpose of the Endo Credit was to deter Endo from launching its reformulated version of Opana ER. (CCF ¶¶ 1057, 1059).

It is equally apparent that the royalty provision for increased sales is not the purported "carrot" that Impax claims. (CCF ¶¶ 1064-65). The royalty was something Endo proposed in its initial term sheet on May 26, 2010—before Impax ever proposed any kind of market protection provision. (CCF ¶¶ 1058). There is no evidence that Impax affirmatively wanted this royalty provision or believed it would have any effect on Endo's behavior. Nor is there any evidence that the parties' negotiations over the Endo Credit ever addressed how Endo's profits would be affected if the royalty provision were triggered.

Moreover, it is wholly implausible that Impax (or Endo) would have expected the Endo Credit and royalty to deter Endo from switching patients to a reformulated product. At most, a payment under the Endo Credit would represent only a small fraction of the hundreds of millions

of dollars Endo expected to gain by switching the market. (CCF ¶¶ 242, 603). The same is true of any revenues that would be paid under the royalty provision. Endo would plainly make more by keeping 100% of the profits from the higher-priced sales of Reformulated Opana ER, than by receiving only 28.5% of the profits from the lower-priced generic sales. (CCF ¶ 603).

In any event, Impax's purported "carrot and stick" argument is not legally cognizable. Impax is essentially arguing that it sought the "carrot and stick" to protect against competition from a new, reformulated product that the market might prefer. Such an anticompetitive objective cannot satisfy Impax's burden to show that the payment it received promoted a legitimate justification. Moreover, if it preserved the Original Opana ER market, the "carrot and stick" would simply ensure that the No-AG provision would have the large value that Impax expected. (CCF ¶¶ 468, 1065). Ensuring that Impax got a large payment from the No-AG provision is not a procompetitive objective.

2. The fact that Impax is currently the only seller of an oxymorphone ER product does not justify the payments

Impax also attempts to justify the reverse-payment agreement on the basis that today, more than seven years after the settlement, it is the only seller of oxymorphone ER. Impax contends that the reason that it (and no one else) is currently selling oxymorphone ER is because of the broad license it received under the settlement. According to Impax, that broad license allowed it to stay on the market after Endo successfully enforced some of the additional patents it obtained after the SLA. Impax ignores the considerable uncertainty surrounding the license and future events, and its proposal to focus on how events unfolded years after the settlement is incorrect and unworkable. More fundamentally, however, Impax still has not provided any logical explanation, let alone any evidence, to explain why it would need to be paid to accept a broader license than Endo had originally proposed. Impax thus cannot establish that the

payments it received from Endo served to achieve consumer benefits arising from the license to future Endo patents provided in the settlement.

As this Court observed in *1-800 Contacts*, "[c]ognizable justifications ordinarily explain how specific restrictions enable the defendants to increase output or improve product quality, service, or innovation." *1-800 Contacts* at 166 (quotation omitted). "An allegedly legitimate objective is, of course, entirely immaterial unless it is served by the challenged restraint." Areeda, *supra*, ¶ 1505a. The connection between the challenged conduct and the asserted procompetitive objective must be sound both in theory and in fact.[31]

Thus, it is not enough simply to show that the settlement contained both the license and the payment. As the Supreme Court explained, parties may, and often do, obtain the benefits of settling without a payment. *Actavis*, 133 S. Ct. at 2236 (parties "may settle in other ways, *e.g.*, by allowing the generic manufacturer to enter the patentee's market before the patent expires without the patentee's paying the challenger to stay out prior to that point."). As a result, Impax must show that the purported legitimate objective (i.e., obtaining the broad patent license) is served by the payment. *See id.* ("An antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason."). Impax cannot do so.

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[31] *See, e.g.*, *NCAA v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 113-14 (1984) (rejecting proffered justification because the defendant failed to show that the challenged conduct, a limit on televised college football games, in fact served the legitimate objective of maintaining competitive balance among teams); *Realcomp II, Ltd. v. FTC*, 635 F.3d 815, 834-35 (6th Cir. 2011) (rejecting free rider justification because Realcomp had not demonstrated that the necessary connection between the challenged restraint (a rule barring certain discount, limited-service agency listings from the Realcomp's website) and the prevention of free-riding); *N. Tex. Specialty Physicians v. FTC*, 528 F.3d 346, 368-70 (5th Cir. 2008) (rejecting an organization's asserted justification that its business model fostered higher quality care because there was "no logical nexus between better performance by NTSP physicians and NTSP's dissemination of polling results or its other challenged practices.").

First, simple logic shows that the license could have been obtained without the payment. Impax received the large payment *and* the license to future patents from Endo. Impax benefited from both. Thus, Impax surely did not need to be paid to accept the broad license. For its part, Endo was willing to give both the large payment *and* the license to Impax in exchange for the January 1, 2013 entry date. Endo certainly would have been willing to give *less*, i.e., just the license and not the payment. As a result, the settlement's license to future patents cannot explain or justify the presence of the payment provisions.

Second, the contemporaneous documents reflecting the settlement negotiations confirm that there is no link between the reverse payment and the future patent license. Impax was well aware of Endo's pending patent applications, but it did not even raise the possibility of a license to future Endo patents until June 5, 2010. (CCF ¶¶ 280, 1412). By that time, Endo and Impax had already reached an agreement in principle on both the date for Impax's entry and the form and substance of the compensation to Impax. (CCF ¶¶ 279-80, 1406). The eventual broadening of the license provision did not materially alter these other elements of the agreement. (CCF ¶ 1406).

Third, even if Impax could show that the parties would not have reached another settlement absent the large payment, Impax's desire to be paid to accept an otherwise unacceptable entry date is not a legitimate objective—it is the essence of the violation under *Actavis*. Even if "some settlements might no longer be possible absent a payment in excess of litigation costs," that fact "is no concern if the ones barred would simply have facilitated the sharing of monopoly profits." *Cipro Cases I & II*, 348 P.3d at 869.

Since Impax cannot show a connection between the payments and the broad license, it simply disclaims this requirement. Instead, Impax insists that the payment is not the "challenged restraint" because the payment on its own does not technically "restrain" Impax's entry. Impax

Pre-Trial Br. 81. This argument misunderstands both *Actavis* and the claims in this case. The "specific restraint at issue" here is "payment in return for staying out of the market." *Actavis,* 133 S. Ct. at 2234. *See also id*. at 2233 (a patentee is not entitled to "pa[y] a competitor to respect its patent" (internal quotation marks omitted)). That is why *Actavis* requires that the defendant justify "the challenged term," i.e., the payment, to "show[] the lawfulness of *that term* under the rule of reason." *Id*. at 2236 (emphasis added).

In the end, Impax's inability to demonstrate that the large payment from Endo served a legitimate objective leaves only an argument that the broad patent license had procompetitive effects. But these effects, even if cognizable, depend entirely on a series of unpredictable events occurring *after* the settlement. Consistent with *Actavis*, courts assess the competitive effects of reverse-payment settlements as of the time they are entered.[32] The "relevant anticompetitive harm"—the harm to the competitive process from the sharing of monopoly profits to avoid the risk of competition—occurred when Impax agreed to stay off the market in exchange for a large reverse payment. *Actavis,* 133 S. Ct. at 2236. *Actavis* makes clear that uncertainty about the patent in suit has no bearing on the antitrust concern. *See id.* at 2231 ("The patent here may or may not be valid, and may or may not be infringed."); *see also Aggrenox,* 94 F. Supp. 3d at 241 (the "salient question is not whether the fully-litigated patent would ultimately be found valid or invalid"). If Impax cannot rely on the uncertainty of the actual, issued patents covering Opana

[32] *See, e,g,, Cipro Cases I & II*, 348 P.3d at 870 ("Agreements must be assessed as of the time they are made" and "consideration of whether the agreement is justified as procompetitive will not turn on whether the patent would ultimately have been proved valid or invalid"); *Apotex, Inc. v. Cephalon, Inc*., No. 2:06-cv-2768, 2017 WL 2473148, at *5 (E.D. Pa. June 8, 2017) (applying "the ex ante framework mandated by the *Actavis* rule of reason analysis" and holding that a post-settlement patent ruling should play no role in assessing the competitive effects of a reverse-payment agreement).

ER, it certainly cannot rely on uncertainty about other potential future patents that would not even issue until years later.

Moreover, relying on such determinations not only would be inconsistent with *Actavis* and general rule of reason principles, but also would be wholly unworkable in practice. Indeed, if post-settlement patent rulings could justify a reverse-payment agreement, antitrust legality could fluctuate over time: the agreement could be unlawful when entered, but later become lawful if a district court upholds the brand's patent, then become *unlawful* again if the Federal Circuit reverses the district court. Such an antitrust enforcement scheme would make no sense.

IV. Remedy

Once a violation is found, the Commission has an obligation to order effective relief to protect the public from future violations and to restore competitive conditions to the marketplace. It is well-established that the Commission has "wide discretion" in selecting the appropriate remedy. *Jacob Siegel Co. v. FTC*¸ 327 U.S. 608, 611 (1946). Courts will not interfere with the Commission's choice unless the remedy has "no reasonable relation to the unlawful practices found to exist." *Gibson v. FTC*, 682 F.2d 554, 572 (5th Cir. 1982) (internal quotation marks and citation omitted).

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:

> If the Commission is to attain the objectives Congress envisioned, it cannot be required to confine its road block to the narrow lane the transgressor has traveled; it must be allowed effectively to close all roads to the prohibited goal, so that its order may not be by-passed with impunity.

FTC v. Ruberoid Co., 343 U.S. 470, 473 (1952).[33] Thus, the Commission can prohibit conduct that would not be illegal standing alone, and ban conduct that would be permitted if engaged in by someone not found to have violated the law.[34]

In this case, Complaint Counsel seeks an injunction that would (1) generally prevent or deter Impax from entering into the same or similar conduct in the future; and (2) specifically prohibit Impax from any ongoing or future conduct that restricts or disincentivizes competition for oxymorphone ER products. Complaint Counsel's proposed order is attached as Appendix A.

A. Injunction to prevent "similar conduct"

Paragraph II.A of the proposed order seeks to prevent and deter Impax from entering into similar reverse-payment agreements in the future. Thus, Paragraph II.A generally prohibits Impax from entering into agreements in which the generic filer receives a payment from the branded company and agrees not to market its product for some period of time. The order would cover all potential forms of reverse payments, including No-AG commitments and business transactions ("side deals') entered shortly before or after the patent settlement. (*See* Proposed Order, I.X. "Payment by the NDA Holder to Generic Filer").

Specifically, the side deal ban would prohibit Impax from entering into any business transaction with the branded company within 45 days of the patent settlement. While this

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[33] *See also FTC v. Nat'l Lead Co.*, 352 U.S. 419, 430 (1957) ("[T]he Court is obliged not only to suppress the unlawful practice but to take such reasonable action as is calculated to preclude the revival of the illegal practices."); *Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 698 (1978) (in fashioning remedy for an antitrust violation, it is "entirely appropriate" to go "beyond a simple proscription against the precise conduct previously pursued.").

[34] *See, e.g., Toys "R" Us, Inc. v. FTC*, 221 F.3d 928, 939-40 (7th Cir. 2000); *Nat'l Soc'y of Prof'l Eng'rs*, 435 U.S. at 698 (upholding broad restriction on expression related to the ethics of competitive bidding because it "represents a reasonable method of eliminating the consequences of the illegal conduct"); *see also Nat'l Lead*, 352 U.S. at 430 ("[D]ecrees often suppress a lawful device when it is used to carry out an unlawful purpose.").

provision may prohibit some agreements that might otherwise be lawful, it is both reasonable and necessary to provide an effective remedy, and it is fully justified given the record in this case. First, as leading antitrust scholars have observed, "[t]he parties to a payment for delay have ample reason to pack complexities into the deal (such as relatively unimportant services) to conceal its genuine nature."[35] Determining in any given case whether a payment is made in exchange for services provided, rather than to induce the generic to abandon its patent challenge, can be a fact-intensive process—as the adjudication of this case illustrates. An order provision that turned on whether the side deal was designed as a payment to stay out of the market would make enforcement of the order unduly complicated and create a substantial loophole.

Second, this provision will not significantly limit Impax's ability to engage in legitimate business transactions, as it will apply only to those conditioned on or executed within a short window of the patent settlement. In light of Impax's past violation, this "fencing-in," which is modeled on numerous existing Commission orders,[36] is reasonable and necessary to provide effective protection to consumers.

Under the proposed order, Impax would remain free to settle by obtaining the right to market its generic product prior to expiration of the allegedly infringed patent, and by receiving an amount equal to the patent holder's saved future litigation expenses, up to $7 million. As the Supreme Court explained in *Actavis*, settlements for an entry date or payments to avoid future litigation costs reflect "traditional settlement considerations" that are unlikely to raise

[35] Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *Activating Actavis,* 28 Antitrust Magazine 18 (Fall 2013).

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

competitive concerns. *Actavis*, 133 S.Ct. at 2236. The order would also carve out other types of payments that are not likely to be anticompetitive, such as acceleration clauses that permit the generic company to begin selling its product at the same time as another generic or provisions that facilitate the regulatory approval of the generic's product. (*See* Proposed Order, I.W "Payment by the NDA Holder to Generic Filer").

The prospective relief sought in Paragraph II.A is appropriate. To demonstrate the need for prospective relief, Complaint Counsel need only show a "cognizable danger" of a repeated violation. *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953); *SCM Corp. v. FTC*, 565 F.2d 807, 812-13 (2d Cir. 1977). The question is not whether Respondent will engage in precisely the same conduct, but whether there is a danger that it will engage in future violations of the same type. *See TRW, Inc. v. FTC*, 647 F.2d 942, 953 (9th Cir. 1981).

This case presents a cognizable danger of recurrence. The Opana ER agreement was a conscious effort to maintain and share monopoly profits at the expense of consumers. Impax never abandoned or disavowed that agreement. Instead, Impax abided by its terms, and refrained from competing until January 2013. (CCF ¶ 360). Where a party "continues to maintain that [its] past conduct was blameless," there is no reason to expect it to desist from that conduct. *SEC v. Cavanagh*, 155 F.3d 129, 135 (2d Cir. 1998). Moreover, Impax remains an active player in the pharmaceutical industry, and is currently engaged in numerous patent infringement litigations. (CCF ¶¶ 1460-78). Impax has powerful incentives to resolve one or more of these patent litigations with a reverse-payment. (CCF ¶¶ 977-82). Indeed, Impax's current CEO has made clear his intentions to "always" seek a No-AG provision in any litigation settlement. (CCF ¶¶ 1481-84). Impax thus has the incentive, desire, and opportunity to continue to enter similar agreements in the future. (CCF ¶¶ 1460-84).

B. Injunction to prevent anticompetitive conduct in the oxymorphone ER market

Paragraph II.B of the proposed order prevents Impax from entering, or being a party to, any agreement that prevents, restricts, or disincentivizes competition for oxymorphone ER—the market at issue in this case. (*See* Paragraph II.B). Under Paragraph II.D, Impax would have 60 days after entry of this proposed order to vacate, amend, or nullify any such agreement. This provision is necessary to eliminate any further impediments to competition in the market for oxymorphone ER. Because Impax caused anticompetitive harm in this market, this injunction is not limited to the same or similar conduct. It instead bars Impax from any conduct that reduces competition within that specific market.

This provision is warranted under the law and the facts of this case. Impax has already shown a propensity to take anticompetitive action with regard to oxymorphone ER products. To ensure that relief is effectual, "otherwise permissible practices connected with the acts found to be illegal must sometimes be enjoined." *United States v. Loew's, Inc.*, 371 U.S. 38, 53 (1962). For example, in *Massachusetts v. Microsoft Corp.*,, the D.C. Circuit affirmed a remedy decree that went beyond mere prohibition of the conduct found to be illegal. 373 F.3d 1199, 1215-16, 1222 (D.C. Cir. 2004). Along with remedial provisions addressing middleware software (which covered the unlawful conduct), the decree required Microsoft to disclose proprietary interfaces and protocols to further interoperability with the Windows operating system. *Id.* at 1215-16. The court acknowledged that "non-disclosure of this proprietary information had played no role in our holding Microsoft violated the antitrust laws." *Id.* at 1215. Nonetheless, the court concluded that such relief was a reasonable method of "facilitating the entry of competitors into a market from which Microsoft's unlawful conduct previously excluded them." *Id.* at 1218.

Similarly, in *Ford Motor Co. v. United States*, the Supreme Court not only affirmed divestiture of an unlawfully acquired spark plug manufacturer, but also determined that it was

appropriate to prohibit Ford from using its own trade name on spark plugs and from manufacturing spark plugs for a specified period of time. 405 U.S. 562, 577-78 (1972). The court stated that "[t]he ancillary injunctive provisions are necessary to give the divested plant an opportunity to re-establish its competitive position and to nurture the competitive forces at work in the market-place." *Id.* at 563; *see also id*. at 576 ("The temporary ban on the use of the Ford name is designed to restore the pre-acquisition competitive structure of the market.").

In addition to Paragraph II.B, Paragraph II.C of the proposed order would specifically nullify the 2017 agreement between Impax and Endo that was entered while Complaint Counsel's case was pending—{ } (CCF ¶¶ 1427, 1485-86). { } (CCF ¶¶ 1427-28, 1487-88).

{ } (CCF ¶ 1490). { } (CCF ¶ 1492). By nullifying the agreement, Paragraph II.C. of the proposed order would be the first step to a final court decision.

C. Reporting and notification requirements

The remaining provisions, Paragraphs III-VII, contain standard reporting and notification requirements to ensure compliance with the proposed order. Paragraph III requires Impax to create and maintain an antitrust compliance program to ensure the company understands and follows the antitrust laws. Paragraph IV requires Impax to file annual compliance reports with the Commission. Paragraph V requires Impax to notify the Commission at least 30 days prior to any change in its corporate control. Paragraph VI requires Impax to provide the Commission access to pertinent business records and documents to assess compliance. This Court has previously approved orders containing similar reporting and notification requirements. *See 1-800 Contacts* at 198.

Paragraph VII of the proposed order specifies that the order shall terminate 20 years from the date it is issued. This is consistent with the Commission's Proposed Rule regarding Duration of Existing Competition and Consumer Protection Orders, 60 Fed. Reg. 42,481 (proposed Aug. 16, 1995) (to be codified at 16 C.F.R. pt. 3).

Respectfully submitted,

Dated: December 28, 2017

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APPENDIX A

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

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

[PROPOSED] ORDER FOR PERMANENT INJUNCTION

I. Definitions

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

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

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

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

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

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

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

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

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

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

J. "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; and

4. waiver or a limitation of a claim for damages based on prior Marketing of the Generic Subject Drug Product, but only if the NDA Holder and the Generic Filer do not agree, and have not agreed, to another Brand/Generic Settlement for a different Drug Product during the 90 day period starting and 45 days before and ending 45 days after the execution of the Brand/Generic Settlement.

5. a continuation or renewal of a pre-existing agreement between an NDA Holder and a Generic Filer but only if: (i) the pre-existing agreement was entered into at least 90 days before the relevant Brand/Generic Settlement Agreement, (ii) the terms of the renewal or continuation, including the duration and the financial terms, are substantially similar to those in the pre-existing agreement, and (iii) entering into the continuation or renewal is not expressly contingent on agreement to a Brand/Generic Settlement.

X. "Subject Drug Product" means the Drug Product for which one or more Patent Infringement Claims are settled under a given Brand/Generic Settlement. For purposes of this Order, the Drug Product of the NDA Holder and the Generic Filer to the same Brand/Generic Settlement shall be considered to be the same Subject Drug Product.

Y. "U.S. Patent" means any patent issued by the United States Patent and Trademark Office, including all divisions, reissues, continuations, continuations-in-part, modifications, or extensions thereof.

II. Prohibited Agreements

IT IS FURTHER ORDERED that:

A. Respondent is prohibited from entering into any Brand/Generic Settlement that includes:

1. (i) a No-AG Commitment and (ii) an agreement by the Generic Filer not to research, develop, manufacture, distribute, Market, or sell the Subject Drug Product for any period of time; or

2. (i) any Payment by the NDA Holder to the Generic Filer and (ii) an agreement by the Generic Filer not to research, develop, manufacture, distribute, Market, or sell the Subject Drug Product for any period of time.

B. Respondent is prohibited from entering into or being party to 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, Inc.;
2. Any proposed acquisition of, or merger or consolidation involving Impax Laboratories, Inc.; or
3. Any other change in Respondent, including assignment or the creation, sale, or dissolution of subsidiaries, if such change may affect compliance obligations arising out of this Order.

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

VI. Access Provisions

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

A. Access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all business and other records and all documentary material and electronically stored information as defined in Section

2.7(a)(1) and (2) of the Commission's Rules, 16 C.F.R. § 2.7(a)(1) (2), in the possession or under the control of the Respondent related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized representative of the Commission and at the expense of the Respondent; and

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

VII. Termination

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

ORDERED:

_____
D. Michael Chappell
Chief Administrative Law Judge

Date: _____, 2018

CERTIFICATE OF SERVICE

I hereby certify that on December 28, 2017, 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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Michael E. Antalics
Benjamin J. Hendricks
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Counsel for Respondent Impax Laboratories, Inc.

December 28, 2017 By: /s/ *Charles A. Loughlin*
Charles A. Loughlin

Counsel Supporting the Complaint

CERTIFICATE FOR ELECTRONIC FILING

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

December 28, 2017 By: /s/ *Charles A. Loughlin*
Charles A. Loughlin