UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

09 12 2018
592157

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

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

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

Markus H. Meier
Assistant Director

Bradley S. Albert
Deputy Assistant Director

Charles A. Loughlin
Chief Trial Counsel

Daniel W. Butrymowicz
Alpa D. Davis
Nicholas A. Leefer
Synda Mark
Lauren Peay
J. Maren Schmidt
Eric M. Sprague
Jamie Towey
James H. Weingarten
Rebecca E. Weinstein
Counsel Supporting the Complaint

Federal Trade Commission
Bureau of Competition
600 Pennsylvania Ave., NW
Washington, DC 20580
Telephone: (202) 326-2114
Email: cloughlin@ftc.gov

Dated: September 12, 2018

Table of Authorities

Cases

Statutes

Other Authorities

GLOSSARY OF RECORD REFERENCES

Compl.	Complaint
CC Pre-Trial Br.	Complaint Counsel's Pre-Trial Brief
CC Post-Trial Br.	Complaint Counsel's Post-Trial Brief
CCF	Complaint Counsel's Proposed Findings of Fact
CCRF	Complaint Counsel's Reply Findings of Fact
RCRF	Respondent's Reply Findings of Fact
ID	Initial Decision
F. or FF.	Initial Decision Findings of Fact
SD Op.	Partial Summary Decision Opinion and Order of the Commission
CCAB	Complaint Counsel's Appeal Brief
Opp.	Respondent's Answering Brief

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

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

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

Second, Impax argues that th

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

entirely immaterial unless it is served by the challenged restraint").

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

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

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

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

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

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

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

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

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

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

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

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

> [T]he fact that a large, unjustifie

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

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

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

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

A no-payment settlement also would be "less

A. Impax misreads *Actavis*

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

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

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

Likewise, *Cipro* does not require proof that entry actually would have occurred earlier.

Cipro

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

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

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

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

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

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

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

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

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

competitive effects of the underlying conduct. For example, Impax cites cases that consider post-

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

Finally, Impax disputes that the Initial Decision's balancing approach applies any "bright line tests" or engages in a "simple mathematical exercise." Opp. 37. But that is exactly what it does. At the end of the balancing analysis, the Initial Decision states that "[e]ven if it is assumed that Impax would have entered the market as early as June 2010, and that the settlement therefore delayed generic entry (and extended Endo's patent monopoly) for two and a half years," the procompetitive benefits still outweigh the harm because the SLA "allowed

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

(CCF ¶1084).

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

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

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

The Initial Decision departed from the established rule-of-reason burden-shifting framework by treating Impax's proffered justifications for the reverse-payment agreement as an element of Complaint Counsel's *prima facie* case. CCAB 39-41. Impax tries to defend this

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

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

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

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

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

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

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

Market definition requires identifying "the market participants and competitive pressures that restrain an individual firm's ability to raise prices or restrict output." *Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 496 (2d Cir. 2004). Impax argues that other LAOs must be included in the relevant market as Opana ER

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

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

The actual impact of generic entry largely confirmed Endo and Impax's expectations. When Impax launched generic oxymorphone ER in 2013,

Endo's reformulated Opana ER. (CCF ¶636 (*in camera*)).

(CCF ¶¶636 (*in camera*), 909). Competition from Impax resulted in substantial savings for consumers who switched to Impax's lower-cost product. (CCF ¶¶636-37). Indeed, despite not being automatically substitutable for reformulated Opana ER, generic oxymorphone ER captured .

(CCF ¶630 (*in camera*

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

3. Other LAOs exhibited little cross elas

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

The medical evidence supports this economic conclusion. Branded Opana ER and generic oxymorphone ER are the only LAOs containing the molecule oxymorphone, which has unique properties. (CCF ¶¶35, 726, 748, 755). Endo itself often touted oxymorphone's "distinct pharmacologic properties compared with most other opioids." (CCF ¶726).[13] Both medical experts agree there are differences among long-acting opioids and that it is important for prescribers to be aware of these differences. (CCF ¶¶504-10, 746-49, 759-60). And it is undisputed that different patients can respond differently to different opioid molecules in terms of effectiveness and side effects. (CCF ¶507). For this reason, opioid treatment requires trial and error to find the best molecule for a specific patient. This medical testimony makes clear that these clinical considerations

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

Instead of rebutting Professor Noll's expert analysis, Impax complains that he did not "try to calculate any cross-elasticities of demand" and merely conducted a "visual inspection" of sales trends to assess the relevant market. Opp. 54. But Professor Noll conducted exactly the type of analysis that courts have relied on to assess the relevant product market. *See SmithKline Corp. v. Eli Lilly & Co.*, 427 F. Supp. 1089, 1118-19 (E.D. Pa. 1976); *Ciprofloxacin*, *3*63 F. Supp. 2d at 522-23; *Lidoderm*, 296 F. Supp. 3d at 1174-75. And Impax's own expert agreed that it was not possible to mathematically calculate cross-price elasticities because of data limitations. (CCF ¶655; RX-547 at 0023-24 (¶42 (Addanki Report))). Indeed, as one of the leading antitrust scholars explains, the detailed econometric cal

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

Impax points to evidence that Endo provided patients with coupons or rebates to reduce their insurance copays and argues that Endo would not have done so if it were a monopolist. Opp. 46. But Impax does not identify any evidence that patients switched LAOs as a result of

DEA's additional regulations for opioids, Endo's patents, and the exclusionary rights provided by the Hatch-Waxman regulatory

Third, prior to generic entry, Endo was able to maintain a supracompetitive price for Opana ER, and a high price-cost margin, without losing sales. (CCF ¶¶895-96 (*in camera*), 909). But once generic oxymorphone ER entered, Endo could not maintain sales at this supracompetitive price: it lost approximately of its market share to Impax's much cheaper product. (CCF ¶¶630, 636 (*in camera*), 909). Impax claims that Endo must have faced

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

---

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

[16] CCF ¶¶1473-78.

[17] CCF ¶¶977-82.

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

. (CCF ¶1428). This provision disincentivizes Endo from competing itself or

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

CERTIFICATE OF SERVICE

I hereby certify that on September 12, 2018, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

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

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

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

Michael E. Antalics
Benjamin J. Hendricks
Eileen M. Brogan
O'Melveny & Myers, LLP
1625 Eye Street NW
Washington, DC 20006
ehassi@omm.com
mantalics@omm.com
bhendricks@omm.com
ebrogan@omm.com

Stephen McIntyre
O'Melveny & Myers, LLP
400 South Hope Street
Los Angeles, CA 90071
afabish@omm.com
smcintyre@omm.com

Edward D. Hassi
Debevoise & Plimpton LLP
801 Pennsylvania Ave NW
Washington, DC 20004
thassi@debevoise.com

Counsel for Respondent Impax Laboratories, Inc.

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

Counsel Supporting the Complaint

PUBLIC

CERTIFICATE FOR ELECTRONIC FILING

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

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

Notice of Electronic Service

I hereby certify that on September 12, 2018, I filed an electronic copy of the foregoing Complaint Counsel's Reply to Respondent Impax Laboratories, LLC's Answering Brief, with:

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

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

I hereby certify that on September 12, 2018, I served via E-Service an electronic copy of the foregoing Complaint Counsel's Reply to Respondent Impax Laboratories, LLC's Answering Brief, upon:

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

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

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

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

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

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

Jamie Towey
Attorney
Federal Trade Commission
jtowey@ftc.gov

Complaint

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

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

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

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

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

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

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

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

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

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

Garth Huston
Attorney

Federal Trade Commission
ghuston@ftc.gov
Complaint

I hereby certify that on September 12, 2018, I served via other means, as provided in 4.4(b) of the foregoing k <83TDlw4er lgo7ust3/tep4tsoy4i da82ee 7y1, RT*v3/t.g/,

_____