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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 IMPAX LABORATORIES, INC.'S POST-TRIAL BRIEF

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INTRODUCTION

There is only one reason patients suffering from chronic pain have access to Opana ER today: Impax Laboratories, Inc. entered into the June 2010 Settlement & License Agreement (the "SLA") at the center of this case. Impax challenged Endo Pharmaceutical's patents in the branded version of Opana ER, and took that case all the way to trial. But Impax knew Endo was pursuing more patents—and that if Endo was successful, those new patents would impede Impax's entry. So Impax struck a deal. It negotiated the SLA, which gave it a license not only to the patents-in-suit, but also to any additional patents covering Opana ER that Endo might later acquire. Under the SLA, Impax secured the right to begin selling generic Opana ER on January 1, 2013, many months before Endo's original patents expired, and to continue selling the drug without interruption, no matter how many additional patents Endo obtained.

The SLA has been a boon for consumers. In the years following the settlement, Endo obtained several more patents covering Opana ER, just as Impax anticipated. Endo has successfully enforced those patents against other drug companies that have sought to sell generic Opana ER. Those companies are now subject to a permanent injunction preventing them from selling generic Opana ER until 2029, when the last of Endo's patents expires.

But not Impax. As a direct result of the SLA, Impax has been selling generic Opana ER on a continual basis for the past five years. In fact, Impax is currently the ***only*** company supplying any version of Opana ER, branded or generic. Absent the SLA, there is no plausible scenario in which Impax would have entered the market as early as it did, or been able to sell generic Opana ER for as long as it has. Consumers have reaped the benefit, since they have had uninterrupted access to a low-cost generic version of Opana ER for the past five years—and will continue to have that benefit for years to come.

Complaint Counsel would have this Court ignore these concrete, real-world consumer benefits. In fact, Complaint Counsel does not want to talk about the real world at all. It alleges that two agreements between Impax and Endo—the SLA, as well as a separate business collaboration called the Development & Co-Promotion Agreement (the "DCA"), under which Impax and Endo agreed to jointly develop and co-promote a new Parkinson's disease treatment—together constitute an anticompetitive "reverse-payment" settlement. At no point in trial, however, did Complaint Counsel put on evidence of actual competitive harm. In fact, ***Complaint Counsel claims it does not have to show that the SLA and DCA harmed consumers***,[1] and even asked the Commission to bar Impax's evidence of procompetitive benefits.[2] The Commission rightly denied that motion, holding that the analysis must "proceed under the rule of reason," and that Impax was allowed to demonstrate at trial that the settlement was procompetitive. Opinion and Order of the Commission at 8, 11–13, *In re Impax Labs., Inc.*, No. 9373 (F.T.C. Oct. 27, 2017) [*hereinafter* "Comm'n Decision"].

Analysis of actual competitive effects is the essence of the rule of reason. As the Supreme Court held in *FTC v. Actavis Inc.*, 133 S. Ct. 2223 (2013), the "basic question" is whether the challenged restraint caused "significant unjustified anticompetitive consequences." *Id.* at 2237–38. Or as Justice Brandeis put it nearly a century ago, the rule of reason asks "whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition." *Bd. of Trade of*

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[1] (*See* Compl. Counsel's Reply in Support. of Mot. for Partial Summ. Dec. at 9, No. 9373 (F.T.C. Sept. 15, 2017) [*hereinafter* "Summ. Dec. Reply"] (arguing that Complaint Counsel need not offer "proof that the agreement 'actually delayed generic competition or resulted in any actual harm to consumers'").)

[2] (*See* Compl. Counsel's Mot. for Partial Summ. Dec. at 15, No. 9373 (F.T.C. Aug. 3, 2017) [*hereinafter* "Summ. Dec. Mot."] (arguing that post-settlement effects should be excluded from rule of reason analysis).)

City of Chi. v. United States, 246 U.S. 231, 238 (1918). To answer that question in this case, this Court must look to how the SLA "actually operates in the market." *Jefferson Par. Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 29 (1984). In other words, this Court must examine the very evidence Complaint Counsel tried to exclude: how competition and consumers have actually fared under the SLA.

This Court should enter judgment for Impax for the following reasons:

***First*, Complaint Counsel did not prove that Impax received a "large and unjustified" payment under the DCA or the SLA.** *Actavis*, 133 S. Ct. at 2237. Impax received just $10 million pursuant the DCA, an amount entirely justified by the valuable profit-sharing rights Endo received in exchange. Dr. Robert Cobuzzi, a Parkinson's disease expert who led the Endo team that evaluated the DCA, concluded that the profit-sharing rights justified Endo's payment obligations. (Respondent Impax's Findings of Fact and Conclusions of Law ("FOF") ¶ 421; Cobuzzi, Tr. 2564.) Dr. Cobuzzi's team devoted significant resources to evaluating the DCA, and described it to Endo's senior management and Board of Directors as a "good deal" and an "exciting opportunity" for the company. (FOF ¶¶ 427–428; CX1209; CX2748; Cobuzzi, Tr. 2545–46, 2549–50).) In particular, Endo concluded that the expected revenues would represent a "very reasonable" internal rate of return. (FOF ¶ 433; Cobuzzi, Tr. 2560; RX-080.) Complaint Counsel did nothing to rebut Endo's valuation. Nor did Complaint Counsel proffer its own valuation of the bundle of rights Endo received; its experts could not even say whether Endo overpaid for those rights. (FOF ¶¶ 502–03, 1419; Geltosky, Tr. 1125; Noll, Tr. 1590.)

Complaint Counsel also failed to show that Impax received a large payment under the SLA. Complaint Counsel contends that two terms—the "Endo Credit" and "No-Authorized

Generic" ("No-AG") provisions—guaranteed a payment to Impax. But as the agency's experts conceded at trial, neither term resulted in a payment at the time of the settlement, and neither term ensured a future payment to Impax. (*See* FOF ¶ 644.) Whether and to what extent Impax (or Endo) might derive any value under those provisions depended on future events that Impax could neither foresee nor control. (FOF ¶ 1421.) There was a distinct possibility that Impax might end up with ***nothing***. (*See, e.g.,* FOF ¶¶ 569, 576, 632.)

To determine whether Impax received any "payment" under these terms at the time of the settlement, one would have to perform an "expected value" calculation that accounts for the probabilities that these various contingencies would actually occur. (FOF ¶ 570, 1532; Noll, Tr. 1613; Addanki, Tr. 2384; Bazerman, Tr. 890, 924.) Complaint Counsel's economic expert, Dr. Roger Noll, conceded as much—but notably did not do ***any*** expected value calculations himself. (FOF ¶ 1423; Noll, Tr. 1590.) Absent proof of the expected value of the challenged SLA terms, Complaint Counsel cannot maintain—and this Court cannot find—that they conveyed a "large and unjustified" payment to Impax in June 2010.

Second, **Complaint Counsel failed to prove that Endo possessed monopoly power in a properly defined relevant market.** Complaint Counsel's allegation that the relevant market is limited to branded and generic versions of Opana ER cannot be squared with "the realities of competition." *FTC v. Whole Foods Mkt, Inc.*, 548 F.3d 1028, 352 (D.C. Cir. 2008) (quoting *Weiss v. York Hosp.*, 745 F.2d 786, 826 (3d Cir. 1984)). Those realities—as reflected in internal business documents, fact witness testimony, and real-world practice, and as confirmed by expert analyses—show that Opana ER competed against numerous other long-acting opioids ("LAOs") in the relevant market. (FOF ¶¶ 788, 796; Bingol, Tr. 1271, 1313; Addanki, Tr. 2259; CX2610-024; *see* Noll, Tr. 1512.)

Complaint Counsel's medical expert, Dr. Seddon Savage, and Impax's medical expert, Dr. Edward Michna, agreed that all LAOs are used to treat chronic pain, that doctors have a range of LAO options when treating a patient for the first time, that all LAOs are similarly safe and effective, and that there is no discernible population of patients and no medical condition for which Opana ER (or any other LAO) is the only or best option. (FOF ¶¶ 933–35; *see* Savage, Tr. 791; Michna, Tr. 2149.) This is borne out by actual prescribing data, which shows that different LAOs are used with comparable frequency in treating dozens upon dozens of the most common pain diagnoses. (FOF ¶ 720; Addanki, Tr. 2245–47; RX-547 (Addanki Rep ¶ 64).) There can be no dispute that Opana ER and other LAOs are "reasonably interchangeable by consumers for the same purpose": to treat chronic pain. *United States v. E.I. Du Pont de Nemours & Co.*, 351 U.S. 377, 395 (1956).

Unrebutted evidence shows that LAO manufacturers competed vigorously. Internal business documents produced by Endo and other companies consistently analyzed the "LAO market," in which a number of "significant competitors" vied for position. (FOF ¶¶ 795, 799, 807, 812; RX-112 at 5; RX-073.0002 at 39; RX-449 at 7.) Impax put on evidence of price competition at every layer of the pharmaceutical industry, demonstrating that LAO manufacturers competed for insurance coverage, patients, and physicians' prescriptions. (FOF ¶¶ 792, 818–20, 878, 899–00; Bingol, Tr. 1284–85, 1324–25; Addanki, Tr. 2224, 2268, 2280.) And Impax showed that patients can and do switch between LAOs in response to changes in relative price. Most significantly, when an insurer preferences one LAO over another on its formulary—thereby reducing patients' out-of-pocket costs for the preferred drug—patients flock to the preferred LAO. (FOF ¶ 60; Bingol, Tr. 1320–22; *see* Michna, Tr. 2146; Addanki, Tr. 2217–18; Noll, Tr. 1552.)

The evidence supports just one conclusion: the relevant market is no narrower than all LAOs. (FOF ¶ 695; Addanki, Tr. 2328.) Endo never even approached a 10% share of this market—woefully inadequately to constitute monopoly power. (FOF ¶ 1002; Addanki, Tr. 2333; RX-547.0132.) Because the settlement cannot be anticompetitive if Endo lacked monopoly power, Complaint Counsel's claims must fail.

Third, **Complaint Counsel failed to prove any actual anticompetitive effects.** The rule of reason is "an inquiry into the actual effect" of a challenged restraint. *Jefferson Par.*, 466 U.S. at 29. Complaint Counsel abdicated its burden under this rule; its experts could not say whether Impax would have launched generic Opana ER any sooner in the but-for world, whether some alternative settlement was possible between Impax and Endo, or even whether consumers were better or worse off under the SLA. (FOF ¶¶ 1382, 1386–88, 1391, 1393–94, 1458, 1496–1499; Hoxie, Tr. 2768, 2769–70, 2808, 2910; Noll, Tr. 1596–97, 1600–01, 1648; Bazerman, Tr. 897, 929.)

Rather than put on evidence of competitive effects, Complaint Counsel relied on a "three-part test" proposed by Dr. Noll, which has never been published, peer-reviewed, or endorsed by any court. (FOF ¶¶ 1406–1407; Noll, Tr. 1642.) Under this rule, ***every*** settlement that includes an "unjustified" payment and even a single day of "delay" is conclusively deemed anticompetitive—reflecting Dr. Noll's long-held opinion that "large, unexplained reverse payments are inherently anticompetitive." (CX5004 (Noll Rebuttal Rep. ¶ 138).) While Dr. Noll and Complaint Counsel may feel that way, the Supreme Court does not. *See Actavis*, 133 S. Ct. at 2237–38. As the Commission explained in denying Complaint Counsel's Motion for Partial Summary Decision, *Actavis* holds that "anticompetitive effects should not be presumed from the mere presence of a reverse payment." Comm'n Decision at 8.

Complaint Counsel did not offer a shred of evidence purporting to show that the SLA actually reduced competition or harmed consumers, and its hired experts disclaimed any opinion of what likely would have happened in the "but-for" world. Any claim that Impax would have sold generic Opana ER earlier or that consumers would have had the benefit of more generic Opana ER if Impax had not settled with Endo is pure speculation. It is also incompatible with real-world evidence showing that, had Impax continued litigating instead of entering the SLA, it would have been mired in patent litigation until well beyond January 1, 2013—and, in all likelihood, would be subject to an injunction preventing it from selling generic Opana ER until 2029, just as other generic companies are today.

Because Complaint Counsel did not put on evidence of the SLA's actual competitive effects, it has not satisfied its initial burden under the rule of reason.

***Fourth*, the settlement's real-world procompetitive benefits outweigh any alleged anticompetitive effects.** Even if Complaint Counsel had proven anticompetitive effects, its claims would still fail because it cannot refute that the settlement caused significant overriding procompetitive benefits. Impax presented unrebutted evidence that consumers were better off under the SLA than they would have been in any conceivable but-for world.

Recognizing that Endo was actively pursuing additional patent protection for Opana ER, Impax negotiated settlement terms that gave it a license to both existing and future patents. Between June 2010 and January 2013, Endo obtained ***three*** additional patents covering Opana ER—which Endo promptly enforced against all other companies that had applied to sell generic Opana ER, including several with which Endo had previously settled. (FOF ¶¶ 233, 1092; JX-001-012 (¶ 55); Snowden, Tr. 441–42.) In 2014, when Endo obtained two more patents, it brought yet another round of litigation against the other generic companies. (FOF ¶¶ 245–46,

249; JX-001-013 (¶¶ 59–60); Snowden, Tr. 451.) Those patent cases have lasted for years, and so far, two district courts have upheld Endo's patents and permanently enjoined generic companies from selling generic Opana ER. (FOF ¶¶ 251–52, 1097; JX-001-013 (¶ 64); *see* Snowden, Tr. 441; RX-575 (not admitted or cited for the truth).) The last of Endo's patents do not expire until 2029. (FOF ¶ 1099; Snowden, Tr. 451; Figg, Tr. 1965–66; *see* CX3255.)

The settlement agreement at the center of this case is the ***only*** reason Impax was able to begin selling generic Opana ER at that early date, and it is the ***only*** reason consumers have access to any Opana ER product today. Complaint Counsel has not even suggested a hypothetical world in which consumers would have had access to generic Opana ER earlier, or for a longer period of time, than they did in the real world. This is concrete, unrebutted evidence that the settlement was procompetitive.

Fifth, **Complaint Counsel did not even attempt to show that a less restrictive alternative would have been possible.** In the event this Court reaches this step in the rule of reason analysis—and it should not, as Complaint Counsel has not proven a large and unjustified payment, monopoly power, or anticompetitive effects—Impax would still prevail. Far from identifying a "substantially less restrictive" alternative to the SLA and proving that it was feasible, Complaint Counsel's experts could not say that any alternative settlement was even ***possible***. (FOF ¶¶ 1458, 1465; Noll, Tr. 1596–97, 1648.) That does not cut it. *See Toscano v. PGA Tour, Inc.*, 201 F. Supp. 2d 1106, 1123 (E.D. Cal. 2002) ("speculat[ion]," unsupported by even a "scintilla of evidence," did not satisfy plaintiff's burden of proving that less restrictive alternative was possible).

Finally, **the remedies sought by Complaint Counsel are improper.** Because Complaint Counsel cannot succeed on the merits of its claims, this Court need not consider the

question of remedies. But it is nonetheless clear that Complaint Counsel's requested remedies do not bear any reasonable relationship to the conduct alleged in this case. Far from being tailored to the facts of this case, they are an overbroad patchwork derived from FTC settlements with other drug makers. These remedies should be denied as a matter of law.

* * *

This is not a close case. Complaint Counsel abjectly failed to meet its burden of showing that Impax received a "large and unjustified" payment, that Endo possessed monopoly power in the relevant market, that the Impax/Endo agreements caused actual anticompetitive effects, or that any less restrictive alternative was feasible. Impax presented compelling, real-world evidence that consumers and competition fared far better under the agreements than would otherwise have been the case. This Court should enter judgment for Impax.

FACTS

I. The Settlement & License Agreement Resolved Patent Litigation Concerning Impax's Generic Opana ER.

A. Impax was the First Company to File an Abbreviated New Drug Application for the Primary Dosage Strengths of Opana ER.

Opana ER (Oxymorphone Hydrochloride) is an extended-release opioid medication for the treatment of chronic pain. (FOF ¶¶ 84, 86; JX-001-006 (¶ 3); (JX-001-006 (¶ 5).) Endo began marketing Opana ER in 2006. (FOF ¶ 89; JX-001-006 (¶ 6).)

In June 2007, Impax filed an Abbreviated New Drug Application ("ANDA") for a generic version of Opana ER. (FOF ¶ 94.) Impax was the first to file an ANDA for the five primary dosages of the drug (5mg, 10mg, 20mg, 30mg, and 40mg). (FOF ¶ 96; JX-001-007 (¶ 13); Snowden, Tr. 353-54, 414.) [redacted] of all Opana ER sales. (FOF ¶ 99; JX-001-007 (¶ 13).) Several other generic companies subsequently filed ANDAs for Opana ER, including Actavis South Atlantic LLC ("Actavis"). (FOF ¶ 100.) Actavis was first to

file an ANDA for the two remaining strengths of Opana ER (7.5mg and 15mg), although its ANDA covered all dosage strengths. (FOF ¶ 101.)

B. Endo Sued to Block Impax's Sale of Generic Opana ER.

At the time Impax filed its ANDA, Endo had listed three patents covering Opana ER in the FDA's "Orange Book."[3] (FOF ¶¶ 94–95; JX-001-007 (¶ 12).) In December 2007, Impax notified Endo that it filed "Paragraph IV" certifications with respect to three of those patents: U.S. Patent Nos. 5,662,933 (the "'933 patent"), 5,958,456 (the "'456 patent"), and 7,276,250 (the "'250 patent"). (FOF ¶ 102; *see* CX2714 (Impax's notice to Endo of Paragraph IV certification).)

Based on those certifications, Endo sued Impax in January 2008. (FOF ¶ 103; JX-001-007 (¶ 15).) Endo's suit claimed infringement of the '933 and '456 patents, both of which would not expire until September 2013. (FOF ¶ 103; JX-001-007 (¶ 15).) Endo also sued Actavis and all other Opana ER ANDA filers, alleging patent infringement as a result of their respective ANDAs pursuant to the Hatch-Waxman Act. (FOF ¶ 113.) Endo eventually settled all of these suits. (FOF ¶ 114.)

C. Impax and Endo Began Settlement Negotiations in 2009.

Impax and Endo first attempted to settle their patent dispute in the fall of 2009. (FOF ¶ 118; *see* RX-359; RX-285.) During those preliminary discussions, Impax sought the earliest possible license date that would allow it to sell generic Opana ER free from patent risk. (FOF ¶ 126; Snowden, Tr. 430; Koch, Tr. 235; *see* CX4014 (Hsu, IHT 36–37) ("when we started

[3] The FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* is colloquially referred to as the "Orange Book." When an NDA is approved and patent information is submitted by the NDA holder, the FDA publishes the patent information for the approved branded drug in the Orange Book. 21 C.F.R. § 314.53.

discussion with Endo, to me, the most important thing is we want to see whether we could get agreement to launch the product, as early as possible").) At the time, Impax was aware that Endo had settled its litigation against Actavis on terms that included a July 2011 license date, but notably did not cover Endo's pending patents. (FOF ¶¶ 115, 147; Snowden, Tr. 370–71; *see* RX-398.0001 (noting that Endo was "banking on [its] pending patents").)[4] Impax pushed Endo for a comparable entry date, but Endo rejected Impax's proposal. (FOF ¶¶ 133, 135; Snowden, Tr. 371–74, 423.) Endo maintained that it would only consider a license date between the date an appeal of the patent litigation would likely be decided and the expiration of the patents-in-suit, a date Endo eventually calculated as March 2013. (FOF ¶ 136; Snowden, Tr. 419.)

D. Impax and Endo Settled After Trial Commenced.

Impax and Endo reinitiated settlement discussions in May 2010. (FOF ¶ 120; Snowden, Tr. 418; *see* RX-333 (Endo's initial term sheet).) The parties were on the eve of trial, and expected the 30-month stay imposed by the Hatch-Waxman Act[5] to expire in June 2010. (FOF ¶¶ 108–09, 120, 1221; JX-001-007 (¶¶ 15–16); *see* Snowden, Tr. 417–18); 21 U.S.C. § 355(j)(5)(B).) Impax approached these settlement talks with two principal goals: **(1)** obtain the earliest possible entry date, and **(2)** obtain a license to all current and future Endo patents so that Impax could sell generic original Opana ER without patent risk. (FOF ¶¶ 126, 152; Snowden, Tr. 430; RX-333.0005; Koch, Tr. 235; CX4014 (Hsu, IHT at 36–37).) On June 8, 2010, two

[4] Because Impax was the first to file an ANDA for the primary dosage strengths of Opana ER, Actavis's license date effectively applied only to the 7.5mg and 15mg strengths for which Actavis was first to file. (FOF ¶ 116; CX4034 (Rogerson, Dep. 13).)

[5] When an ANDA filer makes a Paragraph IV certification, the brand company can immediately sue for patent infringement. 35 U.S.C. § 271(e)(2)(A). If the brand company sues within 45 days of receiving notice of the Paragraph IV certification, the Hatch-Waxman Act provides that the FDA generally cannot grant final approval to the ANDA for a period of 30 months. 21 U.S.C. § 355(j)(5)(B)(iii).

days into trial, the parties executed a settlement, the SLA, which accomplished both of Impax's goals. (FOF ¶¶ 143–144, 155, 157; JX-001-009-10 (¶ 35); Koch, Tr. 236; Mengler, Tr. 566–67.) The SLA is one of the agreements Complaint Counsel challenges in these Part III proceedings.

II. The Terms of the Settlement & License Agreement.

A. The SLA Included the Earliest License Date Impax Could Obtain from Endo and a Broad Patent License.

Impax sought and obtained the earliest entry date Endo would permit. (FOF ¶¶ 127–31; 143–44; Mengler, Tr. 524–26, 564, 566–567; CX4030 (Hsu, Dep. 77, 116); CX4026 (Nguyen, Dep. 160).) Endo proposed a licensed entry date of March 2013 in its initial term sheet. (FOF ¶ 137; *see* RX-333.) Throughout the parties' settlement discussions, Endo steadfastly refused to consider any date before 2013. (FOF ¶ 139; *see* Noll, Tr. 1599–1600 ("Impax's attempt to get an earlier date met with complete resistance.").) Through aggressive negotiation, Impax secured the earliest entry date it could within the post-2013 window that Endo insisted upon: January 1, 2013. (FOF ¶¶ 140, 143–44; Mengler, Tr. 566; *see* Noll, Tr. 1598.)[6]

An early entry date was not enough, however. If the license covered some but not all patents blocking Impax's entry, the licensed entry date would be illusory. (*See* FOF ¶¶ 150–151.) Because Impax is "incredibly conservative" (FOF ¶ 149 (quoting CX4021 (Ben-Maimon, Dep. 34))), as a matter of course in settlement negotiations, Impax seeks a license to all patents covering the drug at issue, including all future patents. (FOF ¶¶ 150–51; *see* CX4026 (Nguyen, Dep. 155–58); CX4014 (Hsu, IHT 116).) This was particularly important in the Endo settlement

[6] The license allowed Impax to sell its generic version of Opana ER free from all patent risk beginning on January 1, 2013, or the earlier of **(1)** a final federal court decision holding all asserted and adjudicated claims of the patents at issue to be invalid, unenforceable, or not infringed by a generic version of Opana ER; or **(2)** the withdrawal of the patents at issue from the Orange Book. (FOF ¶ 141; JX-001-009 (¶ 34); CX2626 (executed settlement agreement); Snowden, Tr. 370.)

talks, since Impax knew that Endo had pending applications for additional patents related to Opana ER. (FOF ¶ 146; RX-398.0001; RX-568.0001; Mengler, Tr. 571–72; Snowden, Tr. 440, 442–43.) Impax thus fought for, and successfully negotiated, a license that covered both the original patents-in-suit and any pending or later-acquired patents "that cover or could potentially cover the manufacture, use, sale, offer for sale, importation, marketing or distribution of products . . . that are the subject of the Impax ANDA." (FOF ¶¶ 154–55 (quoting JX-001-009-10 (¶ 35)); *see* Snowden, Tr. 439; CX2626-009 (executed SLA).)

The SLA's broad license and early entry date meant that Impax could (and did) launch its generic version of Opana ER, free from patent risk, nine months before the expiration of Endo's original patents-in-suit, and 16 years before the expiration of additional patents that Endo later acquired. (FOF ¶ 1448; Figg, Tr. 1972–72; *see* Noll, Tr. 1674; RX-548 (Figg Rep. ¶¶ 112, 130–31, Ex. C).) Impax is the ***only*** ANDA filer for generic Opana ER to obtain a settlement that included a license to patents other than those originally listed in the Orange Book. (FOF ¶ 1442.)

B. The SLA Included "Endo Credit" and Royalty Provisions Intended to Encourage Endo to Support Original Opana ER.

At the time of the settlement talks, Impax was concerned Endo might have plans to shift demand from original Opana ER to a reformulated version of the drug, a tactic pharmaceutical companies sometimes employ to prolong their branded franchises. (FOF ¶ 174; CX0217-001; *see* Snowden, Tr. 433–34; Mengler, Tr. 569–70; CX4017 (Levin, Dep. 118).) Impax wanted to sell as much generic Opana ER product as possible, and that would be more difficult if Endo attempted to shift the market. (FOF ¶ 176; Mengler, Tr. 526-27, 528.) Impax informed Endo of its suspicion that Endo had "a secret plan to damage the market." (FOF ¶ 177 (quoting CX0217-001); *see* Mengler, Tr. 580; CX4012 (Donatiello, IHT 125, 151–52).) Endo "categorically

denied" the existence of any such strategy. (FOF ¶ 178 (quoting Mengler, Tr. 570, 580).)

Rather than take Endo's assurances on faith, Impax sought additional contractual terms that would help Impax hold Endo to its word. (FOF ¶ 180; Mengler, Tr. 580; Snowden, Tr. 432–33.) Impax initially proposed a "market degradation" trigger, which could accelerate Impax's licensed entry date if original Opana ER sales fell below a certain threshold. (FOF ¶ 181; Koch, Tr. 237–38; Snowden, Tr. 432; Mengler, Tr. 532; RX-318.0001.) Endo refused to entertain a market degradation trigger, considering it a "nonnegotiable" concept, even though Impax pressed the issue "very hard." (FOF ¶ 182 (quoting Koch, Tr. 314–16); *see* Snowden, Tr. 432; Mengler, Tr. 581.) The parties then devised another provision—the Endo Credit—to serve a similar purpose. (FOF ¶ 184; Koch, Tr. 236–37, 240–41.)

The Endo Credit term penalized Endo if Opana ER sales dropped below a certain threshold. (FOF ¶ 185; *see* CX2626-003–04.) Specifically, the Endo Credit required Endo to pay a penalty if original Opana ER sales in the last quarter of 2012 were less than 50% of their quarterly peak. (FOF ¶ 185.) The amount of the penalty was determined by multiplying a "Market Share Profit Value"—defined with reference to quarterly peak sales—by the number of percentage points that sales fell below 50%. (FOF ¶ 185.) If, for example, Opana ER sales were 45% of their quarterly peak in December 2012, the penalty would be equal to five times the Market Share Profit Value. (FOF ¶ 186; *see* CX2626-003.) The prospect of a penalty was meant to incentivize Endo to continue to support its original Opana ER product, and thereby protect Impax's ability to sell as much of its generic Opana ER product as possible with the benefit of automatic substitution. (FOF ¶ 187; Koch, Tr. 241; Snowden, Tr. 386.)

Conversely, the SLA's royalty term would reward Endo if it kept its word and grew Opana ER sales. (FOF ¶ 196; CX2626-012; Snowden, Tr. 393; Koch, Tr. 241.) In particular,

Impax agreed to pay a royalty of 28.5% on a portion of its sales if branded Opana ER sales rose above a certain threshold. (FOF ¶ 196.) The royalty provision functioned as an "Impax Credit." (Court, Tr. 614; *see* FOF ¶¶ 195–96.) As Roberto Cuca, Endo's former Vice President of Financial Planning and Analysis, testified at trial, the contingent royalty was "the mirror image of the Endo Credit," incentivizing Endo to grow sales of its original Opana ER product. (FOF ¶ 195 (quoting Cuca, Tr. 613–14).)

Whether and how much Endo would be required to pay under the Endo Credit term depended on Endo's actions and external market forces beyond either party's control. (FOF ¶ 572; Cuca, Tr. 629.) Impax could not control Endo's sales. (FOF ¶¶ 593; Addanki, Tr. 2354-56; Noll, Tr. 1612.) At the time of the settlement, Impax realized that Endo could orchestrate its transition to a reformulated product in a way that avoided any payment under the Endo Credit. (FOF ¶ 576; *see* Mengler, Tr. 583, 589–90; CX4032 (Snowden, Dep. 204–06); CX4002 (Smolenski, IHT 128–30).) Indeed, although Endo was in fact planning a reformulation, it did not expect to make a payment under the Endo Credit term. (FOF ¶¶ 585, 590; Cuca, Tr. 629–31, 673; Noll, Tr. 1649; CX4017 (Levin, Dep. 99-100).) During settlement talks, neither party attempted to forecast under what circumstances the Endo Credit would actually result in any payment, or in what amount. (FOF ¶¶ 583, 585; Mengler, Tr. 582; CX4038 (Engle, Dep. 187–88); *see* CX4017 (Levin, Dep. 96–98); Noll, Tr. 1649.)

Impax's preference was for Endo to preserve and even grow sales of original Opana ER. (FOF ¶ 577; *see* Reasons, Tr. 1226.) In that event, Endo would not be required to pay Impax anything, though Impax might be obligated to pay Endo a royalty. (FOF ¶¶ 575–77; Reasons, Tr. 1226; CX4014 (Hsu, IHT 89, 165–66); CX4002 (Smolenski, IHT 204–05).) Impax preferred this outcome because its executives believed that launching generic Opana ER free from patent

risk and with the benefit of automatic substitution would best serve the company's shareholders, creating a sustainable revenue stream rather than a single lump sum payment. (FOF ¶¶ 577–79; Reasons, Tr. 1226; CX4014 (Hsu, IHT 89, 165–66).)

The parties' negotiation history demonstrates that the Endo Credit term was not in any way intended as a "payment" to delay Impax's licensed entry date. (FOF ¶¶ 571, 612; Mengler, Tr. 567; Cuca, Tr. 666.) The concept of the Endo Credit arose on or around June 1, 2010, by which time the parties had already been negotiating entry dates for some time. (FOF ¶ 613; *see* RX-333 (Endo's initial term sheet with no Endo Credit provision); CX4017 (Levin, Dep. 117) (Endo's initial offer included March 2013 entry but no Endo Credit); RX-386 (June 1, 2010 Mengler email describing status of negotiations).) Endo had originally proposed a March 2013 entry date; by June 1, 2010, Impax had succeeded in moving that up to February 2013. (FOF ¶ 140; Mengler, Tr. 566; *see* Noll, Tr. 1598.) After the Endo Credit was proposed, Impax negotiated an even ***earlier*** entry date of January 1, 2013. (FOF ¶ 614; *see* CX2626 (executed SLA including Endo Credit and January 1, 2013 license date).) In other words, the licensed entry date only got earlier, not later, after the parties devised the Endo Credit. (FOF ¶ 614.)

C. The SLA Included a Co-Exclusive License Term That Was Not the Subject of Any Significant Negotiation.

The SLA also contained a co-exclusive license provision—colloquially referred to as a "No-Authorized Generic" or "No-AG" provision—whereby Endo agreed not to "sell, offer to sell, import, or distribute any generic version of products that are the subject of the Opana NDA," or to license or authorize a third party to do the same, during Impax's 180-day exclusivity period. (FOF ¶ 199; (quoting CX2626-010–11 (SLA § 4.1(c))).) This meant that while Endo could not sell or license an "authorized generic" version of Opana ER until the end of the 180-day exclusivity period, it could continue to sell original Opana ER under its branded

label in competition with Impax's generic product, and could continue to price the brand product as Endo saw fit. (FOF ¶¶ 199–200; CX2626-010–11 (SLA § 4.1(c)).)

The No-AG term was not the subject of any meaningful negotiation. (FOF ¶ 201; Snowden, Tr. 428–29; Mengler, Tr. 567.) Endo simply included the term in the first term sheet it sent to Impax in May 2010. (FOF ¶ 202; Snowden, Tr. 428–29; *see* RX-333 (Endo's initial term sheet); RX-318.0001 (Impax's first counterproposal).) Impax accepted the term without discussion, and remained focused on its core objectives of negotiating the earliest possible entry date and broad patent license. (FOF ¶ 625–626; Mengler, Tr. 528–29; CX4030 (Hsu, Dep. 76–77).) The record shows that Endo was willing to offer the No-AG provision because it never expected to launch an authorized generic version of Opana ER in the first place. (FOF ¶¶ 616–20; Bingol, Tr. 1338–39; CX4019 (Lortie, Dep. 118–19); CX4031 (Bradly, Dep. 198); *see* Bingol, Tr. 1337 ("I don't recall specific forecasts about an authorized generic.").) And, as with the Endo Credit, the parties' negotiation history indicates that there was no connection between the No-AG provision and Impax's licensed entry date. (FOF ¶¶ 628–31; RX-333 (initial term sheet including No-AG and March 2013 license date); CX2626 (executed settlement agreement with No-AG and January 1, 2013 license date); Mengler, Tr. 567; CX4017 (Levin, Dep. 156–57).)

III. Post-Settlement Events Relevant to the SLA.

Two sets of post-settlement events are relevant to the SLA. For one, the settlement agreement allowed Impax to launch its generic Opana ER product in January 2013 and to stay on the market without interruption, despite Endo's acquisition and aggressive prosecution of additional patents. Moreover, unexpected market events unfolded in 2012 such that Endo incurred a liability to Impax under the Endo Credit, resulting in a payment to Impax in 2013.

A. Endo Introduced a Reformulated Opana ER Product Earlier Than It Initially Planned.

A month after the parties executed the SLA, Endo announced that it had submitted a New Drug Application ("NDA") for what it described as a "crush-resistant" formulation of Opana ER, purportedly intended to reduce opioid abuse by preventing individuals from crushing and snorting Opana ER pills. (FOF ¶ 204; JX-001-011 (¶ 48); CX3189.) Contemporaneous documents indicate that Impax was surprised by the announcement, given Endo's representations during settlement negotiations that it had no such plan. (FOF ¶ 207 (quoting CX0117 ("So much for 'Chris, I promise we have no plans to not continue to pursue our existing formulation.'")).)

The FDA approved Endo's NDA for all dosage strengths of reformulated Opana ER in December 2011. (FOF ¶ 208; JX-001-011 (¶ 48).) Endo initially did not plan to launch reformulated Opana ER until the end of 2012, which would have limited—and perhaps even avoided—any liability under the Endo Credit. (FOF ¶ 209; RX-094.0003.) But Endo accelerated the launch of its reformulated product when Novartis was forced to temporarily shut down the plant at which it manufactured the original Opana ER product for Endo. (FOF ¶ 210; CX4017 (Levin, Dep. 136–39).) This unexpected shutdown, which was precipitated by an FDA Warning Letter, created a "supply chain crisis" for original Opana ER. (FOF ¶ 211 (quoting CX4017 (Levin, Dep. 136–39)); *see* RX-094.0003-04; RX-563.0001; RX-139.0001).) As a result, Endo stopped marketing the original formulation of Opana ER in February 2012, and launched its reformulated product in March 2012. (FOF ¶¶ 212–13; CX4017 (Levin, Dep. 138–39).) The FDA then ordered Endo to stop selling any remaining inventory of original Opana ER, so as to avoid creating consumer confusion with reformulated Opana ER. (FOF ¶¶ 213–214; CX4017 (Levin, Dep. 138–39, 155); RX-100.0001; RX-094.0004.) On May 31, 2012, Endo asked the FDA to move original Opana ER to the Orange Book Discontinued List. (FOF ¶ 215;

JX-001-012 (¶ 50); CX1220; CX3241.)

B. Endo Made a Payment under the Endo Credit That Was Unexpected and Impossible to Predict at the Time of Settlement.

Endo ultimately paid Impax $102 million under the Endo Credit in 2013. (FOF ¶ 220; JX-001-011 (¶ 46).) Whether Endo would end up making a payment, and the specific amount of any payment, were impossible to predict at the time of settlement. (FOF ¶ 1425; Addanki, Tr. 2354–56.) In fact, Endo had no expectation in June 2010 that it would make any payment to Impax. (FOF ¶ 590; CX4017 (Levin, Dep. 99–100).) The fact and size of the Endo Credit payment were instead the result of subsequent events outside Impax's and Endo's control, including **(1)** unexpected growth in Opana ER sales, and **(2)** the Novartis supply chain disruption that accelerated Endo's withdrawal of original Opana ER. (FOF ¶ 593; Addanki, Tr. 2354–56.)

In mid-2010, the most optimistic industry analysts forecasted that sales of Opana products could grow by as much as 35% on an annual basis. (FOF ¶ 597.) Others projected a decline in sales. (FOF ¶ 598.) [redacted] (FOF ¶ 599; RX-414.) From that unexpected high, sales of original Opana ER ceased altogether in mid-2012 when the FDA unexpectedly forced the Novartis plant to stop production. (FOF ¶ 601; CX4017 (Levin, Dep. 138–39, 155); RX-100.0001; RX-094.000.) This "perfect storm" of events resulted in the specific liability paid under the Endo Credit in 2013. (FOF ¶¶ 602, 1425; Addanki, Tr. 2354–56; Cuca, Tr. 665; Reasons, Tr. 1203, 1229; CX4017 (Levin, Dep. 126–30); *see* RX-039 (Endo Credit liability discovered in April 2012).)

Endo did not (and could not) estimate the possibility of a payment under the Endo Credit term until April 2012. (FOF ¶¶ 602–03; Cuca, Tr. 665, 677; Reasons, Tr. 1203, 1229; RX-039; RX-094.0003-06.) As Mr. Cuca testified at trial, the fact and amount of any Endo Credit

payment were neither "probable" nor "estimable"—prerequisites for recognizing a contingent credit or liability under generally accepted accounting principles—until after the Novartis plant shutdown. (Cuca, Tr. 664–65; *see* FOF ¶¶ 602–03; RX-95 (Endo accounting memo regarding Endo Credit liability); CX5004 (Noll Rebuttal Rep. ¶ 149) (conceding that Endo Credit was not probable or estimable until March 2012).) Accordingly, Endo did not report a liability under the Endo Credit until May 2012. (FOF ¶ 606; RX-494.0007 (Endo Form 8-K dated May 1, 2012).) The evidence shows that Endo itself was surprised that it ended up owing a payment under the Endo Credit. (FOF ¶¶ 590–92; CX4017 (Levin, Dep. 99–100, 126); Cuca, Tr. 664–65.)

C. Impax Worked to Ensure Consumers Had Access to Generic Opana ER Even After Learning It Would Receive an Endo Credit Payment.

Impax fought hard to ensure that consumers had access to a low-cost version of Opana ER, even after learning it would receive an Endo Credit payment. (FOF ¶ 221; Snowden, Tr. 476–77, 479–80.) These efforts included overcoming Endo's attempts to block Impax's market entry. First, Endo filed a citizen petition with the FDA in August 2012, arguing that the FDA should withdraw approval of any ANDA for original Opana ER because that product was allegedly less safe than reformulated Opana ER, which purportedly has abuse-deterrent properties. (FOF ¶ 222; Snowden, Tr. 476–80; CX3203 (Endo's citizen petitions).) Impax formally responded to the petition and offered scientific evidence that the discontinuation of Endo's original Opana ER was unrelated to safety or efficacy. (FOF ¶ 223; Snowden, Tr. 480.) The FDA ultimately agreed with Impax when it responded to Endo's petition in 2013. (FOF ¶ 224; JX-001-012 (¶ 51).)

Second, Endo filed a federal lawsuit against the FDA at the end of 2012, seeking an order "requiring FDA to suspend approval of any ANDAs citing Original Formulation Opana ER as the [reference listed drug] until FDA makes [the] required safety determination" in response to

Endo's citizen petition. (CX1223-028; see FOF ¶ 225; Snowden, Tr. 480–81.) Impax again intervened, this time joining the FDA and filing a motion to dismiss. (FOF ¶ 226; RX-574.) The court granted Impax's and the FDA's motions, and denied Endo's request for a preliminary injunction. (FOF ¶ 227; Snowden, Tr. 480–81.)

Finally, Endo's discontinuation of original Opana ER meant that consumers would not benefit from automatic substitution of a low-cost generic at pharmacies, because Impax's generic product was not AB-rated to Endo's reformulated Opana ER. (FOF ¶ 228; Engle, Tr. 1705.) To counteract this, in spring 2012, Impax began developing marketing and physician awareness strategies to help promote consumer access to generic Opana ER. (FOF ¶ 229; *see* CX4004 (Engle IHT 218–22); RX-347.0002; RX-394.0001.) These included market research, nationwide communications with healthcare providers, letters to pharmacists, traditional advertisements, and outreach efforts by Impax's brand detailing team. (FOF ¶ 229.)

D. Endo Acquired Additional Patents and Secured a Permanent Injunction Against All Original Opana ER ANDA Filers—Except Impax.

After settling its first round of patent litigation against Impax and all other original Opana ER ANDA filers, Endo obtained an arsenal of additional patents covering Opana ER. (FOF ¶ 233; JX-001-012 (¶ 55).) In 2012, for example, it acquired Patent No. 7,851,482 (the "'482 patent") from Johnson Matthey, and received government approval of Patent Nos. 8,309,060, 8,309,122 and 8,329,216 (the "'122 patent" and "'216 patent," respectively). (FOF ¶¶ 235, 239, 240; JX-001-012 (¶¶ 56–57).) In 2014, Endo received approval for Patent No. 8,808,737 (the "'737 patent") and licensed Patent No. 8,871,779 (the "'779 patent") from Mallinckrodt LLC. (FOF ¶¶ 245–46; JX-001-013 (¶¶ 59–60).)

Endo subsequently filed a second round, and later a third round, of infringement suits against every generic company with which it had previously settled, except Impax. (FOF ¶¶

249–50; Snowden, Tr. 450–451.)[7] Some of these companies argued that their settlements with Endo included an implied license to Endo's later-acquired patents, but the Federal Circuit rejected that position, holding that "[y]ou get what you bargain for." *Endo Pharm., Inc. v. Actavis, Inc.*, 746 F.3d 1371, 1378 (Fed. Cir. 2014); (FOF ¶ 255; Snowden, Tr. 440–41.)

Endo's new patents have proven to be formidable barriers to other ANDA filers. In the second round of patent litigation, a district court in the Southern District of New York held that the ANDA filers infringed the '122 and '216 patents and that the patents were not invalid, and permanently enjoined the ANDA filers from selling generic Opana ER until 2023. (FOF ¶ 243; JX-001-013 (¶ 62); Snowden, Tr. 441, 445–46.) And in Endo's third round of infringement litigation, a district court in the District of Delaware found that the '779 patent was not invalid and was infringed by a number of ANDA filers. (FOF ¶ 251; JX-001-013 (¶ 64).) That court permanently enjoined the defendants from selling generic Opana ER until 2029. (FOF ¶ 252.)

Absent the SLA, Impax too would have been embroiled in patent infringement litigation with Endo far beyond the licensed entry date it obtained through the SLA, and would now be enjoined from selling Opana ER until 2029. (FOF ¶¶ 253, 256; Snowden, Tr. 441–42, 451; CX3255.) In all likelihood, Impax will continue to be the sole provider of generic Opana ER until Endo's last patent expires in 2029. (FOF ¶¶ 1102, 1450; *see* Figg, Tr. 1972.)

E. Impax Is Consumers' Only Source of Any Opana ER Product.

On June 8, 2017, the FDA requested that Endo withdraw reformulated Opana ER. (FOF ¶ 258; JX-001-012 (¶ 52); RX-547 (Addanki Rep. ¶ 28); CX6048.) The FDA's decision was based on an investigation that found "a significant shift in the route of abuse of Opana ER from

[7] Endo did sue Impax for patent infringement with respect to Impax's ANDA for ***reformulated*** Opana ER, which was not covered by the SLA or its broad license. (RX-510.)

nasal to injection following the product's reformulation." (FOF ¶ 259; (quoting CX6048-001).) The FDA concluded that "the benefits of reformulated Opana ER no longer outweigh its risks" because the "injection abuse of reformulated Opana ER has been associated with a serious outbreak of HIV and hepatitis C, as well as cases of serious blood disorder (thrombotic microangiopathy)." (FOF ¶ 260; (quoting CX6048-001).) In July 2017, Endo announced that it would cease shipping reformulated Opana ER. (FOF ¶ 261; JX-001-012 (¶ 53).) As of September 1, 2017, Impax is the ***only*** company permitted to sell Opana ER—branded or generic. (FOF ¶ 1449; JX-003-008 (¶ 59) (Second Set of Joint Stipulations); Figg, Tr. 1972.)

IV. The Development and Co-Promotion Agreement.

In June 2010, Impax and Endo also executed a Development & Co-Promotion Agreement to develop a promising new Parkinson's disease treatment. (FOF ¶ 265; Snowden, Tr. 397, 398–99; Nestor, Tr. 2935; RX-365 (executed DCA).)

A. Origins of the Impax/Endo Collaboration.

Endo and Impax had discussed opportunities to collaborate on several occasions before entering into the DCA. (FOF ¶ 284; Koch, Tr. 319.) As early as 2006, Impax proposed a partnership with Penwest (Endo's development partner for Opana ER[8]) on products treating diseases of the central nervous system, including Parkinson's disease and epilepsy. (FOF ¶ 285; RX-296.0001-02.) [redacted] (FOF ¶ 286; RX-393.0014; Nestor, Tr. 2932; Koch, Tr. 318–19; CX4036 (Fatholahi, Dep. 51–52).) Later in 2009, Impax and Endo again discussed a potential business deal, and executed a non-disclosure agreement in connection with those talks. (FOF ¶ 290; Snowden, Tr. 455–56; *see* CX1816 (non-disclosure

[8] Endo acquired Penwest in September 2010. (FOF ¶ 282; RX-491.0005.)

agreement).) The parties revisited their discussions in April or May of 2010, at which point their focus narrowed to drugs treating Parkinson's disease. (FOF ¶ 291; RX-296.0001.)

Impax's brand division had focused on Parkinson's since its inception in 2006. (FOF ¶ 304; Nestor, Tr. 2929.) At that time, the "gold standard" treatment for Parkinson's—a combination of carbidopa and levodopa—was available in an immediate-release formulation that required frequent dosing and offered imperfect motor symptom control, particularly in long-time patients. (FOF ¶¶ 292–94; Nestor, Tr. 2929–30, 2938; *see* Cobuzzi, Tr. 2528–29.) Impax set out to develop an extended-release formulation of carbidopa-levodopa that would address these shortfalls. (FOF ¶¶ 307–13.) Impax first developed a drug known as Vadova, but ultimately determined that it would not be able to secure regulatory approval for the product. (FOF ¶ 307; Nestor, Tr. 2926, 2929–30.) Impax's second attempt at an extended-release Parkinson's product was known internally as IPX-066. (FOF ¶ 308; Snowden, Tr. 401; Nestor, Tr. 2930–31.) By 2010, that product—which Impax would later sell under the brand name Rytary—had reached publicly disclosed Phase III clinical trials. (FOF ¶ 308.) Like Vadova, IPX-066 was intended to better treat Parkinson's patients by allowing for less frequent dosing and more consistent motor symptom control. (FOF ¶ 310; Nestor, Tr. 2930–31; *see* RX-247.) This would provide a "significant improvement of the patient's quality of life." (FOF ¶ 311 (quoting CX4014 (Hsu, IHT at 38–39)).)

By 2010, Impax had begun efforts to develop a "next generation" of IPX-066 as well. (FOF ¶ 312; *see* RX-247 (2009 feasibility analysis).) The goal of the next-generation product, which is now known as IPX-203, was to improve upon IPX-066 by extending the drug's dosing time even further. (FOF ¶ 312; Nestor, Tr. 2935–36.) Impax hoped this new product would be part of a "Parkinson's disease franchise" and "further establish the business foundation that

[Impax] had laid out . . . with the neurology community in the Parkinson's space." (FOF ¶ 313 (quoting Nestor, Tr. 2936–37).)

When Impax and Endo began negotiating the DCA in 2010, IPX-203 was still in the early stages of development. (FOF ¶ 341.) Impax had research to support its formulation concept for IPX-203, but did not yet have clinical data. (FOF ¶ 342; Nestor, Tr. 3026–27; *see* RX-318.0001.) Impax's Chief Scientific Officer, a renowned formulator, believed the product concept was "doable," but the project was still largely unfunded. (FOF ¶ 333; RX-387.0001.) Impax projected the total cost of development for IPX-203 would be [redacted]. (FOF ¶ 343; RX-387.0001.) Impax had encountered difficulty securing funding for the project; Impax was founded as a generic drug company, and its investors have limited tolerance for the expensive research and development efforts necessary to bring a new branded drug to market. (FOF ¶¶ 471–472; Nestor, Tr. 2940, 3053.) In proposing the IPX-203 collaboration, Impax sought a partner to help shoulder these costs in exchange for a share of the profits if the drug was successfully commercialized. (FOF ¶¶ 473–75; Nestor, Tr. 2941, 3052–53.)

B. Subject Matter Experts at Endo Performed Due Diligence on the DCA and Concluded That It Was a "Good Deal."

A team headed by Endo's Senior Vice President of Corporate Development, Dr. Robert Cobuzzi, [redacted], conducted due diligence on IPX-203 before entering into the DCA. (FOF ¶¶ 383, 389; Cobuzzi, Tr. 2563; *see* RX-072.) In the course of its evaluation, Endo considered information Impax had provided regarding the IPX-203 product concept. (FOF ¶ 390; Cobuzzi, Tr. 2525–26, 2602; *see* RX-377.) This included research Impax had been gathering and analyzing since 2009, together with detailed explanations of how Impax hoped the IPX-203 product would improve upon existing Parkinson's disease therapies,

including IPX-066. (FOF ¶ 391.)

Impax also provided Endo with information on IPX-066 (Rytary). (FOF ¶ 397; Cobuzzi, Tr. 2539.) Since IPX-066 was further along the path to regulatory approval, Impax had more information about the drug. (FOF ¶ 398; Nestor, Tr. 3056.) Impax provided the IPX-066 materials to Endo because **(1)** Impax had already established a data room regarding IPX-066 when it sought a partner to market the product outside the United States, and **(2)** "the foundational aspects of what was in the data room about IPX-066 were relative to the kind of product we envisioned IPX-203 ultimately to be, which is an extended release carbidopa / levodopa formulation that would offer clinically meaningful benefit[s] over and above what the current standard of care was." (FOF ¶ 398 (quoting Nestor, Tr. 3056).) These materials aided Endo's assessment of IPX-203 "tremendously." (FOF ¶ 399 (quoting Cobuzzi, Tr. 2625).)

IPX-066 was also a good commercial proxy for assessing IPX-203, and reflected the baseline symptom control on which IPX-203 was intended to improve. (FOF ¶ 401; CX2772-001.) Endo studied materials regarding IPX-066's clinical, patent, regulatory, commercial, and legal background to "help [Endo] frame their evaluation of the market environment into which IPX-203 could be launched as a successor to IPX-066." (FOF ¶ 402 (quoting RX-376.0001).) The IPX-066 materials, coupled with Endo's experience with other Parkinson's disease treatments, indicated that IPX-203, if successfully developed, would more effectively treat Parkinson's symptoms. (FOF ¶ 403; Cobuzzi, Tr. 2634–35.) The information also suggested strong commercial opportunities for any follow-on product to IPX-066. (FOF ¶ 404; *see* RX-376.0050.)

Dr. Cobuzzi and Dr. Kevin Pong, another member of the diligence team, had significant experience with Parkinson's treatments. (FOF ¶¶ 387–88.) Endo also had institutional

knowledge, since it had previously sold a Parkinson's product and had considered investing in other Parkinson's opportunities. (FOF ¶¶ 316, 416–17; *see* Cobuzzi, Tr. 2521, 2524; CX1007-001.) This preexisting expertise aided Endo's analysis of the DCA. (FOF ¶ 416.)

Endo and its consultants calculated the DCA's net present value, determining that the deal had a "very reasonable rate of return" [redacted]. (FOF ¶ 433 (quoting Cobuzzi, Tr. 2560).) Endo generally requires a 10% rate of return on its investment before agreeing to a business collaboration. (FOF ¶ 432; Cobuzzi, Tr. 2561.) [redacted] (FOF ¶ 434.) On the basis of this analysis, Dr. Cobuzzi and his team recommended to Endo's CEO, CFO, and Board of Directors that Endo should enter the DCA. (FOF ¶ 420; Cobuzzi, Tr. 2544.) They agreed, and Endo executed the DCA on June 7, 2010. (FOF ¶ 265; *see* RX-365 (executed DCA).)

The DCA provided that if the target product were commercialized, Impax and Endo would share the profits and promotional responsibilities. (FOF ¶¶ 269–70; RX-365.) Endo was responsible for promoting to, and would receive all profits generated by, non-neurologists. (FOF ¶ 270; RX-365.) In exchange for its share of the profits, Endo agreed to help fund the development of IPX-203. (FOF ¶ 267; JX-001-010 (¶ 39).) Endo's funding obligations consisted of an initial $10 million investment, followed by additional contributions of up to $30 million, payable upon Impax's successful completion of specific milestones. (FOF ¶¶ 267–68; JX-001-010 (¶¶ 39–40).) Impax agreed to fund the remainder of the anticipated [redacted] in development costs and perform all development work. (FOF ¶ 343; Nestor, Tr. 2944.)

C. Impax Undertook and Continues to Undertake Substantial Efforts to Develop IPX-203.

After executing the DCA, Impax devoted substantial efforts to developing IPX-203. [redacted] (FOF ¶ 479; Nestor, Tr. 2970–71; *see* RX-241.) [redacted] (FOF ¶ 480.) In the course of that work, Impax determined that a new approach was necessary to achieve the IPX-203 target profile, and identified an alternative formulation that met the profile. (FOF ¶¶ 352–54.) [redacted] (FOF ¶ 481.) [redacted] (FOF ¶ 482; RX-157.0020.)

Development work on IPX-203 was temporarily put on hold when Impax encountered issues with IPX-066. (FOF ¶ 483.) Bryan Reasons, Impax's current Chief Financial Officer, explained that when IPX-066 was delayed, "resources were put to focus on the approval of [IPX-066] so that we could get that to market." (FOF ¶ 483 (quoting Reasons, Tr. 1237–38).) Impax also received an FDA Warning Letter in 2011, the resolution of which delayed all development work at Impax, including the company's work on IPX-203. (FOF ¶ 486; Nestor, Tr. 2968.)

Once the FDA Warning Letter was finally resolved in 2015, Impax returned to working on IPX-203. (FOF ¶¶ 487–88.) As of this filing, Impax has completed Phase II clinical trials for IPX-203, and will begin Phase III trials at the beginning of 2018. (FOF ¶ 491; Nestor, Tr. 2978; Reasons, Tr. 1238; Snowden, Tr. 458.)

D. IPX-203 Continues to Be A Promising Program.

IPX-203 is currently Impax's "lead compound on the brand side of [its] R&D program." (FOF ¶ 490 (quoting Reasons, Tr. 1238).) Phase II clinical trials revealed a statistically significant improvement in treatment, reducing the amount of time Parkinson's patients are without control over their motor symptoms. (FOF ¶ 492; Nestor, Tr. 2978.) The studies suggest that IPX-203 will offer an improvement of over two hours in motor symptom control as compared to immediate-release carbidopa-levodopa treatments, and one hour of improvement over IPX-066. (FOF ¶ 493; Nestor, Tr. 2984-85; *see also* RX-208.0015-16.) Michael Nestor, president of Impax's brand division, described these results as "terrific" and "clinically meaningful." (FOF ¶ 494 (quoting Nestor, Tr. 2978, 2984–85).) Indeed, he viewed an improvement of 2.3 hours of symptom control—as IPX-203 has shown in Phase II clinical trials—as a "wow" result. (FOF ¶ 495 (quoting Nestor, Tr. 2978–79).)

The FDA has granted IPX-203 a special protocol assessment, which further limits the regulatory risk associated with this already promising product. (FOF ¶ 497.) A special protocol assessment is an agreement between a pharmaceutical company and the FDA regarding the design of clinical trials. (FOF ¶ 498.) When a special protocol assessment is in place, the FDA will not question the trial designs in Phase III clinical trials. (FOF ¶ 498.)

ARGUMENT

I. Complaint Counsel Is Required to Prove That the Settlement Agreement Was Actually Anticompetitive Under the Traditional Rule of Reason.

Before trial began, Complaint Counsel filed a Motion for Partial Summary Decision in an attempt to reduce its burden under the rule of reason and prevent this Court from considering Impax's evidence of procompetitive effects. (*See* Summ. Dec. Mot.; *see also* Resp. Impax Labs., Inc.'s Opp. to Compl. Counsel's Mot. for Partial Summ. Dec. at 1–3, No. 9373 (F.T.C. Aug. 31,

2017).[9] The Commission denied that motion. *See* Comm'n Decision at 13. The Commission made clear that "the analysis should proceed under the rule of reason," and held that evidence of actual competitive effects is relevant to that analysis. *Id.* at 8, 11–13.

Complaint Counsel may not like it, but its claims are subject to the "traditional, full-fledged rule of reason standard." *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 398 n.15 (3d Cir. 2015), *cert. denied*, 137 S. Ct. 446 (2016). The fact that Complaint Counsel has fashioned its claims to allege a "reverse-payment" settlement does not change that conclusion, nor does it justify departing from the "well-mapped" rule of reason analysis. *Id.* at 411; *see id.* at 399 (*Actavis* did "not redefine . . . the already well-established rule of reason analysis"); *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 551 n.12 (1st Cir. 2016) ("*Loestrin I*") ("considerations" listed in *Actavis* "should not overhaul the rule of reason"); *In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 133 (2d Cir. 2014) (*Actavis* mandates "traditional 'rule of reason'"). To the contrary, as the Supreme Court held in *Actavis*, "the FTC must prove its case ***as in other rule-of-reason cases***." 133 S. Ct. at 2237 (emphasis added).[10]

The proper rule of reason analysis proceeds as follows.

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[9] As this Court noted at the outset of the trial, "complaint counsel, whose job it is to prosecute the case, asked the two commissioners to determine that certain of respondent's asserted procompetitive justifications for the challenged agreements in this case are invalid as a matter of law, in other words, attempting to strike defenses before the trial even began." (Court, Tr. 9.)

[10] This Court asked the parties to brief whether *Actavis* applies to this case, given that the conduct at issue took place years before the Supreme Court decided *Actavis*. Impax acknowledges that when the Supreme Court announces a rule of federal law in a civil case, "that rule is the controlling interpretation of federal law and must be given full retroactive effect . . . as to all events, regardless of whether such events predate or postdate [the Court's] announcement of the rule." *Harper v. Virginia Dep't of Taxation*, 509 U.S. 86, 97 (1993). However, as discussed in Part V, *infra*, the fact that the SLA was clearly lawful under prevailing law in June 2010—which Complaint Counsel does not dispute—means that the remedies sought by Complaint Counsel in this case are improper.

A. Complaint Counsel Is Required to Prove The Existence of a Large and Unjustified Payment From Endo to Impax.

Complaint Counsel may not proceed under the rule of reason until it proves the existence of a "large and unjustified" payment. *See Actavis*, 133 S. Ct. at 2237 ("a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects"); *King Drug*, 791 F.3d at 403 (settlements that include "unexplained large transfer[s] of value from the patent holder to the alleged infringer . . . may be subject to antitrust scrutiny under the rule of reason"); *see also Loestrin I*, 814 F.3d at 552 (reverse-payment claims may not proceed past the pleading stage unless "the plaintiffs plead information sufficient 'to estimate the value of the term, at least to the extent of determining whether it is 'large' and 'unjustified'"') (quoting *In re Actos End Payor Antitrust Litig.*, No. 13-CV-9244 (RA), 2015 WL 5610752, at *13 (S.D.N.Y. Sept. 22, 2015), *rev'd in part on other grounds*, 848 F.3d 89 (2d Cir. 2017)). This means Complaint Counsel must come forward with evidence that allows the "factfinder [to] assess the value of the payment." *Loestrin 24 Fe*, 814 F.3d at 551. The alleged payment should be valued as of the time of the settlement. *See In re Loestrin 24 Fe Antitrust Litig.*, No. 1:13-md-2472-S-PAS, — F. Supp. 3d —, 2017 WL 3600938, at *21 (D.R.I. Aug. 8, 2017) ("*Loestrin II*") ("The deal must be valued at the time the parties entered the deal.").

Complaint Counsel hopes to avoid the burden of proving a large and unjustified payment. According to Complaint Counsel's economic expert, Dr. Noll, any payment "above plausible saved litigation cost" is "large," and any such payment is "unjustified" unless it constitutes "reasonable compensation for goods, services or assets that were acquired by the brand-name firm from the generic firm." (CX5004-008 (Noll Rebuttal Rep. ¶ 11); *see* FOF ¶ 1404.) But nowhere in *Actavis* does the Supreme Court identify saved litigation costs as the benchmark for determining whether a payment is "large." Rather, the Court pointed to litigation costs as an

example of payments that are ***justified***. *See Actavis*, 133 S. Ct. at 2236 (saved litigation costs are a "justification[]"). Dr. Noll's misconception would write the "large" qualifier out of *Actavis*, since ***any*** allegedly "unjustified" payment—that is, any payment amount in excess of saved litigation costs and/or compensation for goods, assets, or services—would invariably be deemed "large" as well.[11] As *Actavis* and its progeny make clear, "large" and "unjustified" are discrete requirements. *See In re Lipitor Antitrust Litig.*, 868 F.3d 231, 251 (3d Cir. 2017) ("Reverse payment settlement agreements give rise to those antitrust concerns . . . when the payments are both 'large and unjustified.'") (quoting *Actavis*, 133 S. Ct. at 2237).

Absent proof that Impax received a large and unjustified payment from Endo as of the time of the settlement, Complaint Counsel's claims should be dismissed and judgment entered in favor of Impax. To hold otherwise would "subject virtually ***any*** settlement to antitrust scrutiny—a result the Court [in *Actavis*] could not have intended." *Actos End Payor*, 2015 WL 5610752, at *14; *see Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC*, No. 15-cv-6549 (CM), 2016 WL 4992690, at *13 (S.D.N.Y. Sept. 13, 2016) ("To trigger antitrust concern under *Actavis*, a settlement term must be (1) a 'payment' that is (2) made in 'reverse' . . . and is [3] 'large,' and (4) 'unexplained.'") (quotations omitted).

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

"Substantial market power is an indispensable ingredient of every claim under the full Rule of Reason." *Chicago Prof'l Sports Ltd. P'ship v. Nat'l Basketball Ass'n*, 95 F.3d 593, 600 (7th Cir. 1996). This requirement—sometimes referred to as a "market power screen" or

[11] Dr. Noll's approach also wrongly implies that potential justifications for a payment are limited to saved litigation costs and compensation for goods, assets, or services. The Court in *Actavis* expressly acknowledged that "[t]here may be other justifications." 133 S. Ct. at 2236.

"monopoly power screen"[12]—is not a subject of dispute in this case. Complaint Counsel's own economic expert acknowledged that the SLA could not have been anticompetitive unless Endo had "[s]ubstantial market power." (Noll, Tr. 1574.)[13]

To establish monopoly power, Complaint Counsel must first prove the existence of a cognizable relevant market. "Without a well-defined relevant market, a court cannot determine the effect that an allegedly illegal act has on competition." Initial Decision at 123, *In re 1-800 Contacts, Inc.*, No. 9372 (F.T.C. Oct. 27, 2017) [hereinafter "*1-800 Contacts*"] (quoting *Se. Mo. Hosp. v. C.R. Bard, Inc.*, 642 F.3d 608, 613 (8th Cir. 2011)); *see In re N.C. Bd. of Dental Examiners*, 152 F.T.C. 75, 160 (2011), *aff'd*, 152 F.T.C. 640 (2011) (assertion that "market definition is not a prerequisite to establishing liability under the rule of reason" is "contrary to established law"); *Deutscher Tennis Bund v. ATP Tour, Inc.*, 610 F.3d 820, 828–33 (3d Cir. 2010) (affirming jury verdict for defendants on rule of reason claim where plaintiffs failed to prove relevant market). Complaint Counsel bears the burden of defining the relevant market with reference to the rule of reasonable interchangeability and cross-elasticity of demand. *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 436 (3d Cir. 1997).

Complaint Counsel must also demonstrate that Endo had monopoly power within the relevant market. This can be done directly or indirectly. *Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1434 (9th Cir. 1995). The direct method requires proof of both supracompetitive prices and restricted output. *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 (3d Cir.

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[12] *See, e.g.*, *PSKS, Inc. v. Leegin Creative Leather Prods., Inc.*, 615 F.3d 412, 418–19 (5th Cir. 2010) (applying market power screen); *State of N.Y. v. Anheuser-Busch, Inc.*, 811 F. Supp. 848, 871–74 (E.D.N.Y. 1993) (same).

[13] The terms "monopoly power" and "market power" are often used interchangeably in antitrust jurisprudence. *See, e.g.*, *Tops Mkts., Inc. v. Quality Mkts., Inc.*, 142 F.3d 90, 97–98 (2d Cir. 1998); *U.S. Anchor Mfg., Inc. v. Rule Indus., Inc.*, 7 F.3d 986, 994 n.12 (11th Cir. 1993). For the sake of precision, this brief generally adopts the term "monopoly power."

2007); *Rebel Oil*, 51 F.3d at 1434. The indirect method requires Complaint Counsel to prove that **(1)** Endo had a significant share of the relevant market, **(2)** there are significant barriers to entry in the relevant market, and **(3)** incumbent competitors in the relevant market cannot increase their output in the short run. *Rebel Oil*, 51 F.3d at 1434; *see In re Gen. Foods Corp.*, 103 F.T.C. 204, 333, 356–57 (1984) (if incumbent firms can "respond [to a restriction of output] by expanding their output to make up the shortfall," then "there is no monopoly power").

If Complaint Counsel cannot establish that Endo possessed monopoly power in a relevant market, the analysis stops there, and judgment should be entered in favor of Impax. *See Buccaneer Energy (USA) Inc. v. Gunnison Energy Corp.*, 846 F.3d 1297, 1313–20 (10th Cir. 2017) (affirming summary judgment for defendant on rule of reason claim where plaintiff failed to show monopoly power in a properly defined market); *Eastern Food Servs., Inc. v. Pontifical Catholic Univ. Servs. Ass'n, Inc.*, 357 F.3d 1, 5–7 (1st Cir. 2004) (affirming dismissal of rule of reason claim where plaintiff did not adequately allege monopoly power within a cognizable relevant market).

C. Complaint Counsel Is Required to Prove Actual Anticompetitive Effects Arising From the Settlement Agreement.

Assuming Complaint Counsel could prove that Endo possessed monopoly power in a properly defined relevant market, it would then bear the burden of "show[ing] that [the alleged] conduct unreasonably restrained competition." *United States v. Microsoft Corp.*, 253 F.3d 34, 95 (D.C. Cir. 2001); *see In re Schering-Plough Corp.* ("*Schering I*"), No. 9297, 2002 WL 1488085, at *88 (F.T.C. June 27, 2002) ("In a rule of reason case, Complaint Counsel must prove that the challenged agreements had the effect of injuring competition."). "In the context of reverse payment patent settlement lawsuits, . . . market power alone cannot be sufficient to demonstrate anticompetitive effects under the rule of reason." *In re Wellbutrin XL Antitrust Litig.*, 133 F.

Supp. 3d 734, 755 (E.D. Pa. 2015), *aff'd*, 868 F.3d 132 (3d Cir. 2017). Proof of actual competitive effects is imperative. *See In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 389–90 (D. Mass. 2013) (requiring plaintiffs to establish both market power and anticompetitive consequences).

As this Court has recently held, the rule of reason "requires courts to engage in a thorough analysis of the relevant market and the effects of the restraint in that market." *1-800 Contacts*, at 119. The question is whether the challenged restraint, "***as it actually operates in the market***, has unreasonably restrained competition." *Jefferson Par.*, 466 U.S. at 29 (emphasis added). This entails an analysis of "real market conditions," *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 903 (2007), and the restraint's "actual effect" therein, *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 768 (1984).

Throughout this litigation, Complaint Counsel has sought to escape its burden of proving actual anticompetitive effects that outweigh the countervailing procompetitive benefits. At the initial pretrial conference, Complaint Counsel insisted that "to the extent Respondents are going to argue that but for this settlement, there would not have been earlier entry, again, we don't have to prove what would happen in the but for world." (Ini. Pretrial Conf. Tr. 50.) And in its failed summary decision briefing, Complaint Counsel argued that its "'initial burden to show anticompetitive effects' does not require proof that the agreement 'actually delayed generic competition or resulted in any actual harm to consumers.'" (Summ. Dec. Reply at 9.) In fact, Complaint Counsel sought to bar ***all*** evidence of post-settlement competitive effects. (*See* Partial Summ. at 15 (arguing that *Actavis* mandates an "*ex ante* approach" that exclusively "focuses on circumstances at the time the agreement was entered").) That is not the law.

Actavis instructs that the "basic question" is the same as in any other rule of reason

case—"that of the presence of significant unjustified anticompetitive consequences." 133 S. Ct. at 2238. Numerous courts have held in reverse-payment cases that the plaintiff must prove, as an element of liability, that the settlement in fact delayed competition. *See, e.g.*, *King Drug*, 791 F.3d at 404 ("'paying the challenger to stay out' of the market . . . for longer than the patent's strength would otherwise allow . . . 'constitutes the relevant anticompetitive harm,' which must then be analyzed under the rule of reason") (quoting *Actavis*, 133 S. Ct. at 2236–37); *In re Cipro Cases I & II*, 348 P.3d 845, 863 (Cal. 2015) ("[T]he relevant benchmark in evaluating reverse payment patent settlements should be no different from the benchmark in evaluating any other challenged agreement: What would the state of competition have been without the agreement?" . . . . "[D]elayed entry . . . beyond what the patent's strength warranted" constitutes "cognizable anticompetitive harm."); *see also In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 163 (3d Cir. 2017) ("[T]here was no delay associated with the 300 mg product and the analysis in *Actavis* does not apply. As a result, any pay-for-delay claim unique to Anchen's 300 mg product must fail.").

And contrary to Complaint Counsel's failed arguments, *Actavis* does not contemplate (much less mandate) that courts myopically focus on *ex ante* conditions while ignoring real-world competitive outcomes. This is only logical; the rule of reason hinges on "anticompetitive consequences," *Actavis*, 133 S. Ct. at 2237–38, and a "consequence" inherently "***follows as an effect*** of something that came before." *Black's Law Dictionary* (10th ed. 2014) (emphasis added). The "true test of legality," as Justice Brandeis famously articulated, examines "the facts peculiar to the business to which the restraint is applied," including "its condition ***before and after*** the restraint was imposed." *Bd. of Trade*, 246 U.S. at 238 (emphasis added). Unsurprisingly, in its order denying Complaint Counsel's Motion for Partial Summary Decision,

the Commission held that post-settlement effects—for example, the fact that the SLA permitted Impax to sell generic Opana ER on a sustained basis, notwithstanding Endo's acquisition of several more patents—are relevant to the rule of reason inquiry. (Comm'n Decision at 11–13.)

This traditional approach should not be a mystery to Complaint Counsel. In *1-800 Contacts*, also decided under the rule of reason, Complaint Counsel put on extensive evidence of actual, post-restraint anticompetitive effects and resulting harm to consumers. *1-800 Contacts*, at 151–56. Complaint Counsel also had two economic experts separately model the but-for world, which "reinforce[d]" record evidence of actual competitive effects. *Id.* at 156–60. This Court concluded that "Complaint Counsel ha[d] proven that the Challenged Agreements ha[d] anticompetitive effects in the form of harm to consumers and competition," thus "establish[ing] Complaint Counsel's *prima facie* case that the agreements [were] anticompetitive." *Id.* at 166. Complaint Counsel has not made any similar showing here—not even close.

If Complaint Counsel cannot demonstrate that the SLA actually harmed competition, Impax is entitled to judgment. *See Procaps S.A. v. Patheon, Inc.*, 845 F.3d 1072, 1087 (11th Cir. 2016) (affirming summary judgment for defendant on rule of reason claim where plaintiffs "failed to adduce concrete evidence of actual anticompetitive effects"); *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 403 (3d Cir. 2016) (affirming summary judgment for defendant on rule of reason claim where plaintiff lacked evidence of anticompetitive effects).

D. Complaint Counsel Is Required to Prove That a Less Restrictive Alternative Was Actually Feasible Under the Circumstances.

Assuming Complaint Counsel could prove that the SLA caused anticompetitive effects, Impax is entitled to show that the SLA was in fact procompetitive. *N.C. Bd. of Dental*, 152 F.T.C. at 205. Ultimately, though, "it is plaintiffs' burden to show that the anticompetitive effect of the conduct outweighs its benefit." *Microsoft*, 253 F.3d at 95; *see id.* ("plaintiffs must show

that Microsoft's conduct was, on balance, anticompetitive"). To shoulder this burden, Complaint Counsel "must demonstrate that the restraint is not reasonably necessary to achieve the stated [procompetitive] objective," *United States v. Brown Univ.*, 5 F.3d 658, 669 (3d Cir. 1993), or in other words, that the "legitimate objectives can be achieved in a substantially less restrictive manner," *O'Bannon v. NCAA*, 802 F.3d 1049, 1070 (9th Cir. 2015), *cert. denied*, 137 S. Ct. (2016), (quoting *Tanaka v. Univ. of S. Cal.*, 252 F.3d 1059, 1063 (9th Cir. 2001)).

This is not an exercise in speculation. The rule of reason requires that Complaint Counsel "make a strong evidentiary showing" that its proposed less restrictive alternative would be "viable." *O'Bannon*, 802 F.3d at 1074. Complaint Counsel's proposed alternative "must be 'virtually as effective' in serving the procompetitive purposes of the [challenged restraint], and 'without significantly increased cost.'" *Id.* (quoting *Cty. of Tuolomne v. Sonora Cmty. Hosp.*, 236 F.3d 1148, 1159 (9th Cir. 2001)).

E. Dr. Noll's "Three-Part Test" Is Inconsistent With The Rule of Reason.

In lieu of the standard rule of reason approach, Complaint Counsel's economic expert, Dr. Noll, proposes an alternative "three-part test" for assessing the settlement in issue. (CX5000-013 (Noll Rep. ¶ 29); see FOF ¶ 1398.) Dr. Noll claims to have developed this test after the Eleventh Circuit's decision in *Schering-Plough Corp. v. FTC* ("*Schering II*"), 402 F.3d 1056 (11th Cir. 2005)—which he considers "incorrect as a matter of economics"—in consultation with Professor Tim Breshnahan, who testified for Complaint Counsel in that case. (Noll, Tr. 1498.) As Dr. Noll admitted at trial, he has never published his three-part test or subjected it to peer review, explaining that he has not "gotten around to writing it yet." (Noll, Tr. 1496, 1642; *see* FOF ¶¶ 1406–07.) Nor has his "specific" test ever been adopted by any court. (FOF ¶ 1407; Noll, Tr. 1496, 1642.)

Dr. Noll's proposed three-part test consists of the following steps:

- "First, did the settlement agreement eliminate the possibility of entry during some period after the date on which the FDA gave final approval to the ANDA?" (CX5000 (Noll Rep. ¶ 29); *see* FOF ¶ 1398.)
- "Second, did the generic entrant receive a payment that is 'large' compared to the savings to the brand-name firm in ending the infringement litigation before the court renders a verdict?" (*Id.*; see FOF ¶ 1401.)
- "Third, was the payment 'unjustified' in that it does not plausibly reflect a payment for other goods and services?" (*Id.; see* FOF ¶ 1402.)

This "test" is highly problematic. To begin with, as Dr. Noll admitted at trial, ***any*** settlement with an entry date that is even one day later than the date of FDA approval would run afoul of the first step. (FOF ¶ 1399; *see* Noll, Tr. 1614–16.) And as discussed above, the second and third steps effectively write the "large" out of "large and unjustified," since they would condemn ***any*** payment Dr. Noll believes is "unjustified"—that is, any amount in excess of saved litigation costs and/or compensation for goods and services. Nor does Dr. Noll's test account for other potential justifications for the payment, despite the Supreme Court's holding that a payment that does not represent saved litigation costs or fair value compensation may still be justified. (*See* Noll, Tr. 1620 ("Q. Your test doesn't consider whether there may be other justifications; correct? A. I'm not aware of any other justifications.")); *Actavis*, 133 S. Ct. at 2236 ("There may be other justifications.").

The main problem with Dr. Noll's three-part test, however, is that it bears no resemblance to the rule of reason. It instead represents a *per se* rule, under which ***any*** settlement that includes a payment in excess of saved litigation costs and/or compensation for goods and services, and even ***one day*** of assumed "delay" beyond the date of ANDA approval, would be

deemed anticompetitive—all without any evidence of actual delay or analysis of actual competitive effects. *See* FOF ¶ 1417. Dr. Noll has repeatedly admitted that his test assumes anticompetitive effects from the reverse payment itself. As stated in his rebuttal report, "large, unexplained reverse payments are ***inherently*** anticompetitive." (FOF ¶ 1418 (quoting CX5004 (Noll Rebuttal Rep. ¶ 138) (emphasis added)); *see* CX5004 (Noll Rebuttal Rep. ¶ 122) ("[T]he ***reverse payment itself*** is a reliable index of the welfare loss of consumers due to a reverse-payment settlement") (emphasis added).) Dr. Noll doubled down on this claim at deposition, testifying that if a settlement includes a payment in excess of saved litigation costs, "***it's a hundred percent certain it's anticompetitive***." (FOF ¶ 1404; CX4039 (Noll, Dep. 26–27) (emphasis added); *see id.* (Noll, Dep. 27 ("Q. So if it's—under your test, if it's greater than the combined—if the payment received by the generic is greater than the sum of the litigation costs, it's necessarily anticompetitive; right? A. Right.").) This is the language of *per se* illegality, not the rule of reason. *See Copperweld*, 467 U.S. at 768 ("Certain agreements . . . are thought so ***inherently anticompetitive*** that each is illegal per se without inquiry into the harm it has actually caused.") (emphasis added); *In re Musical Instruments & Equip. Antitrust Litig.*, 798 F.3d 1186, 1191 (9th Cir. 2015) (under *per se* rule, "[o]nce the agreement's ***existence*** is established, no further inquiry into the practice's actual effect on the market . . . is necessary") (emphasis added).

There is no way to reconcile Dr. Noll's test with *Actavis* or the Commission's recent decision in this case. While Dr. Noll insists that "the ***very existence*** of a large reverse-payment settlement rules out the possibility that the settlement benefits consumers" (CX5000 (Noll Rep. ¶ 271) (emphasis added)), the Commission made clear that "anticompetitive effects should not be presumed from the mere presence of a reverse payment." Comm'n Decision at 8. In *Actavis*, the

FTC argued that courts should presume anticompetitive effects from the very existence of a reverse-payment settlement, but the Supreme Court rejected that approach. 133 S. Ct. at 2237. Complaint Counsel may not resurrect failed theories of presumptive or *per se* illegality under the guise of Dr. Noll's three-part test.[14]

In sum, Complaint Counsel's claims must be analyzed under the traditional rule of reason, as understood and applied by this and other courts for decades.

II. Complaint Counsel Failed to Prove That Impax Received a Large and Unjustified Payment at the Time of the Settlement.

Complaint Counsel's claims hinge on the allegation that the SLA and the DCA together constitute an unlawful reverse-payment settlement. Under *Actavis*, a settlement agreement does not "bring with it the risk of significant anticompetitive effects"—and therefore is not subject to antitrust scrutiny—unless it conveyed to the generic company a payment that is both "large and unjustified." 133 S. Ct. at 2237; *see Lipitor*, 868 F.3d at 251; *Actos End Payor*, 2015 WL 5610752, at *13. Complaint Counsel's case stumbles at this initial step. Because Complaint Counsel failed to present any evidence that would allow this Court to "assess the value" of the alleged payment terms, *Loestrin I*, 814 F.3d at 551, it has not established that Impax received a "large and unjustified" payment under the DCA or the SLA.

[14] Nor does Complaint Counsel's theory find any support in the California Supreme Court's *Cipro* decision, which construed the California Cartwright Act rather than the federal antitrust laws. *Cf. Cipro*, 348 P.3d at 858 ("Interpretations of federal antitrust law are at most instructive, not conclusive, when construing the Cartwright Act, given that the Cartwright Act was modeled not on federal antitrust statutes but instead on statutes enacted by California's sister states around the turn of the 20th century.") (quoting *Aryeh v. Canon Bus. Solutions, Inc.*, 292 P.3d 871, 877 (Cal. 2013)). Under *Cipro*, once the plaintiff has proven the existence of a settlement that includes a large and unjustified payment and that provides for delayed generic entry, the defendant is permitted to "offer legitimate justifications and come forward with evidence that the challenged settlement is in fact procompetitive," consistent with standard rule of reason principles. *Id.* at 869–70. In contrast to the *Cipro* analysis, Dr. Noll's three-part test would cut off defendants from offering evidence of procompetitive effects altogether.

A. Impax Did Not Receive a Large and Unjustified Payment Under the DCA.

The only payment Impax received in June 2010 was Endo's $10 million upfront payment under the DCA. (FOF ¶ 271; JX-001-011 (¶ 44).) Complaint Counsel contends that payment was itself "large and unjustified." (Compl. Counsel, Tr. 57.) But the evidence supports just one conclusion: the $10 million was "justified" as "fair value" compensation for the services Impax agreed to perform, and the profit-sharing rights that Endo received, under the DCA. *Actavis*, 133 S. Ct. at 2236. No logical extrapolation is needed to reach this conclusion. Impax offered evidence—unrebutted by Complaint Counsel—that the DCA was a *bona fide* business collaboration, and that Endo's DCA payment obligations were fair value for the bundle of profit-sharing rights Endo received under the agreement.

1. Endo's Profit-Sharing Rights More Than Justified Any Payment to Impax Under the DCA.

Dr. Robert Cobuzzi, Endo's Senior Vice President of Business Development and leader of the Endo team that evaluated the DCA, spoke to the deal's merits at trial. He testified that his team analyzed information about the IPX-203 product concept (FOF ¶¶ 390–91; *see* RX-377); details on research and formulation work that Impax had performed since 2009, including how IPX-203 would improve upon existing therapies (FOF ¶ 391; *see* RX-270); and financial, commercial, and intellectual property information on a highly relevant comparator drug, IPX-066 (FOF ¶ 402; *see* RX-376.0001; RX-272.0001; *see* RX-080.0006 ("IPX-066 affords a reasonable surrogate for IPX-203 given the anticipated similarities in constituents and formulation")). As reflected in the Opportunity Evaluation Worksheet ("OEW") that Dr. Cobuzzi and his team prepared, their analysis led to the conclusion that Endo's profit-sharing rights "justified the payments Endo agreed to make under the agreement." (Cobuzzi, Tr. 2564; *see* FOF ¶¶ 421, 425–426*; see also* FOF ¶ 422; Cobuzzi, Tr. 2541, 2560; CX1209.)

Dr. Cobuzzi and his team were familiar with Parkinson's disease treatments. Dr. Cobuzzi wrote his doctoral thesis on the topic (FOF ¶ 387; *see* Cobuzzi, Tr. 2511–12), and "personally ha[s] comfort with the area," (Cobuzzi, Tr. 2524; *see* FOF ¶ 316). Dr. Kevin Pong, who was responsible for evaluating Endo's scientific licenses, had a "significant amount of experience in" the area as well. (FOF ¶ 388 (quoting Cobuzzi, Tr. 2512–13).) Endo also had institutional knowledge about Parkinson's: Endo had previously sold IR Sinemet, an immediate-release carbidopa-levadopa product for Parkinson's (FOF ¶¶ 293, 299), and "had looked for a number of years to find [additional Parkinson's disease] products." (FOF ¶ 316; *see* Cobuzzi, Tr. 2524.) In connection with these previous efforts, Endo had commissioned market research on Parkinson's disease therapies. (FOF ¶ 439; *see also* CX12009-011.) In light of this background, Dr. Cobuzzi and his team were readily capable of assessing the DCA using the information they had been provided. (*See* FOF ¶¶ 383, 548–49; Cobuzzi, Tr. 2533, 2553, 2563; *see also* FOF ¶ 416 (quoting CX1007 ("[T]his is an area we know well as a company both in terms of past evaluations and by virtue of the fact that we previously held the rights to IR Sinemet, this should not be a difficult evaluation.")).)

Endo closely considered the allocation of risk under the DCA. Although early stage drug development always entails risk, Dr. Cobuzzi viewed the DCA as mitigating that risk in two ways. (FOF ¶ 536; *see* Cobuzzi, Tr. 2558, 2627–28.) First, the agreement entitled Endo to a share of profits without obligating Endo to perform ***any*** of the resource-intensive formulation and development work. (FOF ¶¶ 454–55; *see* Cobuzzi, Tr. 2543–44.) This contrasts with other early stage development deals Endo has pursued, under which Endo made smaller upfront contributions but was required to perform substantial development work at uncertain cost. (FOF ¶ 561; *see* Cobuzzi, Tr. 2629.) Second, Endo's financial obligations were capped, and beyond

the initial $10 million investment, were contingent on Impax achieving specific milestones—regardless of how much it cost Impax to get there. (FOF ¶¶ 456, 458; *see* Cobuzzi, Tr. 2558.) Endo's profit-sharing rights under the DCA were likewise static percentages, unaffected by the costs of development. (FOF ¶ 459, 522; *see* Geltosky, Tr. 1137–38.) In short, the DCA allowed Endo to "kn[ow] what the cost [to Endo was] up front," without "having to place any internal resources" at risk. (Cobuzzi, Tr. 2558; *see* FOF ¶ 456.)

Dr. Cobuzzi testified that, based on their assessment of the deal terms, the IPX-203 product candidate, and relevant commercial and market information, he and his team concluded that the DCA was "a good deal for Endo," and that they expected it to be profitable. (CX2748-001; *see* FOF ¶ 427; Cobuzzi, Tr. 2545–46, 2554; *see also* FOF ¶ 422.) Contemporaneous documents bear this out. According to the June 2010 OEW, [redacted] (FOF ¶ 433; *see* CX1209-018.) Endo considered this a "good" return that exceeded the company's minimum hurdle rate of 10%. (FOF ¶ 432; *see* Cobuzzi, Tr. 2560–61.) In June 7, 2010 emails to Endo executives Board members, Dr. Cobuzzi described the DCA as a "good deal" that "fits [Endo's] commercial footprint," and "acceptably mitigate[d] Endo's exposure despite the early development stage." (FOF ¶ 427 (quoting CX2748); FOF ¶ 453 (quoting CX1209).)

Michael Nestor, the head of Impax's brand division, likewise viewed IPX-203 as a potentially lucrative commercial opportunity in 2010—so much so that he would have been unwilling to sell the asset entirely. (*See* FOF ¶ 466 (quoting RX-387 ("I would hate to have to sell it")); FOF ¶ 464 (quoting RX-371 [redacted]).) Mr. Nestor had also hoped to retain profits flowing

from prescriptions written by high-prescribing non-neurologists—profits the DCA granted to Endo—because those prescriptions represented a "significant" amount of money. (FOF ¶ 405 (quoting RX-405); *see* FOF ¶ 467; CX4033 (Nestor, Dep. 123) ("I wanted to keep [high-prescribing non-neurologists]"); CX1009-008 (non-neurologists "manage about 40%" of Parkinson's patients).)

At trial, Mr. Nestor testified that his view of IPX-203 has not dimmed since 2010—and with good reason. (FOF ¶¶ 491–95; *see* Nestor, Tr. 2978, 2984–85.) Based on successful Phase II studies completed last year, IPX-203 continues to show tremendous promise. (FOF ¶¶ 491–95; Nestor, Tr. 2984–85; *see also* RX-208.0015–16.) These studies suggest that IPX-203 will offer a vast improvement in motor symptom control as compared to both immediate-release carbidopa-levodopa treatments and Rytary (IPX-066). (FOF ¶ 496; *see* Nestor, Tr. 2984–85; RX-208.0015–16). These "highly statistically significant" and "clinically meaningful" improvements (FOF ¶ 496; *see* Nestor, Tr. 2978, 2984–85) translate into a high likelihood of commercial success, even in a highly genericized market. (*See* FOF ¶ 434; Cobuzzi, Tr. 2622–23.)

2. Complaint Counsel Failed to Show That Impax Received Any "Large and Unjustified" Payment Under the DCA.

Unless Complaint Counsel can establish that Impax received a payment under the DCA that exceeded the value of Endo's profit-sharing rights by a "large" amount, Complaint Counsel cannot meet its burden of proving that the DCA included a "large and unjustified" payment. But Complaint Counsel has offered no evidence—***zero***—suggesting any payments were not justified by the bundle of rights Endo received. This ends any discussion of the DCA conveying a potential large and unjustified payment to Impax.

Complaint Counsel's experts disclaimed any opinion on this topic. Though Complaint

Counsel offered the expert testimony of Dr. John Geltosky to second guess Endo's approach to diligencing the DCA, his report does not address the value of Endo's profit-sharing rights or whether those rights "justified" Endo's payment obligations. (FOF ¶ 528; *see* CX5003 (Geltosky Rep.).) At trial, Dr. Geltosky unequivocally confirmed he was offering no such opinions. (FOF ¶¶ 519–21; *see* Geltosky, Tr. 1124 (no opinions on justification), 1124–25 (no opinions on "market price for the profit-sharing rights that Endo acquired under the DCA" or "the net present value for the DCA at the time it was executed").) Dr. Noll likewise had no opinions on the value of the DCA or whether Endo's payment obligations were justified. (FOF ¶ 525; *see* Noll, Tr. 1456, 1581–82.) Dr. Noll purported to rely on Dr. Geltosky for "a detailed analysis of the degree to which the $10 million payment and co-development deal represented the acquisition of an asset that was approximately valued at a $10 million price" (FOF ¶ 526 (quoting Noll, Tr. 1582)), but Dr. Geltosky clarified that he "did not conduct any valuation analyses of the DCA at all" (Geltosky, Tr. 1125; *see* FOF ¶ 503).

The unrebutted evidence that Endo's profit-sharing rights "justified the payments Endo agreed to make under the agreement" (Cobuzzi, Tr. 2564; *see* FOF ¶ 523) is conclusive. Complaint Counsel's failure to offer any contrary evidence regarding the DCA's value is fatal to its theory that Endo's $10 million payment was "large and unjustified." As Dr. Noll testified when he was asked about the implications of Dr. Geltosky's failure to value the DCA, "I would not include the $10 million as part of the large payment that was unjustified." (FOF ¶ 527 (quoting Noll, Tr. 1585–86).) He indicated that the Court could "pull it out of the case." (Noll, Tr. 1582–83.)

3. Dr. Geltosky's Second Guessing Is Irrelevant to Issues in the Case.

In lieu of offering evidence that Endo's payment was not fair value for the rights Endo received under the DCA, Complaint Counsel had Dr. Geltosky, its paid expert, nitpick around

the edges of the agreement. Dr. Geltosky second guessed the approach Endo (not Impax) took in evaluating and negotiating the DCA, and opined that the DCA's payment terms were "unusual." (FOF ¶ 560; *see* CX5003 (Geltosky Rep. ¶¶ 32, 72, 82).) His Monday morning quarterbacking is beside the point.

To begin with, even if Endo's diligence and negotiation practices were "different than he would expect," that has no bearing on whether the DCA conveyed a "large and unjustified" payment to Impax. The *Schering-Plough* case is instructive. There, Complaint Counsel alleged that the respondents' "side deal" was a fig leaf for transferring value to the generic, and put on expert testimony suggesting that the parties' diligence was "strikingly superficial," *Schering I*, 2002 WL 1488085, at *50, *93, and "fell astonishingly short of industry standards," *Schering II*, 402 F.3d at 1069. This Court concluded—and the Eleventh Circuit ultimately agreed—that this testimony did not establish that the agreement was anything other than "a bona fide side deal for fair value." *Schering I*, 2002 WL 1488085, at *94–95; *see Schering II*, 402 F.3d at 1071. Like Endo, Schering-Plough had a "long-documented and ongoing interest" in the type of product that was the subject of the collaboration, *Schering II*, 402 F.3d at 1069, and was "intimately familiar" with the relevant commercial landscape, *Schering I*, 2002 WL 1488085, at *51; (*see* FOF ¶¶ 316, 417; Cobuzzi, Tr. 2524 (Endo had "looked for a number of years to find products" to treat Parkinson's); Cobuzzi, Tr. 2512, 2524 (Cobuzzi and his team were "quite familiar with" and had "significant amount of experience" in Parkinson's space).) And like Dr. Cobuzzi's team, Schering-Plough's personnel "had little, if any, incentive to inflate [the deal's] value." *Schering II*, 402 F.3d at 1069; (*see* Cobuzzi, 2513 (Cobuzzi was not involved in the SLA negotiations, and was only vaguely aware of them).) In *Schering*, Complaint Counsel's expert criticisms of the diligence process did "nothing to refute that [the brand's] payments [were] a fair price."

Schering II, 402 F.3d at 1071. This Court should disregard Dr. Geltosky's criticisms for the same reason here.

Dr. Geltosky's opinions on the DCA's payment structure are likewise of no import. The DCA's payment structure may be "different" from his own expectations, and he may ruminate that the $10 million payment was "unusually large" in light of IPX-203's early stage of development. (Geltosky, Tr. 1138–39; *see also* FOF ¶ 502.) ***But he failed to compare the DCA payment to the value of the rights Endo received in exchange.*** Whether the payment was "fair value" for what Endo received is the ***only*** metric that matters in assessing whether Impax received a "large and unjustified" payment. *Actavis*, 133 S. Ct. at 2236, 2239. Yet Dr. Geltosky does not speak to the DCA's value, and offers no alternative metric or methodology for determining whether the DCA's payment obligations were justified. (*See* FOF ¶ 503; Geltosky, Tr. 1150.) Indeed, Dr. Geltosky shies away from empirical analyses entirely. (FOF ¶ 506; *see* Geltosky, Tr. 1133.)

Dr. Geltosky's subjective views—which rely on no discernible expert methodology—do not and cannot change the fact that specialists at Endo evaluated the DCA and concluded that it was a "good deal." (FOF ¶ 427; *see also* FOF ¶ 383.) Dr. Geltosky's armchair criticisms, offered years after the negotiations in question, are simply beside the point. They do not address the record evidence,[15] and certainly do not satisfy Complaint Counsel's burden of proving that

[15] Even if Dr. Geltosky's critiques of the DCA terms, negotiation, and diligence were relevant to the issues in this case (and they are not), his opinions suffer from the further defect that they contradict documentary evidence and fact witness testimony. For example, Dr. Geltosky opined that the timeline for negotiating the DCA was "extremely unusual" (Geltosky, Tr. 1065), but Dr. Cobuzzi—a fact witness with decades of experience in the pharmaceutical industry—testified that there is no "usual" timeframe for a business development deal, and that Endo had sufficient time to "assess the information it needed before entering into the [DCA]." (Cobuzzi, Tr. 2543; *see* FOF ¶ 414.) Dr. Geltosky opined that the $10 million payment was "very large" and represented a substantial sum for any company (FOF ¶ 502; Geltosky, Tr. 1072–73), but Dr.

the DCA payment was "large" or "unjustified."

In short, Dr. Geltosky offers no opinions that are relevant to the issues in this litigation. As Dr. Noll suggested, the DCA should be thrown out of the case. (Noll, Tr. 1583; *see* FOF ¶ 527.)

B. Impax Did Not Receive a Large and Unjustified Payment Under the SLA.

Complaint Counsel also did not prove that Impax received a large and unjustified payment under the SLA. Complaint Counsel contends that two SLA terms constituted a "payment" to Impax: the Endo Credit and the No-AG provisions. In Complaint Counsel's telling, the Endo Credit and No-AG terms "worked together to ensure that Impax would get value out of this settlement either by . . . selling its product without competition from an AG or,

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Cobuzzi testified that it was not "a lot of money" for Endo and was "not an uncharacteristically large amount of money" for an in-licensing deal. (Cobuzzi, Tr. 2559; *see* FOF ¶ 513–514.) These examples are merely illustrative of the tension between Dr. Geltosky's views and the actual record evidence.

Nor are Dr. Geltosky's opinions reliable. He repeatedly sought to supplant the role of fact witnesses, going so far as to say that he was an "expert" in interpreting Endo's internal communications—despite never having met the authors of those communications and never having worked for Endo. (Geltosky, Tr. 1133; *see* FOF ¶ 510.) To illustrate the unreliability of this approach: Dr. Geltosky opined that the DCA was not a strategic fit for Endo based ***solely*** on his review of a handful of Endo documents provided to him by counsel. (Geltosky, Tr. 1059, 1071, 1131–32; *see* FOF ¶¶ 537–38, 543.) Of course, he ignored contemporaneous documents in which Dr. Cobuzzi attested that the DCA would "further build[] out [Endo's] product pipeline for the future with a drug candidate that fits [Endo's] commercial footprint." (FOF ¶ 555 (quoting CX1209).) And Dr. Geltosky apparently did not account for the fact that the one time he dealt with Endo in his professional capacity, his expectations about whether Endo would think the proposed deal was a good fit for the company proved ***wrong***. (*See* FOF ¶ 557; Geltosky, Tr. 1172–73.) This does not inspire confidence in his opinions.

When confronted at trial with record evidence that contradicted his views, Dr. Geltosky had little to say—though he did acknowledge that Dr. Cobuzzi was more qualified than he was to speak to the "strategic fit of the DCA with Endo's strategic business goals." (Geltosky, Tr. 1163–68; *see* FOF ¶¶ 558–59.) Thus, even if Dr. Geltosky's opinions were relevant to the issue of whether the DCA conveyed a "large and unjustified" payment, they would carry little (if any) weight.

if Endo had done something to the market, from a cash payment under the Endo credit." (Compl. Counsel, Tr. 48–49.) But Complaint Counsel presented no evidence that the parties viewed these two provisions as guaranteeing any payment to Impax. Far from it, the evidence established that, as Impax employees recognized at the time of the settlement, it was entirely possible that Endo could time the introduction of reformulated Opana ER so as to avoid any payment obligation under the Endo Credit, while still diluting Impax's AB-rated sales of generic original Opana ER—thereby rendering the No-AG commitment valueless to Impax. In this scenario, Impax would receive no "payment" under either provision.

Neither Complaint Counsel nor its experts made any attempt to calculate the ***actual value*** of the Endo Credit and No-AG terms, either separately or in tandem, at the time of the settlement. While Dr. Noll came up with a handful of "possible" payment outcomes, he did ***not*** calculate probability-weighted expected values or account for the possibility of a "zero payment" outcome in any defensible way. (FOF ¶¶ 570, 639–41, 645.) Complaint Counsel's failure to value the alleged "payment" is fatal. *See Loestrin I*, 814 F.3d at 551 (the "court or factfinder" must be able to "assess the value of the payment"); *Actos End Payor*, 2015 WL 5610752, at *13 ("in order for the Court to find an unlawful reverse payment, it must be able to estimate the value of the term, at least to the extent of determining whether it is 'large' and 'unjustified'").

Nor did Complaint Counsel prove that either company viewed the Endo Credit or No-AG provisions as guaranteeing Impax a payment. (FOF ¶¶ 568, 632, 641; *see* Noll, Tr. 1613; Addanki, Tr. 2384.) Indeed, Endo executives testified that at the time of the settlement, they did not expect to pay Impax anything. (FOF ¶¶ 583–85; CX4017 (Levin, Dep. 96–98); *see also* Noll, Tr. 1649 (neither Endo nor Impax forecasted or planned for a payment).) And there is no evidence that Impax expected to receive a payment. (FOF ¶¶ 577–79; CX4014 (Hsu, IHT 89,

165–66); CX4002 (Smolenski, IHT 204–05); Snowden, Tr. 439.) Complaint Counsel failed to offer any evidence that either company tried to estimate the value of these terms prior to executing the settlement. (FOF ¶¶ 581, 583; *see* Mengler, Tr. 582; Cuca, Tr. 629–31; CX4038 (Engle, Dep. 187–88); CX4017 (Levin, Dep. 96–98); Noll, Tr. 1649.)[16] At most, Complaint Counsel sought to demonstrate that the parties ***could have*** calculated hypothetical values for the Endo Credit and No-AG terms. (FOF ¶ 573; *see* Engle, Tr. 1749–50.) That does not substitute for evidence that either party viewed the terms as payments or anticipated that any payment would be made.

1. The Value of the Endo Credit and No-AG Terms Was Contingent on Uncertain Future Events That Impax Could Not Control.

Whether the Endo Credit and No-AG terms resulted in any "payment" to Impax was contingent on uncertain future events that Impax could neither predict nor control. (FOF ¶¶ 568–72, 644; Snowden, Tr. 437–48; *see* Noll, Tr. 1612 ("Whether the Endo credit would be paid or the amount that would be paid depends on contingent events.").) In June 2010, it was uncertain whether Endo would file an NDA for reformulated Opana ER, and if so, whether and when the FDA might approve it. (FOF ¶¶ 167, 170; 174; JX-001-011 (¶ 48); CX4017 (Levin, Dep. 120).) Impax did not and could not know when original Opana ER sales would peak, how high that peak would be, or what Endo's sales of Opana ER would be in the last quarter of 2012. (FOF ¶¶ 593–601; CX4017 (Levin, Dep. 149); RX-108.0002 at 10; RX-419 (not admitted or cited for the

[16] In his opening report, Dr. Noll asserted that Roberto Cuca, Endo's former head of financial planning and analysis, "estimated the likely payment to Impax" under the Endo Credit. (CX5000 (Noll Rep. ¶ 360).) In fact, as Mr. Cuca testified at trial, he merely ran some numbers in an Excel spreadsheet to make sure the Endo Credit formula "produced a sensible result." (FOF ¶ 585 (quoting Cuca, Tr. 629–30).) He estimated that this "would have been about five minutes of work with maybe one or two sets of numbers," just to "make sure the provision worked." (Cuca, Tr. 630–31.) He did not share his figures with anyone. (FOF ¶ 585 (quoting Cuca, Tr. 631).)

truth of matters asserted therein); RX-422 (not admitted or cited for the truth of the matters asserted therein; RX-417 (not admitted or cited for the truth of the matters asserted therein); RX-421 (not admitted or cited for the truth of the matters asserted therein).) Many contingencies—such as the FDA's response to Endo's NDA for reformulated Opana ER—were outside of Endo's control as well. (FOF ¶ 1525–27; Bazerman, Tr. 912, 923.)

Contrary to the assertion that the Endo Credit and No-AG terms "guaranteed" a payment to Impax (Compl. Counsel, Tr. 71), at the time of the settlement, Impax was aware that it might not receive ***any*** value under ***either*** provision. (FOF ¶ 576, 632; CX4032 (Snowden, Dep. 204–06); CX4002 (Smolenski, IHT 128–30).) During settlement negotiations, Ted Smolenski, an Impax Employee, informed his colleagues that Endo could manage the introduction of a reformulated product in such a way as to effectively wipe out sales of original Opana ER by January 2013 (thus depriving Impax of the benefit of AB-rated substitution), while keeping sales of original Opana ER in the fourth quarter of 2012 above the contractual threshold (thus avoiding any payment obligation under the Endo Credit). (FOF ¶¶ 632–33; CX4002 (Smolenski, IHT 50–51, 126–31, 187–88); CX4037 (Smolenski, Dep. 251–52); CX4032 (Snowden, Dep. 205–06); Mengler, Tr. 583; RX-379.) Chris Mengler, who was president of Impax's Generic Division and Impax's chief negotiator, testified at trial that Mr. Smolenski informed him of the zero-payment scenario and that it was "entirely plausible." (FOF ¶ 635 (quoting Mengler, Tr. 589–90).)

If Endo effectuated this "late switch" strategy, Impax would not receive any payment under the Endo Credit. (FOF ¶ 633; Reasons, Tr. 1228; *see* CX4032 (Snowden, Dep. 205–06).) The switch strategy would also make the No-AG commitment essentially worthless to Impax, since it would severely degrade Impax's profit opportunity for generic Opana ER and, in any event, Endo would have no reason to launch an AG of original Opana ER while also selling

reformulated Opana ER. (FOF ¶ 634; *see* CX4032 (Snowden, Dep. 205–06).) That Endo offered up the No-AG commitment in its very first proposed term sheet suggests that Endo saw the term as no more valuable than the sleeves off its vest. (FOF ¶¶ 201–03; Snowden, Tr. 428–29; *see* RX-333 (Endo's initial term sheet).)

Not only was Impax aware of the possibility of a "late switch" strategy, this is exactly what Endo planned to do. (FOF ¶ 636; CX4017 (Levin, Dep. 131); RX-094.) Alan Levin, Endo's chief negotiator, testified that Endo intended to transition from original Opana ER to reformulated Opana ER at the end of 2012, with sales of original Opana ER extending into the fourth quarter of that year. (FOF ¶ 632.) Endo's original budget for 2012 and other contemporaneous documents substantiate this intention. (FOF ¶ 637; RX-108; RX-094.) Indeed, one would rationally expect Endo to manage the launch of reformulated Opana ER so as to minimize patient loss and any potential payment obligation to Impax. (FOF ¶ 1426; Addanki, Tr. 2355.)

That Endo ended up paying Impax $102 million under the Endo Credit provisions is attributable to events that neither party could have foreseen in June 2010. First, Opana ER sales rapidly grew from June 2010 to their peak at the end of 2011. (FOF ¶ 599; RX-414.) In mid-2010, the most optimistic industry analysts forecasted that Opana ER sales could grow by as much as 35% annually; other analysts projected declining sales. (FOF ¶¶ 597–98; *see* RX-417; RX-419; RX-421; RX-422.)[17] In fact, [redacted] (FOF ¶ 599; RX-414.) Complaint Counsel presented no evidence that these stratospheric sales were within either party's

[17] None admitted or cited for the truth of the matters asserted therein.

expectations.[18]

After reaching unanticipated heights in 2011, Endo's sales of Opana ER came crashing down in early 2012, when the plant that manufactured the drug for Endo—which was operated by Novartis, a third party—was forced to cease production. (FOF ¶ 211; CX4017 (Levin, Dep. 136–39); *see* RX-094.0003-04; RX-563.0001; RX-139.0001.) This created a "supply chain crisis" for Opana ER. (FOF ¶ 211; CX4017 (Levin, Dep. 138–39).) Though Endo had intended to wait until late 2012 to introduce reformulated Opana ER, the Novartis shutdown forced Endo to accelerate the launch to March 2012. (FOF ¶ 212; CX4017 (Levin, Dep. 138–39).) Once Endo started selling reformulated Opana ER, the FDA ordered Endo to stop selling any remaining quantities of the original drug so as to avoid consumer confusion. (FOF ¶ 213; CX4017 (Levin, Dep. 138–39, 155); RX-100.) This confluence of events meant that sales of original Opana ER had dropped to nearly zero by the fourth quarter of 2012, which triggered a payment under the Endo Credit. (FOF ¶ 601; JX-001-011 (¶ 45); CX4017 (Levin, Dep. 138–39, 155); RX-100.0001; RX-094.0004; RX-108.0002 at 10.)

As Mr. Cuca testified at trial, it was not until after the Novartis shutdown that Endo knew it would have to make a payment under the Endo Credit provision. (FOF ¶ 604; Cuca, Tr. 669, 671, 677.) Only at that point did the Endo Credit become probable and estimable, and only at that point did Endo book a credit in its financials. (FOF ¶¶ 591–592; Cuca, Tr. 664–65, 668–69.) Even Complaint Counsel's experts admitted that the companies could not have anticipated the

[18] Dr. Noll claims in his opening report that "the rapid growth of Opana ER sales in 2010 and 2011" was "consistent with the expectations of both Endo and Impax," but tellingly does not cite ***any*** supporting evidence. (FOF ¶ 639; CX5000 (Noll Rep. ¶ 379).) Though he later claims that Impax and Endo both anticipated some degree of growth, he points to no evidence that either company anticipated the ***rate of growth*** that actually occurred. (FOF ¶¶ 640–42; s*ee* CX5000 (Noll Rep. ¶ 380) (citing CX0222 and CX2530).) Yet another example of Dr. Noll asserting that his unsupported opinions eclipse real-world facts.

third-party shutdown that triggered the Endo Credit payment. (FOF ¶¶ 1425, 1527; Addanki, Tr. 2354–56; s*ee, e.g.*, CX4039 (Noll, Dep. 99) ("I don't see any documents that rationally expect a Novartis shortage."); *id.* (Noll, Dep. 126) ("they certainly had no way of forecasting that particular event at that particular time"); Bazerman, Tr. 924 ("Q. And indeed, there were events, such as the warning letter that Novartis received from the FDA, that took matters out of their hands; correct? A. Correct.").)

The evidence demonstrates that, far from "guaranteeing" a payment to Impax, the Endo Credit and No-AG terms could have resulted in a range of outcomes, including a plausible scenario in which Impax derived no value under either term. Whether and to what extent Impax received any benefit depended on uncertain future contingencies that Impax and Endo could neither anticipate nor control.

2. Complaint Counsel Did Not Attempt to Determine the Expected Value of the Endo Credit and No-AG Provisions.

In order to estimate the value to Impax of the Endo Credit and No-AG terms, one would have to account for their uncertain and contingent nature. *See In re Xonics Photchem., Inc.*, 841 F.2d 198, 200 (7th Cir. 1988) (Posner, J.) ("By definition, a contingent liability is not certain—and often is highly unlikely—ever to become an actual liability. To value the contingent liability it is necessary to discount it by the probability that the contingency will occur and the liability become real."); *Box v. Northrop Corp.*, 459 F. Supp. 540, 553 (S.D.N.Y. 1978), *aff'd* 598 F.2d 608 (2d Cir. 1979) ("The present value of these payments is a function of both the expected amount of these payments and the probability that that amount will be paid."). This is known as an "expected value" calculation. (FOF ¶ 558; Cuca, Tr. 625–26; *see* Noll, Tr. 1649–50.) According to Dr. Noll, "[e]xpected value is the probability-weighted sum of the values of all possible outcomes." (CX5000 (Noll Rep. ¶ 246 n.276); *see* FOF ¶ 539.) Calculating an

expected value entails multiplying each potential outcome by the probability it will occur. *See Freeland v. Edonis Corp.*, 540 F.3d 721, 730 (7th Cir. 2008) ("a contingent liability is valued at its face amount multiplied by the probability that it will become due"); (FOF ¶¶ 645–48; Noll, Tr. 1591 (one must "multiply the outcome by a probability" to arrive at an expected value).)

"Tempting as it is to correct uncertain probabilities by the now certain fact," value must be assessed "as of the time when the act is done." *Ithaca Trust Co. v. United States*, 279 U.S. 151, 155 (1929) (Holmes, J.); *see Paloian v. LaSalle Bank, N.A.*, 619 F.3d 688, 693 (7th Cir. 2010) (Easterbrook, J.) ("Hindsight is wonderfully clear, but in determining the Hospital's solvency in mid-1997 it was necessary to determine the expected value of this liability as of mid-1997, not the actual value as of 1999 or 2000. Hindsight bias is to be fought rather than embraced."); *Loestrin II*, 2017 WL 3600938, at *21 (payment must be valued at the time of the settlement). In other words, ultimate payment outcomes are no substitute for a probability-weighted expected value calculation. As one court has put it, "[e]quating the value of the ***chance*** with the value of the ***realized*** contingency is somewhat analogous to equating the value of a lottery ticket with the value of the jackpot." *Cty. of Harding v. Frithiof*, 483 F.3d 541, 548 (8th Cir. 2007) (emphasis added). If a lottery ticket has a one in 100 million chance of resulting in a $100 million jackpot, its expected value would be $1 ($100 million × (1 / 100 million)), even if it ends up a winner. As this implies, highly uncertain outcomes often carry little to no expected value. *See Burnet v. Logan*, 283 U.S. 404, 413 (1931) (where "the promise of future money payments [is] wholly contingent upon facts and circumstances not possible to foretell with anything like fair certainty," the contingent promise "ha[s] no ascertainable fair market value").

To determine whether the Endo Credit and No-AG terms constituted a large "payment" to Impax, one would have to calculate their expected value at the time of the settlement. And yet

Complaint Counsel's economic expert made ***no*** attempt to calculate the terms' expected value. Dr. Noll admitted as much. (FOF ¶¶ 570, 639–41; s*ee* Noll, Tr. 1613 ("Q. Sir, you didn't calculate the expected value of the Endo credit; correct? A. No, I did not. Q. And you didn't calculate an expected value for the Endo credit and the no-AG provision either separately or together; correct? A. No."); *see also* CX4039 (Noll, Dep. 116).) Despite the terms' highly uncertain and contingent nature, Dr. Noll testified that he "didn't attach probabilities" to any potential outcomes. (FOF ¶ 649 (quoting Noll, Tr. 1613; *see* Noll, Tr. 1650–51 ("Q. You didn't calculate the probability of any of these scenarios occurring; right? A. I did not calculate the probability of any of these or any of the others that are in the report.").) Without any expected value calculations, we do not know what, if any, value the Endo Credit and No-AG terms conveyed to Impax in June 2010—which means that Complaint Counsel has not proven that Impax received a "large" payment.

All Dr. Noll did was come up with four "examples" of the potential value to Impax of the Endo Credit and No-AG provisions in January 2013, "under various circumstances"—but, again, he "didn't attach probabilities to those." (FOF ¶ 649; Noll, Tr. 1613; *see* CX5000 (Noll Rep. ¶¶ 375–84, App. F).)[19] Dr. Noll merely applied a discount rate (accounting for the time value of money) to estimate the "present value" of these outcomes in June 2010. (FOF ¶ 650; CX5000 (Noll Rep. ¶ 376 & n.424).) But anyone can concoct "examples of outcomes" or "ranges of

[19] In its pretrial brief, Complaint Counsel wrongly suggested that Dr. Noll calculated expected values. (*See* Compl. Counsel's Pretrial Br. at 27–28, Dkt. 9373 (F.T.C. Oct. 10, 2017).) But the four "examples" of potential outcomes Dr. Noll provided are not expected values. (FOF ¶ 649; s*ee* Noll, Tr. 1651 ("Q. And so the numbers on this slide under Approximate Value, those aren't probability-weighted; right? A. I'm sorry. The—no. These are the—these are the numbers without multiplying them—I think I said that yesterday. These are the numbers prior to multiplying by the probability. Q. And so they're not expected values; right? A. No. This is—there's no expected value here. These are just examples of outcomes, ranges of outcomes.").)

outcomes" among infinite possibilities. (FOF ¶ 649; Noll, Tr. 1613, 1615, 1650–51.) Without assigning probabilities and calculating an expected value, we do not know the ***actual*** value, if any, conveyed to Impax in June 2010. As the Court recognized during opening statements, Dr. Noll's "examples" conspicuously exclude any scenario in which Endo executes a "late switch" strategy, whereby Impax would derive ***zero*** "payment" or benefit under either the No-AG or Endo Credit provision. (*See* Court, Tr. 71, 75 ("JUDGE CHAPPELL: Are you going to stand there and tell me that the lowest possible outcome was not going to be zero? You're going to stand there and tell me that because some paid expert tells you that it had to be $62 million floor that it couldn't have been zero? MR. LOUGHLIN: No, Your Honor. There was a theoretical possibility of zero.").) On cross-examination, Dr. Noll himself conceded this omission:

> Q. And that example where you get zero of both, you didn't include that on your demonstrative of scenarios, did you?
>
> A. No, I didn't.

(Noll, Tr. 1654; *see* FOF ¶ 639.)

Rather than grapple with his failure to account for this "zero-payment" outcome, Dr. Noll swept it under the rug. When questioned about the zero-payment scenario, Dr. Noll testified that he did not consider it because "there's nothing in the [parties'] contemporaneous documents that even holds that out as a possibility." (Noll, Tr. 1613; *see* FOF ¶ 640.) That Dr. Noll did not see or consider such evidence does not mean it does not exist. Multiple Impax witnesses testified in this litigation that they were aware of the zero-payment possibility when Impax signed the SLA, and contemporaneous documents bear that out. (FOF ¶¶ 572, 632–33; *e.g.*, Mengler, Tr. 580–90; CX4002 (Smolenski, IHT 50–51, 126–31, 187–88); CX4037 (Smolenski, Dep. 251–52);

CX4032 (Snowden, Dep. 205–06); CX0219; RX-450.)[20] Endo likewise did not expect to make any payment, despite its plans to introduce a reformulated version of Opana ER. (FOF ¶¶ 585, 588; Cuca, Tr. 625–26, 665–66, 673; CX4017 (Levin, Dep. 99–100, 131, 143–44); *see* Noll, Tr. 1649–50.)

Dr. Noll also testified that "[t]he probability of that event [*i.e.*, the zero-payment outcome] happening has to be over 90 percent to get the expected value of the agreement to Impax to be less than the saved litigation costs." (Noll, Tr. 1479–80.) This is nonsensical. Though Dr. Noll invoked the term "expected value" at trial, he did not calculate any expected values. (FOF ¶ 639; Noll, Tr. 1613, 1650–51; CX4039 (Noll, Dep. 116).) He was, in fact, alluding to a back-of-the-envelope calculation in his rebuttal report. There, Dr. Noll assumed that the Endo Credit had a "present value of $65 million at the time of the settlement." (CX5004 (Noll Rebuttal Rep. ¶ 153); *see* FOF ¶ 588.) He arrived at that value simply by applying a 15% annual discount rate to the $102 million that was ***actually*** paid in 2013. (CX5004 (Noll Rebuttal Rep. ¶ 153); *see* CX5000 (Noll Rep. ¶ 376); *see* FOF ¶ 588.) From this premise, Dr. Noll opined that in order to bring the "expected value" of the actual Endo Credit payment below $5 million—his estimate for saved litigation costs—the zero-payment scenario would have to be roughly 92% likely to occur. (CX5004 (Noll Rebuttal Rep. ¶ 153); *see* FOF ¶ 640.)

[20] On June 4, 2010, in the midst of settlement negotiations, Mr. Smolenski emailed Mr. Mengler to say that he and another colleague had spotted some "obvious issues with the contract as drafted." (RX-450; *see* FOF ¶ 632) As Mr. Smolenski testified at his investigational hearing, one of these "issues" was that Endo might execute a late switch strategy, leaving Impax with no value under the No-AG or Endo Credit provisions. (FOF ¶ 632; CX4002 (Smolenski IHT 126–31).) Later, in January 2011, Mr. Smolenski emailed Larry Hsu and Art Koch to inform them that he had "alerted Chris [Mengler] to this downside possibility in the early stages [of settlement negotiation]." (CX0219; *see* FOF ¶ 634; CX4002 (Smolenski, Dep. 187–88).) Mr. Smolenski wrote that the scenario was "probably unlikely" but "certainly not impossible." (CX0219; *see* FOF ¶ 634.)

But this calculation merely compounds Dr. Noll's earlier errors, since it starts with the $102 million that Endo ultimately paid in 2013. That approach ***might*** be defensible if the SLA stated that "Endo shall pay Impax $102 million in 2013 unless Endo switches the market," but it makes no sense given that the fact and amount of any Endo Credit payment hinged on future events that neither party could entirely foresee or control. The eventual $102 million payment was attributable to a perfect storm of unexpected events. (Part II.B.1, *supra*.) As Dr. Noll admitted elsewhere in his rebuttal report, the parties could not estimate the value of the Endo Credit with any degree of precision until the first quarter of 2012, after the Novartis plant shutdown occurred. (FOF ¶ 602; CX5004 (Noll Rebuttal Rep. ¶ 149).) And so the very starting point for Dr. Noll's calculation is infected with hindsight bias, which renders its results unreliable and unhelpful. *See Paloian*, 619 F.3d at 693 ("Hindsight bias is to be fought rather than embraced.").

In the end, Complaint Counsel did not present any evidence that would allow this Court to "assess the value" of the alleged payment terms in June 2010. *Loestrin I*, 814 F.3d at 551. Complaint Counsel therefore failed to carry its burden of proving that Impax received a "large" reverse payment as required by *Actavis*. *Id.*

3. The Endo Credit and No-AG Terms Were Not "Unjustified."

Even if Complaint Counsel had shown that the Endo Credit and No-AG terms constituted a large payment in June 2010, its claims would still fail because it did not show that any alleged payment was "unjustified." In *Actavis*, the Supreme Court held that a large reverse payment may be unjustified—and therefore subject to antitrust scrutiny—where it constitutes "payment in return for staying out of the market." 133 S. Ct. at 2234–37; *see King Drug*, 791 F.3d at 412 ("the plaintiff must prove payment for delay"); *Schering I*, 2002 WL 1488085, at *96 (granting judgment for respondents where, *inter alia*, "direct evidence [showed] that the parties did not

exchange money for delay"). But the alleged payment terms here were not exchanged for an agreement to "stay[] out of the market." *Actavis*, 133 S. Ct. at 2234.

The evidence shows that the Endo Credit term was meant to address Impax's suspicion that Endo had a "secret plan to damage the market." (FOF ¶ 174 (quoting CX0217-001); *see* Snowden, Tr. 433–34; Mengler, Tr. 569–70; CX4017 (Levin, Dep. 118).) As Complaint Counsel apparently concedes,[21] Impax negotiated the Endo Credit to discourage Endo from transitioning to a reformulated Opana ER product. (FOF ¶¶ 184–87; Koch, Tr. 236–41; Snowden, Tr. 386; Mengler, Tr. 533.) The Endo Credit was coupled with a contingent royalty provision—an "Impax Credit," as the Court put it (Court, Tr. 614)—that would require Impax to pay Endo a 28.5% royalty on its sales of generic Opana ER if Endo's sales of branded sales grew beyond a certain threshold. (FOF ¶¶ 195–96; *see* Cuca, Tr. 613–14 (describing royalty provision as "the mirror image of the Endo Credit").) Negotiation of this "carrot and stick" was not tied to the negotiation of the entry date. To the contrary, once the Endo Credit was put on the table, Impax's licensed entry date only got earlier. (FOF ¶¶ 136, 613, 628; *compare* RX-333 (Endo's initial term sheet proposed March 2013 entry date with ***no*** Endo Credit) *to* RX-364 (executed SLA with January 1, 2013 entry date and Endo Credit).) Plainly the Endo Credit was not intended as payment "for delay." *Schering I*, 2002 WL 1488085, at *96.

The same goes for the No-AG provision. The term appeared in the very first term sheet that Endo proposed to Impax, which also included a March 2013 entry date. (FOF ¶ 202; RX-333.) While the No-AG term was not subject to any further negotiation, Impax succeeded in negotiating an even earlier entry date than originally proposed. (FOF ¶ 140; RX-364.) The

[21] (*See* Snowden, Tr. 389 ("[Complaint Counsel:] And the Endo credit was intended to be an incentive for Endo not to move the market and to protect Impax; correct? A. Correct."); *see* FOF ¶¶ 188–90.)

notion that the No-AG term was exchanged for an agreement by Impax to delay its entry is unsupported.

* * *

Complaint Counsel has failed to establish that Impax received a large and unjustified payment. Impax is therefore entitled to judgment.

III. Complaint Counsel Failed to Prove That Endo Possessed Monopoly Power in a Properly Defined Relevant Market.

The SLA could not have harmed competition unless Endo possessed monopoly power in the relevant market at the time. *Chicago Prof'l Sports*, 95 F.3d at 600. Complaint Counsel asserts Endo had monopoly power in a market limited to branded and generic versions of Opana ER. But this contrived market definition does not comport with the real world.

Impax presented voluminous evidence demonstrating that, contrary to Complaint Counsel's allegations, Opana ER competed against other LAOs in a single product market. The evidence ranged from internal business records, to clinical guidelines, to medical expert testimony, to economic analysis. This detailed mosaic brings the following reality into stark relief: Opana ER competes in the broader long-acting opioid market, and Endo never even approached a 10% share of that market. This falls far short of monopoly power. *See Cohlmia v. St. John Med. Ctr.*, 693 F.3d 1269, 1283 (10th Cir. 2012) ("a market share of less than 20% is woefully short under any metric from which to infer market power").

Because Complaint Counsel cannot demonstrate that Endo possessed monopoly power in any cognizable market, this Court should enter judgment for Impax.

A. The Relevant Market Includes Long-Acting Opioids.

It is Complaint Counsel's burden to establish the scope of the relevant market. *Broadcom*, 501 F.3d at 307. The relevant market includes all products that are "reasonably

interchangeable by consumers for the same purposes." *E.I. du Pont*, 351 U.S. at 395; *see N.C. Bd. of Dental*, 152 F.T.C. at 161 ("courts have found the 'reasonable interchangeability' standard to be the essential test for ascertaining the relevant product market"). Reasonable interchangeability does not require identicality or literal equivalence. *See E.I. du Pont*, 351 U.S. at 394 ("[I]llegal monopoly does not exist merely because the product said to be monopolized differs from others. If it were not so, only physically identical products would be a part of the market."). The standard requires only that "one product [be] roughly equivalent to another for the use to which it is put; while there may be some degree of preference for the one over the other, either would work effectively." *Queen City Pizza*, 124 F.3d at 436–37; *see Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 436 (3d Cir. 2016) ("products need not be perfectly fungible to be considered reasonably interchangeable for market-definition purposes"). At bottom, then, the relevant market inquiry centers on "the choices available to consumers." *Little Rock Cardiology Clinic PA v. Baptist Health*, 591 F.3d 591, 596 (8th Cir. 2009).

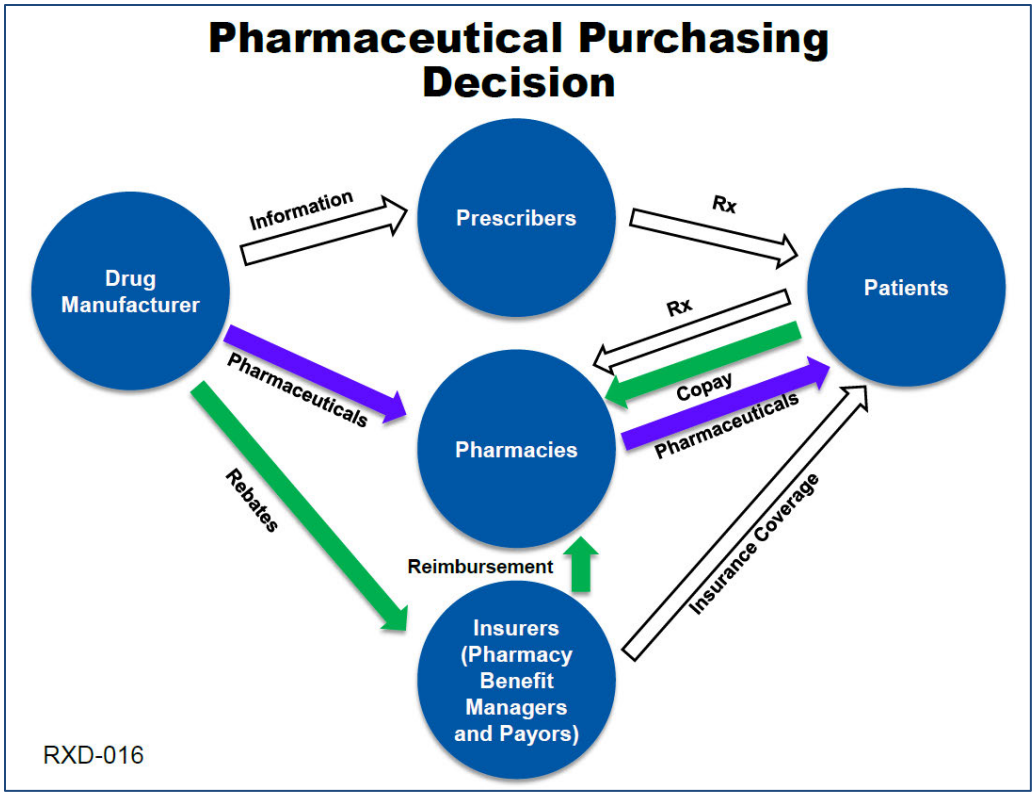
1. Any Market Definition Analysis Must Account For the Commercial Realities of the Pharmaceutical Industry.

As this Court recently emphasized, "[m]arket definition 'must take into account the realities of competition.'" *1-800 Contacts*, at 24 (quoting *FTC v. Whole Foods Mkt.*, 548 F.3d 1028, 1039 (D.C. Cir. 2008)). This is especially important in cases involving the pharmaceutical industry, which exhibits a number of unique institutional features. *See FTC v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 46 (D.D.C. 1998) ("It is imperative that the Court, in determining the relevant market, take into account the economic and commercial realities of the pharmaceutical industry."). Dr. Addanki described these features at length.

Purchasing prescription pharmaceutical products is vastly different from purchasing ordinary consumer products, like bread. (FOF ¶ 816; Addanki, Tr. 2210–17.) When it comes to

buying bread, "the person who's going to consume the bread" is also "the decision maker, the one who chooses which bread to buy, and the payer, the one who pays for the bread, all rolled into one." (Addanki Tr., 2212; *see* FOF ¶ 816.) Because of this, bread makers' competitive efforts—advertisements, price reductions, and so on—are typically "targeted to the consumer." (Addanki Tr., 2212–13; *see* FOF ¶ 816.)

This is not how the prescription pharmaceutical industry operates. When it comes to pharmaceuticals, the initial product choice rests not with the end consumer, but with the prescriber (typically a physician). (FOF ¶ 816; Addanki Tr., 2213–14.) When the consumer takes the prescription to the pharmacy, the pharmacy contacts the consumer's insurance plan, which may be private (such as an employer-provided plan) or public (such as Medicare) (FOF ¶ 82; Addanki, Tr. 2221–23.) If the drug is covered by the consumer's insurance, the insurance plan or its agent will pay the bulk of the cost. ((FOF ¶ 82; Addanki, Tr. 2221–23.) Typically, the consumer only pays a small co-payment ("copay"). (FOF ¶ 816; Addanki, Tr. 2221–23; Addanki, Tr. 2215.) And so "[t]he consumer, the decision maker[,] and the payer of most of the cost are all disjointed." (Addanki, Tr. 2215; *see* FOF ¶ 816) This contrasts to the bread example, in which a single person performs all of these functions.



These institutional features have implications for how competition takes place in the pharmaceutical industry. The disjunction between consumer, decision maker, and payor means that there are "different layers of competition": competition at the payor level, competition at the prescriber level, and competition at the patient level. (FOF ¶ 817; Addanki, Tr. 2215–16, 2233–37.) Any assessment of the relevant product market and Endo's alleged monopoly power must account for these industry realities. *See United States v. Phillipsburg Nat'l Bank & Trust Co.*, 399 U.S. 350, 360 (1970) ("the relevant product market is determine[d] by the nature of the commercial entities involved and by the nature of the competition that they face").

Competition at the Payor Level. Drug manufacturers compete on price for favorable formulary placement. (FOF ¶ 819; Addanki, Tr. 2217–18.) A "formulary" is a list of drugs that an insurer will cover for its members. (FOF ¶ 59; Addanki, Tr. 2217.) Formularies are usually divided into tiers, which "represent the degree to which, from an economic standpoint, the payer,

the insurer, is favoring one product over another." (Addanki, Tr. 2217–18; *see* FOF ¶ 59.) Products on tier one, the most preferred tier, are associated with the lowest copayment for the patient. (FOF ¶ 63; Addanki, Tr. 2218.) A tier two product "is going to involve more payment on the patient's part and less, proportionately, . . . on the insurer's part, and tier three further still." (Addanki, Tr. 2218; *see* FOF ¶ 67.) Some products may be excluded altogether, meaning that the patient is on the hook for the entire cost of the drug. (FOF ¶ 75; Addanki, Tr. 2218.)

As Dr. Addanki explained, the formulary is "the mechanism that insurers use to promote competition and lower costs for therapeutic categories in which there are therapeutic alternatives freely available." (Addanki, Tr. 2218; *see* FOF ¶ 60.) Specifically, insurers invite manufacturers to bid for favorable formulary placement by offering price rebates. (FOF ¶ 819; Addanki, Tr. 2219–24.) Competitive bidders may win placement on tier one or tier two, while those manufacturers who offer less competitive rebates may have their drugs placed on a lower tier or excluded altogether. (FOF ¶ 819; Addanki, Tr. 2219–20.) This competitive bidding process "happens all the time" and "is a fact of life in the pharmaceutical industry." (FOF ¶ 829 (quoting Addanki, Tr. 2220).)

This bidding and negotiation between drug companies and insurers is ***price*** competition. (FOF ¶ 828; Addanki, Tr. 2226.) Drug companies offer rebates that lower the net price the insurers actually pay for their drugs. (FOF ¶ 828; Addanki, Tr. 2220–24.) As an example, assume that a drug manufacturer agrees to a 40% rebate in exchange for placement on tier one of a formulary. Assuming that a pill costs $1, when a patient fills a prescription at the pharmacy, the insurance company will reimburse the pharmacy for the bulk of that $1, with the patient's copay covering the balance. (FOF ¶ 828; Addanki, Tr. 2222–23.) The drug manufacturer will then pay the insurance company a 40-cent rebate, which "reduces the effective cost to the

insurance company for having bought the pill." (Addanki, Tr. 2222–23, 2229; *see* FOF ¶ 828.) This competitive process can be very effective at keeping net prices down. (FOF ¶ 830; Addanki, Tr. 2290.)

When we see this price competition playing out at the payor level, economists can draw inferences about the relevant market. First, competition for formulary placement tells us "that the alternatives in this therapeutic category are in fact regarded as good therapeutic substitutes for one another." (FOF ¶ 876 (quoting Addanki, Tr. 2225).) "The second thing [we] can infer is that ***economic*** substitutability is actually happening," because insurers "wouldn't bother" if formulary adjustments were ineffective at driving volume to favored products. (Addanki Tr. 2225–26 (emphasis added); *see* FOF ¶ 876.) In other words, competition at the payor level provides direct evidence of substitution in response to changes in relative price. (FOF ¶¶ 876-77; *see* Addanki, Tr. 2226, 2232–33 ("[T]hese are net prices that are being changed by these rebates, and there is substitution taking place and contemplated to be taking place in response to those net prices. And that is the essence of economic substitution[.]").) Real-world substitution informs market definition. *See* U.S. Dep't of Justice & Fed. Trade Comm'n, *Horizontal Merger Guidelines* § 4.1.3 (2010) ("how customers have shifted purchases in the past in response to relative changes in price or other terms and conditions" is probative of product market).

Competition at the Patient Level. Pharmaceutical companies also compete on the basis of price at the patient level. (FOF ¶ 899; Addanki, Tr. 2233–34, 2280, 2284.) When a drug maker is not successful in competing for favorable placement on an insurer's formulary, it will have a more difficult time reaching that insurer's members. (FOF ¶ 60; Addanki, Tr. 2217–18, 2234.) If the company's drug is on tier three or tier four, for example, it might be associated with a $75 copay. (FOF ¶ 73; Addanki, Tr. 2218, 2234.) In order to still compete, drug

companies frequently offer price discounts to patients, such as "copay coupons" and "patient assistance cards." (FOF ¶ 903; Addanki, Tr. 2234.) When a patient presents one of these cards or coupons at the pharmacy, the drug company will remit to the pharmacy a specified sum of money, effectively lowering the patient's copay. (FOF ¶ 901; Addanki Tr. 2234–35.) And so, instead of a $75 copay, the patient might "pay $25 and no more for [his or her] copay, and this coupon or card will pick up the rest." (Addanki, Tr. 2235; *see* FOF ¶ 901.)

This critical form of price competition is probative of market definition. At trial, this Court astutely asked Dr. Addanki whether he had "ever seen a rebate being used like this when there's only one brand drug on the market with no competition?" (FOF ¶ 915 (quoting Court, Tr. 2236–37).) Dr. Addanki responded: "No. No. It is the hallmark of when there's actually competition." (FOF ¶ 915 (quoting Addanki, Tr. 2236–7).)[22] This makes good economic sense; a monopolist has no incentive to offer pricing discounts that lower patients' out-of-pocket costs.

Competition at the Prescriber Level. Drug manufacturers also compete for prescriptions by targeting prescribers. (FOF ¶ 817; Addanki, Tr. 2215–16.) For example, drug makers engage in direct promotion or "detailing" by contacting prescribers. (FOF ¶ 878; Bingol, Tr. 1284; Addanki, Tr. 2268.) During these visits, company representatives might provide clinical information, product samples, or aids to help patient compliance. (FOF ¶ 878; Addanki, Tr. 2216, 2268.) These efforts aim to "get the prescribers to prescribe their medicines rather than competing therapeutic alternatives." (Addanki, Tr. 2216, 2269; *see* FOF ¶ 878.)

There is also a price component to competition at the prescriber level. When drug

[22] Dr. Addanki clarified that for certain life-saving drugs that are exorbitantly expensive, such as cancer treatments that may cost thousands of dollars per dose, some drug companies will provide the drugs to indigent patients at a nominal price. These programs are not motivated by price competition, but rather by a desire "to be good citizens." (Addanki, Tr. 2237.)

companies secure favorable formulary placement, they often inform prescribers of that fact. (FOF ¶ 894; CX4044 (Addanki, Dep. 148–49); CX4046 (Michna, Dep. 116–17, 148–49); *see* RX-547 (Addanki Rep. ¶ 77).) Formulary placement affects prescribing practices, since prescribers are concerned with patient compliance and patients are less likely to fill a prescription that carries high out-of-pocket costs. (FOF ¶ 894; CX4044 (Addanki, Dep. 148); CX4046 (Michna, Dep. 115–16).) Awareness of formulary status also reduces administrative burdens, since prescribing a disfavored or off-formulary drug can invite a call from the pharmacy. (FOF ¶ 895; Addanki, Tr. 2230; CX4044 (Addanki, Dep. 148); CX4046 (Michna, Dep. 116).) Finally, prescribers can and often do take account of patients' out-of-pocket costs when selecting a medication. (FOF ¶ 761; Michna, Tr. 2123.)

2. Long-Acting Opioids Are Used Interchangeably to Treat the Exact Same Medical Conditions.

Impax presented unrebutted, real-world evidence showing that LAOs are "reasonably interchangeable by consumers for the same purposes." *E.I. du Pont*, 351 U.S. at 395. To begin with, clinical evidence establishes that LAOs are widely used to treat the same conditions. The FDA-approved labeling is virtually identical across LAOs; all of these drugs are indicated "for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate." (FOF ¶ 711 (quoting RX-549.0010–11); Addanki, Tr. 2239–42; RX-547 (Addanki Rep. ¶ 62); *see* RXD-17 (listing FDA-approved indications for Opana ER, Exalgo, Avinza, Embeda, OxyContin, and Kadian).) The World Health Organization's "analgesic ladder," published in 2009, similarly advises that morphine, oxymorphone, oxycodone, and fentanyl—all of which are ingredients in LAOs—treat "moderate to severe pain." (FOF ¶ 719; Addanki Tr., 2243–44; RX-547 (Addanki Rep. ¶ 62); RX-122.) That LAOs treat the same conditions suggests that they may be reasonable substitutes

for one another. *See Mylan*, 838 F.3d at 436 (the fact that "[t]he FDA has approved virtually identical labeling for most" oral tetracyclines supported their inclusion in single product market).

Real-world medical practice bears out the fact that LAOs are interchangeable for treatment of the exact same conditions. To demonstrate this, Dr. Addanki obtained and analyzed data from IMS Health regarding the diagnoses for which LAOs were prescribed from 2007 to 2017. (FOF ¶¶ 720–723; RX-547 (Addanki Rep. ¶ 64, Ex. 4); Addanki, Tr. 2244–50.) In Exhibit 4 to his report, Dr. Addanki lists the 100 diagnoses with the highest share of uses for six molecules used in LAOs. (FOF ¶ 720; RX-547 (Addanki Rep., Ex. 4).)[23] Dr. Addanki indicates the percentage of each molecule's prescriptions that each of the listed diagnoses accounts for. (FOF ¶¶ 720–723; RX-547 (Addanki Rep., Ex. 4); Addanki, Tr. 2246–47.) Taking the first diagnosis as an example: 9.90% of Fentanyl prescriptions, 8.60% of Hydromorphone HCl prescriptions, 9.66% of Morphine Sulfate prescriptions, 9.71% of Oxycodone HCl prescriptions, 9.25% of Oxymorphone HCl prescriptions, and 6.58% of Tapentadol HCl prescriptions are for Lumbago (*i.e.*, lower back pain):

	Share of Use[3]					
Diagnosis Description[2]	Fentanyl[4]	Hydromorphone HCl[5]	Morphine Sulfate[6]	Oxycodone HCl[7]	Oxymorphone HCl[8]	Tapentadol HCl[9]
	(Percent)					
(b)	(c)	(d)	(e)	(f)	(g)	(h)
Lumbago	9.90 %	8.60 %	9.66 %	9.71 %	9.25 %	6.58 %

(FOF ¶¶ 720–23; RX-547 (Addanki Rep., Ex. 4); Addanki, Tr. 2246.)

As Dr. Addanki's analysis demonstrates, "all of these products are used to a greater or

[23] Specifically, Dr. Addanki analyzed data for Fentanyl (used in the branded LAO Duragesic), Hydromorphone HCl (used in the branded LAO Exalgo), Morphine Sulfate (used in the branded LAOs Avinza, Embeda, Kadian, MS Contin, and Oramorph SR), Oxycodone HCl (used in the branded LAO OxyContin), Oxymorphone HCl (used in the branded LAO Opana ER), and Tapentadol HCL (used in the branded LAO Nucynta ER). (RX-547 (Addanki Rep., Ex. 4).)

lesser extent" for dozens upon dozens of diagnoses. (Addanki, Tr. 2247; *see* FOF ¶ 722; RX-547 (Addanki Rep., Ex. 4).) Critically, there is not a ***single*** diagnosis in Exhibit 4 for which Oxymorphone HCl is the only opioid product used. (FOF ¶ 702; Addanki, Tr. 2248; *see* RX-547 (Addanki Rep. ¶ 64).) Since LAOs are widely prescribed for the exact same conditions, there is no clinical reason why LAOs would not be substitutes. (FOF ¶ 782; Addanki, Tr. 2247–50; RX-547 (Addanki Rep. ¶ 64)); *see HDC Med., Inc. v. Minntech Corp.*, 474 F.3d 543, 547–49 (8th Cir. 2007) (drug products that had "identical uses" belonged to the same relevant market).

Both medical experts testified that LAOs are interchangeable. Dr. Michna, Impax's medical expert—a pain physician who prescribes LAOs on a routine basis (FOF ¶ 756; Michna, Tr. 2102)—testified that there is no scientific evidence that any one opioid is more effective than any other in treating any particular group of patients or any particular disease or injury. (FOF ¶¶ 700–02; Michna, Tr. 2107.) Dr. Michna confirmed Dr. Addanki's conclusion that there is no medical condition for which Opana ER or any other LAO is the only treatment option. (FOF ¶ 708; Michna, Tr. 2148–49; *see* RX-547 (Addanki Rep., Ex. 4); Addanki, Tr. 2248.) When a patient presents with chronic pain, there are numerous LAO treatment options available, including Oxycodone (OxyContin), Methadone (Dolophine), Morphine Sulfate (Kadian, Embeda, MS Contin, Avinza, Oramorph SR), Fentanyl (Duragesic), Tapentadol (Nucynta ER), Hydromorphone (Exalgo, Palladone), Hydrocodone, and Oxymorphone (Opana ER). (FOF ¶ 706; Michna, Tr. 2125, 2148, 2176–77.)

Switching among LAOs is "probably done thousands of times each day" and occurs for a variety of reasons, both clinical and economic. (FOF ¶ 730 (quoting Michna, Tr. 2124–25).) While physicians must oversee switching, it is not complex. (FOF ¶ 734; Michna, Tr. 2127.) As Dr. Michna testified, prescribers "consult conversion tables that show relative equivalency of the

two medications, and then typically . . . cut that dose in half or more just to err on the safe side in terms of how patients react to it." (FOF ¶ 736 (quoting Michna, Tr. 2126–27).) Supervision of a patient's transition from one LAO to another may be as simple as a follow-up phone call or visit. (FOF ¶ 780; Michna, Tr. 2127–28.) Interchangeability among LAOs is so high that many physicians employ "opioid rotation therapy," whereby the physician rotates a patient among different LAOs to avoid tolerance to any medication and to maintain pain relief at lower doses. (FOF ¶ 774; Michna, Tr. 2146–47.) Rotation therapy would not be possible if LAOs were not reasonable substitutes.

Far from rebutting these facts, Complaint Counsel's medical expert, Dr. Savage, ***confirmed*** that LAOs are interchangeable. Dr. Savage agreed that when a patient seeks treatment for chronic pain, physicians have a choice among several LAOs. (FOF ¶ 723; Savage, Tr. 729–32.) In her opinion, no opioid is "superior to any other opioid." (FOF ¶ 704 (quoting Savage, Tr. 743, 790–91).) Likewise, Dr. Savage confirmed that there is no discernible population of individuals for whom Opana ER, or any other LAO, is the only treatment option, or even the best treatment option. (FOF ¶ 933; Savage, Tr. 790–91; CX4041 (Savage, Dep. 60).) She agreed that Opana ER and other LAOs "compet[e] generally for the same consumers." (Savage, Tr. 816; *see* FOF ¶ 970.)

Dr. Savage also testified that switching between LAOs is "frequently necessary or advisable." (FOF ¶ 729 (quoting Savage, Tr. 693–94.)) Like Dr. Michna, Dr. Savage stated that switching can be "simple," especially when a patient is taking a low dosage—and that it is only "a bit more complicated" when the patient is taking a high dosage. (FOF ¶¶ 734, 738 (quoting Savage, Tr. 762, 765–69).) She explained that when patients who a treated with an opioid in the hospital are discharged, it is "common practice" to prescribe a different opioid for the patient to

take at home. (FOF ¶ 743 (quoting Savage, Tr. 798–801).) And Dr. Savage agreed that opioid rotation therapy is a "very important clinical tool." (FOF ¶ 774 (quoting Savage, Tr. 760–61).) Critically, Dr. Savage has ***never*** been unable to switch a patient from Opana ER to another LAO. (FOF ¶ 793; Savage, Tr. 793–94.) All this goes to show that LAOs are interchangeable for the treatment of chronic pain.

Complaint Counsel elicited testimony that patients may react differently to different medications, that one LAO may be superior to other LAOs for individual patients, and that physicians treat patients who present with chronic pain in an individualized manner. (FOF ¶¶ 936–38; Savage, Tr. 743–44, 822; *see* Michna, Tr. 2119.) That may be so, but it is irrelevant. As Dr. Savage admitted, consumers respond differently to different over-the-counter pain medications, like Tylenol, Advil, and Aleve (FOF ¶ 967; Savage, Tr. 811–14)—but that does not mean those products do not compete in the same market. *See Schering I*, 2002 WL 1488085, at *100–03 (finding the relevant product market for oral potassium supplements to be all functionally interchangeable and therapeutic equivalents in the market). Both medical experts agreed that there is no ***discernible*** population of patients for whom Opana ER is the only or best option; as Dr. Savage conceded, there is no way to identify individuals for whom Opana ER may be the best treatment option (to the extent there are any) except through trial and error. (FOF ¶ 928; Michna, Tr. 2169; CX4041 (Savage, Dep. 38).)

And without any way of identifying this supposed population of patients, they cannot delineate a relevant market. *See Horizontal Merger Guidelines* §§ 3, 4.1.4 (markets defined by "targeted customers" must be based on "observable characteristics"). As Dr. Noll himself admitted, Endo would have no ability to price-discriminate against this mystery population. (FOF ¶ 939; CX4039 (Noll, Dep. 171–72 ("[Endo] wouldn't be able to price-discriminate among

patients on the basis of their conditions.")); *In re R.R. Donnelly & Sons Co.*, 120 F.T.C. 36, 51 (1995) ("[A] profitable discriminatory price increase is possible, and therefore sufficient to define a relevant market," only if, *inter alia*, "the hypothetical monopolist can identify . . . customers with sufficiently inelastic demand for [the relevant product]."). And of course, to the extent some patients simply ***prefer*** Opana ER over other LAOs, that does not make them a relevant market unto themselves. *See Queen City Pizza*, 124 F.3d at 437 ("Interchangeability implies that one product is roughly equivalent to another for the use to which it is put; while there may be some degree of preference for the one over the other, either would work effectively.") (quoting *Allen-Myland, Inc. v. IBM Corp.*, 33 F.3d 194, 206 (3d Cir. 1994)); *see also Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co.*, Civ. No. 12-3824, 2015 WL 1736957, at *10 (E.D. Pa. Apr. 16, 2015), *aff'd*, 838 F.3d 421 (3d Cir. 2016) ("even if there are patients for whom Doryx is a preferred treatment, the 'test for a relevant market is not commodities reasonably interchangeable by a particular plaintiff, but commodities reasonably interchangeable by consumers for the same purposes'") (quoting *Queen City Pizza*, 124 F.3d at 438).[24]

Dr. Addanki also confirmed that there is nothing about LAOs' risk profiles that would prevent them from being reasonable substitutes for one another. (FOF ¶¶ 717–18; RX-547 (Addanki Rep. ¶¶ 65–66); Addanki, Tr. 2250–52.) The DEA, for example, lists all LAOs on

[24] Complaint Counsel also presented evidence of certain minor differences between Opana ER and other LAOs, such as Opana ER's lack of "CYP 450 metabolism" and relatively longer half-life. (FOF ¶ 941; Savage, Tr. 714–45.) But there will be similar chemical differences among virtually any group of products in a given therapeutic category—including, as Dr. Savage admitted, among over-the-counter pain medications like Tylenol and Advil. (FOF ¶ 967; Savage, Tr. 812–13.) The relevant market inquiry does not hinge on whether two products are chemically identical; products may belong to the same market if they are reasonably interchangeable. *E.I. du Pont*, 351 U.S. at 399; *see FTC v. Swedish Match N. Am., Inc.*, 131 F. Supp. 2d 151, 157–58 (D.D.C. 2000) (loose leaf and moist snuff tobacco were reasonably interchangeable and belonged to same market).

Schedule II, meaning that the agency views those products as having similar risk profiles. (FOF ¶ 718; RX-547 (Addanki Rep. ¶ 65); Addanki, Tr. 2251.) The FDA has likewise instituted a single Risk Evaluation and Mitigation Strategies ("REMS") program for all all LAOs, imposing common safety measures across the entire class. (FOF ¶ 717; RX-547 (Addanki Rep. ¶ 65); Addanki, Tr. 2251–52.) The fact that LAOs all exhibit substantially the same risk profile further supports the conclusion that they are reasonable substitutes. (Addanki, Tr. 2251–52; *see* FOF ¶ 717.)

The evidence of LAOs' actual clinical usage firmly establishes that LAOs are interchangeable for the same purpose: to treat chronic pain.

3. Drug Makers Viewed LAOs as Directly Competing Products.

Firms' perceptions of competition are highly probative of the relevant market. As this Court has stated, "[o]rdinary course business documents reveal the contours of competition from the perspective of the parties, who may be presumed to 'have accurate perceptions of economic realities.'" *1-800 Contacts*, at 124–25 (quoting *Whole Foods*, 548 F.3d at 1045 (Tatel, J., concurring)); *see Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962) ("industry or public recognition" may serve as "practical" indicator of relevant market); *Town Sound & Custom Tops, Inc. v. Chrysler Motors Corp.*, 959 F.2d 468, 497 (3d Cir. 1992) (evidence that "Chrysler dealers perceive[d] themselves as competing with dealers handling other cars" indicated that the relevant market was not limited to Chrysler cars). Because of this, "courts often pay close attention to the defendants' ordinary course of business documents" when "determining the relevant product market." *United States v. H&R Block, Inc.*, 833 F. Supp. 2d 36, 52 (D.D.C. 2011).

Here, the evidence is irrefutable: LAO manufacturers viewed LAOs as competing in a single market. [redacted] (FOF ¶ 796 (quoting Addanki, Tr. 2259).) [redacted]

[redacted] (FOF ¶ 797; RX-085 at 57.) [redacted] (FOF ¶ 797; RX-085 at 57 (emphasis added).) Similarly, in a June 2009 document titled "OPANA ER – Situation Analysis," Endo estimated that the "Long-Acting Opioid Market" was worth approximately $5 billion. (FOF ¶ 799; RX-112 at 5.) Endo noted that growth in the "LAO market ha[d] been relatively flat" during the previous 12 months, [redacted] (FOF ¶ 799 (quoting RX-112 at at 5, 16).) [redacted] (FOF ¶ 799 (quoting RX-112 at 16).)

In December 2010, just months after the Impax settlement, Endo again analyzed the LAO market, this time with an eye to the eventual launch of its planned reformulated Opana ER. (FOF ¶ 802; RX-078.)[25] In analyzing the "Competitive Landscape," Endo identified several rival LAOs as "Direct Competitors": OxyContin, Embeda, Nucynta ER, Exalgo, Kadian, and Avinza. (FOF ¶ 802; RX-078 23.) Endo also compared its sales force to those of Purdue (maker of OxyContin), King Pharmaceuticals (maker of Embeda), Johnson & Johnson (maker of Nucynta ER), and Covidien (maker of Exalgo). (FOF ¶ 802; RX-078 at 24 ("Competitive Sales

[25] This document refers to reformulated Opana ER as "Revopan." (RX-078.) "Revopan" was a provisional trade name for reformulated Opana ER. (Addanki, Tr. 2261.)

Force Size").) In April 2013, after Endo had launched reformulated Opana ER and Impax had launched its generic product, Endo characterized the LAO market at "flat," with "significant competitors." (FOF ¶ 699; RX-073.0002 at 39.)

One of the most telling documents is a declaration that Demir Bingol, Endo's Senior Director of Marketing, submitted to the court overseeing Endo's original patent litigation against Impax. (FOF ¶ 793; CX3273.) Dated May 21, 2010—less than three weeks before the Impax settlement— the Bingol declaration asserted that "OPANA ER is sold into a market segment referred to as the long acting opioid (LAO) market, which comprises controlled release opioid products." (FOF ¶ 1004; (quoting CX3273 at 3, 10).) Mr. Bingol described the "LAO market [as] a well-established and competitive market that consisted of many products that had been on the market for years." (FOF ¶ 793 (quoting CX3273 at 3).) Mr. Bingol estimated that, as of March 2010, Opana ER accounted for just ***3.4%*** of the LAO market:

Table 1: Long Acting Opioid Market Share (%) by Product

Product	At Opana ER Launch	March 2010
OXYCONTIN/oxycodone ER	44.2	38.1
DURAGESIC/fentanyl patch	31	30.5
MS CONTIN/Morphine sulfate ER	16.7	22.8
OPANA ER	NA	3.4
AVINZA	4.2	1.9
KADIAN	3.9	2.7
EMBEDA	NA	0.6
Total	100	100

(FOF ¶ 1004; *id.*)

In this Court, Mr. Bingol reiterated that in 2010, Endo viewed "all long-acting opioid formulations" as "direct competitors" of Opana ER. ((FOF ¶ 788 (quoting Bingol, Tr. 1271, 1312–13).) These included OxyContin, Avinza, Kadian, generic long-acting morphine, and Exalgo, among others. (FOF ¶ 790 (quoting Bingol, Tr. 1271).) Mr. Bingol explained that competition among LAOs was not limited to branded drugs; Endo, for example, competed

against both generic and branded OxyContin. (FOF ¶ 790; Bingol, Tr. 1278–79.) Moreover, Endo saw both original and reformulated Opana ER as competing against the same "direct competitors" in the LAO market. (FOF ¶ 794; Bingol, Tr. 1214–15.)

Endo was not alone in viewing the LAO market as the relevant field of competition.

[redacted] (FOF ¶ 811; RX-449 at 6–7.) [redacted] (FOF ¶ 814; RX-449 at 7.) [redacted] (FOF ¶ 812 (quoting RX-449 at 7).) [redacted] (FOF ¶ 812; RX-449 at 7.)

The above evidence is merely a sampling.[26] As Dr. Addanki observed—and as Dr. Noll admitted—[redacted] (FOF ¶¶ 788, 809 (quoting Addanki, Tr. 2262, 2264–65); *see* Noll, Tr. 1512 ("[Endo] regards itself as competing with other LAOs.").) These documents are powerful, real-world evidence that Opana ER competed against other

[26] Other business documents reflecting LAO manufacturers perceptions of competition are cited and described in Dr. Addanki's expert report. (FOF ¶¶ 810–12; Addanki, Tr. 2264-67; RX-547 (Addanki Rep. ¶¶ 80–84); *see, e.g.*, RX-060; RX-115.)

LAOs in the relevant market. *See 1-800 Contacts*, at 132 ("Analysis of the market is a matter of business reality—a matter of how the market is perceived by those who strive for profit in it.") (quoting *FTC v. Coca-Cola Co.*, 641 F. Supp. 1128, 1132 (D.D.C. 1986), *vacated as moot*, 829 F.2d 191 (D.C. Cir. 1987)); *Mylan*, 2015 WL 1736957, at *9 ("Years of internal marketing documents further confirm that tetracyclines are reasonable substitutes for one another. Defendants consistently defined the market in which Doryx competed as including other tetracyclines.").

4. Endo Competed Against Other LAO Manufacturers At the Payor Level.

Endo's perceptions of competition are grounded in economic reality. Impax introduced substantial evidence demonstrating that Opana ER competed with other LAOs at every level of the pharmaceutical industry: at the payor level, at the physician level, and at the patient level. These competitive realities lead to the inexorable conclusion that the relevant market includes numerous LAOs. *See United States v. Continental Can Co.*, 378 U.S. 441, 457 (1964) (relevant market's "contours must, as nearly as possible, conform to competitive reality"); *Whole Foods*, 548 F.3d at 1039 ("As always in defining a market, we must 'take into account the realities of competition.'") (quoting *Weiss v. York Hosp.*, 745 F.2d 786, 826 (3d Cir. 1984)).

[redacted] (FOF ¶ 836; Addanki, Tr. 2291.) As Mr. Bingol testified, insurers have "a choice . . . amongst multiple products," and so drug makers have to "create a financial position for the payer that . . . justif[ies] putting you on [a] tier." (FOF ¶ 821 (quoting Bingol, Tr. 1325).) That is exactly what Endo did with Opana ER, time and again.

In 2009, Endo noted that many doctors perceived Opana ER's lack of formulary coverage as its "most negative aspect." (FOF ¶ 837; CX-1106-009.) Endo concluded that it must improve

Opana ER placement on insurance formularies to expand its market share. (FOF ¶ 838; CX-1106.) To do that, [redacted] (FOF ¶ 840; Addanki, Tr. 2293.) For example, "in an effort to improve formulary access" for Opana ER on Prime Therapeutics' formulary for Medicare Part D plans, Endo offered rebates between 31% and 47%. (FOF ¶ 842 (quoting RX-014.0002; *see* Addanki, Tr. 2295).)[27] [redacted] (FOF ¶ 845; RX-21.0005; Addanki, Tr. 2296.) [redacted] (FOF ¶ 846; RX-21.0005.) [redacted] (FOF ¶ 847; RX-21.0007.) [redacted] (FOF ¶ 848; RX-022.0004; Addanki, Tr. 2300–01.)

This ***is*** price competition. [redacted] (FOF ¶ 841; Addanki, Tr. 2296.) Since payors [redacted] are responsible for paying most of a drug's cost, it makes economic sense that price competition would play out at this level. (FOF ¶¶ 815, 824–25; Addanki, Tr. 2220, 2224, 2226, 2289–90.) But this competition has price implications for

[27] [redacted]

ordinary consumers as well, since drugs on more favorable formulary tiers entail lower out-of-pocket costs for the patient. (FOF ¶ 59; Addanki, Tr. 2217.) For instance, [redacted] (FOF ¶ 846; Addanki, Tr. 2298–99.)[28] [redacted] (FOF ¶ 846; *see* RX-21.0005–6.)[29]

Endo's competitive efforts bore fruit. In 2010, an Endo internal analysis reported that Endo had "agreements for OPANA ER with 24 key commercial plan formularies, representing ~275 million lives." (FOF ¶ 841; RX-558.0003.) Endo called out an agreement with University of Pittsburgh Medical Center ("UPMC"), which "removed Oxycontin, leaving OPANA ER as the only Brand on [the] formulary within our Therapeutic Class." ((FOF ¶ 853; RX-087; Addanki, Tr. 2308–09.) Opana ER also had made it on to "Tier 2, or [the] lowest branded copay, on 22 key Medicare Part D Plan formularies, representing an increase of 12 million lives vs. Q2 2010." (FOF ¶ 841; RX-558.0003) Endo specifically noted that it had achieved an "enhanced position" on Medco's national Medicare Part D formulary. (FOF ¶ 841; RX-087.) Elsewhere in the document, [redacted] (FOF ¶ 841; RX-087-0001.)

Endo also won a number of "blocking" agreements with insurers, whereby Opana ER received favorable formulary placement to the express exclusion of one or more rival LAOs—a

[28] [redacted]

[29] [redacted] (FOF ¶ 845; RX-21.005–6 & n.2.)

sure sign of competition. According to a 2013 email, Endo had agreements in place with Humana, Optum, WellCare, and UPMC to "block" OxyContin and give Opana ER preferred placement. (FOF ¶¶ 851–52; RX-17.0001; RX-17.0002 at 12.) Some of these agreements also excluded "crushable [Opana ER] generics," including Impax's generic product. (FOF ¶¶ 851–52; RX-17.0001.)

Evidence of competition among LAO makers for formulary placement is not limited to ordinary course business documents, powerful though they may be. Dr. Addanki also performed an empirical analysis using data from Managed Market Insight & Technology, Inc. ("MMIT"). (FOF ¶ 861; Addanki, Tr. 2310–11; RX-547 (Addanki Rep. ¶¶ 72–76, Exs. 7–9).) The MMIT data indicate, for pharmacy benefit plans, **(1)** each LAO's status, by month, on the formularies used by these plans; and **(2)** the number of covered lives covered by these plans. (FOF ¶ 862; RX-547 (Addanki Rep. ¶ 72).) Dr. Addanki performed the following analyses and reached the following conclusions:

- ***First***, Dr. Addanki evaluated branded LAOs' relative formulary positions in June 2010. (FOF ¶ 862; RX-547 (Addanki Rep. ¶ 74).) He found that most plans did not place all LAOs on the same formulary tier, and that different plans accorded preferential treatment to different LAOs. (FOF ¶ 862; RX-547 (Addanki Rep. ¶ 74, Ex. 7).) This "diversity of outcomes" indicates that the plans' placement decisions were more likely to have been based on economic factors than on clinical ones. (FOF ¶ 862 (quoting Addanki, Tr. 2315–16); *see* RX-547 (Addanki Rep. ¶ 74).)
- ***Second***, Dr. Addanki evaluated, by plan, Opana ER's formulary position relative to other branded LAOs in June 2010. (FOF ¶ 862; RX-547 (Addanki Rep. ¶ 74,

Ex. 8).) Here again, he found a diversity of outcomes that is more consistent with economic competition than with clinical preferences. For example, while OxyContin was more preferred than Opana ER on commercial plans representing about 33% of covered lives, Opana ER was more preferred than OxyContin on Medicare plans covering about 24% of covered lives. (FOF ¶ 864; RX-547 (Addanki Rep. ¶ 74).)

- ***Third***, Dr. Addanki studied the plans' treatment of LAOs over time. (FOF ¶ 862; RX-547 (Addanki Rep. ¶ 76, Ex. 9).) This analysis revealed that "not only do different formularies position [LAOs] differently on their formularies, but individual formularies change the relative positions of these products over time." (FOF ¶ 869; RX-547 (Addanki Rep. ¶ 76).) For instance, from 2007 to 2008, about one-third of individuals covered by commercial plans saw the status of Opana ER change vis-à-vis other LAOs, with Opana ER being more preferred for a slightly higher proportion of covered lives. (FOF ¶ 870; Addanki, Tr. 2318; *see* RX-547 (Addanki Rep., Ex. 9I).) This "churn" over time is consistent with LAO makers "compet[ing] for favorable insurance coverage and there being various 'winners' in that competitive process" both across formularies and over time. (RX-547 (Addanki Rep. ¶ 76); *see* Addanki, Tr. 2227–28, 2318–20.)

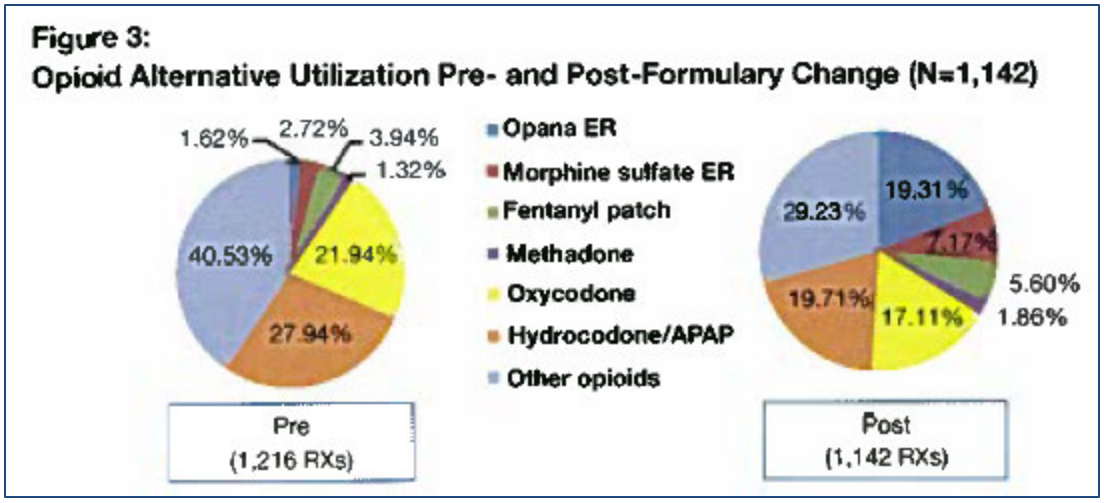
The evidence also shows that LAO manufacturers' competitive efforts—and the resulting diversity in outcomes and "churn" that Dr. Addanki observed—had an actual effect on consumption. As noted, favorable placement on an insurance plan's formulary translates to lower out-of-pocket costs for the plan's members, while unfavorable placement means relatively higher out-of-pocket costs. (FOF ¶ 59; Addanki, Tr. 2217.) These changes in relative price can

lead patients to switch among LAOs. (FOF ¶ 856; Addanki, Tr. 2502.) Dr. Michna confirmed that LAO switches are often driven by formulary changes. (FOF ¶ 731; Michna, Tr. 2125, 2148.) He estimated that formulary changes have caused him to switch patients from one LAO to another ***hundreds*** of times in the past few years alone. (FOF ¶ 756; RX-549 (Michna Rep. ¶ 23).)

The UPMC formulary change that Endo touted in the 2010 document described above[30] precipitated significant switching among LAOs—while saving UPMC money. As shown at trial, UPMC analyzed the effect of this formulary change, which preferenced Opana ER and various generic LAOs (morphine sulfate ER, fentanyl patches, and methadone) while excluding OxyContin. (FOF ¶ 763; RX-087.) The UPMC study centered on 1,639 members who had a paid insurance claim for OxyContin before the formulary change. (FOF ¶ 764; RX-087.) UPMC found that, after the change, 1,310 of those members (nearly 80%) switched away from OxyContin.[31] (FOF ¶ 764; RX-087.) The vast majority of those 1,310 members—1,142 members, representing nearly ***70%*** of the original population—switched to an opioid alternative. (FOF ¶ 764; RX-087.) A large proportion of the switches were to Opana ER; among members taking an LAO other than OxyContin, Opana ER use sprung from a negligible 2.72% before the change to ***19.31%*** after the change:

[30] (*See* RX-558.0003.)

[31] UPMC found that 329 patients, representing just over 20% of the studied population, remained on OxyContin post-formulary change. (FOF ¶ 766; RX-087.)



(FOF ¶ 765; *id.*) The formulary change also reduced UPMC's medical costs, even before rebates. (FOF ¶¶ 767–68; *see id.* (Figure 4; Limitations).)

The UPMC study is compelling proof that Opana ER competes in a broad LAO market. According to the antitrust agencies, evidence of "how customers have shifted purchases in the past in response to relative changes in price" is directly probative of product market definition. *Horizontal Merger Guidelines* § 4.1.3. The UPMC formulary change, which preferenced Opana ER and various generic LAOs over OxyContin, represented a change in relative price—from the perspective of both the insurer (UPMC) and the patient. (FOF ¶ 767; Addanki Tr. 2502–03; RX-087.0001; *see* Noll, Tr. 1561.) As OxyContin became relatively more expensive for patients, nearly 70% of patients in the studied population switched to an alternate LAO, with utilization of Opana ER increasing substantially. (FOF ¶ 764; RX-087.) Such price-induced switching is the ***essence*** of product market definition. (FOF ¶ 877; Addanki, Tr. 2226, 2232–33); *see Apple, Inc. v. Psystar Corp.*, 586 F. Supp. 2d 1190, 1196 (N.D. Cal. 2008) ("Whether products are part of the same or different markets under antitrust law depends on whether consumers view those products as reasonable substitutes for each other and would switch among them in response to changes in relative prices."); *see also Mylan*, 838 F.3d at 437 (evidence of price-related

switching was the "[m]ost convincing[]" proof that Doryx competed in the same market as other oral tetracyclines).

Moreover, the evidence shows that competition at the payor level was effective in constraining net prices for Opana ER. Complaint Counsel's expert, Dr. Noll, expressed that competition for formulary placement had "not been successful in preventing drug prices from going up more rapidly than the rate of inflation by a substantial amount." (FOF ¶ 832 (quoting Noll, Tr. 1523–24).) But Dr. Noll's own analysis shows that [redacted][32] (FOF ¶¶ 830, 833–34; Noll, Tr. 1679–82; CX5000 (Noll Rep., Ex. 7A).) As Dr. Addanki testified, [redacted] (Addanki, Tr. 2290; *see* FOF ¶ 830.)[33]

The record is replete with evidence that LAO makers competed fiercely at the payor level. While Endo did not always emerge the victor—there was significant "churn" in LAOs' formulary positioning across plans and over time—Endo successfully used price concessions to obtain favorable formulary placement for Opana ER on dozens of plans. Real-world evidence shows that changes in relative price, as embodied in formulary changes, caused consumers to

[32] Dr. Noll and Dr. Addanki agreed that list prices are not informative when it comes to assessing competition in the prescription pharmaceutical industry. (FOF ¶ 855; *see* Noll, Tr. 1681 ([redacted]); Addanki, Tr. 2231 ("[Examining list prices] doesn't inform the analysis of competition at all, Your Honor, because list prices and net prices actually paid can go in completely different directions depending on how these rebates are working out.").)

[33] [redacted] (FOF ¶ 834; Addanki, Tr. 2290.)

switch among LAOs. All of this supports the conclusion that the relevant product market consists of numerous competing LAOs.

5. Endo Competed Against Other LAO Manufacturers At the Patient Level.

Endo and rival LAO manufacturers also competed vigorously to attract patients by reducing their out-of-pocket costs. As noted above, when drug makers fail to secure preferred formulary placement, they may offer coupons or other rebates that directly subsidize patients' copayments, effectively making the drugs less expensive. (FOF ¶¶ 819, 828; Addanki, Tr. 2224, 2233–35.) [redacted] (FOF ¶ 840; RX-547 (Addanki Rep. ¶ 79); Addanki, Tr. 2282–87; *see* RX-028.0011; RX-066.0003; RX-123.0006; RX-119.0002.) [redacted] (FOF ¶ 906; RX-028.0011.) [redacted] (FOF ¶ 907; RX-028.0011; RX-066.0003.) In 2011, Endo launched a copay card that could be downloaded from opana.com and was included in "patient kits" distributed by healthcare practitioners. (FOF ¶ 908; RX-123.0006.) And in 2012, [redacted] (FOF ¶ 909; RX-119.0002.) [redacted] (FOF ¶ 902 (quoting Addanki, Tr. 2284).)

It was not just Endo offering price discounts to patients. There was "[a]ggressive competitive couponing from all direct competitors." (FOF ¶ 904 (quoting RX-028.0011).) Purdue, for example, was offering "five months of $50 co-pay assistance via a debit card-type program to help transition patients back to branded Oxycontin"; the copay subsidy was

reportedly "moving to $100 in January 2008." (FOF ¶ 904 (quoting RX-028.0011).) The makers of Avinza and Kadian likewise offered $50 rebates to patients, also using a "debit card-like program." (FOF ¶ 905; RX-028.0011.) [redacted] (FOF ¶ 913; RX-445.0015.)

As Dr. Addanki testified, patient assistance programs allow drug makers to compete on price even when they fail to secure preferred formulary placement. (FOF ¶ 903; Addanki, Tr. 2233–35.) By way of example, [redacted] (FOF ¶ 910; RX-447.0058.) [redacted] (FOF ¶ 910; RX-447.0058.) [redacted] (FOF ¶ 910; RX-447.0058.) [redacted] (FOF ¶ 911; RX-448.0020.)

We would not expect to see such ubiquitous, aggressive price discounting ***unless*** Opana ER competed against other LAOs in the relevant market. (FOF ¶ 914; *see* Addanki, Tr. 2236–37.)

6. Endo Competed Against Other LAO Manufacturers at the Prescriber Level.

Finally, LAO manufacturers competed for prescriptions at the prescriber level. Ordinary course business documents reveal that [redacted] (FOF ¶ 880; Addanki, Tr. 2270.) In its "OPANA® Brand Single Strategy Plan" for the years

2008 to 2012, for instance, Endo identified a potential decrease in its share of voice as a "key issue." (FOF ¶ 880; RX-085 at 21.) Endo was especially concerned that the expected withdrawal of generic OxyContin would "facilitate increased promotion from all competitors, especially Purdue." (FOF ¶ 880; RX-085 at 21.) Endo thus set a goal to "[s]ignificantly grow[] OPANA ER's prescriber base." (FOF ¶ 883; RX-085 at 22.)

By all accounts, Endo invested heavily in prescriber outreach. As of July 2008, [redacted] (FOF ¶ 887; RX-040.0008.) A few years later, [redacted] (FOF ¶ 884; RX-023.0002–3.)

Empirical evidence underscores the seriousness of Endo's efforts. Using IMS data, Dr. Addanki [redacted] (FOF ¶ 885; Addanki, Tr. 2276–79; RX-547 (Addanki Rep. ¶ 71, Exs. 5–6).) Despite Opana ER's relatively small market position, [redacted] (FOF ¶ 888; RX-547 (Addanki Rep. ¶ 71).) This tells us [redacted] (FOF ¶ 889 (quoting Addanki, Tr. 2279).)

There is a relationship between physician detailing and price competition. The pricing information that matters to physicians is embodied in formulary coverage, which relates both to the payor's net price and to the patient's out-of-pocket cost. (FOF ¶ 894; *see* CX4044 (Addanki, Dep. 148–49); CX4046 (Michna, Dep. 115–17).) LAO manufacturers sought to educate

physicians about favorable formulary placement. (FOF ¶ 896; CX4044 (Addanki, Dep. 130); RX-547 (Addanki Rep. ¶ 77).) Endo, for instance, outlined a plan to "inform [healthcare practitioner] targets of OPANA ER formulary access," which entailed both email and hardcopy "detailers." (FOF ¶ 897; RX-16.0002 at 97.) [redacted] (FOF ¶ 892 (quoting RX-445.0021–22).) Dr. Michna testified that drug companies routinely inform him of their products' formulary status. (FOF ¶ 898; CX4046 (Michna, Dep. 148–49).)

* * *

All of this evidence tells a consistent, unambiguous, and irrefutable story: Opana ER competed in a relevant product market is no narrower than the market for LAOs in the United States. (FOF ¶ 695; Addanki, Tr. 2328.) This market, at the very least, encompasses branded and generic versions of transdermal Fentanyl and extended-release Oxycodone, Morphine, Hydromorphone, Tapentadol, Hydrocodone, and Oxymorphone. (FOF ¶ 696; RX-547 (Addanki Rep. ¶ 85).)

The Federal Trade Commission reached virtually the same conclusion in 2009. In the *King Pharmaceuticals* matter, the Commission identified a relevant market consisting of "the manufacture and sale of oral LAOs," which included "orally-administered extended-release formulations of . . . oxycodone, morphine sulfate and oxymorphone." (Compl. ¶¶ 1, 12, *In re King Pharmaceuticals, Inc. & Alpharma Inc.*, No. C-4246 (F.T.C. Feb. 2, 2009).) In its analysis published in the Federal Register, the Commission stated that although "oral LAOs are based on distinct chemical compounds, . . . all of these products have the same mechanisms of action, similar indications, similar dosage forms and similar dosage frequency." King Pharm., Inc. and

Alpharma Inc. Agreement Containing Consent Order to Aid Public Comment, 74 Fed. Reg. 295, 296 (Jan. 5, 2009). The Commission specifically noted that "***Endo Pharmaceutical's Opana ER . . . also competes in the market***." *Id.* (emphasis added). Complaint Counsel's litigation-driven disavowal of the LAO market may be convenient, but it does not comport with "the commercial realities of the industry"—realities the Commission itself recognized. *Brown Shoe*, 370 U.S. at 336 (quotation omitted).[34]

B. Endo Did Not Have Monopoly Power in the Relevant Market.

Endo did not have monopoly power in the relevant market. From January 2009 through December 2012,[35] Opana ER's share of the LAO market never reached 10%. (FOF ¶ 1002; Addanki, Tr. 2233; RX-547 (Addanki Rep. ¶ 94, Ex. 10).) By Endo's own estimate, its market share was just 3.4% near the time of the settlement. (FOF ¶ 1004; CX3273 at 3.) It is "inconceivable" that Endo could command monopoly power with such a small share of the relevant market. (Addanki, Tr. 2233); *see Vollrath Co. v. Sammi Corp.*, 9 F.3d 1455, 1461 (9th Cir. 1993) ("no danger of monopoly power" where defendant "controlled only 10% of the market"); *Ryko Mfg. Co. v. Eden Servs.*, 823 F.2d 1215, 1232 (8th Cir. 1987) ("clearly" defendant whose "share of the entire relevant market is at most between 8% and 10%" does not possess market power); *MHB Distribs., Inc. v. Parker Hannifin Corp.*, 800 F. Supp. 1265, 1270 (E.D. Pa. 1992) ("Even assuming Parker's market share were 10%, the percentage is insufficient to bestow market power upon Parker.").

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[34] As an aside, the Commission required King Pharmaceuticals and Alpharma to divest Kadian as a condition of the acquisition. *See* 74 Fed. Reg. at 296. Endo later attributed growth in Opana ER prescriptions to the "[d]ivestiture of Kadian to Actavis," as well as an "Oxycodone shortage," further underscoring that LAOs are reasonable substitutes. (FOF ¶ 801; RX-026.0005.)

[35] As Dr. Addanki explained at trial, the relevant time period for evaluating monopoly power and competitive effects is the period before and after the settlement, extending to Impax's launch of generic Opana ER in January 2013. (FOF ¶ 658; Addanki Tr. 2206, 2236–37.)

C. Complaint Counsel Failed to Carry Its Burden of Proving That Endo Possessed Monopoly Power in an Oxymorphone ER-Only Market.

Complaint Counsel asserts that Endo possessed monopoly power in a market consisting only of branded and generic Oxymorphone ER products. (Compl. ¶ 85.) Saying it does not make it so; Complaint Counsel has the burden of establishing the relevant market and proving Endo's power in it. *Queen City Pizza*, 124 F.3d at 436; *United States ex rel. Blaum v. Triad Isotopes, Inc.*, 104 F. Supp. 3d 901, 924 (N.D. Ill. 2015). To satisfy this burden, Complaint Counsel relied on the opinions of Dr. Noll, who purported to demonstrate Endo's monopoly power both indirectly and directly. (FOF ¶¶ 672, 977; Noll, Tr. 1365–66, 1404; CX5000 (Noll Rep. ¶ 184).)

Neither of Dr. Noll's "methods" holds water. To begin with, his "indirect" method hinges on a definition of the relevant market that consists ***only*** of branded and generic versions of Opana ER. This contrived market definition ignores real-world competitive realities and is not based on statistical or econometric analysis. Dr. Noll's "direct" method fares no better, as it would classify every business that holds a patent or has high fixed costs as a monopolist. This Court should reject Dr. Noll's conclusions as unsupported by common sense or record fact.

1. Complaint Counsel Did Not Present Indirect Evidence of Monopoly Power.

Dr. Noll primarily employed an "indirect" method of proving monopoly power, which centers on the degree of concentration in the relevant market. (FOF ¶ 977; Noll, Tr. 1405–06.) This, of course, requires him to first define a relevant market. *See Broadcom*, 501 F.3d at 307 ("Proving the existence of monopoly power through indirect evidence requires a definition of the relevant market."). At trial, Dr. Noll testified that his conclusion that the relevant market is limited to branded and generic Oxymorphone ER is based on **(1)** therapeutic differences among LAOs; **(2)** switching costs; **(3)** communications about pricing; **(4)** LAO manufacturers'

promotional efforts; and **(5)** whether various generic LAO entrants had any "visible effect" on sales of Opana ER. (FOF ¶ ¶ 980–86; *see* Noll, Tr. 1377–94.) None of these bases withstands even modest scrutiny.

Therapeutic Differences. Dr. Noll testified that his opinion about market definition rested, in part, on "therapeutic differences" among LAOs. (FOF ¶ 988; Noll, Tr. 1388.) He did not identify any examples at trial, though his report alludes to supposed differences in LAOs' half-lives, side effects, interactions, and modes of metabolism. (FOF ¶ 1000; CX5000 (Noll Rep. ¶¶ 139–44).) At no point did Dr. Noll show that these "differences" are economically meaningful. Nor could he. Both medical experts testified that no LAO is superior to any other, and confirmed that pain physicians have numerous options to choose from when a patient presents with chronic pain. (FOF ¶¶ 704, 708, 723; *see* Michna, Tr. 2125, 2148, 2176–77; Savage, Tr. 729–32, 743, 790–91.) Consistent with this testimony, Dr. Addanki showed that different LAOs are routinely prescribed to treat dozens of the ***exact same*** diagnoses. (FOF ¶ ¶ 721–22; Addanki, Tr. 2247–50; RX-547 (Addanki Rep. ¶ 64, Ex. 4).) Minor chemical distinctions do not create antitrust markets. *See Mylan*, 2015 WL 1736957, at *8–9 (testimony that Doryx had "unique characteristics that differentiate it from other antibiotics," such as its "side-effect profile," did not defeat conclusion that "all oral tetracyclines treat acne with similar effectiveness and so are interchangeable for that purpose").

Switching Costs. Dr. Noll claimed that "switching costs" further support his narrow market definition. (FOF ¶ 988; Noll, Tr. 1388.) In his view, switching between LAOs is costly because patients often have to taper off of the first drug and gradually titrate up on the second under the supervision of a physician. (FOF ¶ 987; Noll, Tr. 1389–90.) But again, Dr. Noll did not show that these costs are economically material. As he admitted on cross-examination, he

did not attempt to estimate or quantify these costs; he merely identified them. (FOF ¶ 986; Noll, Tr. 1553–52.) He also overlooked copious evidence showing that any switching costs, to the extent they exist, have not prevented LAOs from being reasonable substitutes. Dr. Savage testified that switching can be "simple," and that she has ***never*** been unable to switch a patient from Opana ER to another LAO. (FOF ¶ ¶ 734–35, 739; Savage, Tr. 762, 793–94.) Dr. Michna likewise confirmed that switching between LAOs is not complex, and is "probably done thousands of times each day." (FOF ¶ 730; Michna, Tr. 2124–27.) And as the UPMC study showed, switching can result in overall cost ***savings***. (FOF ¶ 853; RX-087.)

Communications About Pricing. In opining on his proposed market definition, Dr. Noll vaguely alluded to documents that "talk about pricing," saying that Endo "rarely considered the prices of other drugs." (FOF ¶ 860 (quoting Noll, Tr. 1392–94).) His report points to several Endo documents that concern changes to Opana ER's WAC (*i.e.*, list) prices. (FOF ¶ 833; *see* CX5000 (Noll Rep. ¶¶ 203, 208–14); *e.g.*, CX2673-004; CX2678-019–20; CX2670-002, -005.) It is not clear why these discussions matter, since, as Dr. Noll himself admitted, [redacted] (FOF ¶ 834; Noll, Tr. 1681.) [redacted] (FOF ¶ 831; Addanki, Tr. 2290; Noll, Tr. 1681, 1684–85), and Dr. Noll's own analysis showed [redacted] (FOF ¶ 830; Noll, Tr. 1679–82; CX5000 (Noll Rep., Ex. 7A).) Dr. Noll did not address that decline, nor did he address the competition from other LAO manufacturers that caused it.

When it came to the kind of price competition that matters in the pharmaceutical industry, Endo ***did*** discuss its rivals' prices. For example, Endo tracked its competitors' "[a]ggressive couponing" when formulating its own patient copay program. (FOF ¶ 906 (quoting RX-028.0011; *see* Addanki, Tr. 2280–82).) [redacted] (FOF ¶ 912; RX-

445.0015.) In Dr. Noll's own report, he discusses an email in which Endo noted that Purdue had offered Group Purchasing Organizations ("GPOs")[36] discounts on OxyContin ranging from 15% to 20%. (FOF ¶ 850; CX5000 (Noll Rep. ¶ 149) (citing CX3206).) In order to "achieve pricing parity to Oxycontin," Endo proposed "an additional 11% discount on Opana ER" in response. (FOF ¶ 850; CX3206-002.) Oddly, rather than viewing this for what it is—evidence that Endo ***did*** consider its competitors' net prices—Dr. Noll faults Endo for "not attempt[ing] to estimate the profitability of the proposal by using an estimate of the cross-elasticity of demand between Opana ER and OxyContin." (FOF ¶ 983; CX5000 (Noll Rep. ¶ 150).) Of course, as Dr. Noll admitted at trial, he also did not attempt to calculate the cross-elasticity between Opana ER and any other LAO. (FOF ¶ 983; Noll, Tr. 1517.)

Promotional Efforts. Dr. Noll claimed that LAO manufacturers' promotional efforts cut against the existence of an LAO market because they "focused primarily on product differentiation." (FOF ¶ 997; Noll, Tr. 1394.) In his view, differentiation efforts can have the effect of "undermining, rather than enhancing, price competition, and in so doing reduce[] . . . the likelihood that two products are in the same relevant market." (FOF ¶ 998; CX5004 (Noll Rebuttal Rep. ¶ 53).) By this logic, the existence of advertising—one of the most ubiquitous forms of competition known to man—is taken as a sign that products ***lack*** competition. This defies common sense. *See* Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 520c (rev. ed. 2017) ("[N]onprice competition is too widespread to indicate power, for it accompanies virtually all product differentiation, and most product differentiation does not indicate substantial

[36] "Group purchasing organizations, or GPOs, are entities that, through the collective buying power of their members, obtain lower prices for . . . products." *FTC v. Sysco Corp.,* 113 F. Supp. 3d 1, 18 (D.D.C. 2015) (discussing GPOs in food purchasing).

market power for anyone. Indeed, highly competitive firms advertise [and] vary products."). That auto makers differentiate their cars on the basis of fuel efficiency, reliability, comfort, and other qualities does not mean that each car occupies a separate market. *See Town Sound*, 959 F.2d at 478–81 (evidence that Chrysler's advertising compared the "features of its autos with other companies' [cars]" ***supported*** the conclusion that "Chrysler cars compete vigorously with many other companies' automobiles").

Dr. Noll fails to appreciate that LAO manufacturers attempted to differentiate their products precisely ***because*** they were close substitutes. As one Endo document observed about the LAO market, "***[p]roducts are not very differentiated***"—which is exactly why Endo's marketing platform emphasized Opana ER's purported advantages over other LAOs, such as its "12 hour dosing." (FOF ¶ 999 (quoting RX-023.0002 (emphasis added)); *see Mylan*, 2015 WL 1736957, at *10 (advertisements emphasizing different oral tetracyclines' purported "advantages" over rivals supported conclusion that they were "effective substitutes for each other."))

Generic Entry. Finally, Dr. Noll asserted that the relevant market is limited to Oxymorphone ER because Impax's and Actavis' generic Opana ER products drew share from Endo's branded Opana ER, while the launch of other generic opioids did not. (FOF ¶ 980; Noll, Tr. 1377–87.) But this is not supported by any statistical or econometric analysis. FOF ¶ 983 Addanki, Tr. 2331.) Dr. Noll admitted that he did not calculate cross-elasticity of demand between Opana ER and any other LOA, nor did he conduct a "SSNIP" test. (FOF ¶¶ 981, 983; Noll, Tr. 1514, 1517.) Dr. Noll merely scanned sales trends for any "visible effect" on Opana ER sales, a metric he did not define. (FOF ¶ 985; Noll Tr. 1384.) Even if Impax's and Actavis' generic products ***were*** more successful than other generic LAOs in stealing share from Endo's

Opana ER—which would not be surprising, given that Actavis' product benefited from an AB-rating and Impax specifically focused its marketing efforts on Opana ER prescribers[37]—that does not rule out competition between Opana ER and other LAOs. The uncontroverted evidence presented at trial establishes that LAOs competed at the payor, patient, and prescriber levels, and that changes in relative price (as embodied in formularies) ***did*** induce significant switching among LAOs. (*See* Part III.A, *supra*; FOF ¶ 993; Addanki, Tr. 2332; RX-087.)

Because Complaint Counsel did not carry its burden of proving that the relevant market was limited to Oxymorphone ER products, it cannot rely on Dr. Noll's "indirect" method for establishing monopoly power.

2. Complaint Counsel Did Not Present Direct Evidence of Monopoly Power.

As a backstop to his unpersuasive "indirect" analysis, Dr. Noll fell back on what he described as "direct indicators of market power." (FOF ¶ 672; Noll, Tr. 1412–14; CX5000 (Noll Rep. ¶ 198).) He identified two supposed "indicators": **(1)** Endo's alleged ability to exclude competitors; and **(2)** Endo's alleged ability to profitably set prices above a competitive level, as supposedly measured by its Lerner Index. (FOF ¶ 672; Noll, Tr. 1412–14.) Both fall flat.

a. *The Possession of Intellectual Property Does Not Inherently Bestow Monopoly Power.*

Dr. Noll asserted that Endo had monopoly power because it "was able to exclude people from the market" through "enforcement of patent rights." (FOF ¶ 685; Noll, Tr. 1412; *see* CX5000 (Noll Rep. ¶ 199).) However, the Supreme Court has squarely rejected the "'patent equals market power' presumption." *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 44 (2006); (FOF ¶ 686; *see* Addanki, Tr. 2343 ("We have known for a very long time now that

[37] (FOF ¶ 158.)

patents do not confer monopoly power.").) As the antitrust agencies aptly put it, "[a]lthough the intellectual property right confers the power to exclude with respect to the specific product, process, or work in question, there will often be sufficient actual or potential close substitutes for such product, process, or work to prevent the exercise of market power." U.S. Dep't of Justice & Fed. Trade Comm'n, *Antitrust Guidelines for the Licensing of Intellectual Property* § 2.2 (2017).

That was exactly the case here. Endo's patents merely "prevent[ed] competitors from making direct copies of Opana ER." (FOF ¶ 687; Addanki, Tr. 2343.) But that is not to say that other drug companies were excluded from ***competing***. "[T]o the extent that other long-acting opioids competed with Opana ER, the patents had no ability to block them." FOF ¶ 688 (quoting Addanki, Tr. 2343).) Drug makers remained free to compete with Opana ER by selling their own pain medications—and indeed, new LAOs were able to enter notwithstanding Endo's patents. (FOF ¶ 688; Addanki, Tr. 2343.)

As a matter of law, the mere fact that Endo has successfully asserted its patent rights does not prove monopoly power. *See Ill. Tool Works*, 547 U.S. at 43–46.

b. *Pricing Above Marginal Cost Does Not Prove Monopoly Power.*

Dr. Noll testified that he relied on Endo's "Lerner Index" to conclude that "Endo could profitably set prices above a competitive level." (FOF ¶ 675 (quoting Noll, Tr. 1412–13).) A Lerner Index is the "markup of price over some estimate of marginal cost." (FOF ¶ 673; Noll, Tr. 1413; *see* CX5000 (Noll Rep. ¶ 215).) In simple terms, a higher Lerner Index indicates a high price-to-marginal cost ratio. (FOF ¶ 673; *see* RX-547 (Addanki Rep. ¶¶ 102–03).) According to Dr. Noll's report, "[h]igher values imply greater market power, and any value significantly above zero indicates the presence of market power." (CX5000 (Noll Rep. ¶ 215); *see* FOF ¶ 674.) He estimated that Endo's Lerner Index for Opana ER was "over 0.7 and often around 0.8," which he interpreted as "indicating the presence of substantial market power."

(FOF ¶ 674 (quoting CX5000 (Noll Rep. ¶ 226)).)

Dr. Noll backed away from these opinions in the course of his direct examination at trial. He acknowledged that, contrary to the statements in his report, a high Lerner Index "doesn't necessarily mean" that a firm has monopoly power. (FOF ¶ 677 (quoting Noll, Tr. 1415).) While a high Lerner Index indicates that a firm can "sustain price above marginal cost," "[w]hether they have monopoly power depends on other things." (FOF ¶ 677 (quoting Noll, Tr. 1415).) For example, because the software industry is characterized by high fixed costs but negligible marginal costs, software developers have a "very high Lerner Index." (FOF ¶ 678 (quoting Noll, Tr. 1415.)) But that does not mean that every app developer is a monopolist. (FOF ¶ 676; Addanki, Tr. 2341–42.) Rather, having a high Lerner Index is a "normal market outcome in an industry with high fixed costs and low marginal costs"—which, as Dr. Noll testified, ***includes the pharmaceutical industry***. (Noll, Tr. 1416; *see* FOF ¶ 681) "But whether there's monopoly profit or not you don't know." (FOF ¶ 676; Addanki, Tr. 2341; Noll, Tr. 1416.)

These unforced concessions completely negate the idea that a high Lerner Index is a "direct indicator" of monopoly power, as asserted in Dr. Noll's report. (FOF ¶ 672; CX5000 (Noll Rep. ¶¶ 198, 215).) As Dr. Noll now appears to realize, the "direct test" for monopoly power is ***not*** whether a firm has a high Lerner Index, but whether there is "direct evidence of supracompetitive prices ***and*** restricted output." *Broadcom*, 501 F.3d at 307 (emphasis added); *see Rebel Oil*, 51 F.3d at 1434 (same). Complaint Counsel has not come forward with evidence that Endo imposed supracompetitive prices or restricted output—much less both.

Proof of supracompetitive prices requires, among other things, evidence that the "defendant had an ***abnormally*** high price-cost margin." *Mylan*, 838 F.3d at 434 (quoting

Geneva Pharm. Tech. Corp. v. Barr Labs, Inc., 386 F.3d 485, 500 (2d Cir. 2004)) (emphasis added). Complaint Counsel has not even attempted to show that Endo's price-cost margins were "abnormal." Far from it, Dr. Noll testified that a high Lerner Index is a "normal market outcome" in the pharmaceutical industry, which has notoriously high fixed costs. (FOF ¶ 681; Noll, Tr. 1416.) High or not, Endo's Lerner Index says nothing about whether it was charging supracompetitive prices or otherwise exercising monopoly power. *See Mylan*, 2015 WL 1736957, at *7–8 (defendant's margin of 83% did not show monopoly power since there was no evidence that margin was "abnormally high"); *In re Wireless Tel. Servs. Antitrust Litig.*, 385 F. Supp. 2d 403, 422 & n.27 (S.D.N.Y. 2005) (testimony that defendants' Lerner Indices were 0.85 and 0.5 did not establish monopoly power).

Nor did Complaint Counsel present evidence that Endo restricted output. In fact, as Dr. Addanki testified, if Endo ***had*** been exercising monopoly power to restrict output, then we should have seen an expansion in overall output when Impax launched generic Opana ER in January 2013. (FOF ¶ 664; Addanki, Tr. 2348–50; RX-547 (Addanki Rep. ¶ 96, Ex. 12).) When Impax entered the market, however, there was ***no*** increase in prescriptions of branded and generic Opana ER, indicating that Endo had not been exercising monopoly power by restricting output. (FOF ¶ 668; Addanki, Tr. 2350; RX-547 (Addanki Rep. ¶ 96).)

Because Complaint Counsel has not shown that Endo charged supracompetitive prices and restricted output, there is no direct evidence of Endo's supposed monopoly power.

* * *

Complaint Counsel did not shoulder its burden of proving monopoly power. In the absence of monopoly power, the challenged settlement agreement cannot be anticompetitive under the rule of reason. *Leegin*, 615 F.3d at 418–19; *Chicago Prof'l Sports*, 95 F.3d at 600;

(*see* Noll, Tr. 1574.) Impax is entitled to judgment on this basis.

IV. Complaint Counsel Failed to Prove Anticompetitive Effects.

Proof that the challenged restraint had anticompetitive effects in the relevant market is the *sin qua non* of the rule of reason. *See In re Se. Milk Antitrust Litig.*, 739 F.3d 262, 270 (6th Cir. 2014) ("If the rule of reason is used, plaintiffs must additionally show that the restraint produced anticompetitive effects within the relevant product and geographic markets."); *Great Escape, Inc. v. Union City Body Co.*, 791 F.2d 532, 539 (7th Cir. 1986) ("Under the rule of reason the plaintiff must allege and prove anticompetitive effects."). This entails an analysis of "real market conditions," *Leegin*, 551 U.S. at 903, and the restraint's "actual effect" therein, *Copperweld*, 467 U.S. at 768. Because Complaint Counsel has failed to prove this fundamental element, judgment should be entered for Impax.

A. Complaint Counsel Does Not Contend—and Did Not Attempt to Prove—That Consumers Would Have Been Better Off Absent the SLA.

Disregarding basic rule of reason principles, Complaint Counsel declined to offer any proof of anticompetitive effects. Dr. Noll opined that he could simply "infer whether a settlement is anticompetitive from the terms of the agreement," (Noll, Tr. 1663; *see* FOF ¶ 1417), and that he need not "model what's going to actually happen in the market," (FOF ¶ 1416 (quoting Noll, Tr. 1661).) Professor Bazerman similarly testified that his "opinions were not dependent on . . . outcomes." (FOF ¶ 1496 (quoting Bazerman, Tr. 897).) Indeed, ***none*** of Complaint Counsel's experts even attempted to measure anticompetitive effects. (*See* FOF ¶¶ 1497–98, 1428, 1457.)[38] This is fatal in a rule of reason case. *See Procaps S.A. v. Patheon Inc.*,

[38] (*See, e.g.*, Bazerman, Tr. 897–98 (admitting that "[his] opinions were not dependent on" whether "the agreements between Endo and Impax were bad for consumers," and that he had not assessed whether consumers would be better off absent settlement); Noll, Tr. 1665 ("Q. You did not measure what the actual anticompetitive effects are[?] A. That's correct."); Hoxie, Tr. 2903

141 F. Supp. 3d 1246, 1281–82 (S.D. Fla. 2015), *aff'd*, 845 F.3d 1072 (11th Cir. 2016) (granting summary judgment in part because plaintiff "never measured the magnitude of the alleged effects on the relevant markets").

Dr. Noll posited that, rather than showing actual competitive effects, Complaint Counsel need only demonstrate that the settlement included a large, unjustified payment and eliminated ***some*** unspecified possibility of earlier entry. (*See* FOF ¶¶ 1398–1402; *see also* Noll, Tr. 1446 (describing three-part test)). Under Dr. Noll's test, even one day of delay beyond the date of ANDA approval would do it. (*See* FOF ¶ 1400.) And at that point, he said, this Court can conclusively ***assume*** anticompetitive effects, because "a large reverse payment settlement rules out the possibility that the settlement could benefit consumers." (FOF ¶ 1418 (quoting CX5004-065).)

This is wrong, of course. The Court may not infer anticompetitive effects "from the mere presence of a reverse payment." Comm'n Decision at 8; *see Actavis*, 133 S. Ct. at 2237. Inferring anticompetitive effects from conduct alone is the hallmark of a *per se* analysis, not the rule of reason. *See Se. Milk Antitrust Litig.*, 739 F.3d at 270 ("If the rule of reason is used, plaintiffs must additionally show that the restraint produced anticompetitive effects within the relevant product and geographic markets, while the per se rule is reserved for restraints that are so clearly unreasonable that their ***anticompetitive effects within geographic and product markets are inferred***.") (emphasis added).

Nonetheless, Complaint Counsel and their experts stuck to their *per se* theory. At trial, Complaint Counsel made clear that it does not contend, and did ***not*** attempt to prove, that:

("Q. Sir, you don't offer any opinions about the effect of the settlement and license agreement in the long-acting opioid market; correct? A. . . . No, I don't offer [that] opinion.").)

- Impax and Endo could have or would have entered into a hypothetical alternative settlement with an earlier licensed entry date. (*See* FOF ¶¶ 914, 1458–59; *see also* Noll, Tr. 1484 ("you don't need to know that"); Noll, Tr. 1596 ("Q. Sir, you're not offering an opinion in this case as to whether a hypothetical alternative settlement with an earlier date would have been feasible between Impax and Endo, are you? A. No."); Bazerman, Tr. 914 ("Q. And you can't say with certainty that an alternative settlement was possible in this case, can you? A. No."));
- Impax would have prevailed in the patent litigation. (FOF ¶¶ 102, 1430, 1109; Noll, Tr. 1441 ("[Y]ou don't need to know anything about the viability of the patent."; Noll, Tr. 1623 ("Q. And you did not conduct any assessment of how likely Endo's patents were to be upheld; correct? A. That's correct.")); ***or***
- Impax would have launched at-risk. (FOF ¶¶ 1385, 1393, 1396; *see also* Noll, Tr. 1600; Noll, Tr. 1484 ("You don't have to evaluate [] the value of at-risk launch"); Hoxie, Tr. 2769 ("Q. And in your report you've not calculated the odds that Impax would launch at risk; correct? A. . . . I don't sum up those risks and come up with odds."); Compl. Counsel, Tr. 27 ("Now, to be clear, complaint counsel is not asserting that absent this settlement Impax absolutely would have launched its generic Opana in June of 2010. We don't know what Impax would have done.").)

In other words, Complaint Counsel does not even have a ***theory***—much less ***proof***—that Impax would have begun selling generic Opana ER any earlier in the but-for world, or that consumers otherwise would have been better off but for the settlement.

Complaint Counsel's failure to put on effects evidence contrasts with what Complaint

Counsel did in *1-800 Contacts*. There, Complaint Counsel carried its burden under the rule of reason by putting on evidence of actual anticompetitive effects and consumer harm, and by "construct[ing] a 'but-for' world without the Challenged Agreements." *1-800 Contacts*, at 151–57. In fact, Complaint Counsel offered up ***two experts*** to model the but-for world: Dr. Susan Athey "constructed a model of a 'counterfactual' world to assess what would happen in the absence of the Challenged Agreements," *id.* at 157, and Dr. David Evans devised a model to "predict[] the number of additional advertisements that would be displayed by the competing retailers . . . if they were not bound by the Challenged Agreements," *id.* at 159. This Court recognized that there are always valid criticisms of predictive models, but held that "the models tend[ed] to reinforce" the record evidence that "the advertising restraints at issue significantly reduced informative advertising . . . [and] resulted in consumers purchasing contact lenses from 1-800 Contacts at higher prices." *Id.* at 160. Complaint Counsel shirked that burden here, proffering neither real-world evidence nor economic modeling to show competitive harm.

Complaint Counsel will likely intone that the SLA "prevent[ed] the risk of competition between June of 2010 and January, 1, 2013." (Compl. Counsel, Tr. 13.) Of course, as Complaint Counsel's experts admit, the same could be said of ***any*** entry-date settlement. (FOF ¶¶ 1399, 1487; *see* Noll, Tr. 1616 ("Q. And so settlements with only an entry date and no payment terms can eliminate the risk of competition; right? A. Yeah."); Bazerman, Tr. 882 ("Q. . . . Would you agree that an entry date-only settlement eliminates the risk of competition from a generic? A. Yes.").) This does not absolve Complaint Counsel of proving anticompetitive effects. In *In re McWane, Inc.*, No. 9351, 2014 WL 556261 (F.T.C. Jan. 30, 2014), Complaint Counsel alleged that McWane had entered into an agreement with Sigma to "***eliminate the risk of competition***." *Id.* at *32 (emphasis added). Evaluating that claim required the Commission to

determine whether Sigma's entry was "reasonably probable in the absence of the [challenged agreement]." *Id.* Despite some "troubling evidence" of McWane's intentions, the Commission concluded that Sigma was unlikely to have entered the market in the but-for world. *Id.* at *32–35. The Commission rejected Complaint Counsel's rule of reason challenge. *Id.* at *36–37.[39]

Try as it may, Complaint Counsel cannot escape the obligation to adduce evidence of anticompetitive effects. As discussed below, Complaint Counsel completely failed to prove at trial that the SLA was anticompetitive under the rule of reason.

B. The SLA Did Not Cause Anticompetitive Effects.

Consistent with Complaint Counsel's erroneous claim that it need not offer "proof that the agreement 'actually delayed generic competition or resulted in any actual harm to consumers,'"[40] Complaint Counsel failed to present ***any*** evidence that the SLA reduced competition or injured consumers. There is no evidence that Impax would have sold generic Opana ER any earlier than January 1, 2013 if it had not settled. Nor is there any evidence that Impax would have imperiled its very solvency by launching generic Opana ER at-risk. Complaint Counsel's abject failure to put on evidence of anticompetitive effects dooms its antitrust claims. *See Cal. Dental Ass'n v. FTC*, 224 F.3d 942, 958 (9th Cir. 2000) ("Under rule-of-reason analysis, then, because CDA's advertising restrictions do not harm consumer welfare, there is no antitrust violation. In other words, the FTC has failed to demonstrate substantial

[39] The Commission first rejected Complaint Counsel's market allocation theory, holding that Sigma was not "sufficiently likely to enter the domestic fittings market to be considered a potential competitor of McWane." *McWane*, 2014 WL 556261, at *32. Complaint Counsel alternatively challenged the McWane/Sigma agreement under the rule of reason, alleging (among other things) that it eliminated the possibility of Sigma entering the domestic fittings market in its own right. *Id.* at *36. The Commission disagreed, holding that its "finding that Sigma was not a probable entrant in the domestic fittings market" meant that "the prohibition against Sigma producing domestic fittings was unlikely to have had an anticompetitive effect." *Id.* at *37.

[40] (Summ. Dec. Reply at 9.)

evidence of a net anticompetitive effect.").

1. But for the SLA, Impax Would Have Been Mired in Litigation Until Well Past January 2013—Regardless of Whether Impax Would Have Prevailed.

Had Impax continued litigating instead of settling, consumers would have been worse off. Complaint Counsel did not offer any fact or opinion evidence to suggest Impax would have prevailed in its litigation with Endo. (FOF ¶¶ 1019, 1106, 1109.) Complaint Counsel's expert, Mr. Hoxie, would only offer the opinion that the outcome was "uncertain." (FOF ¶ 1567.) But even assuming Impax would have prevailed in the original patent suit, Impax would have been mired in litigation—and therefore unable to sell generic Opana ER without significant patent risk—until well beyond January 1, 2013. (FOF ¶¶ 1016–17.) In other words, as compared to continued litigation against Endo, the SLA provided a more expeditious route to selling generic Opana ER on a sustained basis—regardless of patent merits and litigation outcomes.

a. *The Original Patent Litigation Would Have Extended Until November 2011, If Not Longer.*

The trial in the original patent litigation between Impax and Endo began on June 3, 2010, and was scheduled to conclude on June 17, 2010. (FOF ¶¶ 106–07.) Because it was a bench trial, the court was unlikely to issue a ruling on June 17; it would have taken time for the court to issue its findings of fact and conclusions of law. (FOF ¶¶ 1075.) Using statistics from the relevant jurisdiction, Mr. Figg determined that, on average, it would have taken the trial judge between four and five months—or until at least November 2010—to issue a final appealable decision. ((FOF ¶ 1076; *see* Figg, Tr. 1906–07, 2027–28.)

While Complaint Counsel's patent expert, Mr. Hoxie, asserted that judges can issue decisions faster than the average—which is true as a mathematical necessity—he conceded that federal judges can also take "their own sweet time." (FOF ¶ 1077 (quoting Hoxie, Tr. 2860).) For example, in a later case involving additional patents covering Opana ER, it took another

district court over seven months to issue a decision. (FOF ¶ 1078; *see* RX-525.)[41] Had the court taken that much time in the original Impax/Endo litigation, the opinion would not have issued until 2011.

Once a decision is issued by a district court, it takes roughly a month for an appeal to be docketed. *See* Fed. R. Civ. P. 4(a). Statistics for the U.S. Court of Appeals for the Federal Circuit indicate that the median time from docketing to final decision was approximately 11 months in 2010 and 2011—a fact Mr. Hoxie did not dispute. (FOF ¶¶ 1081, 1116; *see* Hoxie, Tr. 2865 (estimate of one year from docketing to decision "sounds about right").) Therefore, the earliest Impax could have launched free from risk—assuming Impax prevailed—"would have been some point after November 2011." (FOF ¶ 1084 (quoting Figg, Tr. 1911).)

But resolution at the Federal Circuit was likely to take even longer than Mr. Figg's "very conservative" estimate. ((FOF ¶ 1081; *see* FOF ¶ 1116; Hoxie, Tr. 2865 (conceding that "it can often take longer").) The Federal Circuit statistics on which Mr. Figg relied include cases that are settled and Rule 36 affirmances, both of which skew the median earlier than a case decided by written opinion. (FOF ¶ 1081; *see* FOF ¶ 1115 (quoting Hoxie, Tr. 2860–61 (testifying that he did not "have any dispute . . . that the times that Mr. Figg puts out for each of those individual steps are . . . fair, reasonable, conservative average estimates").) And both Mr. Hoxie and Mr. Figg agreed that the Federal Circuit Court is amenable to extending deadlines when requested by the parties. (FOF ¶ 1082; *see also* Hoxie, Tr. 2866 (testifying Federal Circuit granted extension in current case).) Because of this, the Federal Circuit may not have issued a decision until long after November 2011. (FOF ¶¶ 1082, 1116; *see* Hoxie, Tr. 2865 ("[I]t can often take longer;

[41] Mr. Hoxie concedes that Impax would not have launched before receiving an opinion from the district court. (FOF ¶ 1215). *See* Part V(B)(2) *supra*.

correct? A. It can.").)

Moreover, if Impax prevailed at the Federal Circuit, the litigation probably would not have concluded with that decision. Mr. Figg testified that, given the nature of Impax's appeal, an appellate victory by Impax would likely have resulted in a remand to the district court for additional factual findings. (FOF ¶ 1086–87.) Remand is probable because, if Impax lost at the trial level, "the centerpiece of an appeal by Impax would have been the court's claim construction." (Figg, Tr. 1911–12; *see* FOF ¶¶ 1085–87 (quoting Hoxie, Tr. 2694 (agreeing that Impax would have "substantial arguments" on appeal about claim construction)).) And if the Federal Circuit sided with Impax on claim construction, it is "highly likely" that remand would have been necessary to resolve factual issues under the alternative claim construction. (Figg, Tr. 1912; *see* FOF ¶¶ 1087, 1120; Hoxie, Tr. 2874 (agreeing that remand is appropriate when there "there's a need for further findings of fact")); *see Pullman-Standard v. Swint*, 456 U.S. 273, 291–92 (1982) ([T]he usual rule is that there should be a remand for further proceedings to permit the trial court to make the missing findings. . . . Likewise, where findings are infirm because of an erroneous view of the law, a remand is the proper course unless the record permits only one resolution of the factual issue.").[42] As Mr. Figg testified, the remand process "would likely take somewhere between 6 and 18 months." (Figg, Tr. 1914; *see* FOF ¶ 1088.)

[42] Remand would have been appropriate because "there would not have been a record developed" on any alternative claim construction adopted by the Federal Circuit. (Figg, Tr. 1913.) This has to do with the structure of patent litigation. As Mr. Figg explained, "once th[e] construction order issued, the [parties] had to tailor their case to that claim construction." (Figg, Tr. 1873.) Mr. Hoxie agreed, testifying that "arguments aimed at a claim construction that had been rejected by the trial court might be excluded as irrelevant to the trial." (Hoxie, Tr. 2875; *see* FOF ¶ 1120.) Consequently, assuming Impax's appeal was successful, "the Federal Circuit would have simply said the claim construction is wrong, we're overturning it, but we don't have a record before us to decide the case under the correct claim construction, so all we can do is remand to the trial court to try the case under the correct claim construction." (Figg, Tr. 1913.)

If this happened, the remand would likely have extended the patent litigation up to or beyond January 2013—the date on which Impax launched generic Opana ER. (FOF ¶ 1089.) Thus, even if Impax ultimately prevailed in the original patent litigation (which was no sure thing), a final, nonappealable decision may not have issued until after January 2013.

b. *Even if Impax Prevailed in the Original Patent Litigation, Additional Patents Would Have Blocked Impax's Entry.*

Setting aside the likelihood of remand, even a total and final Impax victory in November 2011 would not have cleared a path for Impax to sell generic Opana ER free from patent risk. In December 2010, a patent covering Opana ER issued to another pharmaceutical company, Johnson Matthey. (JX-003-005 (¶ 31).) Johnson Matthey contacted Endo in October 2009 and Impax in May 2011 to put the companies on notice of the patent. (FOF ¶ 237; *see* RX-547 (Addanki Rep. ¶ 149); CX3329.003–006; RX-102.0003–4.)[43] Thus, any potential launch by Impax in November 2011 would have been knowingly at-risk as to the Johnson Matthey patent. (FOF ¶ 1094; Addanki, Tr. 2362–63.) Because of this, even if Impax won the original patent case—and somehow won it prior to January 2013—it still would not have been able to launch generic Opana ER free from patent infringement risk.

Consistent with its aggressive patent strategy for Opana ER,[44] Endo acquired the Johnson Matthey patent in March 2012. (FOF ¶ 235; Addanki, Tr. 2362; Figg, Tr. 1949.) Had Endo not settled with Impax, then "based on the economic incentives operating here, that [] same acquisition that Endo made in March 2012 would have been made much sooner because of the urgency of wanting to get that additional patent protection." (Addanki, Tr. 2362; *see* FOF ¶

[43] By way of clarification, Johnson Matthey contacted Endo in October 2009 regarding its then-pending patent ***application***. (FOF ¶ 1237; *see* RX-102.0003.) The patent did not issue until December 2010. (JX-003-006 (¶ 31).)

[44] (*See* FOF ¶ 1093; *see also* RX-547 (Addanki Rep. ¶ 150 & n.236).)

1094; RX-547 (Addanki Rep. ¶¶ 150–51).) Endo could then have asserted that patent against Impax, just as Endo has done with to respect to other generic companies. (*See* FOF ¶¶ 1103, 1443–44; *see* Figg, Tr. 1951, 1963–64; Addanki, Tr. 2360.)

Endo did not stop at the Johnson Matthey patent; Endo obtained two more patents (the '122 and '216 patents) in 2012. (JX-003-006 (¶¶ 37–38).) To clear a path to risk-free entry, Impax would have had to deal with ***those*** patents as well. Even if we assume that Impax had rock solid defenses to Endo's patent claims—and there is no evidence that it would have—there is no plausible set of circumstances in which Impax could have defeated those claims and launched generic Opana ER on a sustained basis before January 1, 2013. To the contrary, regardless of who prevailed in the original patent litigation, Endo's later patents ensured that "Endo and Impax would have been embroiled in continuing patent litigation" until well beyond January 2013, just as the other ANDA filers have been. (FOF ¶ 1104 (quoting Addanki, Tr. 2376, 2378–79); *see* FOF ¶ 1103; Figg, Tr. 1951; RX-547 (Addanki Rep. ¶ 154).)

The blocking power of Endo's later-acquired patents is not a mystery. Endo has successfully enforced its patents against numerous other ANDA filers for generic Opana ER. Endo commenced the second wave of litigation in late 2012, suing ANDA filers in the Southern District of New York for infringement of the '122 and '216 patents. (FOF ¶ 241; *see* RX-495; RX-497; RX-498; RX-499; RX-500; RX-501.) Had Impax not entered into the SLA, there is "little doubt" that "Endo would have included claims of infringement against Impax" in that litigation. (FOF ¶ 1444 (quoting Figg, Tr. 1951); *see* CX3437.) Endo confirmed as much in a later court filing.[45] Endo ultimately prevailed at the trial court, obtaining a permanent injunction

[45] Specifically, in a filing submitted pursuant to Federal Rule of Civil Procedure 11, Endo represented as follows to a federal district court in New Jersey: "As part of the New York Litigation, Endo would have sued Impax for infringing the '122 and '216 patents with respect to

that prevents the generic companies from selling generic Opana ER until February 2023. (FOF ¶ 244; *see* RX-525; Figg, Tr. 1957–59.)

The story does not end there. In November 2014, Endo commenced ***yet another*** wave of infringement litigation against ANDA filers for generic Opana ER relating to ***two more*** later-acquired patents (the '739 and '737 patents). (FOF ¶ 249; *see* RX-507; RX-508; RX-509; RX-510; RX-511; RX-512; RX-513: RX-514.) The most important of these patents is the '779 patent, which specifies a process for keeping impurities in the active pharmaceutical ingredient below a certain level. (FOF ¶ 248; *see* Figg, Tr. 1963–65.) The generic defendants stipulated that their generic Opana ER products infringed the '779 patent, and a district court in the District of Delaware upheld the patent as valid. (FOF ¶¶ 251–52; *see* RX-544; Figg, Tr. 1965.) In September 2017, that same court issued a final order enjoining the defendants from making or selling their generic Opana ER products until the expiration of the '779 patent in 2029. (FOF ¶ 252; *see* RX-575; Figg, Tr. 1963.) Mr. Figg confirmed that without the SLA, Endo would have had a colorable claim that Impax's generic Opana ER product infringes the '779 patent. (Figg, Tr. 1964–65.) Thus, in the but-for world, Impax would most likely also be enjoined from selling generic Opana ER until 2029. (FOF ¶¶ 252, 1102; *see* FOF ¶ 1099; Figg, Tr. 1972.)

Given Endo's success in enforcing its later-acquired patents, had "Impax not had the foresight to negotiate [a] license to future patents," there would most likely not be a "product on the market and available to consumers today." (FOF ¶ 1450 (quoting Figg, Tr. 1975–76).) Impax's decision to negotiate a licensed entry date of January 1, 2013 in combination with a

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the Impax Generic non-CRF Oxymorphone ER Tablets, as it had sued all of those other generics, ***but for*** the fact that unlike Endo's settlements of the New Jersey litigations with those generics, Endo's settlement with Impax included the above-described compromise pursuant to which Impax's license included rights to future issued patents." (CX3437.)

broad patent license "achieve[d] the seamless facilitation of a risk-free generic" launch ***earlier*** than could have been achieved through litigation. *Wellbutrin*, 133 F. Supp. 3d at 758–60; *see also id.* at 759 (Andrx sublicense "eliminat[ed] an independent and substantial hurdle to generic entry" by removing risk of patent infringement claims, thereby promoting competition). The SLA allowed continuous, risk-free sales of generic Opana ER from January 2013 onward, despite Endo's acquisition and successful enforcement of several additional patents.

c. *There Is No Evidence That Impax Would Have Prevailed in the Original Patent Litigation.*

As shown above, continued litigation would not have expedited Impax's ability to sell generic Opana ER on a sustained basis, regardless of whether Impax or Endo prevailed in the original patent suit. But available evidence demonstrates that a reasonable litigant in Impax's position at the time of the settlement would not have expected to win. A loss would have prevented Impax from selling generic Opana ER until September 8, 2013, when the original patents-in-suit expired—***eight months later*** than Impax's licensed entry date under the SLA. (FOF ¶¶ 125, 1448; *see* Figg, Tr. 1928, 1971; Hoxie, Tr. 2834.) And of course, by that point Impax would have faced lawsuits on Endo's later acquired patents. (*See* Part IV.B.1.b, *supra*.)

As Mr. Figg explained, in its March 2010 claim construction ruling, the district court overseeing the original patent litigation sided with Endo. (FOF ¶ 1032; *see* Figg, Tr. 1869.) Impax's proposed claim construction relied on a definition of *hydrophobic* that "described what the material is as well as what it does." (FOF ¶ 1041; *see* Figg, Tr. 1865–66.) Endo, in contrast, sought a "functional" definition that "would have required some kind of testing" to meet. (FOF ¶ 1041; *see* Hoxie, Tr. 2836; Figg, Tr. 1874–75.) After conducting a *Markman* hearing, the district court adopted Endo's proposed claim constructions "word-for-word." (FOF ¶¶ 1029, 1031; *see* Hoxie, Tr. 2836; RX-464; RX-465; RX-484.) Both patent experts agreed that

prevailing at the claim construction phase can be dispositive in patent infringement cases. (FOF ¶¶ 1025–26; Figg, Tr. 1863; Hoxie, Tr. 2671.) Therefore, a reasonable litigant in Impax's position "would have viewed [the claim construction order] as a significant setback for its case." (Figg, Tr. 1869; *see* FOF ¶ 1033.)

Whereas Impax had likely been "banking on" its non-infringement defense prior to claim construction (FOF ¶ 1038; *see* Figg, Tr. 1872), the adverse claim construction decision meant that Endo would probably prevail on that issue (FOF ¶ 1039; *see* Figg, Tr. 1884). The court's adoption of Endo's "functional" construction left Impax without any of the testing required to prove that its generic Opana ER product did not infringe Endo's patents. (FOF ¶ 1044; *see* Figg, Tr. 1874; Hoxie, Tr. 2839.) Instead, Impax was left to "simply criticize[] the testing that was done by the Endo expert." (Figg, Tr. 1874; *see* FOF ¶ 1044.) This put Impax in a difficult position, since Endo only had to prove infringement by a preponderance of the evidence (FOF ¶ 1044; *see* Figg, Tr. 1851; Hoxie, Tr. 2831),[46] and Endo's expert had conducted water uptake tests to support Endo's infringement case. (FOF ¶ 1043; *see* Figg, Tr. 1874–85.) As Mr. Figg explained, this meant that "Endo would have prevailed on proving infringement." (Figg, Tr. 1884; *see* FOF ¶ 1039.) While Mr. Hoxie quibbled with Mr. Figg's analysis, he offered no opinion as to which party would have prevailed on infringement. (FOF ¶ 1010; *see* Hoxie, Tr. 2841.) Mr. Figg's opinion stands unrebutted.

Impax faced a steeper climb in proving invalidity, which is subject to a "clear and convincing" standard of proof. (FOF ¶ 1043; Figg, Tr. 1885; Hoxie, Tr. 2845.)[47] Again,

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[46] *See Spectrum Pharm., Inc. v. Sandoz Inc.*, 802 F.3d 1326, 1336 (Fed. Cir. 2015) ("The burden of proving infringement by a preponderance of the evidence remains on the patentee.").

[47] *See Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011) ("We consider whether § 282 requires an invalidity defense to be proved by clear and convincing evidence. We hold that it does.").

Impax's failure to conduct any testing—this time of the prior art discussed in its expert reports—likely doomed its case with regard to its "anticipation" arguments.[48] (FOF ¶ 1057; *see* Figg, Tr. 1895–96; Hoxie, Tr. 2846.) Impax was unlikely to prevail on its "obviousness" and "written description" arguments as well.[49] (FOF ¶¶ 1059–66; Figg, Tr. 1898–99, 1900–02.) Mr. Hoxie did not contradict Mr. Figg's opinions on these matters because he offered no opinions on the ultimate outcome of these issues. (FOF ¶ 1112; Hoxie, Tr. 2852.)

To put it simply, Impax was more likely than not to lose the original patent case and be enjoined from selling generic Opana ER. (FOF ¶¶ 1018, 1068, 1101.) Mr. Hoxie left this ultimate opinion untouched; while Mr. Hoxie purported to "rebut" Mr. Figg's opinions, he did not offer ***any*** opinion of his own as to whether Endo or Impax was more likely to prevail. (*See* FOF ¶ 1112; Hoxie, Tr. 2693.) As a result, Mr. Figg is the ***only*** expert who offered any opinions in this case regarding the likely outcome of the original patent litigation.[50]

* * *

[48] Anticipation requires that a single prior art reference disclose (explicitly, implicitly, or inherently) every element of the claim, arranged as in the claim. A claim that is anticipated is invalid under 35 U.S.C. § 102 because the claimed subject matter is not novel. *See, e.g.*, *Net MoneyIN, Inc. v. VerisSign, Inc.*, 545 F.3d 1359 (Fed. Cir. 2008).

[49] To prevail on obviousness, a defendant must demonstrate that "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person of ordinary skill in the art to which the subject matter pertains." 35 U.S.C. § 103(a); *see, e.g.*, *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966).

A patent is invalid for lack of written description if a person of skill in the art would not conclude from reading the patent specification that the inventors had possession of the claimed invention as of the filing date. *See Ariad Pharms. Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

[50] The only firm opinions offered by Mr. Hoxie about the litigation were in full agreement with Mr. Figg: Mr. Hoxie agreed that the outcome of litigation is uncertain. (*See* Hoxie, Tr. 2693 ("I think the outcome was uncertain."); Hoxie, Tr. 2753 ("Q. You acknowledge the outcome of litigation is always uncertain, correct? A. Yes.").)

In sum, under no circumstance would continued litigation against Endo have freed Impax to sell generic Opana ER before January 1, 2013 or on a sustained basis, without the risk of infringement claims, injunctions, and potentially ruinous damages. Even if Impax prevailed in the original infringement case—and there is substantial evidence that it would not—it would have been mired in follow-on litigation relating to Endo's subsequently acquired patents until well after January 2013. In all likelihood, Impax would currently be subject to a permanent injunction preventing it from selling generic Opana ER until 2029, just as other ANDA filers are. The SLA indisputably facilitated sustained generic entry ***16 years earlier*** than that, to the benefit of thousands of consumers who suffer from chronic pain.

2. There Is No Evidence That Impax Would Have Launched Generic Opana ER At-Risk.

Given the litigation realities described above, the only avenue by which Impax could have launched generic Opana ER before January 2013 was to launch "at-risk"—that is, to sell product in the face of potential infringement damages. *Wellbutrin*, 133 F. Supp. 3d at 739. But Complaint Counsel offered no evidence—and does not even contend—that Impax would have launched at-risk had it not settled with Endo. To the contrary, the evidence shows that the legal, regulatory, and economic risks far outweighed any hypothetical benefits of an at-risk launch.

a. *Impax's Economic Incentives Disfavored a Launch At-Risk.*

To begin with, as Dr. Addanki explained, Impax's economic incentives were squarely against launching at-risk. (FOF ¶¶ 1363, 1368; *see* Addanki, Tr. 2379–80.) There are two reasons: ***first***, "the potential profit earned by Impax from the launch would fall short of the lost profit exposure should it have been found liable for infringement" (Addanki, Tr. 2380; *see* FOF ¶¶ 1139, 1364–65); and ***second***, "a launch at risk . . . put[s] the 180 days [exclusivity] in jeopardy" (Addanki, Tr. 2381; *see* FOF ¶¶ 1140, 1367). These factors explain why at-risk

launches are rare, especially for small, conservative companies like Impax. (FOF ¶¶ 1157–58; *see* CX4021 (Ben-Maimon, Dep. 34); Koch, Tr. 287.)

The first disincentive identified by Dr. Addanki is the reality that an at-risk launch can leave a generic company on the hook for lost profit damages. (FOF ¶¶ 1130–31, 1139, 1364–65, 1560; Addanki, Tr. 2380; Figg, Tr. 1921; Hoxie, Tr. 2782; Bazerman, Tr. 922.) Lost profit damages are measured by "the profit that the patent owner would have made on sales that it can show that it lost to the generic product." (Figg, Tr. 1922; *see* FOF ¶ 1131.)[51] If a court finds that the infringement was "willful," those lost profit damages can be trebled. (FOF ¶ 1132; Figg, Tr. 1923; Hoxie, Tr. 2786; Snowden, Tr. 494; *see also* FOF ¶ 1365.)[52]

Impax recognized that lost profit damages are a "very serious risk." (Koch, Tr. 286–87; *see* FOF ¶ 1137.) Impax's former CFO, Art Koch, testified that for a small company like Impax, launching at-risk was a "bet-the-company" decision that could imperil "the solvency of the company entirely." (FOF ¶ 1131 (quoting Koch, Tr. 287).) Impax's former CEO, Dr. Larry Hsu, agreed that "the risk can be huge." (FOF ¶ 1131 (quoting CX4030 (Hsu, Dep. 43)).) Indeed, there is ***no scenario*** in which paying lost profit damages can be profitable for a generic company. (FOF ¶ 1139; Figg, Tr. 1922; Addanki, Tr. 2379–80.)

Mr. Hoxie conceded that lost profit damages can be in the "billions" if the sales of the branded drug are sufficiently high. (FOF ¶ 1138; *see* Hoxie, Tr. 2782.) Assuming generic Opana ER would have taken $20 million in monthly sales from Endo, and assuming Endo had a

[51] *See Water Techs. Corp. v. Calco, Ltd.*, 850 F.2d 660, 671 (Fed. Cir. 1988) ("A patent owner may recover as a measure of damages the lost profits caused by the illicit competition of an infringer.") (quotation omitted).

[52] *See Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923, 1928 (2016).

90% margin,[53] Mr. Hoxie agreed that Impax faced upwards of $324 million in damages over six months after trebling (FOF ¶ 1365; *see* Hoxie, Tr. 2785–91), and $108 million without trebling (FOF ¶ 1365; *see* Hoxie, Tr. 2788–89). This potential risk pales in comparison to the $28 million in potential sales projected by Mr. Mengler. (FOF ¶ 1364; *see* CX2662.)

The second significant risk is unique to first-filers under the Hatch-Waxman Act: losing the right to exclusively sell the generic drug for 180 days. (FOF ¶¶ 1140, 1367; *see* Addanki, Tr. 2381; Snowden, Tr. 414; Figg, Tr. 1845; Hoxie, Tr. 2778–79; RX-547 (Addanki Rep. ¶ 142)); *see also Actavis*, 133 S. Ct. at 2228–29 (describing 180-day exclusivity provision). This exclusivity period is extremely valuable, and was included in the Hatch-Waxman Act as an "important carrot[] that helps induce generic companies to file ANDAs." (FOF ¶ 1141(quoting Addanki, Tr. 2381); *see* FOF ¶ 1140; Hoxie, Tr. 2754; Koch, Tr. 232; Noll, Tr. 1429.) The 180-day exclusivity period starts when the generic company launches its product, and once it starts, there is no stopping the clock. (FOF ¶¶ 1142, 1210; *see* Snowden, Tr. 503–04; Figg, Tr. 1923; CX4039 (Noll, Dep. 234–35).) This means that if a generic company that launches at-risk is hit with a temporary restraining order or preliminary injunction—a very real possibility[54]—"the 180-day clock will keep ticking." (FOF ¶ 1210 (quoting Snowden, Tr. 503–04); *see* FOF ¶ 1142; Figg, Tr. 1920, 1923; Noll, Tr. 1606; Addanki, Tr. 2381; Hoxie, Tr. 2778–80.) In that event, Impax would effectively lose the value of the 180-day exclusivity period that it had worked so

[53] Dr. Noll calculated Endo's profit margins using the Learner Index, and came up with a profit margin of 70% to 90% depending on the time period. (Noll, Tr. 1417.)

[54] As Ms. Snowden testified at trial, "what we've seen in this industry is, when a generic launches at risk, being enjoined is quite, quite possible." (Snowden, Tr. 503.) She described an example where Mylan, another pharmaceutical company, launched at-risk following a favorable district court ruling. (Snowden, Tr. 505.) Despite its favorable ruling, the district court issued a preliminary injunction following Mylan's at-risk launch, which resulted in Mylan effectively losing the benefit of its 180-day exclusivity period. (FOF ¶ 505; *see* Snowden, Tr. 505–06.)

hard to obtain.

Despite these daunting risks—and despite his own admission that Impax would not have launched generic Opana ER before the trial court issued its judgment[55]—Mr. Hoxie posited that Impax should have launched because of theoretical risks to not launching. (*See* Hoxie, Tr. 2760.) Specifically, Mr. Hoxie pointed to the risk that **(1)** Endo would switch to a reformulated version of Opana ER; and **(2)** new patents would issue. (Hoxie, Tr. 2706–07.) But these risks are entirely speculative. Mr. Hoxie never attempted to weigh the concrete risks of launching at-risk with the hypothetical risks of not launching. (FOF ¶ 1388; *see* Hoxie, Tr. 2760 ("I didn't take the second step and evaluate all of those risks and say this is what I would do if I were Impax."); *see also* FOF ¶ 1389.)[56] Nor did Mr. Hoxie attempt a risk-benefit analysis of the at-risk launch decision. (FOF ¶ 1387; *see* Hoxie, Tr. 2769–70.) Mr. Hoxie did not even "evaluate the magnitude of the potential lost profit damages that Impax could have faced if it launched at risk." (FOF ¶ 1390; *see* Hoxie, Tr. 2782–83.) Ultimately, Mr. Hoxie offered no opinion as to whether "an at-risk launch would have been a reasonable risk for Impax," opining only that it "***could*** have been a reasonable risk." (Hoxie, Tr. 2808 (emphasis added); *see* FOF ¶ 1391.)

Mr. Hoxie also ignored the fact that at-risk launches are rare, especially for smaller pharmaceutical companies like Impax. (FOF ¶ 1145; *see* Figg, Tr. 1924–26; Hoxie, Tr. 2827–28.) As he conceded at trial, most at-risk launches are taken by large companies with "a greater appetite for risk," like Teva. (FOF ¶ 1145 (quoting Hoxie, Tr. 2820).) Mr. Hoxie admitted that Impax is a "smaller company . . . that doesn't have the resources to spend money willy-nilly"

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[55] (*See* Hoxie, Tr. 2770 ("Q. So you understood Impax to be waiting to see if it got a favorable district court decision; correct? A. Yes."); FOF ¶ 1384.)

[56] Complaint Counsel's economic expert similarly conceded he did not evaluate the risks or benefits of an at-risk launch. (Noll, Tr. 1484 ("You don't have to evaluate [] the value of at-risk launch."); FOF ¶ 1396.)

(FOF ¶ 1162 (quoting Hoxie, Tr. 2772).)—a fact that Impax's former CFO confirmed (*see* FOF ¶ 1157; Koch, Tr. 275 ("Impax, being a small company, could not risk—could not bet the company on any one product")). Despite Mr. Hoxie's decades of experience in the pharmaceutical industry, he could only identify one instance in which he was personally involved with an at-risk launch. (FOF ¶ 1124; *see* Hoxie, Tr. 2761.)[57]

The risk that Impax would incur ruinous lost profit damages and forfeit the value of its 180-day exclusivity period meant that "it would make complete economic sense for Impax to view a launch at risk as a money-losing proposition." (Addanki, Tr. 2381; *see* FOF ¶ 1368.) Complaint Counsel offers no proof to the contrary.

b. *Impax Management Never Recommended, and Never Received Authorization For, an At-Risk Launch of Generic Opana ER.*

Impax presented unrebutted evidence that its management never even sought authorization from the company's Board of Directors to launch generic Opana ER at-risk—an absolute prerequisite for any at-risk launch. (FOF ¶¶ 1206–17; Snowden, Tr. 470; Koch, Tr. 299; CX4014 (Hsu, Dep. 85).) As Mr. Koch explained, deciding whether to launch a product at-risk required "the most significant effort," and entailed several important steps. (FOF ¶ 1184 (quoting Koch, Tr. 276).) If Impax were to consider a potential at-risk launch, the company's new product committee would first "evaluate the science and the legal from a general

[57] Mr. Hoxie's sole experience with an at-risk launch only further underscores why Impax would not have had an incentive to launch generic Opana ER at-risk. Mr. Hoxie conceded that his experience did not involve a product with first-to-file exclusivity, but rather was spurred by a "race" to market, which Mr. Hoxie characterized as a "common fact pattern for launches at risk." (FOF ¶¶ 1156, 1392; *see* Hoxie, Tr. 2704–05, 2781–82.) In this case, there was no "race" because Impax had secured the right to 180 days of exclusivity under the Hatch-Waxman Act. Further, Mr. Hoxie's one at-risk launch experience took place at Novartis, "one of the largest pharmaceutical companies in the world." (Hoxie, Tr. 2770–71; *see* FOF ¶¶ 12, 1183.) If Mr. Hoxie's own experience is any guide, at-risk launches are rare.

perspective." (Koch, Tr. 276; *see* FOF ¶ 1185.) At the committee's recommendation, in-house legal personnel and the research and development department would conduct "further diligence" on the opportunity. (FOF ¶¶ 1186–87; Koch, Tr. 276.) Impax management, including from the legal department, would then prepare a launch risk analysis for presentation to senior management, including the CEO. (FOF ¶¶ 1188–89; Koch, Tr. 267–77; CX3190-011.) If senior management decided to move forward, they would present a formal recommendation to the Board of Directors to authorize the at-risk launch, since "every at-risk launch is a board-level decision." (FOF ¶ 1179 (quoting Koch, Tr. 276–77); *see* Snowden, Tr. 426; CX4014 (Hsu, Dep. 127); CX4021 (Ben-Maimon, Dep. 160).)

Impax's executive committee would make its recommendation to the Board in a "very formal presentation" by Mr. Koch, the president of the generics division, and the heads of the legal and manufacturing divisions. (FOF ¶¶ 1191–92; *see* Koch, Tr. 277.) Mr. Koch indicated that "the board would often drill us on whatever interests or questions they have," and management "would frequently ask the board to appoint a special committee" to evaluate the proposal. (FOF ¶ 1196 (quoting Koch, Tr. 285–86).) Mr. Koch would "draft a resolution seeking [the Board's] vote," and the full Board would vote on whether to authorize the at-risk launch. (FOF ¶¶ 1198, 1201; *see* Koch, Tr. 277, 285–86; Snowden, Tr. 466.) The vote and resolution would then be recorded in the Board of Directors' minute book. (FOF ¶ 1199; Koch, Tr. 286.) At this point, the company ***still*** might not proceed with the launch. As Mr. Koch explained, the situation remains "fluid," and "nothing about an at-risk launch is set in stone." (FOF ¶ 1202; *see* Koch, Tr. 286.)

In the case of generic Opana ER, Impax management never even recommended an at-risk launch to the Board of Directors. (FOF ¶ 1207; Koch, Tr. 299; Snowden, Tr. 470–71; CX4030

(Hsu, Dep. 85).) There was no executive committee decision to recommend an at-risk launch; there was no presentation making such a recommendation; there was no discussion among the Directors of any recommendation; there was no draft resolution for the Board; and there was no vote taken by the Board. (FOF ¶ 1221; Koch, Tr. 295; Snowden, Tr. 470–71; Mengler, Tr. 584–85.) Had a recommendation been presented, discussed, or voted upon, it would have been "very carefully" recorded in the Board's meeting minutes. (FOF ¶ 1236; Koch, Tr. 289–90.) The actual minutes record nothing of the sort. (FOF ¶ 1235; *see* CX2663; Koch, Tr. 295, 297–99.) As Mr. Koch—who as Secretary to the Board of Directors prepared the meeting minutes—testified in response to questioning by this Court, he "[a]bsolutely" would have been aware of whether Impax had planned to launch generic Opana ER at-risk, and the fact of the matter is that Impax had no such plan. (FOF ¶ 1212; (quoting Koch, Tr. 324–25).)[58]

This stands in stark contrast with those situations in which Impax management ***has*** sought Board authorization for a potential at-risk launch. As Ms. Snowden described at trial, Impax has recommended an at-risk launch two times since 2010: once for Dutasteride, and once for Azelastine. (FOF ¶¶ 1172, 1203; *see* Snowden, Tr. 462, 467; CX4021 (Ben-Maimon, Dep. 156).) In each of these cases, the relevant minutes indicate that a full Board meeting was dedicated to discussing the potential launch, and that a Board resolution was presented and voted upon by the Directors. (FOF ¶¶ 1200, 1204; *see* CX3223; CX2689, Snowden, Tr. 463–66, 467–70; *see* CX4021 (Ben-Maimon, Dep. 153–54, 156–57).)[59] The unrebutted fact that ***none*** of this

[58] At most, Impax management chose to put a potential at-risk launch on the Board of Director's "radar screen." (FOF ¶ 1226 (quoting Mengler, Tr. 548); *see also* CX4030 (Hsu, Dep. 82) ("We want[ed] to alert the board that we [were] considering this scenario so that if we d[id] come up with a final recommendation to the board, there will be no surprise. . . . [T]his is very typical.").)

[59] In each instance the Board also limited Impax's risk by curtailing the size of the launch. (FOF ¶¶ 1176, 1204; *see* Snowden, Tr. 464–65, 467–69; CX4021 (Ben-Maimon, Dep. 37–39, 156–57); *see* CX2689; CX3223.)

happened with respect to generic Opana ER fatally undermines any notion that Impax would have launched generic Opana ER at-risk absent the SLA.

c. *The Fact That Impax Engaged in Routine Launch Preparation Activities Does Not Suggest an Intent or Preparedness to Launch At-Risk.*

Despite the lack of any evidence that Impax management sought (much less received) Board authorization to launch generic Opana ER at-risk, Complaint Counsel would apparently have this Court believe that Impax's observance of certain routine planning and preparation activities is indicative of an intent to launch at-risk.[60] No such inferences are warranted. Contemporaneous documents and witness testimony at trial make clear that Impax followed a set of procedures for ***all*** products in its pipeline, regardless of litigation status and independent of any decision to launch the product, at-risk or otherwise. Since Complaint Counsel presented no evidence to the contrary, this Court should disregard counsel's innuendos.

Impax's 10-K Annual Report for the year 2010 states as follows:

> When the Company concludes FDA approval is expected within approximately six months, the Company will generally begin to schedule manufacturing process validation studies as required by the FDA to demonstrate the production process can be scaled up to manufacture commercial batches. Consistent with industry practice, the Company may build quantities of pre-launch inventories of certain products pending required final FDA approval and/or resolution of patent infringement litigation, when, in the Company's assessment, such action is appropriate to increase the commercial opportunity, FDA approval is expected in the near term, and/or the litigation will be resolved in the Company's favor. The capitalization of unapproved pre-launch inventory involves risks, including, among other items, FDA approval of product may not occur; approvals may require additional or different testing and/or specifications than used for unapproved inventory; and, in cases where the unapproved inventory is for a product subject to litigation, the litigation may not be resolved or settled in favor of the Company. If any of these risks were to materialize and the launch of the unapproved product delayed or

[60] (*See* Compl. Counsel, Tr. 19–20 ("And in fact, Impax in early 2010 was taking active steps to be ready to launch a generic version of Opana ER.").)

> prevented, then the net carrying value of unapproved inventory may be partially or fully reserved.

(CX3278-101; *see* FOF ¶¶ 1261, 1264.) According to Mr. Koch, who as CFO had a hand in preparing the 10-K, this is an accurate description of Impax's practices in 2010. (FOF ¶ 1264; *see* Koch, Tr. 267–68, 270.) The rationale for making pre-launch quantities, even in the face of litigation, has to do with a philosophy of being prepared: readiness "sometimes involved long lead items," and it makes sense to incur the "small cost" necessary to "be prepared for the launch into a large market." (Koch, Tr. 270–71; FOF ¶¶ 1267–68; *see also* CX4014 (Hsu, IHT 86).) This practice was "routine" not just at Impax, but in the industry generally. (FOF ¶ 1265; (quoting Koch, Tr. 271).)

Impax followed routine launch preparation procedures for ***all*** products that fell within an 18-month planning window. (FOF ¶¶ 1240–41, 1244; Camargo, Tr. 952–53, 958, 1005–07.) For Paragraph IV products that were subject to litigation, Impax used the expected end of the 30-month stay as the target date for launch readiness. (FOF ¶ 1284; *see* Engle, Tr. 1768–69.) The 30-month stay represented the "earliest possible date" Impax could launch, and its goal was always to "be ready on day one." (Engle, Tr. 1769, 1772–73; *see* FOF ¶¶ 1348, 1359.) Impax followed this practice even when a "day one" launch was doubtful. Thus, while Impax used the expiration of the 30-month-stay in June 2010 to schedule launch planning activities for generic Opana ER, the company's Vice President of Supply Chain, Joe Camargo, recognized that "the odds of launching 6/10 [*i.e.*, June 2010] when the 30-month stay expires" were "low." (FOF ¶ 1289 (quoting RX-181); *see* Camargo, Tr. 1009.) As Mr. Camargo explained at trial, the odds of launching in June 2010 were "low" precisely because Impax "tended to shy away from" at-risk launches. (FOF ¶ 1290 (quoting Camargo, Tr. 1009–10).)

Launch planning activities in the 18-month window included, among other things,

obtaining "quota" from the Drug Enforcement Administration to purchase the necessary active pharmaceutical ingredient ("API")[61]; buying the API; and performing tests to validate the commercial manufacturing process. (FOF ¶¶ 1249–51; *see* Koch, Tr. 269–70; Camargo, Tr. 964–66, 1013; CX2915-003 (rows 20–22, 26–38).) This latter step, known as "process validation," involves manufacturing a certain amount of the product. (FOF ¶¶ 1251, 1259–60; Camargo, Tr. 966–67; Koch, Tr. 269–70; CX4030 (Hsu, Dep. 42).) While process validation batches may ultimately be sold to consumers (assuming validation is successful), they are often insufficient to support a launch. (FOF ¶¶ 1249, 1304; Camargo, Tr. 967–68.) To prepare for an actual launch, Impax would have to manufacture an additional "launch inventory build." (FOF ¶ 1252; *see* Camargo, Tr. 967–68.)

Impax followed many of these routine steps once generic Opana ER entered the 18-month planning horizon. (FOF ¶¶ 1284, 1288; Mengler, Tr. 558; Engle, Tr. 1769; Camargo, Tr. 1006.) In early 2010, Impax requested quota from the DEA to purchase Oxymorphone API; the DEA granted Impax's requests in part.[62] In the spring of 2010, Impax conducted process validation using a "matrix" approach, which entailed making fewer batches than would ordinarily be required. (FOF ¶¶ 1304–05; Camargo, Tr. 1012–13.)[63] While the matrix approach

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[61] Impax was required to request a "procurement quota" from the DEA for Oxymorphone before it could purchase any amount of Oxymorphone API, including to conduct process validation of its generic Opana ER product. The DEA procurement quota process is required for all controlled substances, such as opioids. (FOF ¶ 1293.)

[62] In March 2010, the DEA granted Impax quota to purchase Oxymorphone API, but not in the full quantities that Impax had requested. (FOF ¶¶ 1292–96; *see* JX-001-008 (¶¶ 24–27, 30).) As a consequence, Impax revised the launch inventory build downward from 12 batches to eight batches. (FOF ¶ 1298.) Impax submitted an additional quota request in April, but did not receive a response from the DEA until June 15, 2010—after the settlement had been concluded. (FOF ¶¶ 1299–1300; JX-001-009 (¶ 30).)

[63] As Mr. Camargo testified, "The default plan for process validations is to make three batches of each strength of the product; however, depending on the manufacturing process and how similar it might be between different strengths, you can sometimes abbreviate the process validation by

reduced the cost of process validation, the upshot was that Impax would have to "make up for it" by manufacturing even more batches during the launch inventory build. (Camargo, Tr. 1012–13; *see* FOF ¶ 1305.)

But Impax never did a launch inventory build for generic Opana ER. (FOF ¶ 1315; *see* Camargo, Tr. 1020.) Once the Operations division finished making the validation batches, it "needed management approval to proceed with th[e] launch inventory build." (Camargo, Tr. 1016; *see* FOF ¶ 1316; RX-186.0004 (according to Mr. Camargo's May 7, 2010 report to his direct report, Operations was "await[ing] management decision to proceed with 8-lot launch inventory build"); CX2898 (in May 12, 2010 email to Mr. Engle, Mr. Camargo wrote "we will not commence the launch inventory build until we receive direction to do so from senior mgmt").) Senior management never gave the go-ahead. (FOF ¶ 1317; *see* Camargo, Tr. 1020.) Indeed, when the FDA tentatively approved Impax's ANDA in May 2010, Dr. Hsu, the CEO, indicated that management would "most likely wait" until the district court issued its ruling before making any "launch decision." (FOF ¶ 1214 (quoting CX2929-001).) In late May, the head of Operations instructed Mr. Camargo to devote manufacturing capacity that might have been used to make generic Opana ER to making another product. (FOF ¶¶ 1325–26; *see* CX2904-001; Camargo, Tr. 1017–18.) Because of this, in June 2010, Impax did not have sufficient quantities to sustain a potential launch of generic Opana ER. (FOF ¶¶ 1321–24; *see* Engle, Tr. 1783–85, 1790; Koch, Tr. 292–93.)

Complaint Counsel makes much of the fact that after Impax and Endo settled the patent case, Impax ended up discarding the process validation batches of generic Opana ER, which

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using a matrix approach to cover the overall manufacturing process in a sufficient manner to meet the FDA's requirements. That's where we would do a matrix." (Camargo, Tr. 1012; *see* FOF ¶¶ 1204–05.)

were worth approximately $1.4 million. (FOF ¶ 1308; *see* Camargo, Tr. 994–95.)[64] This red herring is not remotely probative of whether Impax would have launched at-risk absent the SLA. Impax had to discard product "as a matter of course pretty much every month." (FOF ¶ 1277 (quoting Camargo, Tr. 1020–21, 1033.) Impax considered this a "cost of doing business" that happened "routinely." (Koch, Tr. 273; *see* FOF ¶ 1278; Camargo, Tr. 1033.) Discarding product valued in the $1.5 million range "happens frequently" and is "not unusual." (FOF ¶ 1312 (quoting Engle, Tr. 1785–86).) Impax's business records bear this out. For example, in March 2011 alone, Impax added ***over $2 million*** worth of materials to the list of inventory that was at risk of having to be discarded. (FOF ¶ 1282; *see* CX2922-003, -007, -009–10; *see also, e.g.*, CX2896 ($560,000 in rejected inventory in June 2010, not including Opana ER inventory); CX2905 ($1,008,000 in rejected inventory in April 2010); RX-186 ($319,000 in rejected inventory for March 2010).)

Complaint Counsel did not present ***any*** evidence to rebut this showing that Impax's launch planning activities were business as usual. Complaint Counsel therefore cannot contend that, but for the SLA, Impax would have launched generic Opana ER at-risk.

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Because Complaint Counsel has not come forward with a shred of proof that the SLA actually harmed competition or consumers, it has not carried its burden under the rule of reason. *Microsoft*, 253 F.3d at 95. Impax is entitled to judgment on this basis.

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[64] (*E.g.*, Compl. Counsel's Pretrial Br. at 18.) Complaint Counsel also glosses over the fact that Impax was likely able to use the Oxymorphone API it had on hand in June 2010 to support its January 2013 launch of generic Opana ER. (*See* FOF ¶ 1314; *see* Camargo, Tr. 1022 ("I believe that API was eventually used. It has a longer shelf life than the finished product that was manufactured.").)

C. The Settlement's Actual Procompetitive Benefits Far Outweigh Any Alleged Anticompetitive Effects.

The SLA was a good deal for consumers: it allowed Impax to begin selling generic Opana ER earlier than it otherwise could have, and to sustain sales notwithstanding Endo's acquisition and successful enforcement of several new patents. In fact, it is because of the SLA that Impax is the ***only*** company selling ***any*** version of Opana ER today. There can be no dispute that, on net, the SLA promoted competition and enhanced consumer welfare. *See Cal. Dental Ass'n v. FTC*, 526 U.S. 756, 771 (1999) (restraints that have "net procompetitive effect" are not unlawful); *Microsoft*, 253 F.3d at 95 ("[P]laintiffs must show that [defendants'] conduct was, on balance, anticompetitive."). The SLA's concrete procompetitive benefits far outweigh the hypothetical elimination of some unparticularized "risk" of competition. Under the rule of reason, this is dispositive. *See Microsoft*, 253 F.3d at 95 ("[I]t is plaintiffs' burden to show that the anticompetitive effect of the conduct outweighs its benefit.").

The Commission has already recognized that the SLA's broad license distinguishes this case from *Actavis* and its kin. In denying Complaint Counsel's Motion for Partial Summary Decision, the Commission noted that "this case involves factual circumstances not presented in *Actavis*. In particular, this case involves patents beyond those in litigation at the time of the Settlement Agreement, and a provision of that agreement allowed generic entry notwithstanding the potential that such patents might issue." Comm'n Decision at 12. The Commission further held that "the extent to which [the] settlement allow[ed] entry prior to patent expiration" is relevant to "balancing anticompetitive harms and procompetitive benefits." *Id.* (emphasis omitted). The facts, as proven at trial, bear out the Commission's intuition that Impax's freedom to operate under the SLA is central to assessing the deal's procompetitive benefits.

The Supreme Court has held that "enabl[ing] a product to be marketed which might

otherwise be unavailable . . . widen[s] consumer choice . . . and hence can be viewed as procompetitive." *NCAA v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 102 (1984). The SLA did just that—it enabled Impax to begin selling generic Opana ER, without patent risk, earlier than would otherwise have been possible. Impax anticipated that Endo was "banking on [its] pending patents" (FOF ¶¶ 146–47; *see* RX-398), and negotiated settlement terms to ensure that it would not be mired in patent litigation for years into the future—just as other ANDA filers for generic Opana ER have been. (FOF ¶ 244; Snowden, Tr. 441–42.) By "eliminating an independent and substantial hurdle to generic entry" and securing "the 'full freedom to operate' without the risk of [a further] patent infringement claim," the SLA ensured that consumers would have early and reliable access to a low-cost generic version of Opana ER—an indisputable consumer benefit. *Wellbutrin*, 133 F. Supp. 3d at 759; *see FTC v. AbbVie Inc.*, 107 F. Supp. 3d 428, 437 (E.D. Pa. 2015) (agreement that "facilitat[ed] Teva's ability to compete in the cholesterol drug market [was] good for the consumer" and procompetitive under *Actavis*); *Toscano*, 201 F. Supp. 2d at 1123 (challenged restraints "further[ed] consumer welfare" where they "provide[d] a product that would not otherwise exist").

While the SLA's procompetitive nature is not dependent on whether Impax or Endo would have prevailed in the original or follow-on patent cases, the fact that two courts have upheld Endo's patents is further evidence that the SLA was a boon for consumers. *See* Comm'n Decision at 12 (subsequent patent rulings relevant to rule of reason analysis). Had Impax not entered into the SLA, it almost certainly would be in the same boat as other ANDA filers—permanently enjoined from selling generic Opana ER until 2029. (FOF ¶¶ 244, 252, 1102; *see* JX-001-013 (¶ 62); RX-575; Figg, Tr. 1972.) Instead, Impax (and Impax alone) was able to enter the market ***16 years*** before patent expiration, and remain on the market thereafter. *See*

Comm'n Decision at 11–12 ("the ***extent*** to which a settlement allows entry prior to patent expiration" is probative of competitive effects). As the Court stated in *Actavis*, "settlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition, again to the consumer's benefit." 133 S. Ct. at 2234. Here, the extent of that consumer benefit far outweighs any hypothetical anticompetitive effects alleged by Complaint Counsel.

Consumers have benefited not only from having ***early*** access to Impax's generic Opana ER, but also from having ***sustained*** access to it. While there is no evidence that Impax would have launched at-risk absent the SLA, there is also no reason to believe that a theoretical at-risk launch would have provided a net increase in consumer welfare. If Impax had decided to launch at-risk, there was a very real likelihood that it would have been hit with an injunction after making only a small volume of sales. (FOF ¶¶ 1114, 1142; *see* Hoxie, Tr. 2835; Figg, Tr. 1923; RX-547 (Addanki Rep. ¶¶ 155–56).) It also bears noting that even in those few instances in its history when Impax has sought and received Board authorization for an at-risk launch, the Board has always imposed time or quantity limitations so as to minimize Impax's damages exposure. (FOF ¶¶ 1176, 1204; *see* Snowden, Tr. 464–69; RX-547 (Addanki Rep. ¶ 157); CX3223; CX2689.) Impax's five years of sustained sales have benefited far more consumers than likely would have benefited from a hypothetical at-risk launch. *See Eisai*, 821 F.3d at 403 ("assuring [consumers] the availability of supply" is a consumer benefit); *Wellbutrin*, 133 F. Supp. 3d at 760 ("ensuring consistent supply of product" is procompetitive).

Even Dr. Noll concedes that "consumers are better off" because Impax is selling generic Opana ER today. (Noll, Tr. 1669; *see* FOF ¶ 1453.) Dr. Savage agreed, testifying that for some patients, Opana ER is "an especially good medication," and that "having diversity in our choice

of opioids improves patient care and outcomes." (FOF ¶ 1454 (quoting Savage, Tr. 818).) These admitted benefits would not have been possible were it not for the SLA.

Because the SLA is indisputably procompetitive, the Court should enter judgment for Impax. *See Paladin Assocs., Inc. v. Montana Power Co.*, 328 F.3d 1145, 1158 (9th Cir. 2003) (affirming summary judgment for defendants because "the procompetitive benefits of MPC's five-year transportation assignments outweighed any anticompetitive harm they might have caused."); *Nat'l Bancard Corp. (NaBanco) v. VISA U.S.A., Inc.*, 779 F.2d 592, 603 (11th Cir. 1986) (affirming judgment that "on balance, the interchange fee is procompetitive in nature"); *Wellbutrin*, 133 F. Supp. 3d at 760 (granting summary judgment, in part, because defendant offered unrebutted evidence of procompetitive effects).

D. Procompetitive Effects Must Be Assessed with Reference to the Settlement Agreement as a Whole.

Complaint Counsel may urge this Court to ignore these real-world competitive effects, asserting that consumer benefits are not cognizable unless they flow from the alleged payment terms, rather than from the settlement as a whole. (*See* Compl. Counsel's Pretrial Br. at 34–40.) This approach is wrong as a matter of law and logic. For one, it conflates the initial question of whether Impax received a "large and unjustified" ***payment*** with the ultimate question of whether the challenged settlement caused "significant unjustified anticompetitive ***consequences***." *Actavis*, 133 S. Ct. at 2237–38 (emphasis added). These are distinct stages in the analysis. *See, e.g.*, *Lamictal*, 868 F.3d at 251–52 ("Reverse payment ***settlement agreements*** give rise to antitrust concerns," and are thus subject to rule of reason scrutiny, where "the ***payments*** are both 'large and unjustified'") (emphasis added); *Cipro*, 348 P.3d at 869–70 (after plaintiff proves a settlement that entails delay and a large and unjustified ***payment***, the defendant may "offer legitimate justifications and come forward with evidence that the challenged ***settlement*** is in fact

procompetitive") (emphasis added).

Complaint Counsel's argument fails to appreciate that courts "look[] at the whole of the settlement to determine its alleged effect on competition." *Loestrin II*, 2017 WL 3600938, at *16; *see Geneva Pharm.*, 386 F.3d at 507 (defendant entitled to "offer evidence of the pro-competitive effects of the[] ***agreement***") (emphasis added); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 752 (E.D. Pa. 2014) (competitive effects of challenged settlement and side deals must be assessed as a whole rather than "in isolation"). It is inappropriate to "evaluate the settlement . . . in a piecemeal, provision-by-provision approach," since settlements are "negotiated as a whole, agreed to as a whole, and [go] into effect as a whole." *Wellbutrin*, 133 F. Supp. 3d at 753–54; *see also* Comm'n Decision at 12–13 ("Some courts have held that the context of the broader settlement agreement in which a reverse payment occurs is relevant in assessing its anticompetitive effects.") (citing *Wellbutrin*, 133 F. Supp. 3d at 753–54, and *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 243 (D. Conn. 2015)). Even Dr. Noll testified that he "did not unpack the effect of each provision on consumer welfare because ***that's not the appropriate way to do it***." (Noll, Tr. 1647 (emphasis added).)

Finally, Complaint Counsel's assertion that any procompetitive benefits must be attributable to the alleged payment terms is nonsensical, since a payment has ***no*** competitive effect in isolation from the settlement. It is the ***agreement***, of which the alleged payment terms are a part, that restrains trade or promotes competition. *See* 15 U.S.C. § 1 (prohibiting ***agreements*** that unreasonably restrain trade); *Black's Law Dictionary* (10th ed. 2014) (defining "restraint of trade" as "[a]n agreement between two or more businesses" that eliminates competition); *Bd. of Trade*, 246 U.S. at 238 ("restrain" means to "bind"). Complaint Counsel's approach would permit it to cherry-pick value-conveying terms (alleged "payments") that it

considers objectionable, while ignoring others. As an example, Dr. Noll testified that the SLA's broad license made the settlement "more valuable to Impax," but conceded that the broad license "play[ed] no role" in his analysis. (Noll, Tr. 1645–48; *see* FOF ¶ 655.) It makes no sense to say that Impax must connect the SLA's consumer benefits to certain allegedly valuable provisions (*i.e.*, the Endo Credit and No-AG terms), but not ***other*** valuable provisions (*i.e.*, the broad license term). This head-I-win-tails-you-lose mentality is inconsistent with the rule of reason.[65]

E. Complaint Counsel Has Not Identified a Less Restrictive Alternative That Would Achieve the Same Procompetitive Benefits.

Once an antitrust defendant produces evidence of procompetitive benefits, the plaintiff can prevail only if it shows that these benefits "can be achieved in a substantially less restrictive manner." *Tanaka*, 252 F.3d at 1063; *see Geneva Pharm.*, 386 F.3d at 507 ("the burden shifts back to the plaintiffs to prove that any legitimate competitive benefits offered by defendants could have been achieved through less restrictive means"). This is unequivocally Complaint Counsel's burden. *O'Bannon*, 802 F.3d at 1074; *McWane*, 2014 WL 556261, at *36. And yet there can be no debate that Complaint Counsel has not shown—or even ***attempted*** to show—that the procompetitive benefits described above could have been achieved through some less restrictive alternative. This, too, is fatal to Complaint Counsel's claims. *See N. Am. Soccer League, LLC v. U.S. Soccer Fed'n, Inc.*, No. 17-CV-05495 (MKB), — F. Supp. 3d —, 2017 WL 5125771, at 15, *19–21 (E.D.N.Y. Nov. 4, 2017) (plaintiffs failed to show likelihood of success where defendant adduced evidence of procompetitive benefits and plaintiffs failed to "provide some alternative to the [challenged restraint] that offer[ed] the same procompetitive benefits . . .

[65] To the extent Complaint Counsel's argument merely asserts that the alleged payment terms were not necessary to achieve the SLA's procompetitive benefits—*i.e.*, that a substantially less restrictive alternative was feasible under the circumstances—Complaint Counsel has failed to make the necessary showing. (Part V, *infra*.)

'without significantly increased cost'"; denying motion for preliminary injunction) (quoting *O'Bannon*, 802 F.3d at 1074).

Complaint Counsel did not put on any evidence to suggest that any less restrictive alternative was feasible. Complaint Counsel cannot point to a shred of evidence that Endo offered or even would have entertained any settlement with an entry date before January 2013. Rather, every fact witness testified to the exact opposite: Mr. Mengler, Impax's lead negotiator, stated that Endo was "adamant about 2013 and not getting anything into 2012." (FOF ¶ 139 (quoting Mengler, Tr. 565).) Mr. Koch, another negotiator, said that Impax "met complete resistance to the concept of an earlier launch date." (FOF ¶ 138 (quoting Koch, Tr. 239).) Ms. Snowden testified that Impax sought a July 2011 entry date from Endo, but that Endo refused. (FOF ¶ 134–35; *see* Snowden, Tr. 419–20.) Far from rebutting these statements, Dr. Noll conceded that "Impax'[s] attempt to get an earlier date met with complete resistance," and that he was "not aware that they actually came anywhere near agreeing on anything other than what they agreed to." (Noll, Tr. 1597–1600; *see* FOF ¶ 139.) Professor Bazerman likewise admitted that he was aware of no evidence that Endo had ever offered an earlier day, and that, in fact, Endo had rebuffed Impax's requests for one. (FOF ¶ 1504, 1507–09; *see* Bazerman, Tr. 907, 915–16.)

Complaint Counsel did not even attempt to ***hypothesize*** an alternative settlement. While Professor Bazerman asserted that Impax "could have" and "should have negotiated an earlier entry date" (FOF ¶ 1503; *see* Bazerman, Tr. 907–08), he failed to provide this Court with any non-speculative basis for that opinion. As he admitted under cross-examination, he did not try to determine Impax's or Endo's reservation points, he could not identify the "zone of possible agreement between Impax and Endo," and he could not tell this Court what the hypothetical

alternative entry date would have been. (FOF ¶¶ 1505; *see* Bazerman, Tr. 907, 912–14.) In fact, when pressed, Professor Bazerman acknowledged that he could not "say with certainty that an alternative settlement was possible in this case." (FOF ¶ 1506; *see* Bazerman, Tr. 914.) Dr. Noll, for his part, frankly admitted alternative settlements "weren't considered" as part of his analysis. (Noll, Tr. 1596–97; *see* FOF ¶¶ 1458–59.)

To discharge its burden under the rule of reason, Complaint Counsel was required to "make a strong evidentiary showing" that a "substantially less restrictive alternative" was "viable here." *O'Bannon*, 802 F.3d at 1074; *see Wellbutrin*, 133 F. Supp. 3d at 760–61 (granting summary judgment for defendants where plaintiffs "have not presented evidence" that a less restrictive alternative settlement agreement was possible). Aside from Professor Bazerman's vague, offhand speculation, Complaint Counsel did not even ***attempt*** to address this requirement. Plainly this "showing" is inadequate. *Cf. Martin v. Omni Hotels Mgmt. Corp.*, 321 F.R.D. 35, 40–41 (D.D.C. 2017) ("a party cannot avoid summary judgment when it offers an expert opinion that is speculative and provides no basis in the record for its conclusions").

In the event this Court reaches this stage in the rule of reason analysis, Impax is entitled to judgment in full.

V. The Remedies Sought By Complaint Counsel Are Improper.

The Court need not reach the issue of remedies because Complaint Counsel failed to meet any of its burdens under the rule of reason. Nonetheless, this Court should reject each of the six remedies listed in Complaint Counsel's pretrial brief. Even if Complaint Counsel had shown that the Impax/Endo agreements violated the FTC Act under current law—and it has not—no remedy would be appropriate in light of the fact that the agreements complied with prevailing law in June 2010. At that time, most Courts of Appeals held that reverse-payment settlements

were ***lawful*** so long as they did not exceed the scope of the brand company's patents.[66] Complaint Counsel has offered no evidence that the SLA exceeded the scope of Endo's patents. (*See* FOF ¶¶ 378–80; Figg, Tr. 1933; *see also* Hoxie, Tr. 2745 (confirming he offered no opinion related to the scope-of-the-patents).) It would be unnecessary and unjust to impose a penalty on Impax for failing to anticipate a change in law that occurred three years after the fact.

Even setting aside this injustice, each of Complaint Counsel's remedies is inappropriate because it has no "reasonable relation to the unlawful practices" alleged here. *Standard Oil Co. v. FTC*, 577 F.2d 653, 662 (9th Cir. 1978) (quoting *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 394–95 (1965)). Complaint Counsel cannot even show that there is a risk of ***similar*** conduct occurring the future. Each proposed remedy is discussed below:

First, **Complaint Counsel seeks to "[p]rohibit[] Impax from being a party to any agreement that prevents, restricts, or in any way disincentivizes competition between oxymorphone ER products."** (Compl. Counsel's Pretrial Br. at 47.) This proposed remedy is unmoored from the FTC's investigation, the Complaint, and the evidence adduced at trial. There is simply no basis in the record to seek such relief. Based on Complaint Counsel's pretrial brief, this request may be a reaction to the 2017 settlement between Endo and Impax [redacted] (*See* CX3275.) However, Complaint Counsel said nary a peep about this request until it filed its pretrial brief. At no point did Impax give its "express or implied consent" to Complaint Counsel's constructive amendment

[66] *See, e.g.*, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1335 (Fed. Cir. 2008); (adopting the "scope-of-the-patent" test); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212–13 (2d Cir. 2006) (same); *Schering II*, 402 F.3d at 1076 (same); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1310 (11th Cir. 2003) (same). It is undisputed that the SLA fell within the scope of Endo's patents. (Figg, Tr. 1933; *see also* Hoxie, Tr. 2745 (confirming he offered to opinion related to the scope-of-the-patents).)

of its Complaint, as required by Rule of Practice 3.15(a)(2). 16 C.F.R. § 3.15(a)(2).

Complaint Counsel also put on no evidence related to the 2017 settlement. Complaint Counsel's "showing" is essentially limited to 17 lines of testimony from Mr. Hoxie, who offered no opinions about the settlement's competitive nature. (*See* FOF ¶ 1457; Hoxie, Tr. 2725–26.) Given the 2017 settlement's irrelevance to this action, this claim for relief should be struck.

Second, **Complaint Counsel contends that Impax must be prohibited from entering any "agreement settling a patent infringement dispute in which: (1) the brand drug company provides to the generic drug company something of the value other than the right to market its generic drug product prior to the expiration of the patent at issue in the litigation; and (2) the generic drug company agrees not to launch its product for some period of time."** (Compl. Counsel's Pretrial Br. at 47.) This ban on nearly all transfers of value is far broader than what the law requires. Under *Actavis*, reverse-payment settlements are not subject to antitrust scrutiny unless they entail a "large and unjustified" payment. 133 S. Ct. at 2237; *see King Drug*, 791 F.3d at 399, 402–03 (only if a term "represents an unexplained large transfer of value from the patent holder to the alleged infringer" is it "subject to antitrust scrutiny"); *Aggrenox*, 94 F. Supp. 3d at 243 (*Actavis* provides "safe harbor" for small reverse payments). Complaint Counsel's proposed remedy ignores the "large" qualifier, and instead seeks to prohibit any transfer of value, no matter how small.

Complaint Counsel's proposed remedy would also also bar payments that are "justified" under *Actavis*, such as those representing saved litigation costs or "fair value" compensation for goods, services, or other assets provided by the generic company. *See* 133 S. Ct. at 2235–36. Impax would be precluded from entering into legitimate, procompetitive business agreements with branded drug companies around the time of a patent settlement agreement.

Finally, this proposed remedy would bar patent settlements that are procompetitive. The SLA's broad license is "something of the value other than the right to market [Impax's] generic drug product prior to the expiration of the patent at issue in the litigation," and so would run afoul of Complaint Counsel's request—even though, as Dr. Noll admitted, "consumers are better off" because Impax is selling generic Opana ER today. (Noll, Tr. 1669; *see* FOF ¶ 1453.) This remedy would bar Impax from entering any number of procompetitive settlements, such as those in which the brand company waives regulatory exclusivity or releases the generic company from past damages, so long as they were "valuable" to Impax in some way. *See Actavis*, 133 S. Ct. at 2233 ("familiar settlement forms," such as forgiving past damages, not subject to antitrust scrutiny).

In fact, ***every*** settlement can be characterized as conveying "something of value" to the defendant. *See Asahi Glass Co. v. Pentech Pharm, Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J.) ("any settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement"). Because the requested remedy would dramatically hinder Impax's ability to enter into legitimate, procompetitive settlements, it "might well be thought anticompetitive" in its own right. *Id.*

The Court should reject Complaint Counsel's second proposed remedy as woefully unmoored from business realities, consumer welfare, and applicable law.

Third, **Complaint Counsel asks the Court to prohibit Impax "from entering any agreement with another drug company that prevents, restricts, or disincentives the brand drug company from selling or authorizing a competing product for some period of time."** (Compl. Counsel's Pretrial Br. at 47.) This remedy is so broad and ambiguously phrased as to defy practical compliance or enforcement. What does it mean, for example, to "disincentiv[ize]"

a brand company from "selling or authorizing a competing product"? Notably, while the proposed remedy would prohibit Impax from "disincentiv[izing]" a "brand drug company," the relevant agreement need only be with "another drug company"—not necessarily the disincentivized brand manufacturer. It is not clear how Impax could be expected to know how unspecified brand drug companies will react to an agreement.

What ***is*** clear, however, is that the remedy would condemn procompetitive deals. If Impax and "another drug company" entered into an agreement to supply a low-price generic drug at near marginal cost, that may very well "disincentivize" a brand company, with its notoriously high fixed costs, to sell a "competing product" in that market. But the agreement would be procompetitive to the extent it facilitates generic entry. Complaint Counsel's unbounded remedy is not reasonably related to any alleged violation in this case. *See Fanning v. FTC*, 821 F.3d 164, 177 (1st Cir. 2016) (remedy impermissibly overbroad when it lacked limits reasonably related to violation).

Fourth, **Complaint Counsel insists that Impax "document and submit to the Commission all communications with parties in which it is engaged in pharmaceutical patent litigation settlement discussions."** (Compl. Counsel's Pretrial Br. at 47.) In its pretrial brief, Complaint Counsel significantly broadened this proposed remedy from that sought in its Complaint. (*See* CX3233-019, Compl. Notice of Contemplated Remedies ¶ 5 (applying to "Hatch-Waxman litigation" instead of "pharmaceutical patent litigation"; requiring Impax to submit a report instead of "all communications").) Again, at no point did Impax expressly or impliedly consent to this constructive amendment, as required by Rule 3.15(a)(2). 16 C.F.R. § 3.15(a)(2).

In any event, the proposed remedy is absurdly overbroad, and bears little relationship to

the alleged violation. Impax would apparently have to report ***all*** communications with ***any*** opposing parties with which it is engaged in "pharmaceutical patent litigation settlement discussions," even if the communications do not in any way relate to those settlement discussions. This would capture, for example, communications about existing business partnerships, discussions at industry conferences, and any other contact made in the ordinary course of business. This draconian proposal would chill ordinary business contacts and procompetitive conduct, such as discussing joint venture and research-and-development collaborations. *See* U.S. Dep't of Justice & Fed. Trade Comm'n, *Antitrust Guidelines for Collaborations Among Competitors* § 3.31(a) (2000) (recognizing that "[m]ost" research-and-development collaborations are "procompetitive"). The remedy might also prevent Impax from entering future settlements, no matter how mundane, as counter-parties would be forced to agree to submit each and every communication with Impax to the government.

Such an expansive remedy is particularly inappropriate here, given the lack of evidence that Impax acted in "blatant and utter disregard of the law" or has "a history of engaging in unfair trade practices." *See Standard Oil*, 577 F.2d at 662 (both "circumstances which should be considered in evaluating the relation between the order and the unlawful practice"). To the contrary: when Impax entered into the SLA and DCA, alleged reverse-payment settlements that did not exceed the scope of the brand company's patents were ***lawful*** under the prevailing view of the law. (*See supra*.) The FTC did not even initiate its investigation of the SLA until 2014, after the *Actavis* decision came down. (FOF ¶ 374–77; *see* Snowden, Tr. 482, 502.) Complaint Counsel has not adduced any evidence to suggest that Impax had engaged in similar conduct before executing the SLA, or that it has done so at any time since then.

Complaint Counsel seems to recognize this. In its pretrial briefing, Complaint Counsel

abandoned a claim for relief that had been included in the Complaint: an order requiring Impax to "cease and desist" and "take all such measures as are appropriate to correct or remedy, or to prevent the recurrence of, the anticompetitive practices." (CX3233-019, Compl. Notice of Contemplated Remedies ¶ 5.) Complaint Counsel's omission of this remedy from its pretrial brief is telling. There is no evidence that Impax has even contemplated entering any potential reverse-payment settlement post-*Actavis*, and thus no reason to believe that Impax would repeat the conduct alleged in this case.[67]

Complaint Counsel's fourth requested remedy is improper and should be rejected. Additionally, any attempt to resurrect a remedy seeking to "prevent the recurrence" of the alleged conduct should be denied.

***Fifth and Sixth*, Complaint Counsel seeks to require Impax "to submit periodic reports describing its compliance efforts" *and* "fund an independent monitor to determine Impax's compliance with the order."** (Compl. Counsel's Pretrial Br. at 47.) These remedies are needlessly redundant. The submission of periodic reports would obviate any need for an "independent monitor," and vice-versa.

* * *

Complaint Counsel's proposed remedies are not narrowly tailored to prevent future violations. They are vague and unbounded restraints, lacking in any reasonable relation to the violations alleged. They would prohibit lawful business activities and chill procompetitive behavior. This Court should deny each of Complaint Counsel's requested remedies.

[67] To be clear, Complaint Counsel has not shown that the settlement challenged in this action is unlawful or anticompetitive.

CONCLUSION

For the foregoing reasons, this Court should enter judgment in Impax's favor.

Dated: December 20, 2017

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CERTIFICATE OF SERVICE

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CERTIFICATE FOR ELECTRONIC FILING

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

DATED: December 27, 2017

/s/ *Eileen M. Brogan*
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Notice of Electronic Service

I hereby certify that on December 27, 2017, I filed an electronic copy of the foregoing RESPONDENT IMPAX LABORATORIES, INC.'S PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW, RESPONDENT IMPAX LABORATORIES, INC.'S POST-TRIAL BRIEF, with:

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