

PUBLIC

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION



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

In the Matter of:

IMPAX LABORATORIES, INC.,

a corporation.

Docket No. 9373

RESPONDENT IMPAX LABORATORIES, LLC'S ANSWERING BRIEF

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TABLE OF CONTENTS

	Page
STATEMENT OF THE CASE.....	1
STATEMENT OF FACTS	5
I. BACKGROUND	5
A. The Underlying Patent Dispute.....	5
B. The Settlement Agreement	5
C. The Development and Co-Promotion Agreement	6
D. The SLA Benefited Consumers	7
II. THE INITIAL DECISION	8
ARGUMENT.....	11
I. THE INITIAL DECISION SHOULD BE AFFIRMED.....	11
A. The Challenged Settlement Agreement is Procompetitive	12
1. A Payment is Not A Restraint.....	13
2. Complaint Counsel Challenges—and the Commission Must Consider—the Entire SLA.....	15
3. Impax Need Not Prove a “Link” to Any Specific Settlement Term.....	19
4. The Initial Decision Properly Considered the SLA as a Whole	21
B. Complaint Counsel Has Not Demonstrated That a Less Restrictive Alternative was Possible	25
C. The Substantial Procompetitive Benefits Outweigh Any Purported Harm	27
1. There are no Temporal Limitations on Rule-of-Reason Analysis	28
2. The Purported Elimination of Risk Does Not Outweigh Any Procompetitive Benefit	32
3. The Initial Decision Properly Balanced the Competitive Effects.....	37
II. COMPLAINT COUNSEL’S SUIT ALSO FAILS BECAUSE ENDO NEVER POSSESSED MARKET POWER.....	39
A. Market Power Requirements Apply to Every Rule-of-Reason Case.....	39
B. The Initial Decision Did Not Apply Traditional Antitrust Standards.....	40
1. Patents Do Not Bestow Market Power	41
2. The Hatch-Waxman Regime Does Not Create Market Power	42

TABLE OF CONTENTS

	Page
3. A Purportedly Large Reverse Payment Does Not Prove Market Power	43
C. The Relevant Market Includes Numerous LAOs.....	44
1. LAOs are Reasonably Interchangeable for the Treatment of Chronic Pain.....	44
2. LAOs are Economic Substitutes	45
3. LAO Manufacturers Believe All LAOs Compete in the Same Market.....	48
4. The Commission Previously Concluded Opana ER Competed Against Other LAOs in the Same Market.....	50
D. Endo Never Had Market Power in a Properly-Defined LAO Market	50
E. Complaint Counsel Failed to Prove Endo Had Market Power	51
1. Complaint Counsel Failed to Present Indirect Evidence of Market Power	51
2. Complaint Counsel Failed to Present Direct Evidence of Market Power	55
III. THE COMMISSION NEED NOT CORRECT ANY OF THE ADDITIONAL ISSUES IDENTIFIED BY COMPLAINT COUNSEL.....	57
A. The DCA was a Bona Fide Collaboration	57
B. The ALJ Properly Required Proof of a “Large and Unjustified” Payment	59
C. The ALJ Properly Rejected Dr. Noll’s Four “Examples” of <i>Ex Ante</i> Value	60
IV. COMPLAINT COUNSEL’S PROPOSED REMEDIES VIOLATE DUE PROCESS AND ARE INAPPROPRIATE	62
A. Complaint Counsel Has Not Shown a Cognizable Danger of Future Violations.....	62
B. Complaint Counsel’s Proposed Remedies are Unlawful and Overbroad	64
CONCLUSION.....	67

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Agnew v. NCAA</i> , 683 F.3d 328 (7th Cir. 2012)	39
<i>Apple Inc. v. Samsung Elecs. Co. Ltd.</i> , 2018 WL 1586276 (N.D. Cal. Apr. 2, 2018)	20
<i>Asahi Glass Co. v. Pentech Pharm., Inc.</i> , 289 F. Supp. 2d 986 (N.D. Ill. 2003)	64
<i>Assam Drug Co. v. Miller Brewing Co.</i> , 798 F.2d 311 (8th Cir. 1986)	39
<i>Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters</i> , 459 U.S. 519 (1983)	32
<i>Atl. Richfield Co. v. USA Petroleum Co.</i> , 495 U.S. 328 (1990)	33, 46
<i>August News Co. v. Hudson News Co.</i> , 269 F.3d 41 (1st Cir. 2001)	27
<i>Bd. of Trade of Chicago v. United States</i> , 246 U.S. 231 (1918)	<i>passim</i>
<i>Blackburn v. Sweeney</i> , 53 F.3d 825 (7th Cir. 1995)	30
<i>Broadcom Corp. v. Qualcomm Inc.</i> , 501 F.3d 297 (3d Cir. 2007)	56
<i>Brokerage Concepts, Inc. v. U.S. Healthcare, Inc.</i> , 140 F.3d 494 (3d Cir. 1998)	51
<i>Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.</i> , 429 U.S. 477 (1977)	32, 33
<i>Bus. Elecs. Corp. v. Sharp Elecs. Corp.</i> , 485 U.S. 717 (1988)	13, 31
<i>Camaj v. Holder</i> , 625 F.3d 988 (6th Cir. 2010)	61

TABLE OF AUTHORITIES

	Page(s)
<i>Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs., Inc.</i> , 996 F.2d 537 (2d Cir. 1993).....	40
<i>Chi. Prof'l Sports Ltd. P'ship v. NBA</i> , 95 F.3d 593 (7th Cir. 1996)	39
<i>Commercial Data Servers, Inc. v. IBM Corp.</i> , 262 F. Supp. 2d 50 (S.D.N.Y. 2003).....	52
<i>Cont'l T.V., Inc. v. GTE Sylvania Inc.</i> , 433 U.S. 36 (1977).....	17
<i>Crane & Shovel Sales Corp. v. Bucyrus-Erie Co.</i> , 854 F.2d 802 (6th Cir. 1988)	57
<i>Endo Pharm. Inc. v. Teva Pharm. USA, Inc.</i> , 731 F. App'x 962 (Fed. Cir. 2018)	8
<i>Energy Conversion Devices Liquidation Tr. v. Trina Solar Ltd.</i> , 833 F.3d 680 (6th Cir. 2016)	65
<i>FTC v. AbbVie Inc.</i> , 107 F. Supp. 3d 428 (E.D. Pa. 2015)	58, 64
<i>FTC v. AbbVie Inc.</i> , No. 14-5151, slip op. (E.D. Pa. June 29, 2018)	<i>passim</i>
<i>FTC v. Actavis, Inc.</i> , 570 U.S. 136 (2013).....	<i>passim</i>
<i>FTC v. Cardinal Health, Inc.</i> , 12 F. Supp. 2d 34 (D.D.C. 1998).....	45
<i>FTC v. Colgate-Palmolive Co.</i> , 380 U.S. 374 (1965).....	65
<i>FTC v. Ind. Fed'n of Dentists</i> , 476 U.S. 447 (1986).....	<i>passim</i>
<i>FTC v. Nat'l Lead Co.</i> , 352 U.S. 419 (1957).....	65

TABLE OF AUTHORITIES

	Page(s)
<i>FTC v. Shire ViroPharma Inc.</i> , 2018 WL 1401329 (D. Del. Mar. 20, 2018)	64
<i>FTC v. Staples, Inc.</i> , 970 F. Supp. 1066 (D.D.C. 1997)	47
<i>FTC v. Sysco Corp.</i> , 113 F. Supp. 3d 1 (D.D.C. 2015)	54
<i>Golden Grain Macaroni Co. v. FTC</i> , 472 F.2d 882 (9th Cir. 1972)	67
<i>Ill. Tool Works Inc. v. Indep. Ink, Inc.</i> , 547 U.S. 28 (2006)	42
<i>In re Aggrenox Antitrust Litig.</i> , 94 F. Supp. 3d 224 (D. Conn. 2015)	19
<i>In re Aggrenox Antitrust Litig.</i> , 2015 WL 4459607 (D. Conn. July 21, 2015)	36
<i>In re Aggrenox Antitrust Litig.</i> , 199 F. Supp. 3d 662 (D. Conn. 2016)	40
<i>In re Androgel Antitrust Litig. (No. II)</i> , 2018 WL 2984873 (N.D. Ga. June 14, 2018)	20, 36
<i>In re Cipro Cases I & II</i> , 348 P.3d 845 (Cal. 2015)	<i>passim</i>
<i>In re Ind. Fed'n of Dentists</i> , 101 F.T.C. 57 (1983)	29, 30
<i>In re K-Dur Antitrust Litig.</i> , 2016 WL 755623 (D.N.J. Feb. 25, 2016)	36, 59, 60
<i>In re Lipitor Antitrust Litig.</i> , 868 F.3d 231 (3d Cir. 2017)	15
<i>In re Loestrin 24 Fe Antitrust Litig.</i> , 261 F. Supp. 3d 307 (D.R.I. 2017)	19, 43

TABLE OF AUTHORITIES

	Page(s)
<i>In re Loestrin 24 Fe Antitrust Litig.</i> , 814 F.3d 538 (1st Cir. 2016).....	15
<i>In re McWane, Inc.</i> , 2014 WL 556261 (F.T.C. Jan. 30, 2014).....	27, 35, 39
<i>In re Nexium (Esomeprazole) Antitrust Litig.</i> , 842 F.3d 34 (1st Cir. 2016).....	40, 44
<i>In re Niaspan Antitrust Litig.</i> , 42 F. Supp. 3d 735 (E.D. Pa. 2014).....	19
<i>In re N.C. Bd. of Dental Examiners</i> , 152 F.T.C. 640 (2011).....	29
<i>In re Polygram Holding, Inc.</i> , 136 F.T.C. 310 (2003).....	19
<i>In re Quality Trailer Prod. Corp.</i> , 115 F.T.C. 944 (1992).....	65
<i>In re Realcomp II Ltd.</i> , 2007 WL 6936319 (F.T.C. Oct. 30, 2009).....	18
<i>In re Remeron Direct Purchaser Antitrust Litig.</i> , 367 F. Supp. 2d 675 (D.N.J. 2005).....	43, 56
<i>In re Solodyn Antitrust Litig.</i> , 2018 WL 563144 (D. Mass. Jan. 25, 2018).....	27, 44
<i>In re Wellbutrin XL Antitrust Litig.</i> , 133 F. Supp. 3d 734 (E.D. Pa. 2015).....	15, 17, 24, 40
<i>In re Wellbutrin XL Antitrust Litig.</i> , 868 F.3d 132 (3d Cir. 2017).....	36
<i>In re Wireless Tel. Servs. Antitrust Litig.</i> , 385 F. Supp. 2d 403 (S.D.N.Y. 2005).....	56
<i>Jacob Siegel Co. v. FTC</i> , 327 U.S. 608 (1946).....	64, 65

TABLE OF AUTHORITIES

	Page(s)
<i>Jefferson Par. Hosp. Dist. No. 2 v. Hyde</i> , 466 U.S. 2 (1984).....	11, 30, 36, 51
<i>Kaiser Found. v. Abbott Labs.</i> , 2009 WL 3877513 (C.D. Cal. Oct. 8, 2009).....	45
<i>King Drug Co of Florence, Inc. v. Smithkline Beecham Corp.</i> , 791 F.3d 388 (3d Cir. 2015).....	13, 36, 40, 44
<i>Ky. Speedway, LLC v. NASCAR, Inc.</i> , 588 F.3d 908 (6th Cir. 2009)	54
<i>Leegin Creative Leather Prods., Inc. v. PSKS, Inc.</i> , 551 U.S. 877 (2007).....	30, 59, 65
<i>Major League Baseball Props., Inc. v. Salvino, Inc.</i> , 542 F.3d 290 (2d Cir. 2008).....	16, 57
<i>Matsushita Elec. Indus. Co. v. Zenith Radio Corp.</i> , 475 U.S. 574 (1986).....	59
<i>Minebea Co. v. Papst</i> , 444 F. Supp. 2d 68 (D.D.C. 2006)	31
<i>Murphy Oil Corp. v. Fed. Power Comm’n</i> , 431 F.2d 805 (8th Cir. 1970)	67
<i>Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co.</i> , 2015 WL 1736957 (E.D. Pa. Apr. 16, 2015)	42, 46, 49, 52
<i>Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co.</i> , 838 F.3d 421 (3d Cir. 2016).....	<i>passim</i>
<i>N. Am. Soccer League, LLC v. U.S. Soccer Fed’n, Inc.</i> , 883 F.3d 32 (2d Cir. 2018).....	26
<i>N. Pac. Ry. Co. v. United States</i> , 356 U.S. 1 (1958).....	42
<i>N. Tex. Specialty Physicians v. FTC</i> , 528 F.3d 346 (5th Cir. 2008)	18

TABLE OF AUTHORITIES

	Page(s)
<i>Nat'l Soc. of Prof'l Eng'rs v. United States</i> , 435 U.S. 679 (1978).....	<i>passim</i>
<i>NCAA v. Bd. of Regents of Univ. of Okla.</i> , 468 U.S. 85 (1984).....	<i>passim</i>
<i>O'Bannon v. NCAA</i> , 802 F.3d 1049 (9th Cir. 2015)	26
<i>Ohio v. Am. Express Co.</i> , 138 S. Ct. 2274 (2018).....	<i>passim</i>
<i>Okerlund v. United States</i> , 365 F.3d 1044 (Fed. Cir. 2004).....	31
<i>Polk Bros., Inc. v. Forest City Enters., Inc.</i> , 776 F.2d 185 (7th Cir. 1985)	30
<i>Polypore Int'l, Inc. v. FTC</i> , 686 F.3d 1208 (11th Cir. 2012)	45
<i>Queen City Pizza, Inc. v. Domino's Pizza, Inc.</i> , 124 F.3d 430 (3d Cir. 1997).....	41
<i>Rebel Oil Co. v. Atl. Richfield Co.</i> , 51 F.3d 1421 (9th Cir. 1995)	40, 41
<i>Rolfs v. C.I.R.</i> , 668 F.3d 888 (7th Cir. 2012)	59
<i>Rothery Storage & Van Co. v. Atlas Van Lines, Inc.</i> , 792 F.2d 210 (D.C. Cir. 1986).....	40
<i>Sanner v. Bd. of Trade of City of Chi.</i> , 2001 WL 1155277 (N.D. Ill. Sept. 28, 2001)	54
<i>SEC v. Cavanagh</i> , 155 F.3d 129 (2d Cir. 1998).....	63
<i>Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC</i> , 2016 WL 4992690 (S.D.N.Y. Sept. 13, 2016).....	36

TABLE OF AUTHORITIES

	Page(s)
<i>SMS Sys. Maint. Servs., Inc. v. Dig. Equip. Corp.</i> , 188 F.3d 11 (1st Cir. 1999).....	52
<i>Spokeo, Inc. v. Robins</i> , 136 S. Ct. 1540 (2016).....	32
<i>Standard Fashion Co. v. Magrane-Houston Co.</i> , 258 U.S. 346 (1922).....	34
<i>Stobie Creek Invs. LLC v. United States</i> , 608 F.3d 1366 (Fed. Cir. 2010).....	61
<i>Sullivan v. NFL</i> , 34 F.3d 1091 (1st Cir. 1994).....	27
<i>Texaco Inc. v. Dagher</i> , 547 U.S. 1 (2006).....	17
<i>Town of Concord v. Boston Edison Co.</i> , 915 F.2d 17 (1st Cir. 1990).....	34
<i>Town Sound & Custom Tops, Inc. v. Chrysler Motors Corp.</i> , 959 F.2d 468 (3d Cir. 1992).....	47, 53
<i>TRW, Inc. v. FTC</i> , 647 F.2d 942 (9th Cir. 1981)	62
<i>United States v. Abbey</i> , 560 F.3d 513 (6th Cir. 2009)	59
<i>United States v. Aetna Inc.</i> , 240 F. Supp. 3d 1 (D.D.C. 2017).....	48
<i>United States v. Am. Express Co.</i> , 838 F.3d 179 (2d Cir. 2016).....	46
<i>United States v. Bazaarvoice, Inc.</i> , 2014 WL 203966 (N.D. Cal. Jan. 8, 2014).....	49
<i>United States v. Brown Univ.</i> , 5 F.3d 658 (3d Cir. 1993)	19, 25, 26

TABLE OF AUTHORITIES

	Page(s)
<i>United States v. Columbia Steel Co.</i> , 334 U.S. 495 (1948).....	34, 35, 39
<i>United States v. E.I. du Pont de Nemours & Co.</i> , 351 U.S. 377 (1956).....	41, 42, 44, 48
<i>United States v. Eastman Kodak Co.</i> , 853 F. Supp. 1454 (W.D.N.Y. 1994).....	48
<i>United States v. H&R Block, Inc.</i> , 833 F. Supp. 2d 36 (D.D.C. 2011).....	48
<i>United States v. Microsoft Corp.</i> , 253 F.3d 34 (D.C. Cir. 2001).....	34, 67
<i>United States v. Topco Assocs., Inc.</i> , 405 U.S. 596 (1972).....	33
<i>United States v. W.T. Grant Co.</i> , 345 U.S. 629 (1953).....	62, 63
<i>Valley Drug Co. v. Geneva Pharm., Inc.</i> , 344 F.3d 1294 (11th Cir. 2003).....	30
<i>Vollrath Co. v. Sammi Corp.</i> , 9 F.3d 1455 (9th Cir. 1993).....	51
<i>Vt. Agency of Nat. Res. v. United States ex rel. Stevens</i> , 529 U.S. 765 (2000).....	33
Statutes	
15 U.S.C. § 1.....	13
15 U.S.C. § 45(b).....	64
Other Authorities	
Black’s Law Dictionary (10th ed. 2014).....	13, 32
DOJ & FTC, <i>Antitrust Guidelines for Collaborations Among Competitors</i> (2000).....	29

TABLE OF AUTHORITIES

	Page(s)
DOJ & FTC, <i>Antitrust Guidelines for the Licensing of Intellectual Property</i> (2017).....	42
DOJ & FTC, <i>Horizontal Merger Guidelines</i> (2010)	47, 48
King Pharmaceuticals, Inc. and Alpharma Inc. Agreement Containing Consent Order To Aid Public Comment, 74 Fed. Reg. 295 (Jan. 5, 2009)	50
Malcom B. Coate & Joseph J. Simons, <i>In Defense of Market Definition</i> , 57 <i>Antitrust Bulletin</i> 667 (Winter 2012).....	56
Phillip E. Areeda & Herbert Hovenkamp, <i>Antitrust Law</i> (rev. ed. 2017).....	<i>passim</i>
Phillip E. Areeda & Herbert Hovenkamp, <i>Fundamentals of Antitrust Law</i> (rev. ed. 2018)	14, 26
Restatement (First) of Contracts (rev. ed. 2018).....	13

GLOSSARY OF RECORD REFERENCES

ID	Initial Decision
IDF	Initial Decision Findings of Facts
CD	Opinion and Order of the Commission Denying Complaint Counsel's Motion for Partial Summary Decision, <i>In re Impax Labs., Inc.</i> , Dkt. 9373 (F.T.C. Oct. 27, 2017)
CCAB	Complaint Counsel's Appeal Brief
Compl.	Complaint
RFF	Respondent's Proposed Findings of Fact
RRFF	Respondent's Reply to Complaint Counsel's Proposed Findings of Fact
RPTRB	Respondent's Post-Trial Reply Brief
CCFF	Complaint Counsel's Proposed Finding of Facts
CCPTB	Complaint Counsel's Post-Trial Brief
CCRSB	Complaint Counsel's Reply in Support of Partial Summary Decision
EOPR	Intervenor Endo Pharmaceutical's Opposition to Complaint Counsel's Proposed Relief
CX	Complaint Counsel Exhibit
RX	Respondent Exhibit
Tr.	Trial Transcript
{bold}	<i>In Camera</i> Material

STATEMENT OF THE CASE

The only reason consumers have access to any version of Opana ER, an important medication used to treat chronic pain, is because Impax entered the Settlement and License Agreement (“SLA”) at issue in this case. Complaint Counsel does not suggest otherwise. Nor does Complaint Counsel dispute that consumers are better off today than they would have been absent the SLA. Indeed, the record is clear that if Impax had not entered the SLA, it would not have launched its generic product any earlier than January 2013—Impax’s licensed entry date under the SLA—and would now be permanently enjoined from selling Opana ER, just like every other generic manufacturer. Absent the SLA, Opana ER simply would not exist as a treatment for patients today.

Complaint Counsel nevertheless asks the Commission to condemn the SLA for the sole reason that it purportedly contained a reverse payment that helped induce settlement. Complaint Counsel claims that it need not prove any actual harm to consumers or grapple with any real-world benefits flowing from the SLA. CCAB 14, 30. But Complaint Counsel’s position represents a gross and deliberate misreading of *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013). That case expressly rejected the contention that reverse payments are inherently unlawful. It also rejected the suggestion that reverse-payment litigation is unique. It is not. Complaint Counsel “must prove its case as in other rule-of-reason cases.” *Id.* at 158-59.

Yet Complaint Counsel seeks to apply a new legal standard in reverse-payment litigation, one that sounds in *per se* liability and is at odds with both *Actavis* and the entire canon of rule-of-reason jurisprudence. Specifically, Complaint Counsel argues that it is entitled to a series of presumptions, including (1) procompetitive effects are irrelevant unless they arise from the payment term alone; (2) it need not prove that a less restrictive alternative was feasible or that the alternative could have achieved the same procompetitive benefits; and (3) the elimination of

potential competition, no matter how remote, is itself an antitrust violation that outweighs all real-world consumer benefits. Individually, any of these claims distorts the rule of reason beyond recognition. Collectively, they represent a full-scale rewriting of the law and an end run around the Supreme Court. This gambit should be rejected.

First, the Commission must consider the procompetitive benefits flowing from the SLA as a whole. Complaint Counsel challenged the *entire* SLA and consistently pointed to its non-payment terms as purported proof that the agreement was unlawful. Complaint Counsel cannot attempt to plead and prove its case by looking at terms other than the alleged payment and then impose a straightjacket on Impax, limiting it to the alleged payment’s procompetitive benefits. More fundamentally, the payment term did not restrain competition. And when a plaintiff identifies and challenges a specific agreement—here, the SLA (Compl. ¶¶ 1, 49-50, 78)—the plaintiff cannot ignore market effects resulting from that agreement. There is no cherry picking among its terms for purposes of analyzing procompetitive benefits. Indeed, the SLA’s broad patent license was integral to both the settlement and the resulting competitive effects—Impax would not have entered *any* settlement without it.

Second, the rule of reason requires plaintiffs to *prove* that a less restrictive alternative was feasible and could have achieved the same procompetitive benefits. Complaint Counsel cannot satisfy its burden by appealing to “[b]asic common sense” or claiming that it faces an “impossible” task. CCAB 25. This is particularly true when, as here, actual evidence indicates that Complaint Counsel’s “common sense” alternative was tried and failed. Complaint Counsel cannot ignore the record.

Third, the rule of reason has never condemned the mere avoidance of “the possibility of competition, however small,” as an antitrust violation, much less one that outweighs substantial,

real-world consumer benefits. CCAB 30 (quotation omitted). *Every* agreement eliminates possible competition. It is because of that very fact that the rule of reason exists, requiring courts to evaluate any actual “harms [to] consumers” when assessing whether an agreement is unlawful. *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2284 (2018). Condemning reverse-payment settlements because they avoid the possibility of competition, “regardless of whether the generic would have otherwise” competed (CCAB 30), abandons these principles and imposes a *per se* standard—condemning every reverse-payment settlement. But the Supreme Court rejected such an approach in favor of the rule of reason. *Actavis*, 570 U.S. at 159. And that test focuses on actual market effects, not the mere existence of a payment. Without proof that a generic would have competed earlier absent the settlement, no competition was avoided, consumers suffered no harm, and no antitrust violation exists.

Fourth, this suit falters because Complaint Counsel failed to establish market power in a properly defined relevant market. The record is clear that Opana ER competes with many long-acting opioids (“LAOs”), all of which are therapeutic and economic substitutes. Indeed, all LAOs compete on price at the patient, payor, and prescriber levels. When the applicable cost of one LAO increases, patients flock to other, lower-priced LAOs. And Complaint Counsel’s own expert agreed that all LAOs compete for the same customers. When properly defined, Endo never controlled more than 10 percent of the LAO market, undermining any suggestion of market power. This alone is reason to dismiss the Administrative Complaint. While there is much to commend in the Initial Decision, the ALJ did not consider this evidence. Rather, he questioned the applicability of market power requirements generally and concluded that in all

reverse-payment cases the “appropriate” relevant market is limited to a brand-name drug and its generic equivalents, regardless of any evidence to the contrary. ID 97, 139. This was error.¹

Finally, the proposed remedies advanced by Complaint Counsel are both unlawful and unsupported. Most troubling, Complaint Counsel seeks to rewrite and undermine a 2017 settlement agreement between Impax and Endo that has never been investigated or challenged in these proceedings and that does not contain a reverse payment. Stripping Impax of its rights under that agreement, without examining it or hearing evidence, would violate Impax’s due process rights and the Commission’s own rules. Complaint Counsel also attempts to restrict Impax’s ability to enter “any agreement” that may in any way “disincentivize[]” certain competition. CCAB 44. Such unbounded (and undefined) remedies are punitive and improper. But this is true of all of the remedies advanced by Complaint Counsel, which has failed to identify *any* evidence that *any* prospective relief is appropriate.

* * *

At bottom, Complaint Counsel “must prove its case as in other rule-of-reason cases.” *Actavis*, 570 U.S. at 159. Yet Complaint Counsel asks the Commission to excuse it from foundational rule-of-reason requirements, ignore procompetitive benefits arising from the challenged agreement, and condemn the mere avoidance of possible competition, no matter how unlikely and without regard to whether consumers have actually been harmed. These demands would be inappropriate in any other rule-of-reason case. They are inappropriate here too. The Commission should affirm the dismissal of the Administrative Complaint and enter judgment in favor of Impax.

¹ Impax also disagrees with the ALJ’s conclusion that the SLA contained a large reverse payment that helped induce settlement. Given the other findings in the Initial Decision, however, Impax need not appeal that conclusion to dismiss the Administrative Complaint.

STATEMENT OF FACTS

I. BACKGROUND

A. The Underlying Patent Dispute

Opana ER, an extended-release opioid medication for the treatment of chronic pain, was first marketed by Endo in 2006. IDF 43-44, 47. In June 2007, Impax filed the first Abbreviated New Drug Application (“ANDA”) for generic versions of most Opana ER dosage strengths. IDF 55-58. Endo sued Impax in January 2008, claiming infringement of two Opana ER patents that would not expire until September 2013. IDF 53, 61.

Impax and Endo first attempted to settle the patent dispute in the fall of 2009. IDF 112. During those discussions, Impax sought the earliest possible license date that would allow it to sell generic Opana ER free from patent risk. RFF 126. Impax pushed Endo for a mid-2011 licensed entry date without any other settlement terms, but Endo rejected the proposal. IDF 116. Endo maintained that it would only consider a license date between when an appeal would likely be decided and the expiration of the patents-in-suit, a date Endo calculated as March 2013. IDF 116; RFF 136.

B. The Settlement Agreement

Impax and Endo reinitiated settlement discussions in May 2010, shortly before their patent trial and the Hatch-Waxman Act’s thirty-month stay expiration. IDF 122, 283. Impax again approached the 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 Opana ER without patent risk. RFF 126, 152. On June 8, 2010, two days into trial, Impax accomplished both goals when it executed the SLA. IDF 74; RFF 143-44, 155, 157.

First, Impax obtained the earliest entry date possible. RFF 127-31, 143-44. During negotiations, Endo proposed a licensed entry date of March 2013, and steadfastly refused to

consider any 2011 or 2012 dates, even in the absence of other terms. IDF 116, 155. Through aggressive negotiation, Impax secured a January 1, 2013, licensed entry date. RFF 140, 143-44. Second, Impax secured a license covering all patents-in-suit as well as all pending and future patents. IDF 125, 592-93. This was particularly important because Impax knew that Endo had pending applications for additional patents. IDF 167. Together, 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 Endo's original patents-in-suit expired, and sixteen years before Endo's later-acquired patents would expire. IDF 594.

The SLA also included two terms that Complaint Counsel claimed were payments. The first was a co-exclusive license provision—referred to as a “No-Authorized Generic” or “No-AG” provision—whereby Endo agreed not to sell a generic version of Opana ER during Impax's 180-day exclusivity period, although Endo could still sell its branded Opana ER product and compete on price. IDF 127; RFF 199-200. The second term, known as the Endo Credit, would penalize Endo if it shifted demand away from original Opana ER such that sales dropped below a certain threshold in the last quarter of 2012. IDF 129. The parties developed the term after Endo rejected a market degradation trigger, which would have accelerated Impax's licensed entry date if original Opana ER sales fell below a specified threshold. IDF 147.

C. The Development and Co-Promotion Agreement

Impax and Endo also executed a Development & Co-Promotion Agreement (“DCA”) in June 2010. The subject of the collaboration was a promising new Parkinson's disease treatment known as IPX-203, which sought to improve upon IPX-066, the forerunner to IPX-203. IDF 314. Although in its early stages of development in 2010, Impax scientists considered the IPX-203 formulation feasible. IDF 315-17.

The DCA was the culmination of years of efforts by Endo and Impax to collaborate on treatments for central nervous system diseases. IDF 275-80; RFF 284-90. Endo’s due diligence team recommended that Endo enter the DCA because it was a “good deal” for Endo. IDF 307, 348-49. While Endo’s initial term sheet included a \$10 million upfront payment for a deal covering IPX-066 and all follow-on drugs (including IPX-203), it also contained limited profit-sharing rights. The term sheet proposed that Endo would retain only 50 percent of profits from sales generated by non-neurologists. CX0320; RFF 315. The final DCA, which limited the collaboration to IPX-203 and also included a \$10 million payment, gave Endo the right to 100 percent of non-neurologist profits. RX-365; RFF 269. Endo calculated the DCA’s net present value on the basis of these rights and determined that the deal had a “very reasonable rate of return” { [REDACTED] } Endo’s 10 percent benchmark for a business collaboration. IDF 352-53.

After executing the DCA, Impax devoted substantial efforts to developing IPX-203. { [REDACTED] [REDACTED] } IDF 379. IPX-203 is currently Impax’s “lead compound on the brand side of [its] R&D program.” IDF 389. In fact, 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 by up to two hours when compared to existing medications, including IPX-066. IDF 390-94.

D. The SLA Benefited Consumers

The SLA is the only reason consumers have access to any form of Opana ER today. First, Endo obtained six additional patents covering Opana ER starting in March 2012, when it acquired Patent No. 7,851,482 (the “482 patent”) from Johnson Matthey. IDF 573-76, 579-81. Endo used those patents to file infringement suits against every ANDA filer except Impax. IDF 577, 582-84. Two separate district courts—and the Federal Circuit—have ruled that those

ANDA filers infringed valid patents and are permanently enjoined from selling Opana ER until as late as 2029. IDF 578, 586-87; *Endo Pharm. Inc. v. Teva Pharm. USA, Inc.*, 731 F. App'x 962 (Fed. Cir. 2018). Even when Endo and Impax subsequently litigated a purported breach of the SLA, Endo did not seek an injunction to prevent Impax from selling generic Opana ER. RFF 1446-47.

Second, a “supply chain crisis” prompted Endo to launch a reformulated version of Opana ER in March 2012, months earlier than Endo planned. IDF 227-230. The FDA then issued two relevant orders. The first required Endo to stop selling original Opana ER to avoid consumer confusion, after which Endo—in support of its effort to switch consumers to the reformulated product—publicly claimed original Opana ER was unsafe. IDF 229-33. Endo’s public position effectively ended any possibility that Endo would later try to market an “unsafe” authorized generic of original Opana ER. RFF 616-23. The second FDA order, issued in June 2017, requested that Endo withdraw reformulated Opana ER because the risk of abuse through intravenous injection was greater than any pain-relief benefits. IDF 111; RFF 258-60. Endo complied and, as of September 1, 2017, Impax is the only company permitted to sell Opana ER—branded or generic. IDF 111; RFF 1449.

II. THE INITIAL DECISION

On May 11, 2018, Chief Administrative Law Judge D. Michael Chappell dismissed the Administrative Complaint. He concluded that the SLA is not an unreasonable restraint of trade because it is procompetitive under the rule of reason. ID 7, 156-58. He reached this conclusion on the basis of a four-step, burden-shifting framework. *Id.* at 98-100.

First, the ALJ assessed whether there was evidence of any anticompetitive effect from the challenged agreement, including “payment for delay, or, in other words, payment to prevent the risk of competition.” *Id.* at 98 (quotation omitted). He concluded that while the SLA contained

a No-AG term that represented a large payment to Impax, and thereby helped to prevent the risk of competition, any resulting harm was “largely theoretical.” *Id.* at 138-39, 157. Specifically, even if the SLA eliminated “the hypothetical possibility of Impax launching its generic Opana ER earlier than the date set forth in the SLA—either at risk or after litigation”—Impax “was unlikely” to have actually launched its product any earlier. *Id.* at 157. The ALJ found that Impax would not have launched its product at risk because Impax had not undertaken the necessary steps, the risks were too great, and Impax is “incredibly conservative.” *Id.* at 150-52. And if Impax had not entered the SLA it would have been tied up in litigation for years, which would have kept it from launching its product free from patent risk any earlier than January 2013. *Id.* at 155-56; RFF 1016-17, 1089, 1103-05, 1450-52.

Second, the ALJ considered evidence of procompetitive effects arising from the SLA as a whole. *Id.* 99. He explained that focusing “only on the reverse payment, without any consideration of offsetting procompetitive benefits arising from the settlement conflates the initial burden of proving anticompetitive effects with the ultimate burden of proving that an agreement is, on the whole, an unreasonable restraint of trade.” *Id.* at 99. The ALJ further noted that focusing solely on the payment term, as Complaint Counsel advocated, would have been “too abbreviated to permit proper analysis.” *Id.* at 99-100 (quotation omitted).

Employing this approach, the ALJ found that “clear evidence” regarding the strength of Endo’s patents “supports the inference that, absent the SLA, such after-acquired patents also would have been successfully asserted to enjoin Impax from selling generic Opana ER,” even if Impax had prevailed in the initial litigation. *Id.* at 145. In combination with the facts that Impax would not have launched at risk and would have been tied up in patent litigation for years, the ALJ concluded that “consumers have benefited from the SLA by having uninterrupted and

continuous access to generic Opana ER” that would not have otherwise been possible. *Id.* at 146.

Third, the ALJ considered whether the SLA’s procompetitive benefits could reasonably have been achieved through a less restrictive alternative. *Id.* at 100. He found that Complaint Counsel failed to meet its burden at this step. Specifically, Complaint Counsel did not demonstrate that any “hypothetical” alternative settlement was actually possible or would have resulted in the same procompetitive benefits. *Id.* at 146-47.

Finally, the ALJ weighed “the demonstrated anticompetitive effects against the demonstrated procompetitive effects to determine whether the Challenged Agreement is anticompetitive on balance.” *Id.* at 100. In particular, the ALJ assessed whether the settlement “delayed generic competition” and thereby altered the “state of competition” that would have existed absent the agreement. *Id.* (quotation omitted). The ALJ concluded that in “contrast to the largely theoretical anticompetitive harm asserted by Complaint Counsel”—foreclosing “the hypothetical” and “unlikely” “possibility of Impax launching its generic Opana ER earlier” than January 2013—“the real world procompetitive benefits of the Endo-Impax Settlement are substantial.” *Id.* at 157. Those benefits included early and sustained access to Opana ER that would not have otherwise been possible, which left consumers better off than they would have been absent the settlement. *Id.* at 157-58. Accordingly, the ALJ concluded that the SLA was, on balance, procompetitive. *Id.* at 158.

In contrast to this detailed analysis, the Initial Decision paid little attention to market definition and market power. The ALJ’s findings of fact on market power take up less than one page (*id.* at 18), and his legal analysis accounts for just a few pages more (*id.* at 96-97, 139-41). In fact, the Initial Decision expressed doubt about “whether proof of market power is a necessary

element of a reverse payment settlement challenge.” *Id.* at 139. The ALJ nonetheless explained that—to the extent market definition matters—the relevant market in all reverse-payment cases is limited to the branded product at issue and its generic equivalents. *Id.* at 97. As a result, the ALJ concluded that the relevant market in this case included only Opana ER and generic equivalents, and that Endo had power within that narrow market. *Id.* at 141.

The ALJ did not address whether LAOs are reasonably interchangeable or exhibit cross-elasticity of demand. The ALJ’s conclusions instead rested on three predicates: (1) “pharmaceutical patents often carry with them market power”; (2) “regulatory barriers created by the Hatch-Waxman Act” support a conclusion of market power; and (3) “proof of [market] power, derived from the patent, can be found in the reverse payment settlement itself.” *Id.* at 139-40.

ARGUMENT

I. THE INITIAL DECISION SHOULD BE AFFIRMED

It is undisputed that the rule of reason governs this litigation. CD 8; CCAB 13. At issue in this appeal is how the rule of reason operates in practice and, in particular, whether short cuts and presumptions can be used in cases involving “reverse payment settlements”—agreements whereby a patent holder purportedly compensates an alleged infringer to settle patent litigation.

The law, however, is clear: In reverse-payment actions, Complaint Counsel must “prove its case as in other rule-of-reason cases.” *Actavis*, 570 U.S. at 159. There are no alterations, exceptions, or short cuts. The rule of reason requires a “fact-specific assessment of market power and market structure . . . to assess the [restraint]’s actual effect on competition.” *Am. Express*, 138 S. Ct. at 2284 (quotation omitted); see *Jefferson Par. Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 29 (1984) (rule of reason requires “an inquiry into the actual effect of the [relevant] contract on competition”). “The goal [of this inquiry] is to distinguis[h] between restraints with

anticompetitive effect that are harmful to the consumer and restraints stimulating competition that are in the consumer's best interests." *Am. Express*, 138 S. Ct. at 2284 (quotation omitted).

To determine whether a particular action violates the rule of reason, "a three-step, burden-shifting framework applies." *Id.* First, Complaint Counsel has "the initial burden to prove that the challenged restraint has a substantial anticompetitive effect that harms consumers in the relevant market." *Id.* Second, if the plaintiff carries its burden, "then the burden shifts to the defendant to show a procompetitive rationale for the restraint." *Id.* Third, if "the defendant makes this showing, then the burden shifts back to the plaintiff to demonstrate that the procompetitive efficiencies could be reasonably achieved through less anticompetitive means." *Id.*

The ALJ applied this framework to the challenged conduct at issue in this suit. ID 98-100. On appeal, Complaint Counsel argues that the ALJ erred in applying steps two and three. Complaint Counsel's arguments fail as a matter of law.

A. The Challenged Settlement Agreement is Procompetitive

Complaint Counsel does not dispute that the SLA resulted in substantial consumer benefits, including early and uninterrupted access to Opana ER that would not have otherwise been possible. ID 142-46, 156-58; IDF 592-600. Instead, Complaint Counsel argues that the ALJ should not have considered these benefits because they arose "in connection with the settlement agreement as a whole." CCAB 14. Complaint Counsel contends that the rule of reason must focus solely on the procompetitive effects arising from the purported payment term, which it believes is the "challenged restraint" in reverse-payment cases. *Id.* at 20. This simply is not true. A payment on its own does not restrain trade. Nor is the purported payment in this case the sole provision Complaint Counsel challenges. Complaint Counsel's contentions to the contrary seek to mislead and demonstrate a fundamental misunderstanding of antitrust law.

1. *A Payment is Not A Restraint*

To begin, when Complaint Counsel accuses a party of restraining trade, the actual “legal question before [the Commission] is whether” Complaint Counsel has advanced evidence to “make out a violation of Sherman Act § 1.” *FTC v. Ind. Fed’n of Dentists*, 476 U.S. 447, 454 (1986).² That statute prohibits agreements—“[e]very contract, combination . . . or conspiracy”—“in restraint of trade.” 15 U.S.C. § 1. Importantly, the “term ‘restraint of trade’ in the statute” “refers *not* to a particular list of agreements”—or any particular provisions therein—“but to a particular *economic consequence*.” *Bus. Elecs. Corp. v. Sharp Elecs. Corp.*, 485 U.S. 717, 731 (1988) (emphasis added).

Specifically, it is an “anticompetitive reduction in output, which is one that is capable of producing a price increase,” that is “the most appropriate meaning of an antitrust restraint.” Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 1502 (rev. ed. 2017). A payment itself is not a reduction in output. Nor is it a *consequence*—something that “follows as an effect of” that which “came before.” Black’s Law Dictionary (10th ed. 2014) (defining “consequence”); *see King Drug Co of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 409-12 (3d Cir. 2015) (rule of reason satisfied only if there is proof of “payment *for delay*,” meaning a “delay [in] competition for longer than the patent’s strength would otherwise permit”).

But even when the term “restraint” is used in a more colloquial manner, it cannot support Complaint Counsel’s desired approach. To “restrain” means to “bind.” *Bd. of Trade of Chicago v. United States*, 246 U.S. 231, 244 (1918). The “term ‘restraint of trade’ relates *only to limitations*.” Restatement (First) of Contracts § 513 (rev. ed. 2018) (emphasis added). A

² Here, Complaint Counsel alleged a single violation of the FTC Act: “Impax agreed to restrain competition.” Compl. ¶ 101.

payment alone does not bind or limit in any way. Complaint Counsel conceded as much in its post-trial brief: “the payment on its own does not technically ‘restrain’ Impax’s entry.” CCPTB 69. On appeal it underscores this point in explicit terms, contending that “Impax could have obtained the asserted procompetitive benefits—a license to additional patents and entry in January 2013—without also accepting any payment from Endo.” CCAB 20-21. But this hypothetical no-payment settlement *is no less restrictive of competition* than the SLA. Impax would still have launched its product *on the exact same date* and given up its patent challenge *in the exact same manner*. Even without the purported payment terms, the result is the same. The payment “restrains” nothing.

These are not minor points. Restraints are (and always have been) the rule of reason’s sole focus. “The true test of legality is 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*, 246 U.S. at 238 (emphasis added). As Complaint Counsel’s own cases make clear, this means that courts evaluate practices that actually “impede[] the ordinary give and take of the market place,” *Nat’l Soc. of Prof’l Eng’rs v. United States*, 435 U.S. 679, 692 (1978), or “limit [] freedom[s],” *NCAA v. Bd. of Regents of Univ. of Okla.*, 468 U.S. 85, 98 (1984).

And it is black-letter law that when those limitations purportedly arise from a challenged agreement, “the content of the restraint *is the sum total of everything that the parties have ‘agreed’ about and that is alleged to injure competition.*” Phillip E. Areeda & Herbert Hovenkamp, *Fundamentals of Antitrust Law* § 15.02 (rev. ed. 2018) (emphasis added). “In the case of the drafted legal document,” that includes all “the language of the document itself,” but

can also include related behavior. *Id.* (“[c]learly, the restraint consists in any written or formal documents that memorialize the relevant agreements among the parties”).

In reverse-payment cases, this means that the relevant “restraints” are the settlement agreements as a whole, not any particular term found therein. *See, e.g., In re Lipitor Antitrust Litig.*, 868 F.3d 231, 245 (3d Cir. 2017) (plaintiffs “challeng[ed] the settlement agreement as an unlawful restraint of trade”); *In re Loestrin 24 Fe Antitrust Litig.*, 814 F.3d 538, 542 (1st Cir. 2016) (“They contend that these agreements constitute illegal restraints on trade.”); *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 752 (E.D. Pa. 2015) (settlements “are without question [the] agreements in restraint of trade” at issue).

2. Complaint Counsel Challenges—and the Commission Must Consider—the Entire SLA

This conclusion is particularly true in the present proceedings. Complaint Counsel challenged the *entire* SLA. Compl. ¶¶ 1, 49-50, 78; CCAB 13 (“Impax failed to satisfy its burden to justify the challenged agreement”). It seeks remedies prohibiting Impax from entering “any *agreement* that prevents, restricts, or in any way disincentivizes” certain competition, irrespective of any payment in that agreement. CCAB, Appx. A at 4 (emphasis added). And in claiming anticompetitive impact, Complaint Counsel repeatedly relies on disparate provisions of the SLA—including the fact that Impax agreed to (1) “give up its patent challenge” and (2) “not [] launch a generic Opana ER until January 2013”³—as well as the altogether *separate* DCA. CCAB 13-14, 34; *see* Compl. ¶¶ 49-50. In fact, Complaint Counsel built its case on factors that exist *outside* any agreement, ranging from purported subjective intent to timing, and from due

³ These aspects of the settlement exist separate and apart from any purported payment, and are memorialized in different provisions. CX2626 (executed SLA; Article 3 covered the settlement and dismissal of patent challenge; Sections 3.2 and 4.1(a) covered the commencement date of Impax’s license and sales; and Section 4.1(c) contained the No-AG provision).

diligence efforts to strategic fit. CCAB 34. It is for these reasons that Complaint Counsel’s own economic expert conceded that neither he nor Complaint Counsel “unpack[ed] the effect of each provision [in the settlement] on consumer welfare because *that’s not the appropriate way to do it.*” Noll, Tr. 1647 (emphasis added).

Complaint Counsel cannot have it both ways. It cannot, on the one hand, challenge the settlement (and separate DCA) as a whole, engaging in an unbounded effort to establish anticompetitive impact, and then, on the other hand, limit Impax to the purported payment from which to prove procompetitive effects. This inconsistent approach would lead to absurd, unjust, and one-sided results. Complaint Counsel could gerrymander respondents’ defenses simply by declaring that a particular value-conveying term is a payment, while others are not. As just one example, Complaint Counsel’s economic expert testified that the broad patent license in the SLA—the only reason consumers have access to any form of Opana ER today (IDF 592-600)—made the settlement “more valuable to Impax.” Noll, Tr. 1645-48. But because Complaint Counsel does not define that license as a relevant “payment,” Complaint Counsel demands that the provision (or any procompetitive term like it) “play[] no role” in the rule of reason analysis. *Id.*; see RFF 655; CCAB 21-23.

Complaint Counsel’s approach cannot be reconciled with the law. Reverse-payment claims must be assessed “as in other rule-of-reason cases.” *Actavis*, 570 U.S. at 159. In every other rule-of-reason case, defendants can “offer evidence of the pro-competitive effects of their agreement.” *Major League Baseball Props., Inc. v. Salvino, Inc.*, 542 F.3d 290, 317 (2d Cir. 2008) (quotation omitted; emphasis added). And in every other rule-of-reason case, agreements are evaluated “as a whole” because “the competitive effects of an individual restraint are

intertwined with the effects of the remainder of the venture.” *Id.* at 338 (Sotomayor, J., concurring).

So too here. Settlement agreements 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. In this case, Impax’s “top business priority” was ensuring it could sell generic Opana ER free from patent risk. RFF 126. It simply would not have entered the challenged SLA without the broad patent license Complaint Counsel seeks to ignore. IDF 565-66; RFF 126-30, 145-57. Accordingly, the provisions cannot be segregated, and Impax has the right to “offer legitimate justifications and come forward with evidence that the *challenged settlement* is in fact procompetitive.” *In re Cipro Cases I & II*, 348 P.3d 845, 869-70 (Cal. 2015) (emphasis added).⁴

Restricting the rule of reason (or as Complaint Counsel would have it, just the analysis of procompetitive benefits) to “a piecemeal, provision-by-provision approach,” *Wellbutrin*, 133 F. Supp. 3d at 753-54, directly conflicts with the Supreme Court’s instructions that the rule of reason must consider “all of the circumstances of [the] case,” *Cont’l T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 49 (1977). The Court demands that holistic approach because the relevant question is whether “*a particular contract or combination* is in fact unreasonable and anticompetitive.” *Texaco Inc. v. Dagher*, 547 U.S. 1, 5 (2006) (emphasis added).

In *NCAA*, for instance, the Supreme Court evaluated the competitive impact of a “television plan,” a standalone “agreement among competitors on the way in which they [would]

⁴ Complaint Counsel suggests that reliance on *Cipro* is inappropriate because the decision “did not abandon the traditional inquiry into the connection between the challenged restraint and the asserted procompetitive objective.” CCAB 19. Neither Impax nor the Initial Decision contend otherwise. The point is a simple one. In reverse-payment cases, the challenged restraint is the settlement as a whole, and any benefits arising from the “challenged settlement” can be considered. *Cipro*, 348 P.3d at 869-70; *see* ID 141.

compete with one another.” 468 U.S. at 99. The agreement included terms governing, among many other things, output and payment. *Id.* at 91-94, 98-99. Yet the Court never separated out the plan’s payment provision (or any other) when assessing procompetitive efficiencies, it simply concluded that the challenged agreement as a whole was neither “necessary” nor adequately “tailored” to the claimed benefits. *Id.* at 114-19.

Similarly in *National Society of Professional Engineers*, the Court evaluated all aspects of the “canons of ethics,” including specific rules and later policy statements, that the government challenged as an “unlawful agreement.” 435 U.S. at 683-84 & nn.4-6. The Court ultimately rejected defendant’s single defense—that competition was dangerous—not because it related to the wrong aspect of the challenged agreement, but because it “rest[ed] on a fundamental misunderstanding of the Rule of Reason.” *Id.* at 681, 696.

And in *In re Realcomp II Ltd.*, 2007 WL 6936319 (F.T.C. Oct. 30, 2009), Complaint Counsel challenged three separately-adopted policies as “an agreement among horizontal competitors to restrict the availability of information” on a multiple listing service, a “closed database system” facilitating real estate transactions. *Id.* at *6-7, 12-13, 27. The Commission evaluated that “agreement” as a whole without dissecting the terms of the underlying policies into their component parts. *Id.* at *25-27. Like the Supreme Court in *NCAA* and *National Society*, the Commission rejected respondent’s defenses not because they flowed from the wrong provision of the challenged agreement, but because the challenged agreement did not actually advance any identified efficiency. *Id.* at *29.⁵

⁵ See also *Ind. Fed’n of Dentists*, 476 U.S. at 455, 459-64 (considering all “countervailing procompetitive virtue[s]” and arguments that, “notwithstanding [the restraint’s] lack of competitive virtue, the Federation’s policy . . . should not be deemed an unreasonable restraint of trade”); *N. Tex. Specialty Physicians v. FTC*, 528 F.3d 346, 370 (5th Cir. 2008) (evaluating “conduct, taken as a whole”).

Put simply, when Complaint Counsel identifies and challenges a *specific agreement*—here, the SLA and DCA (Compl. ¶¶ 1, 49-50, 78)—all aspects of that agreement are at issue. And while it is appropriate to evaluate whether the agreement actually achieved procompetitive benefits, it must be done by looking at the agreement as a whole. In reverse-payment cases that means looking at “the context of the broader settlement agreement in which a reverse payment occurs.” CD 12-13; *see, e.g., In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 331 (D.R.I. 2017) (courts “look[] at the whole of the settlement to determine its alleged effect on competition”); *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 243 (D. Conn. 2015) (same); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 752 (E.D. Pa. 2014) (same).

3. *Impax Need Not Prove a “Link” to Any Specific Settlement Term*

Complaint Counsel’s related claim that Impax must “articulate a specific link between the challenged restraint and the purported justification” is a misstatement of the law. CCAB 15 (quotation omitted). The argument is based on quick-look jurisprudence, which is distinct from “a rule of reason” because it “shifts to a defendant” relevant burdens. *Actavis*, 570 U.S. at 159 (quotation omitted). As the Commission explained in *In re Polygram Holding, Inc.*, 136 F.T.C. 310 (2003), a respondent must articulate “a specific link” when the challenged conduct is “inherently suspect”—and the Commission “avoid[s] full rule of reason analysis”—in order to “avoid summary condemnation” and trigger a “more detailed” review. *Id.* at 344-50. But the Supreme Court expressly rejected this quick-look approach with respect to reverse-payment settlements. *Actavis*, 570 U.S. at 158-59.

Under the rule of reason, once a defendant advances procompetitive justifications, it is the *plaintiff’s* burden to establish the absence of any connection by demonstrating that the challenged restraint is not reasonably necessary to achieve the stated benefits. *Am. Express*, 138 S. Ct. at 2284; *United States v. Brown Univ.*, 5 F.3d 658, 669 (3d Cir. 1993). *American Express*

is instructive. In that case, federal and state antitrust enforcers alleged that agreements between American Express and merchants were anticompetitive because they contained antisteering provisions, which prevented merchants from discouraging the use of American Express cards. 138 S. Ct. at 2280. To assess any resulting competitive effects, the Supreme Court looked at the record as a whole, including procompetitive benefits arising from factors other than the antisteering provisions specifically.

In particular, the Court placed great weight on the fact that “Amex’s *business model*,” which included things like generous cardholder rewards and access to credit for low-income individuals, “spurred robust interbrand competition and has increased the quality and quantity of credit-card transactions.” *Id.* at 2289-90 (emphasis added); *see id.* at 2303 (Breyer, J., dissenting) (“the majority addresses American Express’ procompetitive justifications”). Even though the benefits had no articulated link to the antisteering provisions specifically, the Court both considered and accorded them decisive weight, concluding that the challenged agreements were not unreasonable restraints of trade. *Id.* at 2290 (majority op.).

In re Androgel Antitrust Litigation (No. II), 2018 WL 2984873 (N.D. Ga. June 14, 2018), is not to the contrary. In that case, the court explicitly acknowledged that it “is acceptable” for defendants to “justify the *settlements* as procompetitive because they allowed generic entry earlier than the patent would have allowed,” a consideration separate and apart from any payment term. *Id.* at *11 (emphasis added). That leaves Complaint Counsel to rely on advocacy contained in one of its own amicus briefs. CCAB 18-19. But an amicus argument simply “is not the law,” especially when the advocated position was not adopted by the relevant court. *Apple Inc. v. Samsung Elecs. Co. Ltd.*, 2018 WL 1586276, at *6, 8 (N.D. Cal. Apr. 2, 2018) (considering Supreme Court brief filed by United States).

Even the statement from *Actavis* to which Complaint Counsel points—defendants may show “legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason”—in no way limits from where procompetitive justifications may flow or otherwise cabins how defendants “show[] lawfulness.” CCAB 18 (quoting *Actavis*, 570 U.S. at 156). In fact, the Supreme Court’s concern was not payment on its own, but any resulting *agreement to stay out of the market*. *Actavis*, 570 U.S. at 145 (alleged violation of FTC Act by “agreeing ‘to share in Solvay’s monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years’”). And the appropriate antitrust question is whether that “particular restraint lies beyond the limits of the patent monopoly.” *Id.* at 149. There are no artificial limitations or linkage requirements when answering that question. *Id.*

4. The Initial Decision Properly Considered the SLA as a Whole

Consistent with these foundational rule-of-reason principles, the ALJ concluded that “procompetitive benefits arising in connection with the settlement agreement as a whole are properly considered as part of a well-structured rule of reason.” ID 141. In response, Complaint Counsel breathlessly declares that the Initial Decision (1) makes “it easy for drug companies to pay generic rivals not to compete without violating the antitrust laws,” CCAB 14; (2) establishes “a simple roadmap for drug companies to use anticompetitive reverse-payment agreements,” *id.* at 22; and (3) “create[s] a new rule that entry before patent expiration—coupled with an ordinary freedom-to-operate license—effectively immunizes an otherwise anticompetitive reverse-payment agreement,” *id.* at 23.

These contentions are so muddled and hyperbolic that it is difficult to know where to begin. But it is worth noting that Complaint Counsel does not cite the Initial Decision once when making these claims. That is because the Initial Decision does none of the things

Complaint Counsel attributes to it. The ALJ did not establish any bright line rules, resurrect any patent-related presumptions, or immunize any behavior. And the ALJ did not conclude that “the mere presence in the SLA of the January 2013 entry date and a freedom-to-operate license” constituted procompetitive benefits. *Id.* at 22.⁶

Rather, the ALJ concluded that “consumers have benefitted from the SLA by having uninterrupted and continuous access to generic Opana ER since January 2013” and that, absent the SLA and its broad patent license, the product would not otherwise have been on the market. ID 146. The ALJ reached this conclusion after a full trial and a review of the voluminous, but “clear,” evidence regarding the agreement’s actual effects. *Id.* at 145. That evidence revealed, among many other things, that:

- Absent the SLA, Impax would have been tied up in litigation long past January 2013—no matter the outcome in *any* patent suit—and Impax would not have launched generic Opana ER at risk. ID 145-52, 155-57; IDF 233-35, 450, 563; RFF 1016-17, 1089, 1103-05, 1450-52.
- No matter the outcome in the original litigation, Endo acquired an arsenal of additional patents covering Opana ER and has asserted those patents aggressively, resulting in “all generic manufacturers, other than Impax, being enjoined from selling a generic version of Opana ER until the last of Endo’s patents expires in 2029.” ID 145; IDF 592-98.
- Absent the SLA and its broad patent license, Endo’s patents “would have been successfully asserted to enjoin Impax from selling generic Opana ER—even if

⁶ Although Complaint Counsel suggests freedom-to-operate terms are “common settlement provisions” (CCAB 22), no other generic manufacturer negotiated a broad patent license in its settlement with Endo, IDF 595.

Impax had gone to trial and won its challenge to the patents at issue in the Endo-Impax patent litigation.” ID 145; IDF 575-88; RFF 1114, 1142.

- The SLA has actually “enabled Impax to sell its generic Opana ER uninterrupted since Impax entered the market in January 2013, while all other generic manufacturers have been enjoined as a result of patent infringement litigation by Endo.” ID 141.
- The “real-world effect” of the SLA is that “there is a product on the market and available to consumers today that would not be there” otherwise. IDF 600; ID 146.
- Consumers are better off because Impax is selling generic Opana ER. ID 145-46; IDF 599; RFF 1453-57.

These case-specific facts do not establish a road map for any future litigation or immunize any settlement based on the mere inclusion of a particular term. Instead, they reflect the SLA’s “actual effect on competition,” *Am. Express*, 138 S. Ct. at 2284, which was to “enable[] a product to be marketed which might otherwise be unavailable” and to “widen consumer choice,” *NCAA*, 468 U.S. at 102. That reality is undeniably procompetitive and the ALJ was correct to consider it. *Id.*; *Ind. Fed’n of Dentists*, 476 U.S. at 459 (“the provision of goods and services” is a “countervailing procompetitive virtue”).

For the same reasons, Complaint Counsel’s contention that the “sole procompetitive benefit” arising from the SLA was “competition after January 2013” misses the point. CCAB 23 n.8. Impax has never argued that a particular “entry date was justified by competition after that date.” *Id.* at 23. Rather, Impax has always maintained—and the ALJ found—that the SLA allowed Impax to launch generic Opana ER *earlier* than otherwise would have been possible,

and to ensure patients had *sustained* access after that point. ID 145, 150-52, 155-57; RFF 1010-1397. Consumers and competition have benefited as a result. *NCAA*, 468 U.S. at 102; *Wellbutrin*, 133 F. Supp. 3d at 760 (“ensuring consistent supply of product” is procompetitive).

While Complaint Counsel may (wrongly) believe that it does not need to demonstrate “any actual harm to consumers” (CCRS 9; *see* CCAB 30), the fact that the ALJ assessed whether the SLA and its “entry date benefited consumers” does not “amount[] to a frontal assault on the antitrust foundations of *Actavis*,” CCAB 24-25. The rule of reason demands “a substantial anticompetitive effect that *harms consumers* in the relevant market.” *Am. Express*, 138 S. Ct. at 2284 (emphasis added). Impax is entitled to prove that no such harm occurred. *Id.* at 2289-90; *Actavis*, 570 U.S. at 156 (“parties may have provided for a reverse payment without having . . . brought about the anticompetitive consequences”); *Cipro*, 348 P.3d at 869-79 (defendant can show “that the challenged settlement is in fact procompetitive”).

In the end, the Commission has already recognized that this case is unique because it “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.” CD 12. Similarly, the Commission has already ruled that facts regarding these many patents, and “the extent to which [the] settlement allow[ed] entry prior to patent expiration,” are relevant to “balancing anticompetitive harms and procompetitive benefits.” *Id.* (emphasis omitted); *see Actavis*, 570 U.S. at 154 (“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”).

As much as Complaint Counsel would like to ignore the existence of these patents—and the fact that they have been upheld as valid and infringed by the Federal Circuit—the Initial

Decision abided by the Commission's guidance in determining that the settlement as whole facilitated early and sustained competition years before Endo's patents expired. The ALJ committed no error in concluding that consumers have benefited.

B. Complaint Counsel Has Not Demonstrated That a Less Restrictive Alternative was Possible

Because Impax demonstrated that the SLA resulted in procompetitive benefits, the rule-of-reason "burden shifts back to the plaintiff to demonstrate that the procompetitive efficiencies could be reasonably achieved through less anticompetitive means." *Am. Express*, 138 S. Ct. at 2284; *Brown Univ.*, 5 F.3d at 679 ("the plaintiff, in order to prevail, bears the burden of proving that there exists a viable less restrictive alternative"). Complaint Counsel, however, has never attempted to prove that a less restrictive settlement was possible, much less that it would have resulted in the same substantial consumer benefits. There is, in fact, a total absence of economic analysis and record evidence supporting any such claim.

Complaint Counsel nevertheless argues that it has satisfied its burden because "[b]asic common sense . . . dictates that Endo would have been willing to agree to the same (or earlier) date and the freedom-to-operate license without having to make a large payment to Impax." CCAB 25. But this argument fails for at least four independent reasons. *First and most fundamentally*, the hypothetical alternative settlement Complaint Counsel proposes is *not less restrictive of competition*. Even if such an agreement were possible, it would have meant that Impax stayed out of the market until the "same" date and then behaved in an identical fashion thereafter. Complaint Counsel's hypothetical does not change when or how Impax would have competed. In any event, Complaint Counsel has proffered no evidence that a hypothetical earlier entry date was available regardless of any purported payment. Complaint Counsel's counterfactual simply does not fall within the bounds of the "less restrictive" inquiry.

Second, Impax *did* pursue an alternative settlement without the purported payment terms (the No-AG and Endo Credit provisions). On two different occasions, Impax proposed a settlement allowing Impax to enter prior to the expiration of the patents-in-suit, but without any other terms. Endo rejected the proposal both times. IDF 116, 155. As much as Complaint Counsel would like to ignore this reality, it cannot. A purported less restrictive alternative fails in the first instance when there is “*evidence* that the proffered alternative has been tried but failed.” Areeda, *Antitrust Law* ¶ 1913b (emphasis added). Indeed, when the only “evidence that does exist cuts against the plaintiffs’ view,” it undermines plaintiff’s rule of reason case. *Am. Express*, 138 S. Ct. at 2288; *see* Areeda, *Antitrust Law* ¶ 1913b (“plaintiffs cannot be permitted to offer possible less restrictive alternatives whose efficacy is mainly a matter of speculation”).

Third, Complaint Counsel’s claim that requiring proof of a less restrictive alternative “would create an almost impossible standard,” cannot be reconciled with the law. CCAB 25 (quotation omitted). The Supreme Court requires that plaintiffs “demonstrate” the existence of a less restrictive alternative. *Am. Express*, 138 S. Ct. at 2284. And they must do so by at least “a preponderance of the evidence.” *Brown Univ.*, 5 F.3d at 679 (alternative must be “viable”). This means that Complaint Counsel “has the burden of alleging *and introducing evidence* that the legitimate objective can be achieved nearly as well by a significantly less restrictive alternative.” Areeda, *Fundamentals of Antitrust Law* § 15.06 (emphasis added). Complaint Counsel cannot “just point to” some alternatives “without additionally showing the equivalent viability of the alternatives proffered.” *N. Am. Soccer League, LLC v. U.S. Soccer Fed’n, Inc.*, 883 F.3d 32, 45 (2d Cir. 2018); *see O’Bannon v. NCAA*, 802 F.3d 1049, 1074 (9th Cir. 2015) (“plaintiffs must make a strong evidentiary showing that its alternatives are viable here”).

Complaint Counsel's citation to *In re Solodyn Antitrust Litigation*, 2018 WL 563144 (D. Mass. Jan. 25, 2018), does not counsel otherwise. The *Solodyn* court was not addressing burdens at the third stage of the rule of reason, but rather the existence of causation for purposes of antitrust standing. *Id.* at *13, 21.⁷ And the court did not accept hypothetical appeals to "common sense." It instead evaluated the "documentation and the admissible expert opinions" to assess whether purported "but for" alternatives created a question of material fact. *Id.* at *21-23. Nothing of the sort exists here. *See, e.g.*, Noll, Tr. 1484 ("you don't need to know" whether there was possible alternative); Bazerman, Tr. 914 (unable to say whether any alternative was "possible").

Finally, Complaint Counsel's claim that "Impax has never argued (let alone offered evidence) that it could not have achieved its claimed objectives" with an alternative settlement turns the rule of reason on its head. CCAB 25. It is *Complaint Counsel's* burden to plead and prove a viable and less restrictive alternative. *Am. Express*, 138 S. Ct. at 2284; *In re McWane, Inc.*, 2014 WL 556261, at *36 (F.T.C. Jan. 30, 2014). Attempting to shift the burden to Impax would "effectively require [Impax] to prove a negative potentially covering an infinite number of possibilities." Areeda, *Antitrust Law* ¶ 1914c. The Initial Decision rightly concluded that Complaint Counsel failed its burden at the third stage of the rule of reason. ID 146-47.

⁷ The First Circuit, for its part, instructs that the rule of reason represents a "difficult task" for plaintiffs and requires that they establish "the possibility of achieving the [competitive benefits] through less restrictive means." *August News Co. v. Hudson News Co.*, 269 F.3d 41, 49 (1st Cir. 2001); *see Sullivan v. NFL*, 34 F.3d 1091, 1103 (1st Cir. 1994) (denying summary judgment only when "record contains evidence of a less restrictive alternative" that "would provide the same benefits").

C. The Substantial Procompetitive Benefits Outweigh Any Purported Harm

At the final stage of his analysis, the ALJ “weigh[ed] the anticompetitive and procompetitive effects of the SLA” and concluded that the settlement “was, on balance, procompetitive.” ID 147, 158. Complaint Counsel claims that this conclusion cannot stand because (1) “an agreement’s legality should be judged as of the time it is entered,” without consideration of how the agreement actually affects consumers thereafter, and (2) the “elimination of the risk of competition” is sufficient to condemn the SLA, even if Impax never “actually would have entered earlier.” CCAB 26. Both arguments fail.

1. *There are no Temporal Limitations on Rule-of-Reason Analysis*

Complaint Counsel not only seeks to limit from *where* in a challenged agreement procompetitive benefits may flow, but also *when* those benefits must accrue. Under Complaint Counsel’s view, Impax must prove that a single contract provision resulted in procompetitive benefits at the exact moment the parties executed the larger agreement in which the term is included. As Impax has repeatedly explained, that is not the law. The Supreme Court could not be clearer: The rule of reason requires courts to examine the market’s “condition *before and after* the restraint was imposed.” *Bd. of Trade*, 246 U.S. at 244. This is equally true under *Actavis*, which instructs that “the FTC must prove its case as in other rule-of-reason cases” since “the parties may have provided for a reverse payment *without having . . . brought about the anticompetitive consequences.*” *Actavis*, 570 U.S. at 156, 159 (emphasis added).

In *American Express*, a post-*Actavis* case, the Supreme Court considered the lawfulness of merchant agreements, some of which were executed as early as the 1950s. 138 S. Ct. at 2283. In applying the rule of reason, the Court did not cabin its analysis to the moment any agreement was executed, even though plaintiffs claimed the relevant antisteering provisions “*exist to decrease [] competition*” and therefore always had the “*potential for interbrand harm.*” Brief for

Petitioner at 32, *Ohio v. Am. Express Co.*, 138 S. Ct. 2274 (2018) (No. 16-1454) (emphasis added). Instead, the Court evaluated whether the agreements had an actual effect on consumers in the decades since the agreements were first executed, concluding that “*while these agreements have been in place*, the credit-card market experienced expanding output and improved quality,” undermining any claim of anticompetitive harm. *Am. Express*, 138 S. Ct. at 2289 (emphasis added).

American Express is not alone. In *Indiana Federation of Dentists*, the Court’s rule-of-reason determination turned on evidence of post-restraint, “actual detrimental effects”—namely, that the defendants’ conduct “eliminate[ed] . . . competition among dentists and prevent[ed] insurers from obtaining access to x-rays in the desired manner.” 476 U.S. at 452, 460-61. And in *Board of Trade of Chicago*, the fact that a lower court improperly excluded *ex ante* evidence regarding the challenged agreement was harmless because that agreement actually “helped to improve market conditions” and “had no appreciable effect on” competition after it was executed. 246 U.S. at 238-41; *see also Nat’l Soc.*, 435 U.S. at 689 (no antitrust violation when a “long-run benefit” “outweighed [a] temporary and limited loss of competition”).

The Commission takes an identical approach, explaining that if an agreement is “already in operation,” one must actually “examine whether the agreement . . . has caused anticompetitive harm.” DOJ & FTC, *Antitrust Guidelines for Collaborations Among Competitors* 4 (2000). Accordingly, in *In re North Carolina Board of Dental Examiners*, 152 F.T.C. 640 (2011), the Commission evaluated post-restraint evidence of “higher prices” and reduced consumer choice to conclude that the challenged restraint was anticompetitive. *Id.* at 686-87 (“as a result of the Board’s action . . . numerous non-dentist teeth whitening providers in North Carolina stopped offering teeth whitening services”). And in *In re Indiana Federation of Dentists*, 101 F.T.C. 57

(1983), the Commission considered post-agreement impacts, including that “dental insurance companies were unable to obtain x-rays with the regularity and frequency [they] desired” and that “[w]ithin one year” Aetna had experienced “a backlog of approximately 600 unpaid claims.” *Id.* at 73-79.

Unable to escape these clear lessons, Complaint Counsel simply ignores them. Complaint Counsel instead advances three cases that do not actually address the rule of reason. CCAB 27. The first, *Polk Bros., Inc. v. Forest City Enterprises, Inc.*, 776 F.2d 185 (7th Cir. 1985), held that when determining whether *an ancillary restraint* should receive *per se* or rule-of-reason treatment, a court should evaluate conditions “at the time [the restraint] was adopted.” *Id.* at 189. *Polk Bros.* says nothing about the rule of reason itself, which the court may or may not apply to the ancillary restraint depending on the threshold determination. The second case, *Blackburn v. Sweeney*, 53 F.3d 825 (7th Cir. 1995), is identical. *Id.* at 828. And in the third case, *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003), the Eleventh Circuit simply cited *Polk Bros.* before applying the scope-of-the-patent test, not the rule of reason. *Id.* at 1306, 1311 & n.27 (“Application of the rule of reason analysis is similarly inappropriate.”). It is also worth noting that *Valley Drug* was decided “well before *Actavis*,” which Complaint Counsel suggests is reason enough to disregard it. CCAB 36.

Taken together, the ALJ did not use “hindsight” to “retroactively justify” the challenged agreement. CCAB 27-28. The Initial Decision considered how the challenged agreement “as it actually operates in the market” impacted consumers, exactly as the Supreme Court demands. *Jefferson Par.*, 466 U.S. at 29; *see Am. Express*, 138 S. Ct. at 2284. In so doing, the ALJ followed the Supreme Court’s instructions to assess “the real market forces at work,” *Leegin*

Creative Leather Prods., Inc. v. PSKS, Inc., 551 U.S. 877, 886 (2007), and “condition[s] before and after the restraint was imposed,” *Bd. of Trade*, 246 U.S. at 238.

The resulting conclusion that the SLA is procompetitive does not, as Complaint Counsel argues, “depend[] entirely on a series of events occurring years after the settlement.” CCAB 27. Nor does it vary based on how any patent is adjudicated. *Id.* at 28.⁸ As discussed above, regardless of whether Impax or Endo prevailed in any patent litigation, Impax would not have been able to sell generic Opana ER free from patent risk before January 2013. And because Impax would never have launched its product at-risk, the settlement (1) enabled competition on a sustained basis earlier than otherwise would have been possible and (2) thereby ensured consumers had access to a product that would not have otherwise existed, both of which are procompetitive. ID 145, 150-52, 155-57; RFF 1010-1397. The fact that the relevant patents have repeatedly been upheld as valid and infringed—including by the Federal Circuit—however, confirms that the SLA was a boon for consumers and demonstrates the true “extent to which [the] settlement allows entry prior to patent expiration,” which “affects the magnitude of any anticompetitive effect.” CD 12 (emphasis omitted).

Consideration of such real-world impact is not “unworkable.” CCAB 28. It is the very cornerstone of the rule of reason, which “evolves with new circumstances and new wisdom.” *Bus. Elecs.*, 485 U.S. at 732; *see Am. Express*, 138 S. Ct. at 2289; *Minebea Co. v. Papst*, 444 F. Supp. 2d 68, 219 (D.D.C. 2006) (“even if Papst had intended to cause anticompetitive effects, none have actually occurred”).⁹

⁸ Complaint Counsel conceded as much in other litigation. Brief of FTC at 14, *FTC v. Actavis, Inc.*, No. 09-cv-955 (N.D. Ga. July 26, 2018), ECF No. 707 (arguing Initial Decision did not turn on merits of any patent dispute; citing ID 148 n.36).

⁹ The fact that the Initial Decision assessed the value of certain terms at the time of settlement is consistent with these rule-of-reason principles. CCAB 27 n.10. Economic

2. ***The Purported Elimination of Risk Does Not Outweigh Any Procompetitive Benefit***

In a last-ditch effort to salvage its suit, Complaint Counsel contends that “avoiding even the possibility of competition, however small, is itself an antitrust violation.” CCAB 30 (quotation omitted). And it claims that “a government antitrust enforcer can prove an antitrust violation even where there is no actual injury” to consumers. *Id.* Complaint Counsel is wrong.

First, the Supreme Court is explicit. The rule of reason, even when invoked by government antitrust enforcers, requires “a substantial anticompetitive effect that *harms consumers* in the relevant market.” *Am. Express*, 138 S. Ct. at 2284 (emphasis added; considering rule-of-reason claims brought by state and federal enforcers). This alone should end the discussion. But it is clear that Complaint Counsel is conflating a private plaintiff’s need to establish antitrust standing with the separate consideration of what the rule of reason requires to establish a substantive antitrust violation.

Every plaintiff must have standing to sue, which requires an injury in fact that is fairly traceable to the challenged conduct. *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). In antitrust litigation, there is an additional requirement of “antitrust standing,” which ensures that, even if a plaintiff has suffered an injury in fact, she “is a proper party to bring a *private* antitrust action.” *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 535 n.31 (1983) (emphasis added).

valuation, which must be done on an *ex ante* basis, is distinct from the antitrust question whether an agreement resulted in any anticompetitive *effects*. *See, e.g., Okerlund v. United States*, 365 F.3d 1044, 1053 (Fed. Cir. 2004) (valuation “must always be made as of the [transfer] date relying primarily on *ex ante* information”); Black’s Law Dictionary (“consequence” “follows as an effect of something that came before”).

“Antitrust injury”—the central element of “antitrust standing”—ensures that the plaintiff’s injury is of “the type the antitrust laws were intended to prevent.” *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977). The injury must “flow[] from that which makes defendants’ acts unlawful” and “reflect the anticompetitive effect [] of the violation.” *Id.* This ensures that a plaintiff does not receive damages “for losses stemming from continued competition” or any other behavior that, while harmful to plaintiff personally, does not actually reflect an anticompetitive effect. *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 334 (1990).

Complaint Counsel need not grapple with these threshold requirements because the government can always enforce its own laws. *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 772 (2000) (United States suffers injury-in-fact “from violation of its laws”). But the fact that Complaint Counsel is a “proper party” to bring an antitrust action in the first instance says nothing about its substantive burden to prove an antitrust violation, which is a “distinct matter[] that must be shown independently.” *Atl. Richfield*, 495 U.S. at 344. And to prove that a challenged agreement is an unreasonable restraint under the rule of reason, Complaint Counsel *must* prove “harms [to] consumers in the relevant market.” *Am. Express*, 138 S. Ct. at 2284; *see Cipro*, 348 P.3d at 864 (relevant “anticompetitive harm” is “delay[ing] entry” for longer than “the expected level of competition” absent settlement).

Second, avoiding the mere “possibility of competition, however small,” is not “itself an antitrust violation,” let alone one that outweighs the substantial procompetitive benefits at issue in this case. CCAB 30 (quotation omitted). All “manufacturers, distributors, merchants, sellers, and buyers could be considered as potential competitors of each other.” *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 606 (1972). All contracts consequently eliminate possible

competition and thereby restrain trade; it “is the very essence of every contract.” *Nat’l Soc.*, 435 U.S. at 687-88. But the antitrust laws have never condemned “contracts that might in some insignificant degree or attenuated sense restrain trade or competition.” *Topco*, 405 U.S. at 606; *see Standard Fashion Co. v. Magrane-Houston Co.*, 258 U.S. 346, 356-57 (1922) (Clayton Act does not “prohibit the mere possibility of the consequences” and “was not intended to reach every remote lessening of competition”).

Accordingly, the “competitive process” is not, as Complaint Counsel claims, “distort[ed]” simply because a contract eliminates some theoretical risk of future competition. CCAB 29. All agreements do that. It is only those agreements that actually “obstruct[] the achievement of competition’s basic goals—lower prices, better products, and more efficient production methods”—that harm anything. *Town of Concord v. Boston Edison Co.*, 915 F.2d 17, 21-22 (1st Cir. 1990) (Breyer, J.) (discussing harm to “competitive process”). The relevant inquiry consequently asks whether the challenged agreement “*deprive[s] purchasers or consumers* of the advantages” they would have enjoyed absent the agreement. *Id.* at 22 (emphasis added; quotation omitted). There simply is no harm to the “competitive process” absent harm to consumers. *United States v. Microsoft Corp.*, 253 F.3d 34, 58 (D.C. Cir. 2001) (“it must *harm* the competitive process and thereby *harm consumers*” (second emphasis added)); *see Am. Express*, 138 S. Ct. at 2284 (“goal” of rule of reason is to determine what is “harmful to the consumer”).

“This principle is apparent in even the earliest cases applying the Rule of Reason.” *Nat’l Soc.*, 435 U.S. at 688. Courts have always instructed that “even though [agreements] deprive the public of the benefit of potential competition” they are not unreasonable restraints of trade if they have actual “long-run benefit[s]” and the competition was unlikely in any event. *Id.* at 688-89 &

n.12 (discussing decisions as early as the 1700s). The Supreme Court reiterated this point in *United States v. Columbia Steel Co.*, 334 U.S. 495 (1948), in which the government claimed an agreement “would preclude and restrain substantial potential competition.” *Id.* at 528. While the Court acknowledged that the challenged agreement “eliminates some potential competition,” it rejected the notion “that possibilities of interference with future competition are serious enough to justify us in declaring that this contract will bring about unlawful restraint” when there was “nothing from the record” to indicate that such competition was likely. *Id.* at 528-29. Mere “suggestions” that competition “might” have occurred were insufficient. *Id.* at 530.

The Commission is no different. When an agreement allegedly “eliminate[s] the risk of competition,” Complaint Counsel must prove that the supposedly excluded competitor’s “entry was reasonably probable in the absence of the [challenged agreement].” *McWane*, 2014 WL 556261, at *32-37. Even when there is “troubling evidence” that one party “entered the [agreement] in order to eliminate [the] possibility” of another’s entry, that is not enough to establish a Section 1 violation, especially when the record demonstrates that the supposedly-restrained entity took only “preliminary acts to enter the market.” *Id.* at *32-35.

Complaint Counsel ignores these foundational principles. It contends that “an agreement to share monopoly profits to avoid generic competition is anticompetitive regardless of whether the generic would have otherwise entered earlier.” CCAB 30. But this subverts the rule of reason. If a generic manufacturer would not have competed in the absence of the agreement, then the agreement does not “avoid generic competition”—and consumers have not suffered any harm. *See Columbia Steel*, 334 U.S. at 529-30; *Cipro*, 348 P.3d at 864 (relevant “anticompetitive harm” is “delay[ing] entry”); *McWane*, 2014 WL 556261, at *32-37.

Equally problematic, Complaint Counsel’s approach would impose a presumption of unlawfulness. It would condemn agreements “regardless” of any impact in the real world so long as they “avoid some competition,” no matter how unlikely. But no settlement “will survive such scrutiny” since “[v]irtually all settlements are, to some extent, designed to avoid the risk of competition.” *In re Androgel*, 2018 WL 2984873, at *9 n.71. And imposing liability because an agreement “by its nature” has a certain “character” (CCAB 29-30) is *per se* liability,¹⁰ which is “disfavored in antitrust law” and has already been rejected with respect to reverse-payment settlements. *Am. Express*, 138 S. Ct. at 2285; *see Actavis*, 570 U.S. at 158-59.

Indeed, the brief allusion to payments that “prevent the risk of competition” in *Actavis* does not obviate the need to show “anticompetitive consequences” “as in other rule-of-reason cases.” 570 U.S. at 156-57, 159. The Court used the phrase only to explain why reverse-payment settlements are not immune from antitrust scrutiny, nothing more. *King Drug*, 791 F.3d at 411. Courts in reverse-payment cases consequently require proof of consumer harm in the form of delayed competition. *Id.* at 404, 409, 412 (“the plaintiff must prove payment for delay”); *see In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 163 (3d Cir. 2017) (“no delay” means “*Actavis* does not apply” and claim “must fail”); *Cipro*, 348 P.3d at 864 (similar); *Sergeants Benevolent Ass’n Health & Welfare Fund v. Actavis, PLC*, 2016 WL 4992690, at *15 (S.D.N.Y. Sept. 13, 2016) (similar); *In re K-Dur Antitrust Litig.*, 2016 WL 755623, at *12 (D.N.J. Feb. 25,

¹⁰ *See Nat’l Soc.*, 435 U.S. at 692 (agreements “whose nature and necessary effect are so plainly anticompetitive that no elaborate study of the industry is needed to establish their illegality” are “illegal *per se*”; the rest “are agreements whose competitive effect can only be evaluated by analyzing the facts”); *Jefferson Par.*, 466 U.S. at 9 (the “character of the restraint produced by [*per se* behavior] is considered a sufficient basis for presuming unreasonableness without the necessity of any analysis of the market context in which the [behavior] may be found”).

2016) (similar); *In re Aggrenox Antitrust Litig.*, 2015 WL 4459607, at *10 (D. Conn. July 21, 2015) (similar).

Still, even if the mere elimination of potential future competition was sufficient to establish cognizable harm under the rule of reason, that would not itself constitute an antitrust violation. Complaint Counsel would still have to prove that the claimed anticompetitive effects outweigh all countervailing procompetitive benefits. And as discussed below, the ALJ rightly concluded that the SLA's real-world consumer benefits outweigh any elimination of theoretical and unlikely competition.

3. The Initial Decision Properly Balanced the Competitive Effects

The ALJ did not “simply look[] at whether the length of time Impax was permitted to be on the market prior to expiration of the licensed patents exceeded the length of time Impax agreed to stay off the market.” CCAB 33. As already discussed, the Initial Decision does not apply any presumptions or bright line tests, and it does not engage in a simple mathematical exercise. Instead, the ALJ evaluated the record as a whole and determined that the “risk” of Impax's entry before January 2013—the elimination of which is the only harm Complaint Counsel alleges—was nothing more than a “hypothetical possibility.” ID 157.

In fact, Complaint Counsel's argument is premised on an assumption that Impax would have launched its product on the day it settled, and therefore agreed to “stay off the market for 2½ years.” CCAB 13. But that kind of reasoning is divorced from common sense and finds no support in the record. Impax would not have launched its product on June 8, 2010—or at any time before January 2013—given the tremendous patent risks. ID 150-58; IDF 451-548, 553-64; RFF 1016-1380. Impax consequently did not agree to “stay off” of anything. It never would have been on the market to begin with. Complaint Counsel does not contend otherwise, arguing only that Impax “pose[d] a real threat of competing before January 2013.” CCAB 31; *see id.* at

32 (“the question is not whether Impax necessarily would have launched”); Compl. Counsel, Tr. 20, 27 (“We don’t know what Impax would have done.”). But while Endo may have considered Impax a threat, Impax was not going to launch absent a licensed entry date, and Complaint Counsel failed to prove otherwise.

To begin, Complaint Counsel suggests that Impax “had strong financial incentives to launch its product as early as possible,” and that Impax “invested significant resources preparing for a June 2010 launch.” CCAB 31 (quotation omitted). But Complaint Counsel ignores the overwhelming evidence that Impax’s activities were consistent with routine planning procedures followed for every product, (ID 153; IDF 503, 506, 511-14, 517-18), that Impax never actually produced enough product to support a full launch, (ID 154; IDF 530-33), and that it would have been “impossible” for Impax to launch “soon after FDA approval,” (ID 154; IDF 536; RRF 181, 204).

Just as important, Complaint Counsel overlooks the fact that Impax never undertook necessary steps to launch at risk, which is the most serious decision and procedural undertaking at Impax. IDF 473-502; RFF 1179-1238. Complaint Counsel similarly disregards the dangers of an at-risk launch, which is a “bet-the-company” gamble that risks ruinous damages and loss of exclusivity rights under the Hatch-Waxman Act. ID 149-50; IDF 451-64. And Complaint Counsel has no response to the fact that Impax had *never* before launched at risk when it was the first ANDA filer. IDF 465-70. For all of these reasons, the ALJ concluded that Impax would not have launched generic Opana ER at risk. ID 150-52, 154; IDF 451-548.

Complaint Counsel also argues that Impax “might” have been “able to enter risk-free before 2013 even if it waited until an appellate decision in the patent case” because that decision could have issued as early as mid-2011. CCAB 32. This is not true. Complaint Counsel

overlooks the '482 patent, which issued to Johnson Matthey in December 2010, and which Impax was given notice of by May 2011. IDF 574; RFF 238; RRFF 1026. Even if Impax could have secured a final, non-appealable patent victory in the initial litigation by mid-2011—and Complaint Counsel has not shown that a win was likely—Impax still would not have been able to launch generic Opana ER without patent risk. RFF 1094; RRFF 1026.

In light of these facts, the ALJ concluded that the “hypothetical possibility” of Impax competing before January 2013 found no support in the record and, in any event, did not outweigh the “substantial” procompetitive benefits that consumers in “the real world” had enjoyed for years. ID 157. Those benefits are amplified by the many judicial decisions that have upheld Endo’s patents as valid. The ALJ committed no error. *Columbia Steel*, 334 U.S. at 529-30 (claims that competition “might” have occurred insufficient); *McWane*, 2014 WL 556261, at *32-37 (elimination of risk insufficient absent reasonable probability of entry).

II. COMPLAINT COUNSEL’S SUIT ALSO FAILS BECAUSE ENDO NEVER POSSESSED MARKET POWER

Complaint Counsel’s case fails for an additional reason: Complaint Counsel has not proved that Endo possessed market power in a properly defined relevant market.

A. Market Power Requirements Apply to Every Rule-of-Reason Case

“The rule of reason *requires* courts to conduct a fact-specific assessment of market power and market structure” before any conclusions can be drawn about a challenged agreement’s “actual effect on competition.” *Am. Express*, 138 S. Ct. at 2284 (quotation omitted; emphasis added). Absent an accurate “definition of [the] market there is no way to measure [the defendant’s] ability to lessen or destroy competition.” *Id.* at 2285 (quotation omitted). A defendant that does not have market power within a relevant market simply cannot “cause

anticompetitive effects on market pricing.” *Agnew v. NCAA*, 683 F.3d 328, 335 (7th Cir. 2012); *see Assam Drug Co. v. Miller Brewing Co.*, 798 F.2d 311, 316 (8th Cir. 1986) (same).

“Substantial market power” consequently “is an indispensable ingredient of every claim under the full Rule of Reason.” *Chi. Prof’l Sports Ltd. P’ship v. NBA*, 95 F.3d 593, 600 (7th Cir. 1996). And a plaintiff’s failure to prove market power requires judgment in favor of defendants. *Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs., Inc.*, 996 F.2d 537, 546-47 (2d Cir. 1993) (affirming summary judgment for lack of market power in horizontal-restraint case); *Rothery Storage & Van Co. v. Atlas Van Lines, Inc.*, 792 F.2d 210, 229 (D.C. Cir. 1986) (same). This is no less true in reverse-payment cases, which must be proved “as in other rule-of-reason cases.” *Actavis*, 570 U.S. at 149, 159 (“antitrust question” must be answered with reference to “traditional antitrust factors,” including “market power”); *see In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 49 (1st Cir. 2016) (same); *Wellbutrin*, 133 F. Supp. 3d at 754-55 (same).

Accordingly, the ALJ’s suggestion that market power may not be a “necessary element of a reverse payment settlement challenge” finds no support in the law. ID 139. Complaint Counsel agrees. CCAB 10 n.3. Even the cases cited in the Initial Decision (ID 96) affirm the centrality of market power. *See King Drug*, 791 F.3d at 411-12 (“traditional” rule of reason applies, which requires market power); *In re Aggrenox Antitrust Litig.*, 199 F. Supp. 3d 662, 666 (D. Conn. 2016) (market power essential, but can be proved directly with evidence that brand could “profitably charge supracompetitive prices over a sustained period”); *Cipro*, 348 F.3d at 873 (under California law, market power can be presumed from a large reverse payment, but defendants may rebut plaintiffs’ *prima facie* showing).

B. The Initial Decision Did Not Apply Traditional Antitrust Standards

Market power may be proven 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. *Id.* Such proof is “rarely available.” *Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 434 (3d Cir. 2016). The more common, indirect method requires proof that the defendant had a significant share of a properly defined relevant market, that there are significant entry barriers, and that incumbents in the market cannot increase output in the short run. *Id.* at 435-36; *Rebel Oil*, 51 F.3d at 1434.

To define a “relevant market,” courts must evaluate the “area of effective competition,” *Am. Express*, 138 S. Ct. at 2285 (quotation omitted), which includes all products that are “reasonably interchangeable by consumers for the same purposes,” *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 395 (1956). This 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, Inc. v. Domino’s Pizza, Inc.*, 124 F.3d 430, 436-37 (3d Cir. 1997); *see Mylan*, 838 F.3d at 436 (pharmaceutical “products need not be perfectly fungible to be considered reasonably interchangeable”). Put differently, “courts should combine different products or services into a single market when that combination reflects commercial realities.” *Am. Express*, 138 S. Ct. at 2285 (quotations omitted). They cannot resort to “formalistic distinctions” or ignore “the particular facts of each case.” *FTC v. AbbVie Inc.*, No. 14-5151, slip op. at 55 (E.D. Pa. June 29, 2018) (quotation omitted).

The Initial Decision did not apply these principles. The ALJ instead defined a relevant market limited to branded and generic Opana ER—and concluded that Endo had power within that narrow market—on the basis of three predicates: (1) the existence of patents, (2) the Hatch-

Waxman regulatory framework, and (3) Endo’s alleged reverse payment to Impax. ID 18, 139-41. None of these factors supports a narrow market definition or a finding of market power.

1. Patents Do Not Bestow Market Power

The ALJ stated that “the patents at issue in the Impax infringement case gave Endo the power to exclude competitors,” and that “pharmaceutical patents often carry with them market power.” ID 18, 139, 141. However, the notion that patents bestow market power because they allow brand-name drug companies to “exclude competitors” is circular. The statutory right of exclusion is not equivalent to market power *unless* one assumes that (1) the patents are valid and (2) only literal copies of the branded drug—*i.e.*, products that would infringe the brand company’s patents—count as “competitors.” Addanki, Tr. 2343 (“[T]o the extent that other long-acting opioids competed with Opana ER, [Endo’s] patents had no ability to block them.”).

But literal equivalence is not the standard by which markets are delineated. *Du Pont*, 351 U.S. at 393; *see Abbvie*, No. 14-5151, slip op. at 64 (“perfect correspondence” not required); *Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co.*, 2015 WL 1736957, at *10 (E.D. Pa. Apr. 16, 2015) (“subtle differences” irrelevant). Recognizing this, the Supreme Court has rejected the “patent equals market power” presumption.” *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 44 (2006); *see N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 10 n.8 (1958). The Commission has put it this way: “Although the intellectual property right confers the power to exclude *with respect to a 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.” DOJ & FTC, *Antitrust Guidelines for the Licensing of Intellectual Property* § 2.2 (2017) (emphasis added).

The agencies’ explanation aptly describes the LAO market, and identifies a fatal flaw in the ALJ’s market power finding. The fact that Endo’s patents prevented others from selling

Opana ER had no effect on the entry of *other LAOs*. See RX-547 (Addanki Rep., Ex. 11) (identifying seven branded LAOs that launched after Opana ER).

2. *The Hatch-Waxman Regime Does Not Create Market Power*

The Initial Decision also concluded that the Hatch-Waxman Act “allow[s] a brand-name drug to be protected against entry in two ways”: (1) via the 30-month stay in Paragraph IV cases, and (2) via the 180-day exclusivity period for first ANDA filers. ID 18. The ALJ reasoned that these “barriers gave Endo the power to exclude competitors even if its patents were eventually found not to be valid or infringed.” *Id.* at 141.

The idea that “excluding rivals . . . itself brings market power” is “erroneous.” Areeda, *Antitrust Law* ¶ 501; see *In re Loestrin*, 261 F. Supp. 3d at 326 n.22 (“the power to exclude competition does not itself bring[] substantial market power” (quotation omitted)). Like patents, these Hatch-Waxman provisions may permit a brand company to forbid competitors from making a *specific product* for a period of time, but not from making *reasonable substitutes* for that product.

To hold that the Hatch-Waxman Act creates market power would mean that every company with an Orange Book-listed patent is a monopolist. That is not the law. *In re Remeron Direct Purchaser Antitrust Litig.*, 367 F. Supp. 2d 675, 683 (D.N.J. 2005) (rejecting rule that “would render most brand name pharmaceutical companies as *per se* monopolists prior to generic entry”); see *Abbvie*, No. 14-5151, slip op. at 61-62 (same).

3. *A Purportedly Large Reverse Payment Does Not Prove Market Power*

The ALJ also held that proof of market power “can be found in the reverse payment settlement itself.” ID 139. This derives from the statement in *Actavis* that “the size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of power—namely, the power to charge prices higher than the competitive level.” *Id.* at 139-40

(quoting 570 U.S. at 157). From this, the ALJ reasoned that Endo’s alleged payment to Impax is “strong proof of Endo’s market power in the relevant market.” *Id.* at 140.

Actavis, however, did not create a new method for proving market power in rule-of-reason cases. The Court’s statement was but one “consideration” that led it to reject antitrust immunity in reverse-payment cases. *See* 570 U.S. at 157-58 (“[T]hese considerations, taken together, outweigh the single strong consideration—the desirability of settlements—that led the Eleventh Circuit to provide near-automatic antitrust immunity to reverse payment settlements.”). Such “considerations” did not modify the rule of reason itself. *King Drug*, 791 F.3d at 411.

It also bears noting that *Actavis* was decided at the pleading stage. At trial and summary judgment, courts continue to demand traditional proof of market power. *See, e.g., Nexium*, 842 F.3d at 49-50 (jury instructed to answer whether defendant had “market power within the relevant market” without reference to a large payment); *Solodyn*, 2018 WL 563144, at *5 (“[T]he Court concludes that it would be inappropriate to equate [a large reverse payment and market power] at the summary judgment stage.”). With the benefit of a voluminous and developed factual record, the ALJ should have done the same.

C. The Relevant Market Includes Numerous LAOs

When assessed pursuant to the proper analytical framework, the following reality is clear: Opana ER competed against many other LAOs in a broad relevant market. The record evidence—ranging from clinical guidelines to medical expert testimony and from internal business records to empirical economic analysis—supports no other conclusion.

1. LAOs are Reasonably Interchangeable for the Treatment of Chronic Pain

At trial, Impax presented un rebutted evidence that LAOs are “reasonably interchangeable by consumers for the same purposes.” *Du Pont*, 351 U.S. at 395. On a therapeutic level, LAOs

carry nearly identical FDA-approved labeling, which states that LAOs are indicated for the management of “pain severe enough to require daily, around-the-clock, long-term opioid treatment.” RFF 711-17; *see Abbvie*, No. 14-5151, slip op. at 63 (“overwhelming[]” evidence that products are “reasonably interchangeable” when FDA approved all for treatment of same condition); *Mylan*, 838 F.3d at 436 (same). The World Health Organization similarly groups opioids together for the treatment of “moderate to severe pain.” RFF 719; RX-122 at 8.

These are not just words on paper. Real-world medical practice confirms LAOs are substitutes. LAOs are prescribed interchangeably to treat scores of the same pain-related diagnoses. RFF 720-22; RX-547 (Addanki Rep., Ex. 4).¹¹ There is no diagnosis for which Opana ER is the only opioid prescribed. RFF 702, 786, 935. And both medical experts agreed that (1) physicians have a choice of LAOs, (2) no LAO is superior, (3) there is no discernible population of patients for whom Opana ER is the only or best option, and (4) switching between LAOs is routine. RFF 698-710, 729-49, 923-39, 972-76; *see Mylan*, 838 F.3d at 436 (“consensus among dermatologists that all oral tetracyclines treat acne with similar effectiveness and so are interchangeable for that purpose” supported broad market definition); *Polypore Int’l, Inc. v. FTC*, 686 F.3d 1208, 1218 (11th Cir. 2012) (broad market definition appropriate when no “distinct customers”).

That LAOs are interchangeable for the treatment of chronic pain is strong evidence that they compete in a single market. *Mylan*, 838 F.3d at 436-37; *Kaiser Found. v. Abbott Labs.*, 2009 WL 3877513, at *8-10 (C.D. Cal. Oct. 8, 2009).

¹¹ The 100 diagnoses included in Dr. Addanki’s study collectively account for nearly 90 percent of all prescriptions for the six opioids studied, and nearly 93 percent of all oxymorphone prescriptions. RRF 922.

2. *LAOs are Economic Substitutes*

The record further indicates that LAOs competed on price and are reasonable economic substitutes. “It is imperative that the [Commission], in determining the relevant market, take into account the economic and commercial realities of the pharmaceutical industry.” *FTC v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 46 (D.D.C. 1998); *see Am. Express*, 138 S. Ct. at 2285 (market definition must “reflect[] commercial realities”). The pharmaceutical industry’s unique institutional features mean that any competition will play out at three levels: patient, prescriber, and payor. The record shows fierce competition among LAOs at each level.

At the patient level, LAO makers offered “copay coupons” and other discounts to attract patients by reducing their out-of-pocket prices. RFF 899-915. As Endo aptly put it, there was “[a]ggressive competitive couponing from all direct competitors.” RX-028.0011. If Endo were a monopolist—and if LAOs were not economic substitutes—there would be no reason for Endo (or its rivals) to engage in “aggressive” price competition. *Atl. Richfield*, 495 U.S. at 343 n.13 (the “incentive” of “any monopolist, is to reduce output and *increase price*” (emphasis added)). Direct-to-patient price discounting “is the hallmark of when there’s actually competition.” Addanki, Tr. 2237; *see United States v. Am. Express Co.*, 838 F.3d 179, 203 (2d Cir. 2016) (“evidence showing that Amex must compete on price in order to attract consumers” demonstrated “a *lack* of market power”); *Abbvie*, No. 14-5151, slip op. at 65-66 (products part of same market when companies “develop[ed] a copay assistance program”). Complaint Counsel offers no evidence reconciling its allegation of an Opana ER-only market with proof of vigorous copay discounting.

At the prescriber level, LAO makers competed for physicians’ attention and prescriptions. RFF 878-98. While LAO makers emphasized their products’ purportedly superior qualities, the fact remained that LAOs “are not very differentiated.” RX-023.0002; RRF 722-

25; *see Mylan*, 2015 WL 1736957, at *10 (relevant market included all oral tetracyclines, even though defendants’ advertisements “emphasized that Doryx is superior to other oral tetracyclines”). In addition to advertising and promotion, LAO makers also informed physicians about formulary placement and copay assistance programs—the primary determinants of patients’ out-of-pocket costs. RFF 892-98; RX-016.0002 at 97; RX-445.0021-22. This messaging would be nonsensical if lower prices did not induce substitution. *See Town Sound & Custom Tops, Inc. v. Chrysler Motors Corp.*, 959 F.2d 468, 480 (3d Cir. 1992) (price-based competitive advertising supported broad market definition; rejecting single-brand market definition). Indeed, formulary coverage and copays play a major role in deciding which LAO to prescribe. RFF 750-72; RX-549 (Michna Rep. ¶¶ 21, 52-53).

At the payor level, LAO makers offered discounts to insurers—which typically pay the lion’s share of a drug’s price—for the express purpose of “improv[ing] formulary access.” RX-014.0002; *see* RFF 818-77. These discounts were directly influenced by competitors’ pricing. *See, e.g.*, CX3206-002 (discussing “an additional 11% discount on Opana ER” to “achieve pricing parity with OxyContin”); RX-073.0002 at 61 (comparing Opana ER and OxyContin price discounts to group purchasing organizations). As the Commission acknowledges, evidence of “industry participants’ behavior in tracking and responding to price changes by some or all rivals” is probative of market definition. DOJ & FTC, *Horizontal Merger Guidelines* § 4.1.3 (2010); *see Abbvie*, No. 14-5151, slip op. at 65 (products part of same market when companies “offer[ed] rebates to payors to obtain better formulary placement and thereby encourage doctors to prescribe” their products); *FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1080 (D.D.C. 1997) (relying on evidence that defendants “price check[ed] the other office superstores” to define market).

Just as important, the record indicates that by winning favorable formulary placement at a competitor's expense, LAO manufacturers could secure their "greatest share gains." RX-073.0002 at 33. As just one example, when the University of Pittsburg Medical Center, a major health system, changed its formulary to preference Opana ER over OxyContin, *nearly 70 percent* of OxyContin patients switched to an alternative LAO, with Opana ER utilization expanding almost *twelve-fold*. RX-087; RFF 763-68. This real-world evidence of cross-elasticity of demand—when insurers made one product relatively more expensive than another, a substantial percentage of consumers switched—supports a broad LAO market definition. *Du Pont*, 351 U.S. at 400 ("An element for consideration as to cross-elasticity of demand between products is the responsiveness of the sales of one product to price changes of the other."); *Abbvie*, No. 14-5151, slip op. at 65-66 (formulary changes, and switching among products as a result, indicates cross-elasticity of demand); *Merger Guidelines* § 4.1.3 (evidence of "how customers have shifted purchases in the past in response to relative changes in price" is probative of market definition).

Complaint Counsel has never rebutted any of these facts. Nor could it. Complaint Counsel's economic expert advanced analysis { [REDACTED] [REDACTED] [REDACTED] [REDACTED] } Noll, Tr. 1679-82; CX5000 (Noll Rep., Ex. 7A); RFF 830-31. Complaint Counsel cannot explain why { [REDACTED] [REDACTED] [REDACTED] }¹²

¹² Below, Complaint Counsel cried "cellophane fallacy" without further elaboration. CCPTB 59. The sole case it invoked, however, concluded that when various brands are of comparable quality and compete for the same customers, they are part of the same market, even if they have subtle quality differences. *United States v. Eastman Kodak Co.*, 853 F. Supp. 1454, 1469-70 & n.9 (W.D.N.Y. 1994). As discussed, that is the case here.

3. *LAO Manufacturers Believe All LAOs Compete in the Same Market*

Industry participants are “presumed to have accurate perceptions of economic realities.” *United States v. Aetna Inc.*, 240 F. Supp. 3d 1, 21 (D.D.C. 2017). 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, LAO manufacturers’ ordinary course documents tell a consistent story: LAOs all competed in a single market.

In internal analyses during the relevant period, Endo identified numerous direct competitors to Opana ER, { [REDACTED] } [REDACTED]. } RFF 795-809. { [REDACTED] } [REDACTED]. } RFF 810-14; see RX-448.0002-3; RX-446.0004; RX-445.0014-18; RX-444.0004. Other LAO makers expressed similar perceptions. RX-547 (Addanki Rep. ¶ 84).

Endo also measured its market share by reference to the LAO market. In 2007, the year after Opana ER launched, Endo stated that { [REDACTED] } [REDACTED] } RX-085 at 57. In mid-2010, just following its settlement with Impax, Endo { [REDACTED] } [REDACTED] } RX-558.0001; see CX3273 at 3 (estimating 3.4% share in March 2010). { [REDACTED] } [REDACTED]. } See, e.g., RX-449.0007; RX-446.0004; RX-445.0003; RX-444.0009.

These internal (and unrebutted) business documents are direct evidence of the reality that Opana ER competed against other LAOs in the relevant market. See *Abbvie*, No. 14-5151, slip op. at 67 (documents indicating “AbbVie tracked the TTRT market and considered other TTRTs

as competitors” supported broad market definition); *Mylan*, 2015 WL 1736957, at *9 (similar); *United States v. Bazaarvoice, Inc.*, 2014 WL 203966, at *22 (N.D. Cal. Jan. 8, 2014) (similar).

4. *The Commission Previously Concluded Opana ER Competed Against Other LAOs in the Same Market*

The record in this case is consistent with the Commission’s own findings. In 2009, the year before the SLA was signed, the Commission identified a market consisting of “the manufacture and sale of oral LAOs.” See Compl. ¶ 12, *In re King Pharm., Inc. & Alparma, Inc.*, No. C-4246 (F.T.C. Feb. 2, 2009). The Commission defined “oral LAOs” to include “orally-administered extended-release formulations of . . . oxycodone, morphine sulfate[,] and oxymorphone.” *Id.* ¶ 1.¹³ In its published analysis of the King/Alparma consent decree, 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 Pharmaceuticals, Inc. and Alparma Inc. Agreement Containing Consent Order To Aid Public Comment*, 74 Fed. Reg. 295, 296 (Jan. 5, 2009). The Commission specifically indicated that “*Opana ER . . . competes in the [oral LAO] market.*” *Id.* (emphasis added). The evidence in this case bears out the Commission’s finding.

* * *

Taken together, the evidence demonstrates that Opana ER competed against numerous LAOs. The relevant market included, at a minimum, branded and generic versions of transdermal fentanyl and extended-release oxycodone, morphine, hydromorphone, tapentadol, hydrocodone, and oxymorphone. RFF 696.

¹³ The Commission further identified a single submarket consisting of oral long-acting morphine sulfate products.

D. Endo Never Had Market Power in a Properly-Defined LAO Market

From January 2009 through December 2012, Opana ER’s share of the LAO market never even reached 10 percent. RFF 1002. It is “inconceivable” that Endo could command market power with that share. RFF 1008; *see Jefferson Par.*, 466 U.S. at 26-27 & n.43 (market share of 30 percent “insufficient as a basis for inferring market power”); *Brokerage Concepts, Inc. v. U.S. Healthcare, Inc.*, 140 F.3d 494, 517 (3d Cir. 1998) (“no court has inferred substantial market power from a market share below 30%”); *Vollrath Co. v. Sammi Corp.*, 9 F.3d 1455, 1461 (9th Cir. 1993) (“no danger of monopoly power” when defendant “controlled only 10% of the market”).

E. Complaint Counsel Failed to Prove Endo Had Market Power

In an attempt to establish market power, Complaint Counsel purported to rely on both “indirect[]” and “direct[]” evidence. CX5000 (Noll Rep. ¶ 184). Neither approach supports Complaint Counsel’s narrow, single-product market.

1. Complaint Counsel Failed to Present Indirect Evidence of Market Power

Complaint Counsel contends that Endo had market power because of (1) therapeutic differences among LAOs; (2) switching costs; (3) communications about pricing; (4) LAO manufacturers’ promotional efforts; and (5) the alleged absence of any “visible effect” on sales of Opana ER following entry. RFF 980-86; *see* Noll, Tr. 1377-94. None of these factors constitutes proof of a narrow market.

Purported therapeutic differences between Opana ER and other LAOs do not support a narrow market definition. Complaint Counsel’s economic expert, Dr. Noll, testified that his market definition opinion rested in part on “therapeutic differences” among LAOs. Noll, Tr. 1388. But Dr. Noll, who lacks medical training, never showed that these purported “differences”

are material. In fact, both medical experts contradicted Dr. Noll, testifying that no LAO is superior and that pain physicians have a choice among numerous products. RFF 698-710, 729-49, 923-39, 972-76. In practice, opioids are prescribed interchangeably to treat scores of diagnoses. RFF 720-22; RX-547 (Addanki Rep. ¶ 64, Ex. 4). Any minor therapeutic distinctions do not create an antitrust market. *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”); *Abbvie*, No. 14-5151, slip op. at 64 (“relative advantages and disadvantages” irrelevant; “rough equivalence” was what mattered to broad market definition including all transdermal testosterone replacement therapies).

Switching costs, if any, are low. Dr. Noll claimed that “switching costs,” such as the need to taper off one drug while titrating up on another, support his narrow market definition. Noll, Tr. 1388-90. But as Dr. Noll admitted, he did not measure or quantify these supposed costs; he merely claimed to identify them. RFF 986. Complaint Counsel cannot rely on such amorphous claims. *See SMS Sys. Maint. Servs., Inc. v. Dig. Equip. Corp.*, 188 F.3d 11, 20 (1st Cir. 1999) (rejecting claim when there was no evidence that “alleged switching cost is material”); *Commercial Data Servers, Inc. v. IBM Corp.*, 262 F. Supp. 2d 50, 68-69 (S.D.N.Y. 2003) (similar; no “customers who wanted to leave” “were unable to migrate due to high switching costs”).

Dr. Noll also ignored the testimony of both medical experts, which indicates that switching costs—to the extent there are any—do not make switching impractical. RFF 734-44, 778-84; RRF 661-64; *see Commercial Data Servers*, 262 F. Supp. 2d at 69 (inquiry is whether switching costs “make migration impractical”). Complaint Counsel’s medical expert affirmed

that switching is often “simple,” and that she herself has *never* been unable to switch a patient from Opana ER to another LAO. RFF 734, 738. If switching costs were high enough to make switching impractical, rotation therapy would not be a viable treatment option, much less a “very important clinical tool,” as Complaint Counsel’s expert described it. RFF 773-77.

Endo’s pricing communications do not support a narrow market definition. Dr. Noll and Complaint Counsel asserted that Endo’s pricing documents for Opana ER “rarely considered the prices of other drugs.” Noll, Tr. 1392-94; CCPTB 54. As support, Dr. Noll pointed to a handful of cherry-picked Endo documents that discuss Opana ER’s list prices (known as WAC prices). RFF 833; RRF 721, 737, 866-67, 873-79. As Dr. Noll admitted, however, { [REDACTED] } RFF 835. { [REDACTED] } RFF 834-35; Addanki, Tr. 2290. And when it came to the prices that consumers and insurers actually paid, Endo *did* discuss competitors’ pricing. *See, e.g.*, RX-028.0011 (discussing competitors’ “[a]ggressive couponing”); CX3206-002 (discussing Purdue’s discounts to payors); RX-073.0002 at 33 (discussing Opana ER’s “[a]dvantaged [f]ormulary [s]tatus vs. OxyContin”); *see also* RRF 940.¹⁴

LAO makers’ promotional efforts do not support a narrow market definition. Dr. Noll asserted that LAO makers’ promotional efforts “focused primarily on product definition,” which he thinks “undermin[es], rather than enhanc[es], price competition.” Noll, Tr. 1394; CX5004 (Noll Rebuttal Rep. ¶ 53). But the need to differentiate was driven by the fact that LAOs “are not very differentiated” to begin with. RX-023.0002; RFF 960-70. In any event, “most product differentiation does not indicate substantial market power for anyone,” since even “highly

¹⁴ Endo also discussed competitors’ WAC prices, despite the relative unimportance of those prices. *See, e.g.*, CX2673-008; RX-073.0002 at 72.

competitive firms advertise [and] vary products.” Areeda, *Antitrust Law* ¶ 520c; see *Town Sound*, 959 F.2d at 478-81 (evidence that “Chrysler’s advertising compare[d] the . . . features of its autos with other companies” indicated relevant market was “all new automobiles”).

Dr. Noll’s visual inspection of LAO sales trends does not support a narrow market definition. Finally, Dr. Noll performed a “visual” inspection of Opana ER sales. He opined that the relevant market should be limited to branded and generic Opana ER because, in his assessment, Impax’s and Actavis’ generic Opana ER products drew share from Endo’s branded Opana ER, but the launch of other generic opioids did not. Noll, Tr. 1377-87. To be clear, Dr. Noll did not support these opinions with quantitative or statistical analysis. RFF 981-84; RRF 684-85, 689, 696-97. He did not try to calculate any cross-elasticities of demand. RFF 983. Nor did he conduct a “SSNIP” test. RFF 981. He merely scanned charts of Opana ER sales (prepared for him by an FTC economist) for any “visible effect,” a metric he never bothered to define. RFF 985. A cursory visual inspection relying on unspecified criteria is not proof of market definition. See *Ky. Speedway, LLC v. NASCAR, Inc.*, 588 F.3d 908, 918 (6th Cir. 2009) (excluding testimony when expert simply looked at averages without a “standard SSNIP test”); *Sanner v. Bd. of Trade of City of Chi.*, 2001 WL 1155277, at *7 (N.D. Ill. Sept. 28, 2001) (“eyeballing” market data does not “satisfy the dictates of *Daubert*”).

But even if generic Opana ER was more successful than other generic LAOs in stealing share from Endo, that does not mean the relevant market is limited to Opana ER products. RRF 935. The relevant market is not limited to the *closest* substitutes; it includes all “*reasonable*” substitutes, even though the products themselves are not entirely the same.” *FTC v. Sysco Corp.*, 113 F. Supp. 3d 1, 25 (D.D.C. 2015) (emphasis added). And as discussed above, the uncontroverted evidence shows that LAOs are reasonable therapeutic and economic substitutes

that competed fiercely on price, and that changes in relative price induced significant switching among products.

2. Complaint Counsel Failed to Present Direct Evidence of Market Power

Complaint Counsel also purports to rely on two “direct indicators” of Endo’s market power: (1) Endo’s alleged ability to exclude competitors; and (2) Endo’s alleged supracompetitive prices, as measured by a Lerner Index. Noll, Tr. 1412-14; CX5000 (Noll Rep. ¶ 198). Neither “indicator” proves market power.

Endo’s alleged ability to exclude competitors does not indicate market power. Dr. Noll asserted that Endo had market power because it could “exclude people from the market” through “patent rights.” Noll, Tr. 1412; CX5000 (Noll Rep. ¶ 199). Complaint Counsel similarly pointed to Endo’s “triggering of the 30-month regulatory Hatch-Waxman stay” as ostensible evidence of market power. CCPTB 55. As discussed above, the mere existence of patents or other regulatory barriers does not give rise to an inference of market power. To hold otherwise would categorically—and improperly—make *every* holder of an Orange Book-listed patent a *per se* monopolist. *See Abbvie*, No. 14-5151, slip op. at 61-62.

Endo’s Lerner Index does not indicate market power. Dr. Noll also testified that he relied on Endo’s “Lerner Index” to conclude that “Endo could profitably set prices above a competitive level.” Noll, Tr. 1412-13. A Lerner Index is a “markup of price over some estimate of marginal cost.” Noll, Tr. 1413; *see* CX5000 (Noll Rep. ¶ 215). A higher Lerner Index indicates a higher price-to-marginal cost ratio. RX-547 (Addanki Rep. ¶¶ 102-03). Dr. Noll estimated { [REDACTED] } CX5000 (Noll Rep. ¶ 226).

Dr. Noll backed away from these assertions at trial. He acknowledged that a high Lerner Index “doesn’t necessarily mean” a firm has market power. Noll, Tr. 1415; RFF 677. While a

high Lerner Index indicates a firm can “sustain price above marginal cost,” “whether they have monopoly power depends on other things.” Noll, Tr. 1415; RFF 677. Dr. Noll testified that a high Lerner Index is a “normal market outcome in an industry with high fixed costs and low marginal costs,” which, he explained, *includes the pharmaceutical industry*. Noll, Tr. 1416; RFF 678-82. He conceded that even if prices are significantly above marginal cost, they may not be supracompetitive. Noll, Tr. 1416 (“whether there’s monopoly profit or not you don’t know”).

Accordingly, proof of supracompetitive pricing requires more than a high Lerner Index or price differentials with generic products. *See In re Remeron*, 367 F. Supp. 2d at 683 (“Clearly, there must be more proof than just a showing that a brand name drug costs more than a generic equivalent.”); *In re Wireless Tel. Servs. Antitrust Litig.*, 385 F. Supp. 2d 403, 422 & n.27 (S.D.N.Y. 2005) (Lerner Indices of 0.85 and 0.5 did not establish market power). Among other things, the plaintiff must show that the “defendant had an *abnormally* high price-cost margin.” *Mylan*, 838 F.3d at 434 (quotation omitted; emphasis added). And Complaint Counsel advanced no evidence that Endo’s Lerner Index was “abnormal” in any way. RFF 878, 956; *see* Malcom B. Coate & Joseph J. Simons, *In Defense of Market Definition*, 57 Antitrust Bulletin 667, 690 (Winter 2012) (“it is impossible to use the Lerner index to choose the ‘best’ market definition”).

Even assuming Complaint Counsel proved supracompetitive pricing, however, its “direct” evidence of market power would fail because it did not show that Endo restricted output. *Am. Express*, 138 S. Ct. at 2288 (“Market power is the ability to raise price profitably *by restricting output*.” (quotation omitted)); *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 (3d Cir. 2007) (direct evidence requires “supracompetitive prices and restricted output”). If Endo had been restricting output, then there should have been an expansion in overall Opana ER output when Impax launched its generic product in 2013. RFF 664-69. But there was *no* overall

increase in prescriptions of branded or generic Opana ER, indicating that Endo was *not* restricting output. RFF 668-69.¹⁵

III. THE COMMISSION NEED NOT CORRECT ANY OF THE ADDITIONAL ISSUES IDENTIFIED BY COMPLAINT COUNSEL

Complaint Counsel challenges three ancillary holdings in the Initial Decision: (1) the payment pursuant to the DCA was justified; (2) Complaint Counsel must demonstrate that a purported payment is both “large and unjustified” as part of its *prima facie* case; and (3) Dr. Noll’s four “examples” of *ex ante* payment values were unreliable. CCAB 33-43. These holdings are both legally and factually correct and should not be disturbed.

A. The DCA was a Bona Fide Collaboration

Actavis is explicit: If a payment represents “fair value” for “other services that the generic has promised to perform” then “there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation” and therefore no antitrust problem exists. 570 U.S. at 156. The record unambiguously supports the ALJ’s conclusion that the payment made pursuant to the DCA reflected “compensation for other services the generic has promised to perform” and was “justified by the profit-sharing rights given to Endo under the DCA.” ID 115, 132; *see* ID 120-38; IDF 244-439.

Complaint Counsel claims that this conclusion was error because the DCA did not comport with its expert’s views of “industry standards.” CCAB 36. But even if true, Complaint Counsel does not explain why entering into what its expert viewed as an “unusual” deal represents a “large and unjustified” payment to Impax. *Crane & Shovel Sales Corp. v. Bucyrus-*

¹⁵ In his rebuttal report, Dr. Noll attempted to show an increase in output by measuring distribution to pharmacies. RRF 964. But prescriptions dispensed to consumers is the appropriate measure of output, since it measures actual consumption. *Id.*; *see Salvino*, 542 F.3d at 318-19 (measuring “output” by consumption).

Erie Co., 854 F.2d 802, 809 (6th Cir. 1988) (“antitrust liability cannot be premised on improvident business decisions”); *FTC v. AbbVie Inc.*, 107 F. Supp. 3d 428, 434, 436-37 (E.D. Pa. 2015) (“unusually favorable” and non-“customary” deal not an actionable reverse-payment).

More problematically, Complaint Counsel’s purported expert, Dr. Geltosky, refused to testify that the DCA was anything but a bona fide collaboration. IDF 416-17; RFF 515-18. Indeed, Dr. Geltosky offered no opinion about the merits of the deal or whether Endo exercised sound business judgment in signing it. IDF 427-32; RFF 515-18. His opinion that the DCA was “unusual” was instead based on his personal experience—which had nothing to do with deals like the DCA—and was contradicted by his own admission that there is no one-size-fits all approach to pharmaceutical collaborations. IDF 431; RFF 1103, 1111, 1136.

Complaint Counsel’s economic expert, moreover, advocated that the DCA payment should be “pull[ed] out of the case” if Dr. Geltosky failed to establish that the rights received under the DCA were worth less than \$10 million. ID 138; IDF 435-39; RFF 525-27. Because Dr. Geltosky did not conduct any valuation of the DCA, or even opine whether Endo paid fair value for its profit-sharing rights, the ALJ concluded that the DCA payment was justified by the profit-sharing rights. IDF 429; ID 137-38.

Complaint Counsel argues that the Commission should still condemn the DCA—even if it is an undisputedly bona fide collaboration with payments that represent fair value for services—if the “basic reason” any party entered the collaboration is objectionable. CCAB 34. It claims that because *Endo* purportedly had a certain subjective motivation for entering the DCA, the Commission should impose liability on *Impax*. *Id.* That makes no sense. Even if Complaint Counsel could read minds to divine Endo’s subjective intent with certainty—and even if it were appropriate to punish *Impax* for another corporation’s intentions—damning a

procompetitive agreement in spite of its actual market effects conflicts with the very purpose of the antitrust laws. *Leegin*, 551 U.S. at 895 (courts should not “prohibit[] procompetitive conduct the antitrust laws should encourage”); *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986) (similar).

For that reason, antitrust “implications for a reverse payment *only arise* if the payment is separate from compensation for the fair market value of other products and services bargained for in the settlement.” *In re K-Dur*, 2016 WL 755623, at *12 (emphasis added). And the question whether a payment represents fair market value is always an objective one. Intent plays no role. *Rolfs v. C.I.R.*, 668 F.3d 888, 891 (7th Cir. 2012) (“fair market value requires an objective, economic inquiry”); *United States v. Abbey*, 560 F.3d 513, 523 (6th Cir. 2009) (same; “argument that the standard is subjective is thus foreclosed”).

In any event, the inference Complaint Counsel proffers is contrary to the record. The evidence does not indicate that either Endo or Impax executed the DCA for the “basic reason” of delaying competition. The record establishes that Impax entered the DCA to obtain “a partner who would fund some of the costs to get [IPX-203] approved” (IDF 374), while Endo sought to place a potentially lucrative drug in its pipeline since it does not develop drugs on its own (IDF 254-55, 349-53). And the process by which the parties entered their deal was no shorter than other Endo collaborations (RFF 411), allowed Endo sufficient time to assess the opportunity (IDF 342-45), mitigated Endo’s risks (IDF 365-69), and contained a payment term that was not uncharacteristically large (IDF 370). The DCA was legitimate.

B. The ALJ Properly Required Proof of a “Large and Unjustified” Payment

Complaint Counsel contends that the Initial Decision departed from the rule of reason by considering Impax’s “proffered justifications for the reverse payment at the initial stage” of the rule of reason. CCAB 39-40. Not so.

Complaint Counsel is confusing *Actavis*'s threshold requirement that plaintiffs demonstrate that a payment is "large and unjustified" with the separate consideration of what the rule of reason requires to then prove a substantive violation, including the presence of any procompetitive benefits. The Supreme Court is clear: "a reverse payment, where large *and unjustified*, can bring with it the *risk of significant anticompetitive effects*." *Actavis*, 570 U.S. at 158 (emphasis added). But under the rule of reason, the "basic question" remains "that of the *presence* of significant unjustified anticompetitive consequences." *Id.* at 160 (emphasis added). This means a plaintiff can move forward with its claims only if it has demonstrated (1) a payment was large and unjustified, and (2) the purported "risk of significant anticompetitive effects" actually resulted in "anticompetitive consequences."

Any other reading strains *Actavis* past the breaking point. *Actavis* was decided at the pleading stage and considered only whether reverse-payment settlements are immune from antitrust scrutiny. It concluded that they are not because when a reverse payment is both large and unjustified, it carries a *risk* of anticompetitive effects. *Id.* Accordingly, courts require that plaintiffs prove—as part of their *prima facie* case—that a purported payment was unjustified, namely to "establish the consideration to the generic challenger exceeds the value of any other collateral products or services provided by the generic to the brand." *Cipro*, 348 P.3d at 865; *see In re K-Dur*, 2016 WL 755623, at *12-14 (same). This is exactly the structure imposed in the Initial Decision.

C. The ALJ Properly Rejected Dr. Noll's Four "Examples" of *Ex Ante* Value

Complaint Counsel also contends that the ALJ should have accepted four "examples" of *ex ante* payment value advanced by Dr. Noll. CCAB 41; *see* Noll, Tr. 1613 (explaining he only offered "examples of what, what [the values] would be under various circumstances"). The Initial Decision concluded that the examples were not reliable because Dr. Noll did "not

calculate the expected value of the Endo Credit at the time of the settlement,” and “failed to adequately describe or explain the bases for his assumptions or his calculations, either in his expert report, or his testimony.” IDF 240; ID 111. In doing so, the ALJ did not commit any error.

First, Complaint Counsel’s assertion that Dr. Noll assessed “all plausible outcomes” finds no support in the record. CCAB 43. Complaint Counsel has no basis to assert that these “examples” are any more “plausible” than the many potential outcomes Dr. Noll did not consider, since none of his examples are probability-weighted. RFF 648-49. Complaint Counsel cannot simply declare some outcomes “plausible” (and others implausible) because it believes probability weighting is impractical. *Camaj v. Holder*, 625 F.3d 988, 991 n.3 (6th Cir. 2010) (“unsupported assertions of counsel are not evidence”); *Stobie Creek Invs. LLC v. United States*, 608 F.3d 1366, 1376 (Fed. Cir. 2010) (rejecting “possible outcomes” when unsupported by “probabilities”).

Second, Complaint Counsel’s cherry-picked “examples” deliberately mislead. Complaint Counsel does not account for the time value of money. Thus, while Complaint Counsel says the No-AG provision was worth “at least” \$16.5 million (CCAB 42), it does not mention that at the time of the settlement, the present value of that “example” would have been just \$11 million, according to its own expert. CCF 471. Similarly, Complaint Counsel’s assertion that the Endo Credit payment had an *ex ante* value of “at least” \$62 million ignores the fact that Dr. Noll conjured that figure without reference to the SLA’s Endo Credit formula. IDF 239; RRF 470. And the estimate assumes that Endo expected no sales of original Opana ER in the fourth quarter of 2012, which is contradicted by the record. RFF 636; RRF 470. This is not a minor point. If Endo’s fourth quarter 2012 sales of original Opana ER were 49.9 percent of peak sales, then,

assuming (as Dr. Noll did) that Opana ER sales peaked in the third quarter of 2010, the Endo Credit payment would have been roughly \$100,000—less than 1 percent of Complaint Counsel’s \$62 million minimum. RRF 470. Dr. Noll’s “examples” have no evidentiary value and the ALJ correctly rejected them as unreliable.

IV. COMPLAINT COUNSEL’S PROPOSED REMEDIES VIOLATE DUE PROCESS AND ARE INAPPROPRIATE

Because Complaint Counsel has failed to prove that the challenged settlement agreement was an unreasonable restraint of trade, the Commission need not consider any proposed remedies. Nevertheless, Complaint Counsel has failed to justify the sweeping remedies it seeks.

Complaint Counsel asks the Commission to issue three cease-and-desist orders: (1) a prohibition against entering “any Brand/Generic Settlement” that includes a transfer of value from the brand to the generic; (2) a prohibition on “entering into or being party to any agreement” that “in any way disincentivizes competition between Oxymorphone ER Products”; and (3) a specific order stripping Impax of its rights to enforce a separate “Contract Settlement Agreement” (the “2017 Settlement”). CCAB 44-45 & App. A at 4. None of these requests is appropriate.

A. Complaint Counsel Has Not Shown a Cognizable Danger of Future Violations

“[C]omplaint counsel bears the burden of showing the need for injunctive relief.” *TRW, Inc. v. FTC*, 647 F.2d 942, 954 (9th Cir. 1981). Before the Commission can impose a prospective remedy, Complaint Counsel must demonstrate that Impax presents a “cognizable danger” of repeating the condemned conduct—here, a patent settlement that includes a “large and unjustified” reverse payment. *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953). The “mere existence” of a proven antitrust violation does not “justify prospective relief regardless of the circumstances.” *TRW*, 647 F.2d at 954 (setting aside cease-and-desist order).

Key to the “cognizable danger” inquiry is “scienter” and “whether the infraction is an isolated occurrence.” *SEC v. Cavanagh*, 155 F.3d 129, 135 (2d Cir. 1998) (quotation omitted). Injunctive relief may be warranted when there is a “history of . . . violations” and a “general lack of concern for the seriousness of the charges.” *Id.* at 135-36. Nothing of the sort exists here. Impax has never been found liable for an antitrust violation, either before or after the SLA. At the time of Impax’s settlement with Endo, the agreement was lawful under then prevailing law. *See* RPTRB 93 n.57 (collecting authority). And although Impax filed the SLA with the FTC in 2010, the agency did not commence its investigation until years later, after the Supreme Court decided *Actavis*. This is not the stuff of “cognizable danger.” *W.T. Grant*, 345 U.S. at 635 (fact that “[n]one of the corporations appeared to have engaged in more than one alleged violation” weighed against injunctive relief); *AbbVie*, No. 14-5151, slip op. at 100 (two sham lawsuits “does not establish that defendants have a pattern or practice doing so” and therefore “no basis to conclude that defendants’ misconduct is likely to reoccur”).

Nor do any of the specific points that Complaint Counsel raised below—that Impax still operates in the pharmaceutical industry, that Impax is engaged in litigation, that there are incentives to settle, and that Impax has never disavowed the SLA—show anything approaching cognizable danger. Impax cannot be expected to cease all operations—or avoid all litigation—to establish a lack of cognizable danger. *W.T. Grant*, 345 U.S. at 633 (“cognizant danger of recurren[ce]” must consist of “something more than the mere possibility”). The fact that patent litigants face certain settlement incentives, moreover, has nothing to do with Impax. The incentives are built into the Hatch-Waxman Act. *Actavis*, 570 U.S. at 141-44, 155. In any event, simply contending that a party has “incentive and opportunity to continue to engage in similar conduct” is not enough to suggest—even at pleading stage—that a company “is about to violate

any law enforced by the FTC.” *FTC v. Shire ViroPharma Inc.*, 2018 WL 1401329, at *6 (D. Del. Mar. 20, 2018). Finally, the suggestion that Impax must disavow the SLA to avoid an injunction would mean that consumers would lose access to Opana ER entirely, while Impax would be subject to breach-of-contract and patent infringement liability. Avoiding those outcomes is not “cognizable danger” of future unlawful conduct.¹⁶

B. Complaint Counsel’s Proposed Remedies are Unlawful and Overbroad

Complaint Counsel may only seek remedies that have a “reasonable relation to the unlawful practices.” *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 613 (1946); *see* 15 U.S.C. § 45(b). Here, the alleged “unlawful practice” is a 2010 settlement agreement that contained a purported reverse payment. Comp. ¶ 1. Yet Complaint Counsel seeks remedies that have no reasonable relation to the challenged agreement, or even reverse-payments generally.

First, Complaint Counsel seeks to prohibit Impax from entering any settlement in which a brand company makes “any Payment”—defined as any “transfer of value”—to a generic company. CCAB, App. A at 3-4. But every contract entails consideration, and the universe of lawful, value-conveying settlement terms cannot be reduced to a list of five items. *Id.*; *see AbbVie*, 107 F. Supp. 3d at 436 (“something of value invariably flows both ways as a result of any contract”); *Asahi Glass Co. v. Pentech Pharm., Inc.*, 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (same).

The remedy would, moreover, prevent Impax from purchasing for fair value any services or materials from a brand company, even if the purpose was to market a product earlier than

¹⁶ Complaint Counsel also suggested that Impax’s CEO at the time of trial stated that he “always” seeks a No-AG provision. CCPTB 74. The statement, however, concerned Mr. Bisaro’s understanding of the parameters of the Hatch-Waxman Act and his adherence to that market dynamic. CX4000 (Bisaro, IHT at 33-34). The statement, moreover, was made years before Mr. Bisaro had any connection to Impax. CX4000 (Bisaro, IHT at 7-8).

otherwise possible. CCAB, App. A at 3 (prohibiting transfer of value “regardless of whether [Impax] purportedly transfers value in return”). Enjoining such procompetitive behavior is overbroad and improper. *Leegin*, 551 U.S. at 895 (courts should not “prohibit[] procompetitive conduct the antitrust laws should encourage”); *In re Quality Trailer Prod. Corp.*, 115 F.T.C. 944, 952 (1992) (Comm’r Owen, concurring) (injunction should not “prohibit attempts to implement procompetitive joint activities”); see *Actavis*, 570 U.S. at 156 (traditional settlement terms include “fair value for services”).

Second, Complaint Counsel asks the Commission to enjoin “any agreement” that “disincentivizes” competition between oxymorphone ER products, regardless of whether the agreement contains a reverse payment. CCAB, App. A at 4. But the fact that an agreement may have some relation to a relevant *product* (oxymorphone ER) is no basis for injunctive relief. A remedy must relate to the challenged *practice* (reverse-payment settlement). *FTC v. Nat’l Lead Co.*, 352 U.S. 419, 428 (1957) (improper remedy if “no reasonable relation to the unlawful *practices* found to exist” (emphasis added)); *Siegel*, 327 U.S. at 611 (same).

The proposed remedy is also hopelessly vague. None of the operative terms—“prevents,” “restricts,” “disincentivizes”—are defined. This is fatal. *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 392 (1965) (prohibitions must be “clear and precise in order that they may be understood by those against whom they are directed”). And such opaque injunctions will lead to illogical results. On its face, the proposed order prohibits agreements that lead to lower prices—for instance, an agreement to develop and market a low-priced generic drug—simply because they might disincentivize other potential entrants from developing a competing product. This is at odds with the antitrust laws. *Energy Conversion Devices Liquidation Tr. v. Trina Solar Ltd.*,

833 F.3d 680, 682 (6th Cir. 2016) (“Consumers benefit when market competition leads to lower prices. Competitors do not.”).

It is also “overbroad and punitive in nature.” *AbbVie*, No. 14-5151, slip op. at 101. Complaint Counsel cannot constrain Impax’s ability to enter “any agreement” simply because Complaint Counsel objects to a single (lawful-at-the-time) agreement Impax entered eight years ago. *Id.* at 100-01 (rejecting attempt to limit “defendants’ ability to file patent infringement suits” or “use the governmental process with respect to any patent” simply because defendants filed two sham lawsuits).

Finally and most problematically, Complaint Counsel seeks to strip Impax of its right to enforce a 2017 settlement agreement between Endo and Impax. CCAB 45. That settlement resolved litigation involving Impax’s alleged failure to negotiate a royalty for Endo’s later-obtained patents, to which Impax received a license under the SLA. IDF 589-90. [REDACTED]

[REDACTED] } IDF 591;

CX3275. This is not a reverse payment; it is exactly the kind of “commonplace settlement form” that *Actavis* leaves untouched. 570 U.S. at 152.

What is more, Complaint Counsel’s claim that the 2017 Settlement “disincentivizes competition for oxymorphone ER” is devoid of factual support. CCAB 44. Complaint Counsel has never investigated the agreement; never taken discovery concerning it; never adduced evidence at trial regarding it; and never formally challenged it in these proceedings.¹⁷ To now

¹⁷ What *is* in the record are two facts: (1) Complaint Counsel’s admission that absent the 2017 Settlement, Impax may have been “required to withdraw its Original Opana ER from the market,” leaving consumers without access to any Opana ER product (CCFF 1430); and (2) Endo’s representation to the FDA that original Opana ER is unsafe, undermining any suggestion that Endo would reintroduce the product (ID 113 n.27; IDF 233; RFF 222, 225, 622).

condemn it as anticompetitive without any evidence whatsoever is an abuse of the most basic notions of administrative law. “Once the Commission has chosen a particular legal rationale for holding a practice to be unfair . . . familiar principles of administrative law dictate that its decision must stand or fall on that basis, and a reviewing court may not consider other reasons why the practice might be deemed unfair.” *Ind. Fed’n of Dentists*, 476 U.S. at 455; *see Microsoft*, 253 F.3d at 101, 103 (“judicial resolution of disputed facts” is essential to determine “appropriate relief”).

Complaint Counsel’s attempt to undermine and rewrite the 2017 Settlement also violates Impax’s due process rights. Because Complaint Counsel did not even suggest that it intended to invalidate¹⁸ the settlement until *after the trial*, it circumvented the entire investigatory and Part III process and thereby deprived Impax of the opportunity to develop evidence and expert testimony to refute Complaint Counsel’s impromptu allegations. Such behavior is unlawful and should be rejected. *See Golden Grain Macaroni Co. v. FTC*, 472 F.2d 882, 886 (9th Cir. 1972) (“if an issue was not litigated, and the party proceeded against was not given an opportunity to defend himself, an adverse finding on that issue by the agency does violate due process”); *Murphy Oil Corp. v. Fed. Power Comm’n*, 431 F.2d 805, 813 (8th Cir. 1970) (same).

CONCLUSION

For all the reasons discussed above, the Commission should affirm the Initial Decision and enter judgment in favor of Impax.

¹⁸ Post-trial, Complaint Counsel sought remedies nullifying the 2017 Settlement. CCPTB, App. A at 5. Endo objected to this unprecedented violation of its due process rights. EOPR 8-16. Complaint Counsel now seeks to prevent Impax from enforcing its rights under the agreement, leaving Endo little room to complain. But stripping Impax of the benefit of its bargain without first honoring Impax’s due process rights is equally wrong.

Dated: August 10, 2018

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CERTIFICATE OF SERVICE

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

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I also certify that I caused a copy of the foregoing to be served upon the following individuals by electronic mail:

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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: August 10, 2018

/s/ Benjamin J. Hendricks
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Notice of Electronic Service

I hereby certify that on August 16, 2018, I filed an electronic copy of the foregoing Respondent Impax Laboratories, LLC's Answering Brief, with:

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I hereby certify that on August 16, 2018, I served via E-Service an electronic copy of the foregoing Respondent Impax Laboratories, LLC's Answering Brief, upon:

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I hereby certify that on August 16, 2018, I served via other means, as provided in 4.4(b) of the foregoing Respondent Impax Laboratories, LLC's Answering Brief, upon:

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