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# [***In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5RGS-X0H1-JG02-S02P-00000-00&context=)

United States District Court for the District of Massachusetts

January 25, 2018, Decided; January 25, 2018, Filed

Civil Action No. 14-md-02503

**Reporter**

2018 U.S. Dist. LEXIS 11921 \*; 2018-1 Trade Cas. (CCH) P80,260; 2018 WL 563144

IN RE SOLODYN (MINOCYCLINE HYDROCHLORIDE) ***ANTITRUST*** LITIGATION

**Prior History:** [*In re Solodyn (Minocycline Hydrochloride)* ***Antitrust*** *Litig., 999 F. Supp. 2d 1383, 2014 U.S. Dist. LEXIS 23354 (J.P.M.L., Feb. 25, 2014)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5BKV-P1M1-F04T-8088-00000-00&context=)

**Core Terms**

patent, generic, Defendants', market power, Plaintiffs', launch, settlement, prices, Retailer, DENIES, brand, summary judgment motion, motion to exclude, margins, at-risk, opine, direct evidence, relevant market, prescriptions, ***antitrust***, minocycline, causation, interchangeability, pharmaceutical, products, scenario, conclusions, costs, expert testimony, supracompetitive

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For International Union of Operating Engineers Local 132 Health, And Welfare Fund, Movant: ADAM E. POLK, Christina C. Sharp, Daniel C. Girard, LEAD ATTORNEYS, PRO HAC VICE, GIRARD GIBBS LLP, San Francisco, CA USA; Robert S. Kitchenoff, LEAD ATTORNEY, PRO HAC VICE, Weinstein Kitchenoff & Asher LLC, Philadelphia, PA USA; James Douglas Baldridge, Venable LLP, Washington, DC USA; Michael M. Buchman, Motley Rice LLC, New York, NY USA; Nathaniel L. Orenstein, Norman Berman, Berman Tabacco, Boston, MA USA; Steve D. Shadowen, Hilliard & Shadowen LLP, Austin, TX USA.

For International Union of Operating Engineers Stationary, Engineers Local 39 Health & Welfare Trust Fund, Movant: ANNE K. FORNECKER, LEAD ATTORNEY, PRO HAC VICE, HILLIARD & SHADOWEN LLC, Austin, TX USA; Daniel M. Gonzales, LEAD ATTORNEY, PRO HAC VICE, Hilliard & Shadowen LLP., Austin, TX USA; David R. Cheverie, LEAD ATTORNEY, Hach Rose Schirripa & Cheverie LLLP, New York, NY USA; Sharon K. Robertson, LEAD ATTORNEY, PRO HAC VICE, Donna M. Evans, Cohen Milstein Sellers & Toll PLLC, New York, NY USA; James Douglas Baldridge,**[\*9]** Venable LLP, Washington, DC USA; Michael M. Buchman, Motley Rice LLC, New York, NY USA; Nathaniel L. Orenstein, Norman Berman, Berman Tabacco, Boston, MA USA; Steve D. Shadowen, Hilliard & Shadowen LLP, Austin, TX USA.

For Painters District Council No. 30 Health And Welfare Fund, Movant: Matthew E. Van Tine, LEAD ATTORNEY, Miller Law LLC, Chicago, IL USA; James Douglas Baldridge, Venable LLP, Washington, DC USA; Michael M. Buchman, Motley Rice LLC, New York, NY USA; Nathaniel L. Orenstein, Norman Berman, Berman Tabacco, Boston, MA USA; Steve D. Shadowen, Hilliard & Shadowen LLP, Austin, TX USA.

For Plumbers & Pipefitters Local 178 Health And Welfare Trust Fund, Movant: BRENT W. LANDAU, JEANNINE M. KENNEY, LEAD ATTORNEYS, HAUSFELD LLP, Philadelphia, PA USA; Gregory Linkh, LEAD ATTORNEY, Murray, Frank & Sailer LLP, New York, NY USA; Lee Albert, LEAD ATTORNEY, PRO HAC VICE, Glancy Prongay & Murray LLP, New York, NY USA; James Douglas Baldridge, Venable LLP, Washington, DC USA; Michael M. Buchman, Motley Rice LLC, New York, NY USA; Nathaniel L. Orenstein, Norman Berman, Berman Tabacco, Boston, MA USA; Steve D. Shadowen, Hilliard & Shadowen LLP, Austin, TX USA.

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For Man-U Service Contract Trust Fund, Movant: Krishna B. Narine, LEAD ATTORNEY, PRO HAC VICE, Schiffrin & Barroway, LLP, Bala Cynwyd, PA USA; James Douglas Baldridge, Venable LLP, Washington, DC USA; Michael M. Buchman, Motley Rice LLC, New York, NY USA; Nathaniel L. Orenstein, Norman Berman, Berman Tabacco, Boston, MA USA; Steve D. Shadowen, Hilliard & Shadowen LLP, Austin, TX USA.

For Sheet Metal Workers Local No. 25 Health & Welfare Fund, Movant: JEFFREY S. ISTVAN, LEAD ATTORNEY, FINE, KAPLAN AND BLACK, Phila, PA USA; Michael Coren, LEAD ATTORNEY, Cohen, Placitella & Roth, P.C., Philadelphia, PA USA; PAUL COSTA, LEAD ATTORNEY, FINE, KAPLAN & BLACK, RPC, Philadelphia, PA USA; Roberta D. Liebenberg, LEAD ATTORNEY, Fine, Kaplan and Black, RPC, Philadelphia, PA USA; Stewart L. Cohen, LEAD ATTORNEY, PRO HAC VICE, Cohen, Placitella & Roth, P.C., Philadelphia,**[\*11]** PA USA; James Douglas Baldridge, Venable LLP, Washington, DC USA; Michael M. Buchman, Motley Rice LLC, New York, NY USA; Nathaniel L. Orenstein, Norman Berman, Berman Tabacco, Boston, MA USA; Steve D. Shadowen, Hilliard & Shadowen LLP, Austin, TX USA.

For Local 274 Health & Welfare Fund, Movant: PAUL COSTA, LEAD ATTORNEY, FINE, KAPLAN & BLACK, RPC, Philadelphia, PA USA James Douglas Baldridge, Venable LLP, Washington, DC USA; Michael M. Buchman, Motley Rice LLC, New York, NY USA; Nathaniel L. Orenstein, Norman Berman, Berman Tabacco, Boston, MA USA; Steve D. Shadowen, Hilliard & Shadowen LLP, Austin, TX USA.

For Neca-Ibew Welfare Trust Fund, Movant: Nathaniel L. Orenstein, Berman Tabacco, Boston, MA USA; Theodore M. Hess-Mahan, Hutchings, Barsamian, Cross and Mandelcorn, LLP, Wellesley Hills, MA USA.

For Allied Services Division Welfare Fund, Movant: David B. Franco, Lanson Leon Bordelon, LEAD ATTORNEY, PRO HAC VICE, The Dugan Law Firm, APLC, New Orleans, LA USA; David Scott Scalia, LEAD ATTORNEY, PRO HAC VICE, The Dugan Law Firm, New Orleans, MA USA; Douglas R. Plymale, James R. Dugan, II, LEAD ATTORNEYS, The Dugan Law Firm, New Orleans, LA USA; James Douglas Baldridge, Venable LLP,**[\*12]** Washington, DC USA; Michael M. Buchman, Motley Rice LLC, New York, NY USA; Nathaniel L. Orenstein, Norman Berman, Berman Tabacco, Boston, MA USA; Steve D. Shadowen, Hilliard & Shadowen LLP, Austin, TX USA.

For United Healthcare Services, Inc., Objector: Jamie R Kurtz, LEAD ATTORNEY, Robins Kaplan LLP, Minneapolis,, Mn; Jeffrey S. Gleason, Robins Kaplan LLP, Minneapolis, MN USA; Peter N. Foundas, Robins Kaplan LLP, Boston, MA USA.

For Optumrx, Inc., Objector: Jeffrey S. Gleason, Robins Kaplan LLP, Minneapolis, MN USA; Peter N. Foundas, Robins Kaplan LLP, Boston, MA USA.

For National Medical Health Card Systems, Inc., Objector: Jeffrey S. Gleason, Robins Kaplan LLP, Minneapolis, MN USA; Peter N. Foundas, Robins Kaplan LLP, Boston, MA USA.

**Judges:** Denise J. Casper, United States District Judge.

**Opinion by:** Denise J. Casper

**Opinion**

**MEMORANDUM AND ORDER**

**CASPER, J.**

**I. Introduction**

This is a class action in which Direct Purchaser Plaintiffs ("DPPs" or "direct purchasers") allege that Defendants Medicis Pharmaceutical Corporation ("Medicis") and Impax Laboratories, Inc. ("Impax") (collectively, "Defendants"), violated *Section 1 of the Sherman Act*, *15 U.S.C. § 1*, D. 91, and End-Payor Plaintiffs ("EPPs" or "end-payors") allege that Defendants have violated**[\*13]** various state laws, D. 92.[[1]](#footnote-0)1 The remaining claim of Retailer Plaintiffs[[2]](#footnote-1)2 is that Defendants' actions violate *Section 2 of the Sherman Act*, *15 U.S.C. § 2*. D. 216; D. 218; D. 266. After the Court granted the parties leave to file summary judgment motions, D. 684, Defendants filed three motions, seeking summary judgment on market power, D. 717, causation, D. 718, and all claims arising out of Medicis's settlements with Sandoz and Lupin, D. 719. The Plaintiff classes and Retail Plaintiffs ("Consolidated Plaintiffs" or "Plaintiffs") filed a motion for partial summary judgment. D. 747. Additionally, the parties have filed numerous motions to exclude expert testimony. D. 711; D. 712; D. 713; D. 714; D. 715; D. 716; D. 741; D. 742; D. 743; D. 744; D. 745; D. 746; D.748; D. 749; D. 750; D. 751. Defendants have also filed a motion for leave to serve an additional expert opinion, of Dr. Louis Rossiter, to rebut the testimony of Plaintiffs' expert Dr. Stephen Schondelmeyer. D. 892.

For the reasons set forth below, the Court DENIES Consolidated Plaintiffs' motion for summary judgment on market power, D. 747, and ALLOWS IN PART and DENIES IN PART Defendants' motion for summary judgment on market power, D. 717. The Court**[\*14]** DENIES Defendants' motion for summary judgment on causation, D. 718, and DENIES Defendants' motion for summary judgment on claims arising from Medicis's settlements with Sandoz and Lupin, D. 719. Of the numerous Daubert motions, the Court, at this time, resolves only those relating to the pending motions for summary judgment. The Court DENIES the following motions to exclude: Plaintiffs' expert Dr. Christopher Baum, D. 741; Plaintiffs' expert Dr. Arthur Kibbe, D. 716; Retailer Plaintiffs' expert Dr. Keith Leffler, D. 712; Plaintiffs' expert Dr. Meredith Rosenthal, D. 745; Plaintiffs' expert Dr. Stephen Schondelmeyer, D. 711; Plaintiffs' expert Dr. Neelam Vashi, D. 714; Defendants' experts Dr. Sumanth Addanki and Dr. Guy Webster, D. 748; and Defendants' experts Dr. Robert S. Langer and R. Polk Wagner, D. 751. The Court ALLOWS IN PART and DENIES IN PART the motions to exclude Plaintiffs' expert John Doll, D. 715; and Plaintiffs' expert Dr. Thomas McGuire, D. 744, and Plaintiffs' experts John Thomas and Peter Hardigan, D. 713.[[3]](#footnote-2)3 The Court also ALLOWS Defendants' motion for leave to serve Dr. Louis Rossiter's expert testimony, D. 892.

**II. Standard of Review**

**A. Summary Judgment**

The Court**[\*15]** grants summary judgment where there is no genuine dispute as to any material fact and the undisputed facts demonstrate that the moving party is entitled to judgment as a matter of law. [*Fed. R. Civ. P. 56(a)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5GYC-2421-6N19-F165-00000-00&context=). "An issue is genuine if 'it may reasonably be resolved in favor of either party' at trial, and material if it 'possess[es] the capacity to sway the outcome of the litigation under the applicable law.'" [*Iverson v. City of Boston, 452 F.3d 94, 98 (1st Cir. 2006)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4K9D-N0P0-0038-X528-00000-00&context=) (alteration in original) (quoting [*Cadle Co. v. Hayes, 116 F.3d 957, 960 (1st Cir. 1997))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-FSV0-00B1-D298-00000-00&context=). The movant "bears the burden of demonstrating the absence of a genuine issue of material fact." [*Rosciti v. Ins. Co. of Pa., 659 F.3d 92, 96 (1st Cir. 2011)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:83BX-GR31-652P-Y07K-00000-00&context=) (quoting [*Carmona v. Toledo, 215 F.3d 124, 132 (1st Cir. 2000))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:40HD-7170-0038-X38W-00000-00&context=). If the movant meets its burden, the nonmovant "must, with respect to each issue on which she would bear the burden of proof at trial, demonstrate that a trier of fact could reasonably resolve that issue in her favor." [*Borges ex rel. S.M.B.W. v. Serrano-Isern, 605 F.3d 1, 5 (1st Cir. 2010)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:7YCK-X7B0-YB0V-C003-00000-00&context=). "As a general rule, that requires the production of evidence that is 'significant[ly] probative.'" Id. (alteration in original) (quoting [*Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-6H80-0039-N37M-00000-00&context=). "Neither party may rely on conclusory allegations or unsubstantiated denials, but must identify specific facts derived from the pleadings, depositions, answers to interrogatories, admissions and affidavits to demonstrate either the existence or absence of an issue of fact."**[\*16]** [*Magee v. United States, 121 F.3d 1, 3 (1st Cir. 1997)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S42-38K0-00B1-D1W4-00000-00&context=). The Court views the record "in the light most favorable to the non-moving part[y]" and draws all reasonable inferences in the nonmovant's favor. [*Pineda v. Toomey, 533 F.3d 50, 53 (1st Cir. 2008)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4T0V-YYS0-TX4N-G12B-00000-00&context=).

**B. Motions to Exclude Expert Opinions (*Daubert* Motions)**

Pursuant to [*Fed. R. Evid. 702*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5GYC-2991-FG36-120S-00000-00&context=), a qualified expert witness can testify "in the form of an opinion, or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." [*United States v. Mooney, 315 F.3d 54, 62 (1st Cir. 2002)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:47JW-VHF0-0038-X3PG-00000-00&context=) (quoting [*Fed. R. Evid. 702*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5GYC-2991-FG36-120S-00000-00&context=)). The Court must "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." [*Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 597, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-XDR0-003B-R3R6-00000-00&context=). "The district court, as gatekeeper, must 'ensure that there is an adequate fit between the expert's methods and his conclusions.'" [*Am. Sales Co., LLC v. AstraZeneca LP (In re Nexium (Esomeprazole)* ***Antitrust*** *Litig.) ("Nexium"), 842 F.3d 34, 52 (1st Cir. 2016)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5M73-M0F1-F04K-H003-00000-00&context=) (quoting [*Samaan v. St. Joseph's Hosp., 670 F.3d 21, 32 (1st Cir. 2012))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:54NY-8W31-F04K-H03K-00000-00&context=). "[T]he district court must perform [this] gatekeeping function by preliminarily assessing 'whether the reasoning or methodology . . . properly can be applied to the facts in issue'" by examining multiple factors through a case-specific inquiry. [*Seahorse Marine Supplies, Inc. v. P.R. Sun Oil Co., 295 F.3d 68, 80-81 (1st Cir. 2002)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:467S-Y1G0-0038-X3BM-00000-00&context=) (quoting [*Daubert, 509 U.S. at 592-93*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-XDR0-003B-R3R6-00000-00&context=)). "As long as an expert's scientific testimony**[\*17]** rests upon 'good grounds, based on what is known,' it should be tested by the adversary process—competing expert testimony and active cross-examination—rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies." [*Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co., 161 F.3d 77, 85 (1st Cir. 1998)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3V7J-BT70-0038-X2GR-00000-00&context=) (quoting [*Daubert, 509 U.S. at 590*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-XDR0-003B-R3R6-00000-00&context=)). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." [*Daubert, 509 U.S. at 596*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-XDR0-003B-R3R6-00000-00&context=).

**III. Relevant Factual Background**

In light of the Court's prior rulings, see D. 184; D. 682, the Court will not recite all of the facts of this case, but instead addresses only the factual and procedural background relevant to the motions addressed herein.

Medicis is the New Drug Application ("NDA") holder of Solodyn, an extended release minocycline hydrochloride tablet, used to treat moderate to severe acne vulgaris. D. 724-1 ¶ 15; D. 847 ¶ 15. Minocycline is a tetracycline-class antibiotic, a category that also includes doxycycline, the branded delayed-release form of which is Doryx. D. 724-1 ¶¶ 19-20; D. 847 ¶¶ 19-20. Tetracyclines are considered "first-line therapy for moderate to severe acne."**[\*18]** D. 724-1 ¶ 22; D. 847 ¶ 22.

On May 8, 2006, the FDA approved Solodyn in the 45 mg, 90 mg and 135 mg strengths ("Legacy Strengths"). D. 724-1 ¶ 16; D. 847 ¶¶ 16, 18. Medicis launched Solodyn in 2006. D. 724-1 ¶ 18; D. 847 ¶ 18. At the time of Solodyn's launch, there were other drugs on the market that also treated moderate-to-severe acne. D. 747-2 ¶ 1; D. 860 ¶ 1. Since its launch, Medicis engaged in promotional activity such as offering significant rebates to secure preferred formulary placement with health insurance companies and pharmacy benefit managers ("PBMs") and occasionally issued co-pay cards to certain patients, which reduced the price the patient paid for Solodyn at the pharmacy. D. 724-1 ¶ 25, 30; D. 847 ¶ 25, 30.

Medicis holds U.S. Patent No. 5,908,838 (the "'838 patent"), a "[m]ethod for the [t]reatment of [a]cne," which was filed on February 19, 1998, issued on June 1, 1999, and expires on February 19, 2018. D. 724-1 ¶¶ 49-50; D. 747-2 ¶ 42; D. 847 ¶¶ 49-50. In 2008, a third party submitted a request for reexamination of the '838 patent, and in June 2010, the United States Patent and Trademark Office ("PTO") upheld the validity of the patent and reissued it with several claims. D. 724-1 ¶¶ 51, 55; D. 847 ¶¶ 51, 55.**[\*19]** On September 7, 2010, the PTO issued an additional patent to Medicis—U.S. Patent No. 7,790,705 (the "'705 patent"), covering "the method of dosing extended release minocycline hydrochloride according to weight to prevent certain adverse effects," D. 184 at 10—which expires in 2025. D. 724-1 ¶ 56; D. 847 ¶ 56. Medicis asserted the '705 patent against Lupin as to its Legacy Strength formulations. D. 724-1 ¶ 142; D. 847 ¶ 142. In July 2009 and August 2010, the FDA approved Solodyn in the 55mg, 65mg, 80 mg, 105mg and 11mg strengths ("Add-On Strengths"). D. 724-1 ¶¶ 109, 111; D. 847 ¶¶ 109, 111.

In October 2007, Impax submitted an Abbreviated New Drug Application ("ANDA") to the FDA to market generic Solodyn, amended in November 2007 to include all Legacy Strengths. D. 724-1 ¶ 77; D. 847 ¶ 77. In January 2008, Impax sought a declaratory judgment in the U.S. District Court for the Northern District of California that the '838 patent was invalid and/or not infringed by Impax's generic Legacy Strength Solodyn ANDA. D. 724-1 ¶ 78; D. 847 ¶ 78. The court dismissed the matter for lack of subject matter jurisdiction and Impax timely appealed. D. 724-1 ¶¶ 79-80; D. 847 ¶¶ 79-80. On November 26, 2008, while the appeal was pending, Impax and Medicis negotiated**[\*20]** a settlement and entered into two agreements: a license and settlement agreement and a joint development agreement. D. 724-1 ¶¶ 81, 84; D. 847 ¶¶ 81, 84. Under these agreements, Impax could begin selling its generic Legacy Strength Solodyn under Medicis's patents starting on November 26, 2011. D. 724-1 ¶ 82; D. 847 ¶ 82. Medicis agreed to pay Impax $40 million upfront, with an additional $23 million in "milestones," and there were several provisions for revenue sharing. D. 847 ¶ 84; D. 858-26 at 10-11.

In December 2008, four generic manufacturers—Mylan, Impax, Sandoz and Barr/Teva—challenged Medicis's '838 patent. D. 724-1 ¶ 88; D. 847 ¶ 88. Medicis sued three of them—Teva, Mylan and Sandoz—for infringement in January 2009. D. 724-1 ¶ 89; D. 847 ¶ 89. On August 13, 2009, the FDA approved Sandoz's generic version of Solodyn Legacy Strengths. D. 724-1 ¶ 90; D. 847 ¶ 90. The next day, August 14, Sandoz launched its generic Solodyn Legacy Strengths. D. 724-1 ¶ 91; D. 847 ¶ 91. On August 18, 2009, Medicis and Sandoz executed a settlement agreement whereby Sandoz sold its ANDA to Medicis for $14 million and Sandoz obtained a license to relaunch sales of its generic version on November 26, 2011, the**[\*21]** same day that Impax and Medicis had negotiated for Impax's generic launch. D. 724-1 ¶¶ 96-98; D. 847 ¶¶ 96-98. Medicis also filed a patent infringement suit against Lupin in November 2009 in connection with Lupin's ANDA for generic versions of Solodyn. D. 724-1 ¶ 100; D. 847 ¶ 100. Medicis and Lupin entered into a settlement agreement in July 2011, providing Lupin with a license to sell its generic Solodyn on November 26, 2011, the same day as the other negotiated generic launches. D. 724-1 ¶¶ 101-02; D. 847 ¶ 101-02. Sandoz and Lupin were originally also defendants in this case, but the DPP and EPP classes have since settled with them. D. 806; D. 808.[[4]](#footnote-3)4

**IV. Relevant Procedural History**

On November 1, 2017, Defendants filed three motions for summary judgment, seeking summary judgment on market power, D. 717, causation, D. 718, and all claims arising out of Medicis's settlements with Sandoz and Lupin, D. 719, and Consolidated Plaintiffs filed a motion for partial summary judgment, D. 747. Also on that day, the parties filed numerous motions to exclude expert testimony. D. 711; D. 712; D. 713; D. 714; D. 715; D. 716; D. 741; D. 742; D. 743; D. 744; D. 745; D. 746; D.748; D. 749; D. 750; D.751.**[\*22]** The Court heard the parties on the pending summary judgment motions on January 12, 2018, D. 938, and took these matters under advisement.

**V. Discussion**

The Court addresses each of Defendants' motions for summary judgment and the Daubert motions related to those motions in turn. Plaintiffs' motion for partial summary judgment addresses both market power and infringement. D. 747 at 1. On December 5, 2017, the Court struck the infringement portion of Plaintiffs' summary judgment motion, due to the timing of Plaintiffs' disclosure of its noninfringement theory. D. 827. The Court, therefore, only addresses Plaintiffs' remaining ground in its partial summary judgment motion, regarding market power, and does so in conjunction with Defendants' motion regarding that issue, D. 717.

**A. Market Power**

The DPP class's Sherman Act *Section 1* claim is governed by rule-of-reason analysis, see [*FTC v. Actavis, Inc., 570 U.S. 136, 133 S. Ct. 2223, 2237, 186 L. Ed. 2d 343 (2013)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:58NW-3VK1-F04K-F006-00000-00&context=), under which Plaintiffs must "show that the [D]efendants' actions enhanced market power—i.e., the power to raise prices or exclude competition—which in turn requires some economic analysis of the relevant market."[[5]](#footnote-4)5 [*Am. Steel Erectors, Inc. v. Local Union No. 7, Int'l Ass'n of Bridge, 815 F.3d 43, 61 (1st Cir. 2016)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5J5H-KVC1-F04K-H07X-00000-00&context=) (quoting [*Díaz Aviation Corp. v. Airport Aviation Servs., 716 F.3d 256, 265 (1st Cir. 2013))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:58N8-64X1-F04K-H00Y-00000-00&context=); see [*Flovac, Inc. v. Airvac, Inc., 817 F.3d 849, 853 (1st Cir. 2016)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5JFV-9CV1-F04K-H0C3-00000-00&context=) (explaining that the plaintiff's *Section 1* claim requires proof that the defendant "exercises or could**[\*23]** exercise a threshold degree of market power," which is the defendant's "power to lessen or eliminate competition in the relevant market"). Both parties seek summary judgment on this issue. See D. 717; D. 747. Defendants argue that the relevant market includes all oral tetracyclines—including not only Solodyn and its generic equivalents, but also all other branded oral tetracyclines and their generic equivalents—a market in which Solodyn's share "never exceeded 17%."[[6]](#footnote-5)6 D. 721 at 7, 20; D. 724-1 ¶¶ 25, 27; see D. 753-1 at 129 ("Addanki Rpt."). Plaintiffs argue that the relevant market includes only Solodyn and its AB-rated generic equivalents, of which Medicis had a 100% market share during the relevant period. D. 747-1 at 9, 12.

Plaintiffs argue that evidence of a reverse payment by itself is sufficient to show market power. D. 851 at 8-9; see D. 747-1 at 10 n.7. They argue that the Supreme Court "recognized that proof of a large reverse payment is itself proof of the brand's market power" in Actavis. D. 851 at 8. In Actavis, however, the Court was reviewing the lower court's decision to allow a motion**[\*24]** to dismiss.[[7]](#footnote-6)7 [*Actavis, 133 S. Ct. at 2227*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:58NW-3VK1-F04K-F006-00000-00&context=). This Court followed Actavis, accordingly, when denying Defendants' motion to dismiss Plaintiffs' *Section 1* claim. D. 184 at 13-16. Although the Court acknowledges the logic of the interconnectivity of market power and a sizable reverse payment, see [*Aggrenox, 199 F. Supp. 3d at 665*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KDV-P4H1-F04C-W0MK-00000-00&context=), the Court concludes that it would be inappropriate to equate the two at the summary judgment phase. That is, an allegation of a "large, unjustified" reverse payment is sufficient for a plaintiff to state a claim under *Section 1*, [*Actavis, 133 S. Ct. at 2237*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:58NW-3VK1-F04K-F006-00000-00&context=); see D. 184 at 15, but it is not necessarily sufficient to demonstrate market power at the summary judgment stage, particularly where, as here, the Defendants dispute that the reverse payments at issue were both large and unjustified, see D. 895 at 8 n.8 (noting that whether the Sandoz payment "was large and unexplained" is in dispute). Rather, the Court will follow the traditional analysis, by which "[m]arket power can be shown through two types of proof," through "direct evidence of market power," or through "circumstantial evidence of market power." [*Coastal Fuels of P.R., Inc. v. Caribbean Petroleum Corp., 79 F.3d 182, 196-97 (1st Cir. 1996)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3560-006F-M4N9-00000-00&context=).

*1. Circumstantial Evidence*

"[C]ircumstantial evidence of market power" includes evidence "that the defendant has a dominant share in a well-defined relevant**[\*25]** market and that there are significant barriers to entry in that market and that existing competitors lack the capacity to increase their output in the short run." [*Coastal Fuels, 79 F.3d at 197*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3560-006F-M4N9-00000-00&context=). Before determining market power by circumstantial evidence, the relevant market must be defined. Id. The relevant market is both the relevant geographic market and the relevant product market, [*Flovac, 817 F.3d at 853*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5JFV-9CV1-F04K-H0C3-00000-00&context=), but the parties here agree that the relevant geographic market is the United States, see D. 747-1 at 16 n.35; D. 860 ¶ 41, so the Court focuses on the relevant product market here. "The market is established by examining both the substitutes that a consumer might employ and 'the extent to which consumers will change their consumption of one product in response to a price change in another, i.e., the cross-elasticity of demand.'" [*Flovac, 817 F.3d at 854*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5JFV-9CV1-F04K-H0C3-00000-00&context=) (quoting [*Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451, 469, 112 S. Ct. 2072, 119 L. Ed. 2d 265 (1992))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3RV9-X170-003B-R185-00000-00&context=). The focus in this demand analysis is on the perspective of the consumers, and not manufacturers, for "[i]t is the consumer's options and the consumer's choices among them on which relevant market analysis ultimately depends." [*Id. at 855*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5JFV-9CV1-F04K-H0C3-00000-00&context=). "The definition of the relevant market is ordinarily a question of fact, and the plaintiff bears the burden of adducing enough evidence to permit a reasonable factfinder**[\*26]** to define the relevant market." [*Id. at 853*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5JFV-9CV1-F04K-H0C3-00000-00&context=); see [*In re Nexium (Esomeprazole)* ***Antitrust*** *Litig., 968 F. Supp. 2d 367, 388 n.19 (D. Mass. 2013)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:59BB-KNF1-F04D-D05Y-00000-00&context=) (denying defendants' motion to dismiss on this ground and stating that "the reasonable interchangeability of brand Nexium with other drugs" is "a factually intensive determination [that] is better left for resolution by a jury").

Defendants argue that "it is undisputed that 'all oral tetracyclines treat acne with similar effectiveness and so are interchangeable for that purpose.'" D. 721 at 7 (quoting [*Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd. Co., No. 12-3824, 2015 U.S. Dist. LEXIS 50026, at \*25 (E.D. Pa. Apr. 16, 2015)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5FSB-PD81-F04F-420Y-00000-00&context=) ("Doryx I"), aff'd, [*838 F.3d 421 (3d Cir. 2016)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KTJ-FRX1-F04K-K30Y-00000-00&context=) ("Doryx II")). In Doryx II, the Third Circuit held that the relevant market for Doryx consisted of all oral tetracyclines prescribed to treat acne—including branded Solodyn and its generic equivalents—and held that Doryx composed only eighteen percent of that share, which was insufficient to establish an ***antitrust*** violation. [*Doryx II, 838 F.3d at 437-38*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KTJ-FRX1-F04K-K30Y-00000-00&context=). To demonstrate functional interchangeability here, Defendants point to statements by dermatological experts Dr. Neelam A. Vashi ("Vashi") for Plaintiffs and Dr. Guy Webster ("Webster") for Defendants confirming that dermatologists may choose between several options for treating acne, the American Academy of Dermatology's "Guidelines of Care for the Management of Acne Vulgaris" demonstrating this, insurance**[\*27]** companies and pharmacy benefit managers that "grouped Solodyn with other oral tetracyclines in their coverage plans" and the "vigorous" competition between Medicis and other manufacturers using coupons and rebates. D. 721 at 12-14. Plaintiffs dispute that Solodyn is therapeutically interchangeable with all other oral tetracyclines simply because these other drugs may also treat acne. D. 851 at 23. Their dermatological expert, Vashi, opines that "[d]ue to various differences in side effects, mechanism of action, indications, and dosage forms between Solodyn and other drugs also used to treat moderate to severe acne vulgaris, Solodyn is not reasonably interchangeable with any other such drug." D. 851 at 23 n.55 (quoting D. 732-6 ¶ 24 ("Vashi Rpt.")). Vashi concludes that "Solodyn is not interchangeable with tetracyclines such as doxycycline (immediate-release and extended release versions), immediate-release minocycline, and other oral antibiotics" or "any topical form of acne medications."[[8]](#footnote-7)8 Vashi Rpt. ¶ 24.

Even if Solodyn were functionally interchangeable with other branded products, however, circumstantial evidence of market definition also requires a showing of economic interchangeability**[\*28]** with these therapeutic alternatives. See [*Flovac, 817 F.3d at 854*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5JFV-9CV1-F04K-H0C3-00000-00&context=); [*United Food & Commer. Workers Local 1776 v. Teikoku Pharma USA ("Lidoderm"), No. 14-md-02521-WHO, 296 F. Supp. 3d 1142, 2017 U.S. Dist. LEXIS 182940, at \*88 (N.D. Cal. Nov. 3, 2017)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5PW6-FR61-F04C-T49K-00000-00&context=) (stating that "something *more* than mere therapeutic equivalency is required to define the relevant ***antitrust*** product market. There must be some showing of cross-elasticity" (emphasis in original)); see also D. 755-35 (ABA Model Jury Instructions in Civil ***Antitrust*** Cases (2016), A-108 n.2 (explaining that "[i]n assessing whether products are within the relevant market, the jury must consider not only whether the products are functionally similar but also whether the products are economically interchangeable. That is, there must be cross-price elasticity of demand")). Demonstrating economic interchangeability requires analysis of Solodyn's cross-price elasticity of demand with respect to products allegedly in the same market. See [*Flovac, 817 F.3d at 854*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5JFV-9CV1-F04K-H0C3-00000-00&context=); [*In re Asacol* ***Antitrust*** *Litig., No. 15-cv-12730-DJC, 323 F.R.D. 451, 2017 U.S. Dist. LEXIS 186009, at \*97 (D. Mass. Nov. 9, 2017)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5PXG-01N1-JBT7-X2KX-00000-00&context=); [*Nexium, 968 F. Supp. 2d at 387-88*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:59BB-KNF1-F04D-D05Y-00000-00&context=) (explaining that "reasonable interchangeability of a set of products is not dependent on the similarity of their forms or functions" but rather based on the cross-elasticity of demand). As Plaintiffs' expert Dr. Meredith Rosenthal ("Rosenthal") explains, "economic theory suggests**[\*29]** that products with the most similar features will compete most aggressively on price." D. 732 ¶ 55 ("Rosenthal Rpt."). Cross-elasticity, therefore, measures "the substitutability of products" by gauging the "responsiveness of the demand for one product [X] to changes in the price of a different product [Y]." [*Doryx II, 838 F.3d at 437*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KTJ-FRX1-F04K-K30Y-00000-00&context=) (quoting [*Queen City Pizza, Inc. v. Domino's Pizza, 124 F.3d 430, 438 n.6 (3d Cir. 1996))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S1P-DD50-00B1-D0PS-00000-00&context=). When products are close economic substitutes, a small change in price of one product will cause consumers to shift and sales to respond accordingly, meaning the cross-elasticity of demand will be high. See [*Flovac, 817 F.3d at 854*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5JFV-9CV1-F04K-H0C3-00000-00&context=); [*Asacol, 323 F.R.D. 451, 2017 U.S. Dist. LEXIS 186009, at \*98*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5PXG-01N1-JBT7-X2KX-00000-00&context=); D. 747-1 at 13 (citing cases); D. 732-4 ¶ 33 ("Leffler Rpt."). Plaintiffs argue that Defendants have not demonstrated, and cannot demonstrate, that Solodyn is economically interchangeable with the products Defendants identify as therapeutic alternatives.[[9]](#footnote-8)9 D. 747-1 at 12-16; D. 851 at 15-26. Rather, Plaintiffs argue that Solodyn exhibits cross-price elasticity only with its AB-rated generic alternatives. D. 747-1 at 12; D. 851 at 19-23.

Plaintiffs argue that they alone have identified evidence of Solodyn's cross-price elasticity of demand, through expert opinions by Rosenthal, Dr. Christopher Baum ("Baum") and Dr. Keith Leffler ("Leffler"), all concluding "that no**[\*30]** product other than generic Solodyn exhibits substantial cross-price elasticity of demand with Solodyn." D. 747-1 at 14-15; see D. 747-2 ¶¶ 21-34. Leffler analyzed the cross-elasticity of Solodyn and Doryx, Leffler Rpt. ¶¶ 36-37.[[10]](#footnote-9)10 In 2011, the first version of generic Doryx entered the market, causing a significant reduction in price of all doxycycline hyclate delayed release antibiotics. Id. ¶ 36. Solodyn sales did not drop, however, but actually were 4% higher three quarters after generic Doryx's entry than they were three quarters before. Id. ¶¶ 36-37. Leffler thus concludes that "the product that Medicis considers to be Solodyn's closest therapeutic competitor is not a close economic substitute."[[11]](#footnote-10)11 Id. ¶ 38.

Rosenthal and Baum conduct a quantitative analysis of cross-price elasticity. Rosenthal Rpt. ¶¶ 57-60; D. 741-2 ¶¶ 13-20 ("Baum Rpt."). Baum is a professor of economics and social work at Boston College with a focus on econometrics. Baum Rpt. ¶¶ 1-2. Rosenthal is a Professor of Health Economics and Policy at the Harvard T.H. Chan School of Public Health. Rosenthal Rpt. ¶ 1. Rosenthal and Baum use IMS data[[12]](#footnote-11)12 on dispensed prescriptions to determine Solodyn's top competitors**[\*31]** in acne treatment and conduct an econometric test of observed price competition between them. Rosenthal Rpt. ¶¶ 57-59. They use an econometric model known as the "AIDS"—Almost Ideal Demand System—model to examine cross-price elasticity.[[13]](#footnote-12)13 Baum Rpt. ¶ 13. The model predicts expenditure shares for Solodyn and six other oral antibiotic drugs[[14]](#footnote-13)14 and their AB-rated generic alternatives from May 2011 to December 2016, "the period when generic equivalents are present in the retail data." Id. Baum explains that he captures Medicis's rebating strategies and promotional efforts in his model by adding an additional variable to his regression analysis and adding a typical monthly discount rate. Baum Rpt. Attach. C. ¶¶ 6-7. He concludes that Solodyn did not exhibit a significant cross-price elasticity with any other drug from May 2011 to December 2016. Baum Rpt. ¶ 18. Likewise, Rosenthal concludes that "there is no evidence suggesting that price increases of Solodyn by Medicis were constrained by price elastic substitution to the other competitive treatments."[[15]](#footnote-14)15 Rosenthal Rpt. ¶ 60. Conducting the same analysis for the May 2006 to February 2009 time period—following Solodyn's launch but prior to any generic**[\*32]** launch—and comparing Solodyn to the four other drugs available at that time—Doryx, doxycycline, Minocin and minocycline HC1—Baum again concludes that "there is no evidence of any drug having a positive, significant compensated cross-price elasticity with respect to the price of Solodyn." Baum Rpt. ¶¶ 19-20.

Defendants seek to exclude Baum's testimony. D. 741. They argue that Baum's model does not fit the pharmaceutical industry or the facts of the case. D. 741-1 at 6-9. Specifically, they argue that the AIDS model does not apply to prescription drugs because physicians, the principal decision-makers in that market, do not know prescription drug prices and insurers, the principal payors, do not make the prescription decisions. D. 741-1 at 7-9. Plaintiffs argue that "numerous high-quality peer-reviewed studies" use demand models like Baum's AIDS model to analyze the pharmaceutical industry. D. 845 at 10; see Baum Rpt. Attach. C ¶¶ 2-3. Moreover, Defendants' critique that the model is unreliable because "physicians are the principal decision makers and generally they do not know prescription drug prices," D. 741-1 at 7, is unpersuasive, particularly in light of Defendants'**[\*33]** expert's reliance on the assumption that physicians have some general awareness of costs to patients and rebate programs for his own analysis, Addanki Rpt. ¶¶ 115-16. Defendants also object that Baum's model is particularly unreliable because it does not account for Medicis rebates and coupons. D. 741-1 at 9-11. Plaintiffs argue, however, that Baum's model works with percentage changes rather than absolute prices, so the inclusion of rebates and coupons would not have any meaningful effect. D. 845 at 14-15. Additionally, Baum explains how he contemplates promotional efforts in his model. Baum Rpt. Attach. C ¶¶ 6-7. Defendants can critique Baum's report relying upon the opinion of their own expert (Addanki, discussed infra), vigorous cross-examination, and other traditional methods. The Court declines to exclude his proffered opinion on this basis.

Plaintiffs also proffer evidence that Defendants themselves did not previously view any of the allegedly therapeutically interchangeable products they now identify as economic competitors. Defendants did not identify other acne treatments as competitors in their forecasts, reports or advertising. See, e.g., D. 747-1 at 15 (citing Impax's 2012**[\*34]** representations to the FTC); D. 747-2 ¶ 13 (referring to Impax's forecasts from 2008). In Impax's filings to the Federal Trade Commission in 2012 in response to a civil investigative demand, Impax listed the competing products of Solodyn and generic Solodyn as "the brand AB-rated equivalents, currently Barr/Teva, Lupin, Matrix Labs, Sandoz, and Medicis." D. 747-1 at 15 n.29 (quoting D. 755-42 at 2). In Medicis's own forecasts, Medicis identified the entry of generic Solodyn, and not the entry of generic Doryx or any other product, as likely to lower Solodyn's prices and capture brand sales. D. 916 at 12; D. 747-2 ¶¶ 11-13; Leffler Rpt. ¶ 40. Medicis marketing documents from 2006 describe Solodyn as having "unique pharmacokinetics." Rosenthal Rpt. ¶ 19. In Medicis's 2011 and 2012 strategic overview establishing its plan for marketing to physicians, it emphasized the therapeutic differences Solodyn provided, or its "clinical efficacy," rather than benefits Medicis offered on a price dimension, stating that the emphasis on clinical efficacy and safety led to an increase in Solodyn prescriptions in 2011. Id.; see Leffler Rpt. ¶ 42. This evidence further supports Plaintiffs' arguments that**[\*35]** Solodyn operated in a relevant market limited to its AB-rated generic equivalents. See [*Lidoderm, 2017 U.S. Dist. LEXIS 182940, at \*88-89*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5PW6-FR61-F04C-T49K-00000-00&context=).

Thus, Plaintiffs argue that the relevant market did not include any products beyond Solodyn and its AB-rated generic equivalents. As to Medicis's conduct in 2009, Rosenthal opines that "price competition was part of their strategic response" to generic launches that year, even if those launches were abbreviated. Rosenthal Rpt. ¶ 63. She demonstrates that in a but-for world of generic launch in September 2008—in accordance with Medicis and Impax forecasts—these AB-rated generics exhibit large cross-price elasticity with Solodyn.[[16]](#footnote-15)16 Id. ¶ 64. At the time when Medicis and Impax entered their agreements, Medicis controlled 100% of this narrower market. D. 747-1 at 15; Leffler Rpt. ¶ 48.

Defendants argue that an econometric analysis supports a broader view of the relevant market. D. 721 at 15-16. Defendants' expert Dr. Sumanth Addanki ("Addanki"), an economist and managing director at National Economic Research Associates, Inc., concludes that Solodyn also competed with other branded and generic minocyclines and doxycyclines. Addanki Rpt. ¶¶ 1, 68. Addanki argues that because of the pharmaceutical distribution**[\*36]** chain, or "the institutional structure of this market," an econometric demand model like Baum's and Rosenthal's cannot "provide reliable or meaningful elasticity estimates in the market for prescription pharmaceutical products." Id. ¶ 34. Addanki details the way therapeutic alternatives compete at many steps in the distribution chain, including at the physician, third-party payor, pharmacy and consumer levels. Id. ¶¶ 71-75. Even in the pharmaceutical market, however, cross-elasticity must be demonstrated between products to establish a market definition that includes them. See [*Lidoderm, 2017 U.S. Dist. LEXIS 182940, at \*81-92*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5PW6-FR61-F04C-T49K-00000-00&context=) (rejecting the argument, similar to Defendants' argument here, that cross-elasticity need not be shown because of the unique characteristics of the pharmaceutical market). Addanki's critique, therefore, does not undermine Plaintiffs' showing that cross-elasticity exists for Solodyn and its generics, but not the broader market.

Given Addanki's criticisms, Defendants concede that Addanki does not quantify the magnitude of cross-price elasticity in his report. D. 859 at 19. Instead, Addanki explains that Medicis's "[e]xtensive promotional activity" demonstrates that "Medicis viewed other minocycline and doxycycline**[\*37]** oral tetracycline products as competing with Solodyn." Addanki Rpt. ¶ 98. He concludes that promotional activities at the prescriber and payor levels by Medicis resulted in increased sales of Solodyn. Id. ¶¶ 97-108. Addanki analyzes economic interchangeability by focusing on the effect rebate and promotional programs for Solodyn and its alleged competitors (Doryx, Adoxa, Monodox, Oracea, and their generic equivalents) had on prescriptions of Solodyn and those competitors. Id. ¶¶ 110-22. Addanki's model uses IMS data on prescriptions to analyze the effects of "several market events, such as changes in coupons offered by branded manufacturers, on new prescriptions of branded and generic minocycline and doxycycline products." Id. ¶ 120. He concludes that "the number of new Solodyn prescriptions written were sensitive to changes in the price of Solodyn as well as price changes of competing products, such as doxycycline." Id. ¶ 122.

Plaintiffs seek to exclude Addanki's opinion, D. 748, on the basis that he "did not consider Solodyn's cross-price elasticity of demand." D. 748-1 at 8. Addanki does not purport to conduct such an econometric test, but he uses other models to examine how Medicis's**[\*38]** rebate programs and Doryx's launch impacted the rate of new Solodyn prescriptions and new prescriptions of "generic immediate-release minocycline"—or generic Solodyn—arguing that particularities of the pharmaceutical market limit the ability to conduct a SSNIP (Small but Significant and Non-transitory Increase in Price) test. See Addanki Rpt. ¶¶ 118-22. Although Plaintiffs dispute his approach, they have not demonstrated that his methods are unreliable or poorly fit the question of market power. See D. 894 at 9 (explaining that Addanki "conduct[ed] a regression analysis here that shows Solodyn and other oral tetracyclines are economic substitutes: demand for these drugs is sensitive to price changes among them"). Plaintiffs' motion to exclude portions of Addanki's opinion is thus denied.

Even admitting Addanki's expert testimony, however, Plaintiffs argue that Addanki's report does not create a genuine dispute of material fact as to market definition. Addanki's report is not a quantitative cross-price elasticity of demand study. See D. 862 at 11; D. 916 at 13-14. Plaintiffs argue that Addanki's focus on new prescriptions omits reference to actual prices of the alleged competitors, total**[\*39]** prescriptions and total sales. See D. 916 at 14 n.49. Plaintiffs rely heavily upon Lidoderm to argue that Addanki's testimony does not amount to an opinion on cross-price elasticity. D. 851 at 16-17; D. 916 at 13-14; see [*Lidoderm, 2017 U.S. Dist. LEXIS 182940, at \*96*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5PW6-FR61-F04C-T49K-00000-00&context=) (explaining that defendants' evidence of the impact of rebates on branded product use creates "at most, an issue regarding Lidoderm's market share for PHN and pain treatment with respect to only a few of the drugs defendants believe should be included in the relevant ***antitrust*** market . . . but those discrete references are insufficient to raise a material question of fact on whether the availability of those drugs constrained the price charged for Lidoderm" (emphasis in original)).

The Court understands Plaintiffs' point, but concludes that Lidoderm is distinguishable for at least two reasons. First, the relevant market that Defendants there sought to have the court adopt was a broad one, including a wide array of pain medications, including opioids, anticonvulsants, antidepressants, muscle relaxers, nonsteroidal anti-inflammatory drugs and topical anesthetic creams and gels as the relevant market for Lidoderm, a lidocaine 5% patch. [*Lidoderm, 2017 U.S. Dist. LEXIS 182940, at \*74-75*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5PW6-FR61-F04C-T49K-00000-00&context=). Defendants here do not take such**[\*40]** a broad view, seeking to define the relevant market as a class of oral tetracyclines used for acne, both branded and generic, a point for which, although disputed by Plaintiffs, they proffer significant product interchangeability evidence as to Solodyn. See D. 721 at 7, 12-19. Second, unlike the defendants in Lidoderm, Defendants appear to acknowledge, as the current state of law requires, that some showing of cross-elasticity of demand is a necessary part of defining the relevant market. See D. 721 at 16; D. 859 at 19-20; cf. [*Lidoderm, 2017 U.S. Dist. LEXIS 182940, at \*81-90*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5PW6-FR61-F04C-T49K-00000-00&context=). Unlike defendants there, "essentially ignoring cross-elasticity," [*Lidoderm, 2017 U.S. Dist. LEXIS 182940, at \*84*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5PW6-FR61-F04C-T49K-00000-00&context=), Defendants here provide a basis, which amounts to a disputed issue of fact, regarding Plaintiffs' purported showing that cross-elasticity of demand, under Baum and Rosenthal models, demonstrate that the relevant market is limited to Solodyn and its generic equivalents.

Even putting aside Addanki's critique that demand models are not appropriately used in the pharmaceutical field, Addanki Rpt. ¶¶ 34-37, his report opines that Plaintiffs' experts' analysis contains critical flaws in estimation of price, id. ¶¶ 46-53, for example, failing to account for Solodyn's rebating, id. ¶ 59, samples distributed**[\*41]** to physicians, id. ¶ 60, and other matters, such that he provides a sufficient basis for questioning whether Plaintiffs have shown (or can show at trial) that no cross-elasticity of demand exists beyond Solodyn and its generics. While rejecting a demand model given the contours of the pharmaceutical field (which involves consumers, physicians, pharmacies and insurance companies as decisionmakers), Addanki uses an econometric model to determine whether there was any effect on new prescriptions of oral tetracyclines based upon effective price changes corresponding with certain marketplace events. Id. ¶¶ 120-22. Accordingly, he concludes that the number of new Solodyn prescriptions were not only sensitive to its own price changes, but also the price changes of other products, including doxycycline and a number of new generic immediate-release minocycline prescriptions that, in turn, were also sensitive to changes in Solodyn's price. Id. ¶ 122. That Addanki uses a different economic analysis, one that explicitly considers the changes in effective pricing (i.e., accounting for coupons, discounts and rebates) does not mean that such analysis fails to bear upon a showing of cross-elasticity**[\*42]** of demand. Whether, when weighed against the Rosenthal and Baum demand models, such analysis will carry the day as a matter of fact is for the jury to decide.

This ruling, denying summary judgment as to both parties, is not inconsistent with Doryx II, in which the Third Circuit affirmed the lower court's ruling for the defendants on market definition. [*Doryx II, 838 F.3d at 437-38*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KTJ-FRX1-F04K-K30Y-00000-00&context=). In Doryx II, the court characterized Addanki's study there as demonstrating that "when Defendants increased the price of Doryx, its sales decreased, and the sales of other tetracyclines increased." [*Id. at 437*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KTJ-FRX1-F04K-K30Y-00000-00&context=). There, however, plaintiffs failed to rebut this testimony with any "quantitative analyses." Id. That is not the situation here. Plaintiffs' experts have provided quantitative analyses analyzing sales and prices of Solodyn and its supposed competitors.

The Court thus DENIES both summary judgment motions, D. 717; D. 747, as to this issue. Circumstantial evidence of market power—including the question of what is the relevant market—goes to the jury.

*2. Direct Evidence*

Plaintiffs also argue that undisputed direct evidence establishes market power here. D. 747-1 at 10-12; D. 851 at 9-15. Defendants argue that Plaintiffs' purported direct evidence**[\*43]** is insufficient as a matter of law. D. 721 at 22-26. Direct evidence of market power may include evidence of "actual supracompetitive prices and restricted output." [*Coastal Fuels, 79 F.3d at 196*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3560-006F-M4N9-00000-00&context=). Proof of market power using direct evidence does not require that the plaintiff first establish the relevant market. See [*Díaz Aviation, 716 F.3d at 265*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:58N8-64X1-F04K-H00Y-00000-00&context=) (explaining that "[a]bsent direct proof of supracompetitive prices, monopoly power is typically proven by defining a relevant market and showing that the defendant has a dominant share of that market"); [*Nexium, 968 F. Supp. 2d at 388 n.19*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:59BB-KNF1-F04D-D05Y-00000-00&context=) (explaining that "[w]here direct evidence of market power is available . . . a plaintiff need not attempt to define the relevant market").

Plaintiffs argue that their evidence of supracompetitive prices is sufficient to show market power because "the ability to charge supracompetitive prices . . . is the *sine qua non* of market power." D. 747-1 at 10 (quoting [*Aggrenox, 199 F. Supp. 3d at 664-65*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KDV-P4H1-F04C-W0MK-00000-00&context=)). They contend that undisputed evidence here demonstrates that "[f]rom 2006 through 2012, Medicis's price for Solodyn was 10 to 16 times its cost of production, distribution and marketing." D. 747-1 at 10; D. 747-2 ¶ 8. Retailer Plaintiffs' expert economist Leffler opines on Medicis's pricing of Solodyn during this period. See Leffler Rpt. ¶¶ 51-55.**[\*44]** Leffler explains that Solodyn's prices were nearly ten times the cost of generic minocycline and three times the cost of branded competitors Doryx and Adoxa. Id. ¶ 51. Leffler concedes, however, that the branded product Minocin was priced seventeen percent higher than brand Solodyn during this period. Id. ¶ 51 n.57. Leffler's analysis of market power uses the Lerner Index, which is a ratio of a product's margin, or the difference between the price and marginal cost, to its price. Id. ¶ 51; see D. 847 ¶ 43. The ratio falls between 0 and 1, 0 indicating complete absence of market power and 1 representing complete market power, and Plaintiffs argue—and Defendants dispute, D. 859 at 13 n.10—that a ratio of .05 indicates potentially supracompetitive market power. D. 747-1 at 10-11; Leffler Rpt. ¶ 51. Here, Solodyn's prices produce a ratio of over 0.9, Leffler Rpt. ¶ 52, twenty times the typical threshold of supracompetitive market power. D. 747-1 at 11.

Plaintiffs' expert Rosenthal also opines on direct evidence of Medicis's market power. See Rosenthal Rpt. ¶¶ 45-53. Rosenthal's Lerner Index calculations conclude that Medicis's margins averaged ninety percent between 2009 and 2011, while**[\*45]** generic firms averaged between forty and sixty-two percent during that time. Rosenthal Rpt. ¶ 48. Rosenthal explains that "when generic companies were selling pills at prices that were about double their marginal costs on average, Solodyn was selling at prices that were 25 to 50 times higher." D. 851 at 15. Plaintiffs argue that these margins provide sufficient direct evidence of market power.[[17]](#footnote-16)17 D. 747-1 at 10-11; D. 851 at 10-15.

Defendants argue that direct evidence of market power cannot be demonstrated solely through high margins and prices. D. 859 at 11-12. Defendants explain that high margins ignore the high fixed or sunk costs "prevalent in innovation-intensive industries" such as the pharmaceutical industry. D. 721 at 23; see [*United States v. Eastman Kodak Co., 63 F.3d 95, 109 (2d Cir. 1995)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-CRH0-001T-D3YX-00000-00&context=) (explaining that "deviations between marginal cost and price, such as those resulting from high fixed costs, are not evidence of market power"). Plaintiffs do not dispute that models like the Lerner Index do not take sunk costs into account, but they argue that sunk costs are not relevant to margins and pricing. D. 847 ¶ 44; D. 851 at 13. Plaintiffs urge the Court instead to follow Aggrenox, in which the court rejected brand manufacturers' sunk costs**[\*46]** argument because the fact that "brand manufacturers incur enormous fixed costs developing and marketing new drugs . . . . does not mean that the price of the brand drug is not supracompetitive," [*Aggrenox, 199 F. Supp. 3d at 666*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KDV-P4H1-F04C-W0MK-00000-00&context=). D. 851 at 13. The court there explained that "prices in a competitive market will tend (perhaps asymptotically) toward marginal cost, so prices substantially above that cost are supracompetitive by definition." [*Aggrenox, 199 F. Supp. 3d at 667*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KDV-P4H1-F04C-W0MK-00000-00&context=). While the Court agrees that existence of sunk costs may not be sufficient, without more, to show that apparently supracompetitive prices were in fact only competitive, sunk costs are relevant to the inquiry because in a market with high fixed costs like the pharmaceutical industry, "even competitive prices may exceed marginal cost." [*Asacol, 323 F.R.D. 451, 2017 U.S. Dist. LEXIS 186009, at \*94-96*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5PXG-01N1-JBT7-X2KX-00000-00&context=). Indeed, Plaintiffs concede that during the period in question, generic firms' gross margins ranged from forty to sixty-two percent. D. 747-1 at 11 n.13. Although this is significantly lower than ninety percent, as those margins are alleged as to Solodyn, it is also significantly higher than the five percent point that, according to Plaintiffs, establishes "market power of concern." D. 747-1 at 11; see Leffler Rpt. ¶ 51. That is, generic pricing during**[\*47]** this time illustrates that high margins alone do not conclusively demonstrate supracompetitive pricing.

The parties do not dispute that brand pharmaceutical companies like Medicis "incur substantial sunk costs to develop new products." D. 724-1 ¶ 48; D. 847 ¶ 48. The parties dispute, however, whether Leffler took fixed costs into account sufficiently when calculating supracompetitive prices here. Compare D. 721 at 24 with D. 851 at 10 n.7. Leffler's analysis using the Lerner Index incorporated Medicis's "marginal costs" for Solodyn development, see D. 747-1 at 10, including "the costs of producing, distribution, and marketing Solodyn, and also on-going R&D, and certain fixed costs such as Building/Office," Leffler Rpt. ¶ 52. Defendants argue that the margin did not include "*all* of the relevant costs Medicis faced," including all sunk costs. D. 721 at 25. Leffler concedes he is "not aware of data sufficient to answer th[e] question" of "whether Medicis made a long run economic profit on its sales of Solodyn." Leffler Rpt. ¶ 58. Leffler does note, however, that from 2006 to 2015, Medicis made profits of $2.1 billion from Solodyn, compared to its $43 million for research and development**[\*48]** costs. Id.

Defendants also argue that high margins cannot show market power alone because such margins can be explained by factors that are not inherently anticompetitive, such as a superior product or superior advertising or marketing.[[18]](#footnote-17)18 D. 721 at 23. Plaintiffs counter that if Defendants' advertising and product were indeed superior, "Medicis would have had no reason to pay Impax to delay generic entry." D. 851 at 11.

Defendants again proffer the expert testimony of Addanki, who criticizes the reports of both Rosenthal and Leffler, arguing that they conclude that Solodyn was priced supracompetitively without determining what a competitive price for Solodyn would be. Addanki Rpt. ¶ 13. Addanki explains that high margins do not automatically indicate market power, and he argues that Rosenthal and Leffler incorrectly compare the margins of brand Solodyn with generic margins, which are typically lower, as they should be. Id. ¶ 24. Additionally, Addanki opines that "[p]rice premiums that result from brand- and demand-building efforts are simply the economic returns earned by those efforts" and "do not connote market power." Id. ¶ 25. For all of these reasons, Defendants have**[\*49]** presented a legitimate dispute as to whether Solodyn's prices were supracompetitive.

More significantly, as to the resolution of this issue as a matter of law, Defendants also contend that even if Plaintiffs' evidence of high margins were sufficient to establish that Solodyn's pricing was actually supracompetitive, Plaintiffs have failed to carry their burden on this theory because evidence of supracompetitive prices alone is insufficient direct evidence to show market power. D. 721 at 22-23; D. 859 at 9-12. They argue that direct evidence also requires evidence of restricted output. D. 859 at 10-11. Indeed, in Coastal Fuels, the First Circuit explained that a plaintiff can show direct evidence of market power "perhaps by showing actual competitive prices and restricted output." [*Coastal Fuels, 79 F.3d at 196*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-3560-006F-M4N9-00000-00&context=); see [*Sterling Merch., Inc. v. Nestle, S.A., 724 F. Supp. 2d 245, 268 (D.P.R. 2010)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:7YSM-DMW1-652J-K00S-00000-00&context=) (explaining that "market power exists only when competitors lack capacity to increase short run output, allowing for the monopolist to unilaterally restrict output in order to charge higher prices"), aff'd, [*656 F.3d 112 (1st Cir. 2011)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:8337-V571-652P-Y05B-00000-00&context=); [*Broadcom Corp. v. Qualcomm, Inc., 501 F.3d 297, 307 (3d Cir. 2007)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4PKD-KMP0-TXFX-52CY-00000-00&context=) (stating that "monopoly power may be proven through direct evidence of supracompetitive prices and restricted output"); [*Rebel Oil Co. v. Atlantic Richfield Co., 51 F.3d 1421, 1434 (9th Cir. 1995)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-FT10-001T-D3HS-00000-00&context=) (explaining that "evidence of restricted output and supracompetitive prices"**[\*50]** is "direct proof" of exercise of market power).

Plaintiffs argue that the evidence of supracompetitive prices "necessarily means that Medicis's conduct reduced output," relying upon "the law of supply and demand," D. 916 at 9, but evidence of restricted output is used to determine whether high margins and prices are indicative of monopoly power. See [*Geneva Pharms. Tech. Corp. v. Barr Labs., Inc., 386 F.3d 485, 500 (2d Cir. 2004)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4DK6-R430-0038-X3T5-00000-00&context=) (explaining that without evidence of restricted output, plaintiffs were "asking [the court] to infer the basis for the higher prices"). Plaintiffs have failed to provide any actual evidence of restricted output here. See [*Doryx II, 838 F.3d at 435*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KTJ-FRX1-F04K-K30Y-00000-00&context=) (holding that Mylan failed to provide direct evidence of monopoly power where Mylan had not provided evidence of restricted output); [*Meijer, Inc. v. Barr Pharms. Inc., 572 F. Supp. 2d 38, 55-56 (D.D.C. 2008)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4TB2-H890-TX4N-G139-00000-00&context=) (holding that plaintiffs had failed to show that high prices were the result of restricted output); cf. [*Asacol, 323 F.R.D. 451, 2017 U.S. Dist. LEXIS 186009, at \*95*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5PXG-01N1-JBT7-X2KX-00000-00&context=) (noting that plaintiffs offered evidence of restricted output in addition to high margins, ultimately establishing a question for the jury).

Absent any evidence of restricted output, Plaintiffs' evidence of high margins is insufficient direct evidence as a matter of law to demonstrate market power. Demonstrating market power through direct evidence requires additional evidence beyond high**[\*51]** margins alone. See, e.g., [*Meijer, 572 F. Supp. 2d at 56*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4TB2-H890-TX4N-G139-00000-00&context=) (holding that plaintiffs could not establish market power through the proffered evidence of high margins alone); [*Geneva Pharms., 386 F.3d at 500*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4DK6-R430-0038-X3T5-00000-00&context=); [*Remeron, 367 F. Supp. 2d at 681*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4G1X-NHW0-TVVX-S22P-00000-00&context=). For all of the aforementioned reasons, Defendants have demonstrated the dangers in inferring market power from high margins alone. Plaintiffs have provided no evidence of restricted output. See [*Geneva Pharms., 386 F.3d at 500*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4DK6-R430-0038-X3T5-00000-00&context=). Direct evidence of market power is "rarely available," [*United States v. Microsoft, Corp., 253 F.3d 34, 51, 346 U.S. App. D.C. 330 (D.C. Cir. 2001))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:43CK-3HW0-0038-X4RT-00000-00&context=); see [*Doryx II, 838 F.3d at 434*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KTJ-FRX1-F04K-K30Y-00000-00&context=) (reiterating that direct evidence of market power is "rare"), and Plaintiffs have not cited any case—and certainly none that is binding on this Court—that found direct evidence was sufficient for a showing of market power beyond the pleading stage. Given the dispute as to whether Plaintiffs' evidence suffices to show supracompetitive pricing, along with the absence of actual evidence of restricted output, Plaintiffs have failed to provide sufficient evidence of this "rare" variety to meet their burden here.

The Court notes, however, that as Plaintiffs acknowledged at the summary judgment hearing, Plaintiffs need not prove or prevail by showing market power by direct evidence if they succeed in doing so by circumstantial evidence. The case will thus proceed to the jury on the basis of Plaintiffs'**[\*52]** circumstantial evidence of market power—requiring that Plaintiffs first define the market—and not on Plaintiffs' direct evidence theory.

The Court thus ALLOWS Defendants' motion for summary judgment on market power, D. 717, as to direct evidence only, and DENIES Plaintiffs' summary judgment motion, D. 747, on that basis.

**B. Causation**

Defendants also move for summary judgment on the basis that "Plaintiffs cannot establish a causal connection between their alleged injuries and any conduct by Defendants" as a matter of law. D. 718. In an ***antitrust*** case, plaintiffs must demonstrate that the ***antitrust*** violation was a "material cause" of their injury. [*Sullivan v. Nat'l Football League, 34 F.3d 1091, 1103 (1st Cir. 1994)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-2GB0-003B-P3SF-00000-00&context=) (quoting [*Engine Specialties, Inc. v. Bombardier Ltd., 605 F.2d 1, 14 (1st Cir. 1979))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-VBS0-0039-M4YV-00000-00&context=). An ***antitrust*** violation can be the material cause—often interpreted as proximate cause—"even if there are additional independent causes of the injury." [*Nexium, 42 F. Supp. 3d at 267*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5D2K-NTJ1-F04D-D04Y-00000-00&context=) (quoting [*In re Flonase* ***Antitrust*** *Litig., 798 F. Supp. 2d 619, 627 (E.D. Pa. 2011))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:539X-7SD1-JCNC-D0S4-00000-00&context=). As in tort law, a plaintiff need not "prove a series of negatives" or "offer evidence which positively exclude[s] every other possible cause" of the conduct. [*Kaiser Found. Health Plan, Inc. v. Pfizer, Inc. (In re Neurontin Mktg. & Sales Practices Litig.), 712 F.3d 21, 45 (1st Cir. 2013)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:583X-49S1-F04K-H05P-00000-00&context=) (quoting [*BCS Servs., Inc. v. Heartwood 88, LLC, 637 F.3d 750, 757 (7th Cir. 2011))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:52FW-1VM1-F04K-R033-00000-00&context=) (alteration in original). Rather, "'[o]nce a plaintiff presents evidence that he suffered the sort of injury that would be expected consequence of the defendant's wrongful conduct,' the burden shifts to the**[\*53]** defendant to rebut this causal inference." Id. (quoting [*BCS Servs., 637 F.3d at 758*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:52FW-1VM1-F04K-R033-00000-00&context=)). The Court also notes that causation is generally a question best left for the jury to decide. See [*Peckham v. Cont'l Cas. Ins. Co., 895 F.2d 830, 837 (1st Cir. 1990)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-6YG0-003B-51X3-00000-00&context=). In ***antitrust*** suits, moreover, "juries are allowed to act upon probable and inferential as well as [upon] direct and positive proof." [*Bigelow v. RKO Radio Pictures, Inc., 327 U.S. 251, 264, 66 S. Ct. 574, 90 L. Ed. 652 (1946)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-JXT0-003B-S324-00000-00&context=) (quoting [*Story Parchment Co. v. Paterson Parchment Paper Co., 282 U.S. 555, 564, 51 S. Ct. 248, 75 L. Ed. 544 (1931))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-DH60-003B-755V-00000-00&context=).

Defendants argue that the three "but-for" scenarios Plaintiffs initially proposed—establishing what would have occurred absent the Medicis-Impax agreement—lack evidentiary support. D. 722 at 8. Plaintiffs agree that they have now abandoned the first of these three scenarios—that Impax would have prevailed in its patent litigation before launching. D. 850 at 10 n.27. Accordingly, as to this theory of causation, the Court denies Defendants' motion for summary judgment as to this scenario as moot. The Court now turns to the other two remaining "but-for" scenarios and addresses each in turn.

*1. Scenario A: Impax Would Have Launched At-Risk Prior to November 2011*

To succeed on an at-risk launch theory, Plaintiffs must show that Impax could have launched at-risk lawfully, i.e., without infringing any lawful patent held by Medicis. See [*Nexium, 842 F.3d at 63*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5M73-M0F1-F04K-H003-00000-00&context=); [*Wellbutrin XL, 133 F. Supp. 3d at 764-67*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5H0G-1WK1-F04F-414G-00000-00&context=). Without such a showing, the patent held by Medicis would**[\*54]** serve as "an independent ***regulatory*** bar" to Impax's at-risk launch. [*Nexium, 842 F.3d at 63*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5M73-M0F1-F04K-H003-00000-00&context=) (quoting [*Wellbutrin XL, 133 F. Supp. 3d at 767*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5H0G-1WK1-F04F-414G-00000-00&context=)); see [*RSA Media, 260 F.3d at 15*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:43NW-W140-0038-X391-00000-00&context=) (holding that there was no ***antitrust*** liability because the cause of the plaintiff's exclusion from the market was Massachusetts' ***regulatory*** scheme, and not the defendant's conduct). To pursue this causation theory, then, Plaintiffs must produce "some evidence" of patent invalidity or noninfringement. [*Nexium, 842 F.3d at 63*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5M73-M0F1-F04K-H003-00000-00&context=).

In Actavis, however, the Supreme Court explained that "it is normally not necessary to litigate patent validity to answer the ***antitrust*** question (unless, perhaps, to determine whether the patent litigation is a sham)" because "[a]n unexplained large reverse payment itself would normally suggest that the patentee has some serious doubts about the patent's survival." [*Actavis, 133 S. Ct. at 2236*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:58NW-3VK1-F04K-F006-00000-00&context=). Consequently, "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." [*Id. at 2236-37*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:58NW-3VK1-F04K-F006-00000-00&context=). Additionally, as a general matter, "[i]t is well established that the burden of proving infringement generally rests upon the patentee." [*Medtronic, Inc. v. Mirowski Family Ventures, LLC, 571 U.S. 191, 134 S. Ct. 843, 849, 187 L. Ed. 2d 703 (2014)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5BBJ-V6R1-F04K-F148-00000-00&context=). The Court thus agrees that the standard requiring Plaintiffs to produce "some evidence"**[\*55]** of invalidity or noninfringement does not require Plaintiffs "to prove that the generic defendant *would have* won, only that it *could have*." [*Lidoderm, 2017 U.S. Dist. LEXIS 182940, at \*49*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5PW6-FR61-F04C-T49K-00000-00&context=) (emphasis in original).

Defendants argue that Impax could not have launched at-risk lawfully because there is no evidence that Solodyn's patents would have been found invalid, unenforceable, or not infringed. D. 722 at 14. Although Plaintiffs carry a burden to provide some evidence that at-risk launch would be lawful, Defendants carry the burden as movants here to show the absence of a genuine issue of material fact on this issue relating to causation. In Wellbutrin XL, for example, the court granted summary judgment to the defendants on the issue of causation because defendants' expert concluded that the brand manufacturer had an eighty percent chance of winning its patent litigation and plaintiffs offered no evidence in rebuttal. [*Wellbutrin XL, 133 F. Supp. 3d at 767*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5H0G-1WK1-F04F-414G-00000-00&context=). Here, by contrast, Plaintiffs argue that their evidence demonstrates that a generic manufacturer was more likely than not to prevail in a patent suit against Medicis. D. 850 at 14-19. Defendants do not provide any contrary estimate of Impax's likelihood of success in its patent suit against Medicis, but rather rely**[\*56]** upon their attacks against Plaintiffs' evidence on this point, D. 722 at 9-20, including that the '838 patent "has never been found to be invalid or non-infringed," D. 722 at 14, and the PTO reissued the patent in 2010 despite invalidity claims pending against it at the time, id.

a) Evidence of Patent Invalidity

Plaintiffs argue that their evidence demonstrates that the '838 patent was invalid for obviousness. D. 850 at 17. Subject matter cannot be patented if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." *35 U.S.C. § 103*. Obviousness is a mixed question of law and fact. See [*InTouch Techs., Inc. v. VGo Commuc'ns, Inc., 751 F.3d 1327, 1347 (Fed. Cir. 2014)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5C5C-R381-F04B-M021-00000-00&context=). An obviousness determination will often require that a court "look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." **[\*57]**[*UFCW v. Novartis Pharms. Corp., No. 15-cv-12389, 2017 U.S. Dist. LEXIS 102389, at \*36 (D. Mass. June 30, 2017)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5NXC-BKF1-F04D-D0VG-00000-00&context=) (quoting [*KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 418, 127 S. Ct. 1727, 167 L. Ed. 2d 705 (2007))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4NM5-WKN0-004C-101K-00000-00&context=)." Objective indicia of nonobviousness are often the most probative evidence of nonobviousness in the record and help protect against the use of hindsight in the analysis. [*InTouch, 751 F.3d at 1347*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5C5C-R381-F04B-M021-00000-00&context=).

Here, Plaintiffs' expert, pharmaceutical professor at the Wilkes University School of Pharmacy Arthur Kibbe, Ph. D., concludes that the claims of the '838 patent were obvious. D. 732-12 ¶¶ 1, 19, 144 ("Kibbe Rpt."). Kibbe relies upon controlled release minocycline formulations from 1989 through 1995, by Valorose, Dwyer and a Minocin label. Id. ¶¶ 151-59; D. 724-1 ¶ 60; D. 847 ¶ 60. In 1996, "a modified release minocycline was disclosed" in a publication studying the "[s]afety of long-term high-dose minocycline in the treatment of [a]cne." Kibbe Rpt. ¶ 160. Kibbe concludes that a person of "ordinary skill in the art would find it obvious to combine Valorose (1989), the Minocin MR label, Dwyer (1994), and Goulden (1996) to achieve the inventions claims in each of the independent claims of the '838 patent." Id. ¶ 162.

Defendants argue that Kibbe's report is conclusory and relies upon impermissible hindsight. See D. 716; D. 722 at 16; D. 727 at 4-11. Hindsight is generally considered "read[ing]**[\*58]** into the prior art the teachings of the invention in issue." [*Mintz v. Dietz & Watson, Inc., 679 F.3d 1372, 1378 (Fed. Cir. 2012)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:55S6-BSD1-F04B-M0PP-00000-00&context=) (quoting [*Graham v. John Deere Co., 383 U.S. 1, 36, 86 S. Ct. 684, 15 L. Ed. 2d 545 (1966))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-G940-003B-S46K-00000-00&context=). Defendants argue, using Kibbe's deposition testimony as fodder, that he "go[es] looking for references that have the elements," that his methodology involved relying upon hindsight. D. 727 at 8. Plaintiffs argue that Kibbe merely "described the process by which one of ordinary skill in the art would search for and consider prior art references, and then performed the steps himself." D. 848 at 16. Defendants aver that Kibbe should have applied the "teaching, suggestion, or motivation (TSM) test," [*Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc., 520 F.3d 1358, 1364 (Fed. Cir. 2008)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4S5X-4040-TXFN-62K1-00000-00&context=). D. 899 at 12. In the very case Defendants cite, however, which was a patent suit and not an ***antitrust*** suit, the court emphasized that the application of the test must be flexible, so as not to "unduly confine the use of the knowledge and creativity within the grasp of an ordinarily skilled artisan." [*Ortho-McNeil, 520 F.3d at 1364*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4S5X-4040-TXFN-62K1-00000-00&context=). Given Kibbe's reliance on both supporting literature and his own expertise, the Court is not persuaded that his report is inadmissible on this basis.

Defendants also argue that any expert opining on obviousness must provide an explanation as to why a person of ordinary skill would have combined the prior art references and**[\*59]** Kibbe has not done so here. D. 727 at 5-6; see [*Veracode, Inc. v. Appthority, Inc., 137 F. Supp. 3d 17, 38 (D. Mass. 2015)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5H23-0Y71-F04D-D02X-00000-00&context=); [*InTouch, 751 F.3d at 1348-49*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5C5C-R381-F04B-M021-00000-00&context=). Plaintiffs argue, however, that Kibbe provides this necessary link in his "road map" paragraph, in which he explains that a person skilled in the art would seek to combine "a known excipient" with the "active pharmaceutical ingredient" to produce a "stable" dosage that "will release the active ingredient in a manner that supports good therapy," Kibbe Rpt. ¶ 84.[[19]](#footnote-18)19 D. 848 at 7-8. This roadmap is a general statement that applies to his obviousness analyses of multiple Solodyn patents; it is not specific to the '838 patent. See Kibbe Rpt. ¶ 84. Although Kibbe's failure to provide more of a specific explanation as to motivation to combine the prior art, that flaw is not sufficient reason to exclude Kibbe's opinion. First, the standard for their showing in this ***antitrust*** suit, as opposed to a patent case, is lower.[[20]](#footnote-19)20 Second, Defendants have not presented any objective indicia of nonobviousness that Kibbe should have, but failed to, consider, which would provide stronger grounds that his report is conclusory or otherwise unreliable. See [*InTouch, 751 F.3d at 1347*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5C5C-R381-F04B-M021-00000-00&context=). Defendants' objections to Kibbe's report "question the factual underpinnings" of his investigation, and, therefore,**[\*60]** go to the weight of his testimony, not to its admissibility. See [*Crowe v. Marchand, 506 F.3d 13, 18 (1st Cir. 2007)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4PY1-3BJ0-TXFX-32RY-00000-00&context=). Defendants can challenge his conclusions through cross-examination at trial. The Court denies their motion to exclude his opinion, D. 716.

Plaintiffs also proffer the opinion of patent law expert John Thomas, whose report concludes that Medicis would have had "a virtually zero percent chance (i.e., less than 5 percent) of prevailing against any of the generic companies in litigation over the '838 patent." D. 732-10 ¶ 122 ("Thomas Rpt."). Defendants argue that Thomas's expert opinion should be excluded, as should the opinion of economics professor Peter Hardigan, because it relies upon Thomas's improper opinion. D. 713. Defendants generally argue that Thomas is unqualified to opine on the validity or infringement of the Solodyn patents because he is not skilled in the requisite art. D. 731 at 10-13.[[21]](#footnote-20)21 Thomas, however, does not opine on the technical or scientific validity of the patents, but rather, relies upon Plaintiffs' technical experts' conclusions as bases for his own conclusions, based upon his own expertise and experience in the field of patent law, regarding Medicis's likelihood of success in patent litigation. D. 855 at**[\*61]** 13; see [*Wellbutrin XL, 868 F.3d at 169*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5P8F-M5D1-F04K-K049-00000-00&context=); [*Lidoderm, 2017 U.S. Dist. LEXIS 182940, at \*117-20*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5PW6-FR61-F04C-T49K-00000-00&context=).[[22]](#footnote-21)22 To the extent Defendants seek to challenge Thomas's conclusions as to the likely outcome of the patent challenges, they may do so with their own expert testimony—as they have proposed to do, with experts Wagner and Langer.[[23]](#footnote-22)23

Defendants argue that Thomas's opinion on the litigation timeline for the Medicis-Impax patent dispute is unreliable and speculative, D. 731 at 19-24, and on this aspect of Thomas's opinion, the Court agrees. Thomas's conclusions regarding expected time of trial (and resolution of any subsequent appeal) rely upon court documents from the patent dispute, statistics from the Federal Circuit, and other relevant patent suits. Thomas Rpt. ¶¶ 230-32. Plaintiffs also point out that in King Drug Co. of Florence v. Cephalon, Inc., the court held that Thomas's opinion establishing a likely timeline for FDA approval satisfied [*Rule 702*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5GYC-2991-FG36-120S-00000-00&context=)'s reliability requirement, [*King Drug, No. 2:06-cv-1797, 2015 U.S. Dist. LEXIS 182030, 2015 WL 12645764, at \*4 (E.D. Pa. Dec. 22, 2015)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5M12-M9G1-F04F-407J-00000-00&context=). D. 855 at 20 n.71. That such review leads Thomas to the opinion that Medicis or Impax could have expected litigation would have led to a final judgment within eighteen months, even when such timeline was not achieved in other contemporaneous Solodyn patent cases, seems unsupported**[\*62]** by the record even as proffered by Plaintiffs. See D. 855 at 20. Accordingly, Thomas's opinion on this point is excluded. That is, however, not to say that Plaintiffs are barred from proffering factual evidence about the time to trial of other Solodyn cases as a basis for later arguing this point to a jury, nor was it impermissible for Hardigan, Leffler and others to rely upon a 'hypothetical' length of litigation of eighteen months to address impact of anticipated litigation costs on the likelihood of but-for scenarios. The Court, therefore, will not strike those opinions on this basis. Such a timing estimate is permissible to estimate litigation costs, as Plaintiff experts Hardigan, Leffler and others did to opine on whether Impax would have launched at-risk, or whether the parties would have entered into an alternative settlement. The Court thus allows Defendants' motion to exclude Thomas's opinion regarding a litigation timeline, including time to trial and resolution of appeal, but denies Defendants' motion to exclude Hardigan's testimony.

In light of Kibbe's expert opinion on obviousness and Thomas's expert opinion on Medicis's low likelihood of success in the patent litigation,**[\*63]** Plaintiffs have provided "some evidence" of the invalidity of Medicis's patent, sufficient to raise a genuine dispute of material fact on this causation theory and overcome Defendants' motion for summary judgment.

b) Evidence of Patent Unenforceability on Inequitable Grounds

Plaintiffs argue that Impax was likely to prevail in its patent litigation against Medicis because the '838 patent was unenforceable as a result of Medicis's inequitable conduct. D. 850 at 17-18; cf. [*Lidoderm, 2017 U.S. Dist. LEXIS 182940, at \*59-61*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5PW6-FR61-F04C-T49K-00000-00&context=). Establishing patent unenforceability on this basis requires a showing by clear and convincing evidence that "the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it." [*Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1290 (Fed. Cir. 2011)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:52YB-5241-652G-21HV-00000-00&context=). Patent ***regulations*** impose upon filers of patent applications a "duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability." [*37 C.F.R. § 1.56*](https://advance.lexis.com/api/document?collection=administrative-codes&id=urn:contentItem:5NK5-F6W0-008H-01CX-00000-00&context=). "When an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art." [*Therasense, 649 F.3d at 1291*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:52YB-5241-652G-21HV-00000-00&context=). Plaintiffs' expert John Doll ("Doll"), former acting director of the PTO, states**[\*64]** that Medicis failed to disclose material information—that Dynacin, a previously-available minocycline, had been on sale for at least five years prior to the '838 patent application—which, if disclosed, would have caused the PTO to reject its application. D. 850 at 17-18; D. 738-2 ¶¶ 10-12 ("Doll Reply").

This Court rejected this theory as part of concluding that Plaintiffs had failed to allege plausibly sham litigation claims under *Section 2*. See D. 184 at 25-26. The Court held then that given that Medicis ultimately provided the Dynacin Study to the PTO during the patent re-examination process in 2008, Plaintiffs had failed to present substantial evidence that Impax could have succeeded in an unenforceability showing based on inequitable conduct. Id. Plaintiffs argue now, however, that Doll "explains why the latter reexamination process could not cleanse Medicis's failure to have submitted that information during the original examination" because "[b]y statute, the PTO could not consider information about the on-sale bar in the context of the reexamination and could consider only prior art publications and patents." D. 850 at 18; Doll Reply ¶¶ 29-30. Defendants argue that Doll's testimony alone is insufficient**[\*65]** to create a genuine dispute of material fact on this issue. D. 893 at 11.

Defendants have also moved to exclude Doll's opinion based on his qualifications and various alleged flaws with his reports. D. 715. Defendants argue that Doll is unqualified to opine on issues of patent noninfringement or invalidity because he is not a person of ordinary skill in the pertinent art. D. 730 at 6-9; see [*Sundance, Inc. v. DeMonte Fabricating Ltd., 550 F.3d 1356, 1363 (Fed. Cir. 2008)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4V71-YP50-TXFN-63B9-00000-00&context=); Fontem Ventures, B.V. v. NJOY, Inc., No. 14-cv-1645, 2015 WL 12743861, at \*19 (C.D. Cal. Oct. 22, 2015) (excluding Doll opinion on patent validity). Doll nevertheless analyzes the '838 patent as compared to the preexisting Dynacin formulation. D. 730 at 6-7; D. 738-1 ¶¶ 60-61 ("Doll Rpt."). Plaintiffs argue that Doll has sufficient experience, due to his thirty-five year career at the PTO, training in chemistry, and the fact that the PTO would have considered him qualified to review the '838 patent application. D. 846 at 6-7. Although that does not qualify him to opine on legal conclusions, that does qualify him to opine on what a reasonable patent officer would find material in a patent application. See [*Holmes Grp., Inc. v. RPS Prods., No. 03-40146-FDS, 2010 U.S. Dist. LEXIS 102727, at \*16 (D. Mass. June 25, 2010)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:514B-46N1-652H-V002-00000-00&context=); cf. [*Asacol, 323 F.R.D. 451, 2017 U.S. Dist. LEXIS 186009, at \*58-59*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5PXG-01N1-JBT7-X2KX-00000-00&context=) (permitting former FDA commissioner to opine on what the FDA would have done regarding a different formulation**[\*66]** of the drug).[[24]](#footnote-23)24

Defendants next argue that his opinion on inequitable conduct, including materiality and intent, should be excluded. D. 730 at 9-14. Plaintiffs argue that Doll can opine on the materiality of the Dynacin study—both from his perspective and that of a hypothetical examiner. See [*Holmes Grp., Inc., 2010 U.S. Dist. LEXIS 102727, at \*16*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:514B-46N1-652H-V002-00000-00&context=). Doll cannot testify, however, to Medicis's intent in any alleged nondisclosure. See [*id. at \*15*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4PY1-3BJ0-TXFX-32RY-00000-00&context=). The Court thus allows Defendants' motion to exclude Doll's expert opinion, D. 715, only to the extent that it seeks to exclude Doll's opinion on Medicis's intent and legal conclusions, but denies the motion to exclude Doll's opinion as to PTO policies and procedures and what a reasonable patent officer would find important in a patent application.

Even if Doll's opinion were sufficient to establish materiality, Plaintiffs must also demonstrate that Medicis withheld the Dynacin study "with an intent to deceive or mislead." [*Holmes Grp., Inc., 2010 U.S. Dist. LEXIS 102727, at \*36*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:514B-46N1-652H-V002-00000-00&context=); see [*Therasense, 649 F.3d at 1290*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:52YB-5241-652G-21HV-00000-00&context=) (explaining that "a district court may not infer intent solely from materiality"). Intent to deceive is ordinarily a question of fact. See [*Meds. Co. v. Mylan Inc., No. 11-cv-1285, 2014 U.S. Dist. LEXIS 61084, at \*15 (N.D. Ill. May 2, 2014)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5C3X-3DM1-F04D-7080-00000-00&context=); [*Holmes Grp., Inc., 2010 U.S. Dist. LEXIS 102727, at \*36*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:514B-46N1-652H-V002-00000-00&context=); To demonstrate intent, "the accused infringer must prove by clear and convincing evidence that the applicant**[\*67]** knew of the reference, knew that it was material, and made a deliberate decision to withhold it." [*Therasense, 649 F.3d at 1290*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:52YB-5241-652G-21HV-00000-00&context=). "Proving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO" is insufficient. Id. Defendants argue that Plaintiffs cannot meet this standard, as they present only expert testimony of the Medicis inventor's intent to deceive, which is inadmissible. D. 722 at 18-19 (citing [*ART+COM Innovationpool GmbH v. Google Inc., 155 F. Supp. 3d 489, 510 (D. Del. 2016))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5JMY-V9J1-F04D-019G-00000-00&context=). Defendants are correct that Plaintiffs face a high bar in proving intent, and that expert testimony as to another's state of mind is inadmissible, but intent is often shown through circumstantial evidence. See [*Therasense, 649 F.3d at 1290*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:52YB-5241-652G-21HV-00000-00&context=) (explaining that "[b]ecause direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence"); [*ART+COM, 155 F. Supp. 3d at 503*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5JMY-V9J1-F04D-019G-00000-00&context=). "However, to meet the clear and convincing evidence standard, the specific intent to deceive must be 'the single most reasonable inference able to be drawn from the evidence.'" [*Therasense, 649 F.3d at 1290*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:52YB-5241-652G-21HV-00000-00&context=) (quoting [*Star Sci., Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1366 (Fed. Cir. 2008))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4T9J-23J0-TX4N-G1MB-00000-00&context=). Plaintiffs argue that the Dynacin formulation that was the subject of the study at issue was on sale in the United States beginning in 1992, and that Dr. Eugene Gans ("Gans"), the Chairman of Medicis's**[\*68]** Central Research Committee, published the Dynacin study in a Medicis promotional publication in 1997. Doll Rpt. PP 47, 52; Thomas Rpt. ¶ 108; D. 847 ¶ 16.[[25]](#footnote-24)25 Gans himself then filed the patent application in February 1998 that was issued as the '838 patent. Doll Rpt. ¶ 57. Gans submitted the study to the FDA in April 1998 but did not submit it to the PTO. Thomas Rpt. ¶ 108. This evidence amounts to circumstantial evidence of knowledge of the study, coupled with the context of expert testimony about materiality, such that a jury could infer that Gans and Medicis possessed the specific intent to deceive the PTO by omitting it from the Solodyn application. See [*ART+COM, 155 F. Supp. 3d at 503*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5JMY-V9J1-F04D-019G-00000-00&context=) (finding that evidence that the withheld information was "known in the art" at the time the application was filed could give rise to the inference of intent to deceive).

c) Evidence of Patent Noninfringement

Plaintiffs also argue that there is no evidence that Impax's generic minocycline would have infringed Medicis's '838 patent. D. 850 at 15-16; see 747-1 at 16-26. Plaintiffs first rely on an anticipation theory, explaining that Dynacin, a previously-available minocycline, invalidates Medicis's subsequent '838 patent. D. 850 at 15. Alternatively, if Medicis**[\*69]** is correct that Dynacin does not invalidate the patent, then likewise, Impax's generic formulation could not have infringed it. D. 850 at 16.

Plaintiffs argue that Defendants have failed to proffer any evidence that Impax would have induced infringement of the '838 patent or any later patents. D. 850 at 16-17. Plaintiffs seek to exclude portions of the expert opinions of Dr. Robert S. Langer ("Langer") and R. Polk Wagner ("Wagner") that opine on infringement. D. 751. Plaintiffs argue that Langer's opinion fails to reach any conclusion as to infringement on the Solodyn patents. D. 751-1 at 7-8. They argue that his opinion would, therefore, fail to help the jury decide any fact in issue. D. 751-1 at 9. Defendants argue, however, that Langer's opinion is rebuttal to counter Kibbe's opinion on infringement. D. 863 at 6-8. As such, even if he fails to conclude that an accused product did or did not infringe a claim, his conclusions serve to demonstrate weaknesses in Kibbe's conclusions, which could be helpful to a jury. Plaintiffs argue that because Langer's opinions are incomplete, they would, therefore, mislead the jury. D. 914 at 10. The Court is not persuaded that traditional methods such as cross-examination**[\*70]** and limiting instructions are insufficient to allow Plaintiffs to stress such alleged weaknesses. Finally, to the extent Plaintiffs seek to exclude portions of Wagner's opinion because it relies upon Langer's opinion, the Court does not find fault with it. Experts are permitted to rely on one another's opinions in forming their own conclusions, and the Court declines to exclude Langer's report here. Absent any other objection, the Court denies Plaintiffs' motion to exclude portions of Langer's and Wagner's expert opinions, D. 751.

Plaintiffs present additional reasons why Impax's launch would not have infringed Medicis's patent, D. 850 at 16-17, but the Court declines to address them here. Defendants have objected to Plaintiffs' noninfringement arguments as untimely, D. 722 at 19; D. 823, and after reviewing the parties' positions on the matter, e.g., D. 823; D. 825, this Court previously ruled that considering this issue on summary judgment would be unduly prejudicial to Defendants. D. 827. The Court, therefore, struck this portion of Plaintiffs' summary judgment motion. Id.

d) Impax's Willingness to Launch At-Risk

Evidence of Impax's willingness to launch at-risk, based on Impax's contemporaneous**[\*71]** statements and actions, is also relevant to Plaintiffs' pursuit of this but-for scenario. See [*Lidoderm, 2017 U.S. Dist. LEXIS 182940, at \*52-54*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5PW6-FR61-F04C-T49K-00000-00&context=); [*Wellbutrin XL, 133 F. Supp. 3d at 767*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5H0G-1WK1-F04F-414G-00000-00&context=); [*Nexium, 42 F. Supp. 3d at 270-71*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5D2K-NTJ1-F04D-D04Y-00000-00&context=).

Although Defendants argue that there is no evidence of Impax's willingness to launch at-risk, in summer 2008, the Impax board approved at-risk launch with a few conditions. D. 722 at 12-13. Defendants argue that this "limited, conditional board approval for an at-risk launch confirms the baselessness of Plaintiffs' but-for world." D. 722 at 13. Additionally, Defendants argue that it would not have made economic sense for Impax to launch at-risk as Plaintiffs contemplate. Id. They explain that Impax would have launched at the same time as Teva in this but-for world, "significantly reduc[ing] the potential upside" of such a decision. Id.

Plaintiffs offer the board approval vote, which contemplated myriad scenarios upon an at-risk launch and did not include the specific conditions Defendants suggest. D. 850 at 19-20. Impax also took orders from customers—Plaintiffs estimate the orders secured eighty-four percent of the market—and manufactured at least three months of supply. D. 850 at 20. Finally, Plaintiffs argue that Impax's actions "make perfect sense," citing Plaintiffs' expert Dr. Thomas**[\*72]** McGuire's ("McGuire") analysis of Impax's projected profits. Id.; D. 732-16 ¶¶ 257-71 ("McGuire Rpt."). As will be detailed further in Scenario B, McGuire opines that even assuming Impax won the litigation suit, the expected litigation costs vastly exceed the anticipated profits. Id. ¶¶ 255-56.

Plaintiffs have presented sufficient evidence to show that Impax was willing to launch at-risk. At best, the facts provided by both parties could support inferences in either direction, and reading all reasonable inferences in Plaintiffs' favor on Defendants' motion for summary judgment, Defendants have not shown the contrary as a matter of undisputed fact.

e) The '705 patent

Finally, Defendants argue that Plaintiffs cannot prove this at-risk launch causation theory without also proving that Impax would have prevailed against the subsequently issued '705 patent. D. 722 at 19-20. The question when analyzing an at-risk launch but-for scenario is whether the plaintiffs have produced some evidence that the generic manufacturer would have and could have launched at-risk. See [*Nexium, 842 F.3d at 63*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5M73-M0F1-F04K-H003-00000-00&context=). Courts analyze this question to determine whether a valid patent served as "an independent ***regulatory*** bar to [a generic's] launch." Id. (quoting [*Wellbutrin XL, 133 F. Supp. 3d at 767*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5H0G-1WK1-F04F-414G-00000-00&context=)**[\*73]**). Plaintiffs argue that the '705 patent would not have served as a bar to Impax's generic entry because the '705 patent did not issue until September 10, 2010, long after the at-risk launch dates contemplated in Plaintiffs' but-for scenarios. D. 850 at 18. Defendants reply that "a patent owner may recover damages for infringement of a published patent application prior to the issuance date," and the '705 patent application was published was February 12, 2009, prior to the earliest at-risk launch dates Plaintiffs have proposed. D. 893 at 12 (citing *35 U.S.C. § 154(d)*). Even if this is true, however, as to the ability to recover damages up to the date the application was published does not mean that the '705 patent would have served as "an independent ***regulatory*** bar" to Impax's launch from that date, see [*Nexium, 842 F.3d at 63*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5M73-M0F1-F04K-H003-00000-00&context=). To be entitled to such "pre-issuance royalties," Medicis would need to demonstrate that Impax had actual notice of the '705 patent application and that "the invention as claimed in the patent is substantially identical to the invention as claimed in the published patent application," *35 U.S.C. § 154(d)(2)*. [*K-TEC, Inc. v. Vita-Mix Corp., No. 2:06-cv-108-TC, 2010 U.S. Dist. LEXIS 51858, at \*21-22 (D. Utah May 24, 2010)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:7YJP-J941-2RHM-J018-00000-00&context=).

Defendants have failed to demonstrate as a matter of law that the '705 patent would serve as an independent bar to Impax's at-risk launch. Although Defendants are correct that Plaintiffs must provide evidence of noninfringement as part of their at-risk scenario, Plaintiffs need only provide "some evidence" that their at-risk launch would have been lawful. They have done that through Kibbe's expert report. Kibbe explains that one claim of the '705 patent is irrelevant to generics, as it requires a particular weight ratio the generics do not have. Kibbe Rpt. ¶¶ 14, 81. Kibbe also concludes that all of the claims of the '705 patent would have been obvious to a person of ordinary skill in the art and explains the bases for his conclusions. Id. ¶¶ 105-23. Defendants reiterate their objections to Kibbe's expert testimony, D. 722 at 19-20, but the Court has addressed those issues and ruled that Kibbe's report is admissible. Plaintiffs have proffered sufficient evidence of noninfringement as to this '705 patent to withstand Defendants' summary judgment motion.

*2. Scenario B: A No-Payment Settlement Agreement Would Have Allowed Impax to Launch Prior to November 2011*

Plaintiffs'**[\*74]** second but-for theory of causation contemplates a scenario in which the parties would have agreed to a settlement where no payment was made and early generic entry was allowed. D. 850 at 10; see [*Lidoderm, 2017 U.S. Dist. LEXIS 182940, at \*63-66*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5PW6-FR61-F04C-T49K-00000-00&context=) (holding that a no-payment settlement theory is cognizable); [*Wellbutrin XL, 133 F. Supp. 3d at 757*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5H0G-1WK1-F04F-414G-00000-00&context=).

Plaintiffs point out that Impax and Medicis each contemplated Impax launch dates prior to November 2011 in their respective documents during settlement negotiations. D. 850 at 10 n.31. Defendants argue that nothing in the record suggests that "Impax and Medicis ever discussed or negotiated a licensed entry date earlier than November 2011." D. 722 at 20. Requiring such evidence, however, would be an almost impossible standard to require of Plaintiffs, given that this is a but-for scenario. See [*Lidoderm, 2017 U.S. Dist. LEXIS 182940, at \*133-34*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5PW6-FR61-F04C-T49K-00000-00&context=) (explaining that "[b]ecause this case is set in a but-for world, it is not surprising that no evidence shows that defendants were contemplating anything other than the actual [s]ettlement"). That is, if, as Plaintiffs contend, Medicis and Impax were acting unlawfully to eliminate competition throughout their settlement negotiations, then it is unreasonable to expect a paper trail signifying rational, lawful business choices.

Plaintiffs primarily**[\*75]** rely upon expert opinions—specifically the opinions of McGuire and Leffler—to support this causation theory. D. 850 at 10-12. Defendants criticize these expert opinions and seek their exclusion. D. 722 at 20-21; see D. 712; D. 744. They argue that both experts' conclusions are "speculative, counterfactual, and based on flawed methodology," with the unreliability of their conclusions evidenced by the fact that the date ranges for entry differ. D. 722 at 21.

McGuire relied upon "the parties' financial planning documents" to determine a date range that comprises both "the *earliest* entry date a reasonable brand pharmaceutical company in the position of Medicis would have agreed to in a settlement without a reverse payment," focusing on the date that leaves Medicis just as well off as if it did not settle, and "the *latest* date of entry that a reasonable generic pharmaceutical company in the position of Impax would have agreed to in such a settlement," when entry would leave Impax as well off as at-risk entry. McGuire Rpt. ¶ 275 (emphasis in original). McGuire explains that if the latest date acceptable to Impax is later than the earliest date acceptable to Medicis, then a settlement with**[\*76]** a compromise date is feasible. Id. ¶ 276. McGuire first opines, using anticipated litigation costs as compared to expected profits, that a generic company in Impax's position acting rationally would have sought settlement as early in the patent litigation process as possible. Id. ¶¶ 252-56. Using Medicis's forecasts of Solodyn profits, McGuire then concludes that February 2009 is the earliest date acceptable to Medicis, and using Impax's forecasts for expected generic Legacy Strength profits, McGuire finds that June 2009 is the latest date acceptable to Impax. D. 850 at 11-12; McGuire Rpt. ¶¶ 281, 286. He thus concludes that the entry contemplated by a no-payment settlement would have occurred between February and June 2009. McGuire Rpt. ¶ 287. Plaintiffs also reference McGuire's "stock price event study" and explain that it is "an independent but confirmatory analysis" that supports these findings.[[26]](#footnote-25)26 D. 850 at 12 n.36; see McGuire Rpt. ¶ 290.

Defendants seek to exclude portions of McGuire's opinion. D. 744. Defendants mostly criticize his stock market "event study" and argue that it does not "fit" a reverse payment case. D. 722 at 21; D. 744-1 at 13-16. In Nexium, McGuire was an expert**[\*77]** for the plaintiffs, and he presented an "event study" there specifically to support a no-payment settlement date, which the district court excluded under the Daubert standard. [*Nexium, 842 F.3d at 48*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5M73-M0F1-F04K-H003-00000-00&context=). The First Circuit held that the district court did not abuse its discretion in excluding the study, as the methodology—econometric analysis of stock market data—did not fit the conclusions for which it was offered—an estimate of an entry date in an alternative settlement scenario. [*Id. at 52*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5M73-M0F1-F04K-H003-00000-00&context=). Plaintiffs have not expounded on how the stock price event study is a better fit here than in Nexium. Thus, to the extent Plaintiffs seek to use McGuire's the stock price event study to support his alternative settlement dates, they have failed to show an adequate fit between the two. To the extent, however, that McGuire's stock price event study is meant to demonstrate the anticompetitive nature of the reverse payment through observations about reverse payment settlements in the past—which appears to be McGuire's intention in his report—he may do so.[[27]](#footnote-26)27

Defendants also criticize McGuire's other methodology for determining the no-payment settlement date range. D. 722 at 21; D. 744-1 at 17-20. Defendants argue that McGuire's**[\*78]** opinion on estimated litigation costs should be excluded because his expertise is economics and not patent law, D. 744-1 at 18, but McGuire's estimates are not legal predictions, but rather rely upon industry surveys and Medicis's and Impax's own representations. D. 852 at 22. Defendants also argue that McGuire's opinion improperly relies upon Plaintiff expert Thomas's conclusion of Medicis's five percent likelihood of success in the patent dispute. D. 744-1 at 22-23. McGuire may rely upon this opinion of Thomas's, however, where that opinion has not been excluded here. See *Ferrara & DiMercurio v. St. Paul Mercury, 240 F.3d 1, 9 (1st Cir. 2001)*; [*Lidoderm, 2017 U.S. Dist. LEXIS 182940, at \*132-34*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5PW6-FR61-F04C-T49K-00000-00&context=). Finally, Defendants seek exclusion of McGuire's opinions that address "what an entity would have done under circumstances that never occurred." D. 744-1 at 21. Defendants are correct that experts cannot opine on the intent, motives or states of mind of corporations, see, e.g., [*In re Rezulin Prods. Liab. Litig., 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4C2G-8490-0038-Y3WP-00000-00&context=), but that is not what McGuire does in his report, D. 852 at 23-24; see [*Lidoderm, 2017 U.S. Dist. LEXIS 182940, at \*143-44*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5PW6-FR61-F04C-T49K-00000-00&context=) (explaining that testimony about what companies are "prepared to do" based on record evidence is not "motivation" or "state of mind" testimony), or what he would be permitted to do at trial. The Court will not prevent McGuire from opining on a but-for scenario as**[\*79]** a general matter. Thus, Defendants' motion to exclude his testimony, D. 744, is allowed to the extent McGuire would have used his stock price event study to support his proposed date range or to the extent that he seeks to opine on intent, motive or states of mind of corporations. Otherwise, it is denied.

Leffler also opines on this causation theory. Leffler Rpt. ¶¶ 75-84. He evaluates the expected profits from litigation as compared to that from a no-payment alternative settlement, explaining that if the latter exceed the former, the settlement would be economically efficient and thus acceptable to Medicis. Id. ¶ 80. He calculates Medicis's expected value of litigation as the sum of the expected profit from a Medicis win—guaranteeing Medicis' monopoly until the patent's February 2018 expiration—and a Medicis loss—which would have allowed Impax generic entry in March 2009, a date he calculates based on the FDA's approval of its ANDA in February 2009—weighted by the expectation of win or loss. Id. ¶¶ 81, 83 n.93. He concludes that the entry range would have fell between September 22 and October 1, 2009. Id. ¶ 84.

Defendants seek to exclude Leffler's opinion on the no-payment entry date.**[\*80]** D. 712. They argue that his model "relies on assumptions with no foundation in record evidence, yields nonsensical results when tested, and is based on a novel, non-peer-reviewed methodology that has not been accepted by the economic community." D. 722 at 21; see D. 726 at 9-10. The Court is not persuaded that Defendants' challenges warrant exclusion under Daubert. First, Defendants argue that Leffler's opinion is speculative because there is no record evidence that Medicis and Impax discussed a no-payment settlement, D. 726 at 12, but Defendants would have this causation theory rise and fall solely on whether there is evidence that, essentially, the but-for scenario in question actually occurred. As the Court has stated, that is not and cannot be the standard. Second, Defendants argue that Leffler's opinion is not founded on well-established economic principles. D. 726 at 9. Leffler states his methodology "follows the standard and accepted economic analysis of settlements by evaluating the expected profits from litigation as compared to that from an alternative settlement," and cites to numerous sources. Leffler Rpt. ¶¶ 80, 80 n.89. Defendants argue, however, that these sources do**[\*81]** not "employ or teach" the particular analysis he attempts. D. 726 at 10-11. Plaintiffs have detailed the economic theories provided in Leffler's sources that appear to support his methodology. D. 849 at 12-13. That this particular analysis is not provided in his source material does not automatically defeat Leffler's report. In Lidoderm, Leffler presented a similar analysis, and the defendants presented the same challenge, and the court explained that "that prior experts or academics have not combined different but *accepted* economic theories and modes of analysis for patent settlements and then applied them to this specific set of facts . . . is not surprising and does not require exclusion." [*Lidoderm, 2017 U.S. Dist. LEXIS 182940, at \*131*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5PW6-FR61-F04C-T49K-00000-00&context=) (denying defendants' motion to exclude Leffler's opinion). Third, Defendants argue that Leffler's study erroneously assumes that Medicis's probability of success in the patent litigation was only five percent, and does not consider that even if that number were accurate, Medicis and Impax would not have both perceived that likelihood of Medicis's success. D. 726 at 15. This and Defendants' similar critiques of Leffler's model, however, are best addressed by cross-examination. The Court thus denies**[\*82]** Defendants' motion to exclude Leffler's expert opinion, D. 712.

In light of Plaintiffs' proposed evidence, then, using Impax and Medicis documentation and the admissible expert opinions of McGuire and Leffler, Plaintiffs have presented sufficient factual support for this causation theory to withstand summary judgment.

*3. Additional Arguments*

Defendants raise a few objections about Plaintiffs' contentions regarding causation more broadly. They argue that the Impax-Medicis Settlement did not prevent other generic entry: Teva, Sandoz and Mylan still launched before November 2011 and generic Solodyn was available and sold from March 2009 forward. D. 722 at 22. Defendants argue here that supply actually exceeded demand, as evidenced by substantial returns of generic product, during that time. D. 722 at 23. As Plaintiffs point out, however, D. 850 at 21-22, this Court has rejected this argument before (in connection with class certification) because the "brief generic entry by generic competitors in 2009 and 2010 did not establish unfettered competition between generics and brand Solodyn," D. 682 at 17. Defendants' dispute about whether the Medicis-Impax agreement stifled competition goes to**[\*83]** the heart of the ***antitrust*** question of this case and it remains a question for the jury to resolve. See D. 682 at 18.

Defendants also argue that Plaintiffs' causation arguments fail because the Impax-Medicis Settlement had no effect on prescriptions of Solodyn Add-On Strengths. D. 722 at 23-24. They explain that because generic Legacy Strengths are not AB-rated equivalents to Add-On Strengths, and automatic substitution only occurs for AB-rated generic equivalents, the Impax-Medicis settlement had no effect on prescriptions for Solodyn Add-On Strengths. D. 722 at 24. Additionally, Defendants argue that physicians prescribed patients with Add-On Strengths in accordance with FDA weight-based guidance and there is no evidence that physicians would have done otherwise. Id. As this Court explained in regard to class certification, however, if the jury finds that the Medicis-Impax agreement was unlawfully anticompetitive, and that—as Plaintiffs argue—without it, some of the actual conversion to the Add-On Strengths would not have occurred, then a reasonable juror can conclude that the Medicis-Impax agreement caused overcharges for at least some portion of Add-On Strength purchasers. D. 682**[\*84]** at 20. Defendants are correct that the standard of proof is different at summary judgment than at class certification, see D. 893 at 15, but Plaintiffs have presented expert clinical opinion suggesting that Add-On Strengths do not always serve the same purpose and provide the same treatment as Legacy Strengths, Vashi Rpt. ¶ 24, economic reports substantiating the claim that conversion is generally more difficult when the first branded drug faces full competition, D. 944 at 65, 74-75 ("Leitzinger Reb."), and expert testimony detailing Medicis' execution of the conversion here, McGuire Rpt. ¶¶ 40-44. D. 847 ¶ 108. Plaintiffs also point to Medicis's own forecast data, predicting that the move to Add-On Strengths would be less successful with full-fledged generic competition, see D. 850 at 23 n.95. In sum, Plaintiffs have shown a genuine dispute of fact on this issue.

**C. Claims Arising from Lupin and Sandoz Settlements**

Finally, Defendants seek summary judgment for all claims arising from Medicis's settlements with Sandoz and Lupin. D. 719. Defendants have explained that Retailer Plaintiffs were willing to dismiss *Section 1* claims only after receiving final approval from the Court for the then-pending**[\*85]** class settlements with Lupin and Sandoz, and that Retailer Plaintiffs nevertheless intended to pursue *Section 2* claims on the basis of Medicis's settlements with Sandoz and Lupin. D. 723 at 5, 9.[[28]](#footnote-27)28 After the summary judgment motion deadline, the Court approved the Lupin and Sandoz settlements with the DPP and EPP classes.[[29]](#footnote-28)29 D. 806; D. 808. The Court then issued an order on December 8, 2017 informing the parties that in light of its approval of the settlements, unless they contended otherwise, the Court would dismiss Defendants' third summary judgment motion as moot. D. 832.[[30]](#footnote-29)30 Retailer Plaintiffs filed a response to the Court's order arguing that Defendants' summary judgment motion "is only partly moot." D. 834 at 4. Now conceding that they are no longer pursuing *Section 1* claims arising from the Lupin and Sandoz settlements or *Section 2* claims based upon the Lupin settlement, Retailer Plaintiffs argue that Defendants' motion is "not moot insofar as it seeks to preclude Retailer Plaintiffs from relying on the Sandoz settlement as an element of Medicis's alleged *section 2* violations." D. 834 at 5-6. The Court thus focuses on Defendants' summary judgment motion only as it pertains to Retailer Plaintiffs' *Section 2* claim arising from the**[\*86]** Medicis-Sandoz settlement.

*Section 2* monopolization claims require that plaintiffs demonstrate "(1) possession of monopoly power in a relevant market [by the defendant]; and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." [*Díaz Aviation, 716 F.3d at 265*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:58N8-64X1-F04K-H00Y-00000-00&context=). In other words, plaintiffs must demonstrate that the defendant acquired or maintained monopoly power by improper methods, or "exclusionary conduct." [*Town of Concord, Mass. v. Bos. Edison Co., 915 F.2d 17, 21 (1st Cir. 1990)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-2B70-003B-5538-00000-00&context=). To demonstrate that conduct is exclusionary, Retailer Plaintiffs here must show that Medicis's conduct had an "anticompetitive effect," in that it "harm[ed] the competitive process and thereby harm[ed] consumers." See [*United States v. Microsoft Corp., 253 F.3d 34, 58, 346 U.S. App. D.C. 330 (D.C. Cir. 2001)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:43CK-3HW0-0038-X4RT-00000-00&context=). The Court notes, however, that "[i]n ***antitrust*** cases in which a scheme is alleged, 'plaintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each.'" [*In re Asacol* ***Antitrust*** *Litig., 233 F. Supp. 3d 247, 261 (D. Mass. 2017)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5P74-VN61-F04D-D022-00000-00&context=) (quoting [*Cont'l Ore Co. v. Union Carbide & Carbon Corp., 370 U.S. 690, 698-99, 82 S. Ct. 1404, 8 L. Ed. 2d 777 (1962))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-H8B0-003B-S01X-00000-00&context=). The Court must, therefore, consider individual components in light of the alleged overall scheme. Id.

Defendants argue that the Medicis-Sandoz settlement cannot serve as the basis for a *Section 2* claim**[\*87]** because Retailer Plaintiffs cannot demonstrate that Medicis engaged in any exclusionary conduct through its settlement with Sandoz. D. 723 at 13-19. Defendants further contend that Retailer Plaintiffs cannot show that Medicis induced Sandoz to delay entry or that the Medicis-Sandoz settlement caused any injury. Id.

Retailer Plaintiffs argue that they are not required to prove injury from the Medicis-Sandoz settlement to challenge it as a component of an overall scheme that violates *Section 2*, as long as they can prove impact or injury to the scheme as a whole. D. 834 at 6 (citing [*Asacol, 233 F. Supp. 3d at 266*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5P74-VN61-F04D-D022-00000-00&context=)). In Asacol, this Court held that the direct purchaser plaintiffs had not demonstrated standing to bring a reverse payment claim—they failed to show the settlement in question was the but-for cause of the failure to launch a generic product—but that those allegations could nevertheless support their claims as to an overall monopolization scheme. [*Asacol, 233 F. Supp. 3d at 265-66*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5P74-VN61-F04D-D022-00000-00&context=). The Asacol plaintiffs could rely on these allegations to "provide background as to the overall anticompetitive scheme or at least as to the Defendants' recognition of impending generic competition." [*Id. at 266*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5P74-VN61-F04D-D022-00000-00&context=). Retailer Plaintiffs argue that because "[t]his Court held in 2015 that**[\*88]** Plaintiffs had adequately alleged a large and unjustified reverse payment from Medicis to Sandoz," D. 834 at 8 (citing D. 184 at 20) and "Medicis's overall scheme delayed generic entry and caused injury," the same logic applies here. D. 834 at 10.

Defendants argue that Asacol does not govern this case because there, this Court held that the plaintiffs had adequately alleged a payment "in exchange" for delayed generic entry, whereas here, Retailer Plaintiffs have failed to demonstrate that Medicis's payment to Sandoz induced Sandoz to abandon its patent challenge or delay entry. D. 895 at 6-7 (quoting [*Asacol, 233 F. Supp. 3d at 263*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5P74-VN61-F04D-D022-00000-00&context=)). They argue that Retailer Plaintiffs cannot prove that Medicis induced Sandoz to delay entry because Sandoz "had unilaterally decided how much generic product it would launch at-risk on August 14, 2009," and launched its entire inventory of generic product—over 3.1 million tablets, D. 724-1 ¶ 122—on that date. D. 723 at 14; D. 895 at 7. To support this point, Defendants point to email correspondence demonstrating that Sandoz chose to sell the entirety of its stock on the date of launch, and the reasons why Sandoz made that choice. D. 724-1 ¶ 93; D. 735-27. Additionally, Defendants contend**[\*89]** that Sandoz's representative conceded in his deposition that "Sandoz unilaterally decided to settle with Medicis and accept the same November 26, 2011 entry date as had been granted to Impax and other generic firms with whom Medicis had settled *before* Sandoz had any discussions with Medicis about selling the doxycycline asset to Medicis." D. 723 at 14 (emphasis in original); see D. 724-1 ¶ 94; D. 735-4 at 19-21. Defendants identify Retailer Plaintiffs' sole proffered evidence as certain conclusory statements made by their expert, Leffler, which are not supported by any factual or methodological evidence in his report.[[31]](#footnote-30)31 They contend that Retailer Plaintiffs, therefore, have no actual evidence to establish any causation theory suggesting that but for the Medicis-Sandoz settlement, Sandoz would have continued selling at risk or launched earlier than November 26, 2011. D. 723 at 15.

Retailer Plaintiffs argue that Sandoz's forecasts contemplated that it would stay on the market past the launch date, through at least 2011. D. 847 ¶¶ 93, 122. They point to the Sandoz representative's deposition testimony, in which he indicated that absent a settlement agreement, Sandoz would have stayed**[\*90]** on the market,[[32]](#footnote-31)32 Sandoz documents forecasting sales through December 2011, and an internal Sandoz email from August 13, 2009 attaching forecasts and contemplating that "[a]dditional supply would become available to the customer at the end of September," D. 858-36 at 40-41. D. 847 ¶ 122 n.609. They also provide internal emails and slideshow presentations from March 2009 seeking at-risk approval and contemplating market presence from 2009 through 2011, and a launch meeting agenda stating that the finance committee had approved at-risk launch. Id. (citing D. 944-10 at 16-23, 54). Additional Sandoz documents demonstrate that further orders of Sandoz generic product were pending at the time of settlement. D. 847 ¶ 94 n.461. Retailer Plaintiffs also provide Sandoz documents demonstrating their awareness of Medicis's settlements with other generic competitors at the time, including Impax and Teva. D. 847 ¶¶ 94-95.

Retailer Plaintiffs have provided sufficient evidence to withstand Defendants' motion for summary judgment on their *Section 2* claim based upon the Medicis-Sandoz settlement. In Asacol, reviewing a motion to dismiss, the plaintiffs had successfully alleged exclusionary conduct on the part of**[\*91]** the defendants through a reverse payment, but the lack of FDA approval defeated the plaintiffs' standing to sue on that claim. [*Asacol, 233 F. Supp. 3d at 263-66*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5P74-VN61-F04D-D022-00000-00&context=). Defendants contend that Sandoz would not have inserted any additional generic product into the market after its one-day launch, but Retailer Plaintiffs have provided evidence to rebut this showing, demonstrating that Sandoz contemplated launching at-risk, had approval to do so, and might have remained on the market until at least 2011. Moreover, even if Sandoz had decided to settle prior to commencing negotiations with Medicis, Sandoz's internal documents could support a reasonable inference that this choice was influenced by Medicis's settlements with other generic manufacturers. Sandoz's brief launch and settlement may indeed "provide background as to the overall anticompetitive scheme or at least as to the Defendants' recognition of impending generic competition," [*Asacol, 233 F. Supp. 3d at 266*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5P74-VN61-F04D-D022-00000-00&context=). In sum, Retailer Plaintiffs have provided a sufficient factual showing to support the inference that Medicis engaged in exclusionary conduct.

Thus, the Court denies Defendants' third motion for summary judgment, D. 719.[[33]](#footnote-32)33

**D. Disputed Responsive Expert Reports**

Although the following expert testimony**[\*92]** is unrelated to the parties' summary judgment motions, the Court addresses them here for timing purposes, given the parties' respective objections to the timeliness of these opinions. See D. 892; D. 937.

*1. Stephen Schondelmeyer*

Defendants seek to exclude the opinion of Dr. Stephen Schondelmeyer ("Schondelmeyer"), D. 711, Plaintiffs' pharmacy expert. See D. 738-9 ¶¶ 4-6 ("Schondelmeyer Rpt.").

Plaintiffs aver that they retained Schondelmeyer "to address a novel argument made by Drs. Johnson and Leonard, two of Defendants' experts," that concludes that Medicis's marketing of Solodyn was so robust that full generic competition would have had no impact on the demand of generic Solodyn (or lack thereof) during that time. D. 854 at 6. Schondelmeyer opines that in the but-for world of full-fledged generic competition, demand for generic Legacy Strength Solodyn would have been greater than it was in the actual world because the short duration of the at-risk launches prevented the generic substitution that would normally otherwise occur. Schondelmeyer Rpt. ¶ 27. Schondelmeyer explains that pharmacies are encouraged to sell generic drugs through a "MAC"—maximum allowable cost—price program. Id.**[\*93]** ¶¶ 11-12. The MAC price is the upper limit on the amount a "pharmacy will be paid for dispensing a prescription using one of several therapeutically equivalent generic versions of a drug product," and it is "set so that the pharmacy loses money if it dispenses a prescription using a drug product (including the brand name product) that costs more than the MAC amount." Id. ¶ 11. Schondelmeyer opines that the brief launches by Teva, Sandoz and Mylan would not have been sufficient time for PBMs to set MAC prices accordingly. Id. ¶¶ 24-26.

Defendants argue that Schondelmeyer's opinion is speculative, unreliable and without support in the record. D. 728 at 7-16. Plaintiffs argue that Schondelmeyer based his conclusions on review of formularies for major PBMs and health systems, Schondelmeyer Rpt. ¶ 27 n.9, and drew his conclusions based on his experience, which is permitted. See D. 854 at 9-12; [*United States v. Martinez-Armestica, 846 F.3d 436, 444 (1st Cir. 2017)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5MPG-TRV1-F04K-H04T-00000-00&context=). Schondelmeyer's report thus sets out the basis for his opinions therein, and it appears both relevant and sufficiently reliable to survive this motion. To the extent Defendants object that the bases for his opinion are faulty or shaky, or that Schondelmeyer should have reviewed additional sources**[\*94]** or documents, these objections go to the weight of his testimony, and not its admissibility. See [*Crowe, 506 F.3d at 18*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4PY1-3BJ0-TXFX-32RY-00000-00&context=). Indeed, Defendants proffer a counter opinion by Dr. Louis Rossiter, addressed below, to illustrate the alleged weaknesses in Schondelmeyer's opinion. D. 892; D. 892-1. This contrary evidence is the "traditional and appropriate" means of attacking Schondelmeyer's opinion, and it allows the jury to have the ultimate say on the balance of the evidence. [*Daubert, 509 U.S. at 596*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-XDR0-003B-R3R6-00000-00&context=).

The Court thus denies Defendants' motion to exclude Schondelmeyer's opinion, D. 711.

*2. Louis Rossiter*

On January 5, 2018, Defendants filed a motion seeking leave to serve the expert report of Dr. Louis Rossiter ("Rossiter") in response to the Schondelmeyer report, D. 892, which Plaintiffs opposed, D. 937. Defendants sought to strike Schondelmeyer's expert testimony when the class certification motions were pending before the Court, see D. 642, but the Court denied the motion as moot in its Memorandum and Order because it did not rely upon Schondelmeyer's opinion in its analysis. D. 682 at 13 n.8. Defendants argue that the scheduling order precluded them from serving a rebuttal report to Schondelmeyer's "new opinions," but that Rossiter's report**[\*95]** "squarely addresses" these opinions and provides Defendants' critiques thereof.

Plaintiffs argue that Schondelmeyer's report responds to Defendants' expert opinions—those of Dr. John Johnson and Dr. Gregory Leonard—and addresses opinions Defendants anticipated, and, therefore, was filed appropriately as a rebuttal rather than affirmative report. D. 937 at 3, 5. Plaintiffs also argue that allowing a sur-rebuttal report at this stage would be unfair to Plaintiffs, given that Defendants waited to proffer Rossiter's opinion until January, the reply deadline for Daubert motions, rather than the initial filing deadline of November 1, 2017. D. 937 at 4-5.

Although the Court agrees that in light of its decision not to address the motion to strike in its class certification order, Defendants ideally should have filed Rossiter's opinion with their Daubert motion in November, fairness favors allowing Defendants' motion here. Assuming Rossiter's opinion is limited in scope to rebutting Schondelmeyer's testimony—and Plaintiffs do not argue otherwise—Defendants may serve it at this time.

**VI. Conclusion**

For the foregoing reasons, the Court:

1. DENIES IN PART Defendants' motion for summary judgment on**[\*96]** market power, D. 717, and DENIES Plaintiffs' motion for partial summary judgment on market power, D. 747, to the extent that parties rely upon circumstantial evidence of market power (including the definition of the relevant market); ALLOWS IN PART Defendants' motion for summary judgment as to direct evidence of market power. The disputed issue of market power (including definition of relevant market) shall go to the jury as to circumstantial evidence.

2. DENIES Defendants' motion for summary judgment on causation, D. 718: Plaintiffs may pursue Scenarios A and B at trial, but they have abandoned (former) Scenario 1;

3. DENIES Defendants' motion for summary judgment on all claims arising out of Medicis's settlements with Sandoz and Lupin. D. 719.

As to the Daubert motions to exclude certain expert testimony, the Court:

1. DENIES Defendants' motion to exclude Dr. Christopher Baum, D. 741;

2. DENIES Defendants' motion to exclude Dr. Arthur Kibbe, D. 716;

3. DENIES Defendants' motion to exclude Dr. Keith Leffler, D. 712;

4. DENIES Defendants' motion to exclude Dr. Meredith Rosenthal, D. 745;

5. DENIES Defendants' motion to exclude Dr. Stephen Schondelmeyer, D. 711;

6. DENIES Defendants' motion**[\*97]** to exclude Dr. Neelam Vashi, D. 714;

7. ALLOWS IN PART and DENIES IN PART Defendants' motion to exclude the opinion of John Doll, D. 715, excluding testimony as to Medicis's intent and legal conclusions;

8. ALLOWS IN PART and DENIES IN PART Defendants' motion to exclude portions of Dr. Thomas McGuire, D. 744, allowing the motion to the extent that McGuire's testimony connects his stock price event study to alternative no-payment settlement dates, but otherwise denying the motion;

9. ALLOWS IN PART and DENIES IN PART Defendants' motion to exclude John Thomas and Peter Hardigan, D. 713, allowing the motion to the extent Thomas opines on the time to trial (and appeal) of the underlying patent dispute, materiality, Medicis's intent and any legal conclusions presented as expert testimony, but otherwise denying the motion;

10. DENIES Plaintiffs' motion to exclude portions of Dr. Sumanth Addanki and Dr. Guy Webster's opinions, D. 748;

11. DENIES Plaintiffs' motion to exclude portions of Dr. Robert S. Langer's and R. Polk Wagner's opinions, D. 751;

12. ALLOWS Defendants' motion to serve the expert opinion of Dr. Louis Rossiter, D. 892.

**So Ordered**.

/s/ Denise J. Casper

United States District Judge

**End of Document**

1. 1Both classes settled with respect to Defendants Sandoz Inc. ("Sandoz") and Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, "Lupin") on November 27, 2017. D. 806; D. 808. [↑](#footnote-ref-0)
2. 2This group includes the following Plaintiffs, who joined the suit after the Court issued its ruling on Defendants' motion to dismiss, D. 184: Albertson's LLC, HEB Grocery Company L.P., Safeway, Inc., The Kroger Company and Walgreen Co., D. 216; Rite Aid Corporation and Rite Aid Headquarters Corporation, D. 218; and CVS Pharmacy, Inc., D. 266 (collectively, "Retailer Plaintiffs"). [↑](#footnote-ref-1)
3. 3The Court will address the other Daubert motions, D. 742; D. 743; D. 746; D. 749; D. 750, in connection with the January 31, 2018 hearing. [↑](#footnote-ref-2)
4. 4Retailer Plaintiffs also filed stipulations of dismissal of their claims against Sandoz and Lupin. D. 875; D. 876. [↑](#footnote-ref-3)
5. 5Retailer Plaintiffs also seek to pursue claims under ***Section 2*** of the Sherman Act, ***15 U.S.C. § 2***, see D. 834, which requires proof that Defendants possessed "monopoly power" in the relevant market, see [*Díaz Aviation, 716 F.3d at 265*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:58N8-64X1-F04K-H00Y-00000-00&context=). Plaintiffs may demonstrate monopoly power the same way they demonstrate market power, see [*In re Asacol* ***Antitrust*** *Litig., No. 15-cv-12730-DJC, 323 F.R.D. 451, 2017 U.S. Dist. LEXIS 186009, at \*93-102 (D. Mass. Nov. 9, 2017)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5PXG-01N1-JBT7-X2KX-00000-00&context=), although a showing of monopoly power for the purposes of ***Section 2*** is held to a higher standard than for ***Section 1***. See [*Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451, 481, 112 S. Ct. 2072, 119 L. Ed. 2d 265 (1992)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3RV9-X170-003B-R185-00000-00&context=) (explaining that a monopoly power showing "requires, of course, something greater than market power under ***[Section] 1***"); [*In re Remeron Direct Purchaser* ***Antitrust*** *Litig., 367 F. Supp. 2d 675, 683 (D.N.J. 2005)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4G1X-NHW0-TVVX-S22P-00000-00&context=) (noting that ***Section 1*** claims "have a lower standard for finding market power than cases under ***section 2***"); [*Fortner Enters. v. U.S. Steel Corp., 394 U.S. 495, 502-03, 89 S. Ct. 1252, 22 L. Ed. 2d 495 (1969)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-F8P0-003B-S22G-00000-00&context=) (explaining that market power does not require showing "that the defendant have a monopoly or even a dominant position throughout the market"). [↑](#footnote-ref-4)
6. 6Defendants base this percentage—17%—on their expert Dr. Sumanth Addanki's opinion that Solodyn had "at most a 16.9% of [sic] share of new oral tetracycline prescriptions among dermatologists during the relevant time period." D. 721 at 21; Addanki Rpt. at 129. [↑](#footnote-ref-5)
7. 7The same is true with many of the other cases upon which Plaintiffs rely. See [*King Drug Co. of Florence v. SmithKline Beecham Corp., 791 F.3d 388, 392 (3d Cir. 2015)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5G9F-WC71-F04K-K028-00000-00&context=) (reversing lower court grant of motion to dismiss); cf. [*In re Aggrenox* ***Antitrust*** *Litig., 199 F. Supp. 3d 662, 663 (D. Conn. 2016)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5KDV-P4H1-F04C-W0MK-00000-00&context=) (determining the scope of the market prior to start of discovery). [↑](#footnote-ref-6)
8. 8Defendants move to exclude portions of Vashi's testimony, D. 714, arguing that she misunderstands the term "interchangeable" to mean "pharmacological equivalence" rather than "functional interchangeability," rendering her opinion irrelevant and unreliable. D. 729 at 6-8. They also argue Vashi's own medical practices and the record cut against her testimony on interchangeability. D. 729 at 8-11. Vashi's definition of therapeutic interchangeability may differ from Defendants' definition, but it is relevant to the jury and grounded in her medical experience along with the documents and medical literature she relied upon in rendering her opinion. See D. 857 at 9-7. Defendants also argue that her conclusions regarding the clinical value of Solodyn Add-On Strengths—that because Legacy Strengths "are sufficient to treat the vast majority of moderate to severe acne patients . . . all of the Add-On Strengths except for the 65mg version are not clinically valuable when the Legacy Strengths are an option," Vashi Rpt. ¶ 25—are speculative. D. 729 at 11-12. Vashi opines that Legacy Strength "could effectively treat the vast majority of patients" based on the weight range of her own patient population and prescription practices. Vashi Rpt. ¶¶ 94-98. Defendants' critiques of her opinion on this point go to the weight of her opinion. The Court thus denies Defendants' motion to exclude these portions of her expert testimony, D. 714. [↑](#footnote-ref-7)
9. 9Plaintiffs seek to exclude portions of the opinion of Defendants' dermatology expert Webster's opinion on therapeutic interchangeability because he does not also address cross-price elasticity. D. 748; D. 748-1 at 7-10. Webster is a medical doctor, however, whose expertise is in dermatology, D. 753-19 ¶ 1 ("Webster Rpt."), and his report is thus appropriately limited to his area of expertise in focusing on therapeutic interchangeability, rather than economic [↑](#footnote-ref-8)
10. 10Defendants seek to exclude Leffler's expert testimony, D. 712, but their motion does not focus on Leffler's opinion on market definition, but rather his opinion on causation. See D. 726 at 5-16. Defendants mention in a footnote that Leffler's market power conclusions fail to satisfy the requirements of [*Rule 702*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5GYC-2991-FG36-120S-00000-00&context=), explaining that they express their objections to his testimony within their summary judgment motion. D. 726 at 6 n.4; D. 900 at 5 n.1. Defendants argue that Leffler's analysis is "[c]ursory and [s]peculative," and, therefore, "insufficient to carry Plaintiffs' burden." D. 721 at 20. Defendants may raise highlight such alleged weaknesses in Leffler's testimony at trial. The Court thus declines to exclude Leffler's opinions as to market power, and addresses the crux of Defendants' Daubert motion about Leffler's causation opinions in Part B below. [↑](#footnote-ref-9)
11. 11Leffler also compares Solodyn to Adoxa, the "next closest therapeutic alternative emphasized by Medicis," and draws the same conclusion. Leffler Rpt. ¶ 39. Leffler explains that although a generic version of Adoxa entered the market in 2005, in 2009, Solodyn's average net price was over fifteen times its cost, with sales over twenty-five times those of generic and branded Adoxa. Id. Leffler's Adoxa analysis is not quite a cross-elasticity analysis, however, as he does not demonstrate whether Adoxa's entry or price affected Solodyn's sales or price, or vice versa. [↑](#footnote-ref-10)
12. 12IMS data has been relied upon by courts in litigation involving pharmaceutical markets. See [*New Eng. Carpenters Health Benefits Fund v. First Databank, Inc., 248 F.R.D. 363, 370 (D. Mass. 2008)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4S39-5KY0-TXFR-01SX-00000-00&context=); [*In re Cardizem CD* ***Antitrust*** *Litig., 218 F.R.D. 508, 538 (E.D. Mich. 2003)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4BNK-S540-0038-Y3H7-00000-00&context=) (characterizing IMS Health, Inc. as "the recognized leader in data collection for the pharmaceutical industry"). Rosenthal and Baum used IMS National Disease and Therapeutic Index data, "monthly audit data of office-based physicians, providing data on disease diagnoses and prescribed drug therapies," and IMS Xponent data, "robust monthly sample data of retail, mail order and long term care prescriptions." Rosenthal Rpt. ¶¶ 57(a) n.96, 97. [↑](#footnote-ref-11)
13. 13The AIDS model presents "monthly expenditure shares" of the drugs in question through analyzing their "real prices, real total expenditure on this category of drugs, and specific factors relevant to these products." Baum Rpt. Attach. C. ¶ 2. [↑](#footnote-ref-12)
14. 14Rosenthal explains how she selected the "most important drugs to be included in the analysis" in her report. Rosenthal Rpt. ¶ 57. The drugs Rosenthal and Baum include in the analysis are: Solodyn; Doryx, "a branded delayed release doxycycline hyclate intended to treat acne"; Doxycycline DR, a generic equivalent of Doryx; other doxycyclines, or "generic broad-spectrum antibiotics used to treat acne" with the same active ingredient as Doryx but lacking delayed release; minocycline HC1, a generic acne treating antibiotic that "shares the same active ingredient as Solodyn but lacks its extended release"; Minocin, a branded minocycline HC1; and Minocycline HC1 ER, the generic equivalent of Solodyn. Baum Rpt. ¶ 13; see Rosenthal Rpt. ¶ 57(c). [↑](#footnote-ref-13)
15. 15Defendants seek to exclude Rosenthal's expert opinion, D. 745, but their motion focuses upon Rosenthal's testimony regarding direct evidence, see D. 745-1 at 1-6, so the Court will address it in that context. They also argue that her opinion impermissibly relies upon Baum's opinion, D. 745-1 at 7, but for the reasons discussed infra the Court declines to exclude Baum's testimony. The Court likewise declines to exclude Rosenthal's opinion on that basis. [↑](#footnote-ref-14)
16. 16As Rosenthal posits, a cross-price elasticity model using actual data from 2009 onward does not represent the typical market because of the atypical abbreviated generic launches and Medicis's switch to Add-On Strength Solodyn by the time generics could launch in full. Rosenthal Rpt. ¶¶ 61-62. [↑](#footnote-ref-15)
17. 17Defendants seek to exclude Rosenthal's opinion. D. 745. Defendants argue that Rosenthal's conclusions on direct evidence of Medicis's market power are "based solely on evidence of Medicis's gross margins," a standard that they dispute, and that Rosenthal's methodology is thus unreliable. Id.; D. 745-1 at 4-6. First, Plaintiffs correctly argue that Rosenthal need not define the market before offering direct evidence of market power; that is only required for circumstantial evidence. D. 853 at 10. Second, Plaintiffs argue that evidence of high margins does reflect market power. D. 853 at 12-15. Although Defendants may dispute the latter point, as with Baum's testimony, Defendants' objections are best suited for trial examination. For all of these reasons, the Court denies Defendants' motion to exclude Rosenthal's opinion. [↑](#footnote-ref-16)
18. 18The rule of reason analysis does not ask how or why a defendant has market power; the question is simply whether the brand manufacturer held sufficient market power to "work unjustified competitive harm." [*Actavis, 133 S. Ct. at 2236*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:58NW-3VK1-F04K-F006-00000-00&context=); see, e.g., [*Am. Steel, 815 F.3d at 61*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5J5H-KVC1-F04K-H07X-00000-00&context=); [*Díaz Aviation, 716 F.3d at 265*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:58N8-64X1-F04K-H00Y-00000-00&context=). In other words, the focus is not on whether the brand manufacturer obtained market power by anticompetitive means, but whether (1) the manufacturer possessed "a threshold degree of market power," [*Flovac, 817 F.3d at 853*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5JFV-9CV1-F04K-H0C3-00000-00&context=), through which (2) the manufacturer's reverse payment settlement(s) could—and did—inflict anticompetitive effects. See [*Actavis, 133 S. Ct. at 2237*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:58NW-3VK1-F04K-F006-00000-00&context=); [*Nexium, 968 F. Supp. 2d at 387*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:59BB-KNF1-F04D-D05Y-00000-00&context=) (providing three-step rule-of-reason inquiry, the first of which is "whether 'the alleged agreement involved the exercise of power in a relevant economic market'" (quoting [*Stop & Shop Supermarket Co. v. Blue Cross & Blue Shield of R.I., 373 F.3d 57, 61 (1st Cir. 2004))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4CPF-49N0-0038-X3XG-00000-00&context=). [↑](#footnote-ref-17)
19. 19Kibbe's roadmap explanation states in full that "[t]he role of a formulator is to take a known excipient or excipients [inactive substances] with known physical and chemical characteristics and combine them with the API [active pharmaceutical ingredient] to get a dosage form that will be stable and will release the active ingredient in a manner that supports good therapy. The testing that is done during this process may be extensive, but is clearly not inventive when you consider the breadth of the prior art that has been reported that describes the formulation of a controlled release dosage form. Solodyn's API, minocycline hydrochloride, has a reported half-life between 11 and 16 hours, which make the development of a once a day product relatively easy. Thus, a person of ordinary skill in the art would look to the literature for suggestions of combinations of excipients that have been shown to be effective in extending the release of API and, through routine testing, arrive at a formulation that would be appropriate for this API." Kibbe Rpt. ¶ 84. [↑](#footnote-ref-18)
20. 20In a patent suit, a party seeking to invalidate a patent on obviousness grounds must do so by clear and convincing evidence. [*InTouch, 751 F.3d at 1347*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5C5C-R381-F04B-M021-00000-00&context=). In an ***antitrust*** suit, by contrast, plaintiffs must, as aforementioned, only show "some evidence" that the patent is invalid. [*Nexium, 842 F.3d at 63*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5M73-M0F1-F04K-H003-00000-00&context=). [↑](#footnote-ref-19)
21. 21To the extent that Defendants seek Thomas's exclusion because his opinion on noninfringement is untimely, such issue is no longer relevant to the resolution of the pending summary judgment motions. See D. 827. The Court likewise declines to exclude that portion of Thomas's report. [↑](#footnote-ref-20)
22. 22Defendants argue that Thomas erroneously relies upon the (inadmissible) testimony of experts Kibbe and Vashi, but as the Court has explained, their testimony is admissible, and, accordingly, Thomas may rely upon their scientific and technical expertise as a basis for his opinions. [↑](#footnote-ref-21)
23. 23The parties also dispute Thomas's ability to opine on unenforceability due to inequitable conduct. D. 731 at 14-18; D. 855 at 14-18. The Court will address this portion of Thomas's testimony in Part 1(b) infra. [↑](#footnote-ref-22)
24. 24Defendants seek to exclude Thomas's testimony on the question of materiality, arguing again that he is unqualified to opine on the issue because he is not skilled in the requisite art. D. 731 at 15-16. Thomas may be a patent law expert but, unlike Doll, Thomas does not have any expertise into what a reasonable patent officer would find material in a patent application. The Court thus allows Defendants' motion to exclude this portion of Thomas's testimony. [↑](#footnote-ref-23)
25. 25Doll and Thomas may identify certain facts from file history and record to support an inference of intent to deceive short of presenting an inadmissible opinion as to the inventor's state of mind. See [*Meds. Co., 2014 U.S. Dist. LEXIS 61084, at \*17*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5C3X-3DM1-F04D-7080-00000-00&context=). The Court allows Defendants' motions to exclude Doll's, D. 715, and Thomas's, D. 713, testimony to the extent they opine on subjective intent of Medicis or its inventor, however, as well as any legal conclusions they draw in their testimony. [↑](#footnote-ref-24)
26. 26The "stock price study" suggests that a stock market price jump upon the announcement of an agreement serves as evidence that investors had not fully anticipated such an agreement, and, thus, the agreement is anticompetitive. McGuire Rpt. ¶¶ 189. McGuire references his publication, which demonstrated that in a twenty-year period, settlements with reverse payments were associated with stock price jumps, and agreements without indicia of reverse payments were not. Id. ¶ 191. [↑](#footnote-ref-25)
27. 27The Nexium court also mentioned that the plaintiffs could not produce any studies supporting McGuire's methodology apart from his own papers on the topic, [*Nexium, 842 F.3d at 52*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5M73-M0F1-F04K-H003-00000-00&context=), and Defendants here argue that his methodology remains unreliable on that basis, D. 744-1 at 13. As Plaintiffs explain, however, McGuire's stock price analysis approach was published after peer review in two economics publications since Nexium. D. 852 at 9, 20. To the extent that this argument had force before, it does not have the same force now. [↑](#footnote-ref-26)
28. 28The Court allowed Defendants' motion to dismiss regarding the EPP and DPP Plaintiffs' ***Section 2*** claims in 2015, see D. 184 at 23-29, 47, but Retailer Plaintiffs filed their suits, which were transferred to this Court, while Defendants' motion to dismiss was still pending, see D. 216; D. 218; D. 266. Retailer Plaintiffs stipulated that their amended complaints were subject to this Court's motion to dismiss opinion with the exception of the Court's decision as to plaintiffs' ***Section 2*** claims. D. 244 at 2-3; D. 271 at 2. Defendants did not move to dismiss Retailer Plaintiffs' ***Section 2*** claims. See, e.g., D. 247; D. 248; D. 275. Later, DPPs, EPPs and Retailer Plaintiffs moved to file second amended complaints that included additional monopolization claims, D. 306; D. 308; D. 310; D. 312; D. 314, and Defendants moved to dismiss those claims, D. 331. The Court denied the classes' motions to amend. D. 364. Retailer Plaintiffs, however, continued to assert their ***section 2*** claims against Medicis "based solely on the Impax, Sandoz and Lupin settlements that the Court had ruled were potentially unlawful under [S]ection 1." D. 834 at 4. [↑](#footnote-ref-27)
29. 29Retailer Plaintiffs later filed stipulations of dismissal of claims against Sandoz and Lupin, which the Court granted. D. 875; D. 876. [↑](#footnote-ref-28)
30. 30The Court did so knowing that it had dismissed DPP and EPP classes' ***Section 2*** claims previously, D. 184; D. 364, and on the understanding that Retailer Plaintiffs were not a separate entity from, but rather members in the direct purchaser class. It is now clear, however, that Retailer Plaintiffs intend to pursue their ***Section 2*** claims and that intent has been unabated since the start of discovery, see D. 244; D. 271. [↑](#footnote-ref-29)
31. 31Leffler states that if Sandoz had remained on the market, Retailer Plaintiffs would have seen "increased competition among generic suppliers and substantial decreases in the prices" for branded Solodyn, and that absent the allegedly unlawful Medicis-Impax agreement, Impax would have launched earlier, and consequently, Sandoz would have as well, Leffler Rpt. ¶¶ 10(C), 10(E). See D. 723 at 17. Defendants argue that Retailer Plaintiffs cannot point to any facts to support these conclusions. D. 723 at 18-19. Retailer Plaintiffs, however, do not rely upon Leffler's report in their opposition to Defendants' motion for summary judgment. [↑](#footnote-ref-30)
32. 32Specifically, responding to the question "in a scenario where you didn't settle, the plan was to continue selling minocycline into the market, your generic version of minocycline, is that correct?" James Mastakas responded "Yes. We did not sell, yes." D. 944-1 at 216. [↑](#footnote-ref-31)
33. 33In response to Retailer Plaintiffs' opposition, Defendants filed a motion seeking dismissal with prejudice of all of Plaintiffs' claims arising out of the Lupin and Sandoz settlements. D. 835. In light of the Court's ruling on Defendants' summary judgment motion, the Court denies Defendants' subsequent motion, id. [↑](#footnote-ref-32)