UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE AMITIZA ANTITRUST LITIGATION	)	Civil Action No. 21-11057-MJJ

MEMORANDUM OF DECISION

October 29, 2025

JOUN, D.J.

This is an anti-trust class-action between Plaintiffs FWK Holdings, LLC and KPH Healthcare Services, Inc., a/k/a Kinney Drugs, Inc.,[1] (the "Direct Purchaser Class Plaintiffs" or "DPPs"), Premera Blue Cross (the "End Payor Class Plaintiffs" or "EPPs"); and certain large retailers including Walgreen Co. and CVS Pharmacy, Inc. (the "Retailer Plaintiffs," collectively with the DPPs and EPPs, "Plaintiffs") and Defendants Takeda Pharmaceutical Company Limited and Takeda Pharmaceutical U.S.A. (together, "Defendants" or "Takeda").

Plaintiffs are direct and indirect purchasers of Amitiza, a branded drug containing the active pharmaceutical compound lubiprostone, designed to treat chronic idiopathic constipation. The U.S. Food and Drug Administration ("FDA") approved Sucampo's new drug application for Amitiza in 2006, and Sucampo and Takeda partnered up to bring Amitiza to market thereafter. In 2014, Takeda/Sucampo entered into a Settlement Agreement with Par Pharmaceutical, Inc. ("Par"), a company seeking to launch its own generic version of Amitiza. Plaintiffs allege violations of Section 1 of the Sherman Act, 15 U.S.C. § 1, as well as state antitrust and consumer

[1] While these motions were pending, I ruled on Class Certification, [Doc. No. 616], where I held that Meijer, Inc., and Meijer Distribution, Inc. must arbitrate their claims and thus have been excluded from the class.

protection statutes, arising from this Settlement Agreement. Plaintiffs allege that the Settlement Agreement was an implicit "no-AG [authorized generic]" "pay-for-delay" or "reverse payment" agreement causing Plaintiffs to pay higher prices for brand or generic Amitiza. Specifically, Plaintiffs allege that but-for the Settlement Agreement, Par would have entered the market earlier than 2021, and other generic drugs would have followed, increasing competition in the marketplace for generic Amitiza, thereby reducing costs for consumers. Plaintiffs seek damages for the amount they allegedly overpaid for Amitiza-branded and generic products due to the Settlement Agreement.

Before me are Plaintiffs' Motion for Partial Summary Judgment, [Doc. No. 416], Defendants' Motion for Summary Judgment, [Doc. No. 421], Plaintiffs' *Daubert* motions to exclude certain of Defendants' experts, [*see* Doc. Nos. 457, 459, and 461], Defendants' *Daubert* motions to exclude certain of Plaintiffs' experts, [*see* Doc. Nos. 404, 406, 408, 410, 412, 414], as well as Defendants' Motion to Strike portions of Section XII of Plaintiffs' Statement of Material Facts, [Doc. No. 506]. For the reasons explained below, Plaintiffs' Motion for Partial Summary Judgment is GRANTED in part and DENIED in part. Defendants' Motion for Summary Judgment is DENIED. Each of the parties' *Daubert* Motions are DENIED. Defendants' Motion to Strike is also DENIED. [Doc. No. 506].

The following is a summary of the issues on which the parties have moved for summary judgment:

1. ***Market Power***: Plaintiffs argue that Takeda had market power in the relevant U.S. market for Amitiza and its generic equivalents. Takeda argues that Plaintiffs have not proven that Takeda possessed such market power. As explained below, I find that triable issues of fact exist as to whether Takeda had market power and the parties' motions for summary judgment as to market power are DENIED.

2. ***Reverse Payment***: Plaintiffs seek a finding that Takeda/Sucampo and Par entered into a written, complete agreement, effective on September 30, 2014, that (i) terminated the patent

litigation between them, (ii) set an entry date for Par to enter the market seven years later (January 1, 2021, or earlier as specified), and, in exchange, (iii) the parties agreed to a 50/50 gross profit split of Par's eventual generic sales so long as Par was the only seller of generic lubiprostone product in the market. Defendants concede that an agreement was entered that terminated the patent agreement and set an entry date for Par to enter the market on January 1, 2021, or earlier, as specified. [*See* Doc. No. 470 at 27–29]. As such, Plaintiffs' Motion for Summary Judgment is GRANTED in part as to these terms in the Settlement Agreement. However, the parties disagree as to whether the 50% profit split and the declining royalty rate provisions are evidence of a reverse payment. As explained below, I find that there are material disputes of fact as to whether (1) the declining royalty rate applies to both Par's ANDA and Par's AG product such that the declining royalty rate constitutes a reverse payment, and (2) the 50% profit split alone constitutes a reverse payment. Accordingly, the parties' motions for summary judgment as to these disputes are DENIED.

Defendants seek summary judgment on the following additional issues:

3. ***Anticompetitive Agreement***: Defendants argue that Plaintiffs have failed to put forth any evidence of an anticompetitive agreement. As explained below, Defendants' motion for summary judgment as to an antitrust agreement is DENIED, to the extent that triable issues of fact exist as to whether Plaintiffs have put forth indirect evidence of an antitrust agreement.

4. ***Causation***: Defendants argue that Plaintiffs cannot prove that the Settlement Agreement caused injury because (1) Plaintiffs failed to consider the impact of two additional patents on Par's ability to launch, (2) Plaintiffs have not shown that Par would have overcome regulatory barriers to launch on the but-for dates they assume, and (3) there is no evidence that the ANDA Filers were launch-ready at the times that Plaintiffs' but-for scenarios assume. As explained below, triable issues of fact exist as to causation, and Defendants' motion for summary judgment is DENIED.

5. ***Injury to Brand-Only Purchasers***: Defendants argue that at least 23 proposed class members have no claims. These include thirteen generic-only purchasers and ten brand-only purchasers. As I explained in my decision on class certification, [Doc. No. 616 at 22], the thirteen generic-only purchasers do not have standing and have been dismissed from this action. As such, I will only address Defendants' arguments as to the ten brand-only purchasers. As explained below, Defendants' motion for summary judgment as to these ten brand-only purchasers is DENIED.

6. ***Statute of Limitations***: Defendants argue that DPPs and Retailer Plaintiffs have failed to put forth evidence of fraudulent concealment such that the statute of limitations on their claims should be tolled. Therefore, Defendants argue any claimed damages must be limited to sales after June 25, 2017. For the reasons explained below, I find that the statute of limitations is tolled and Defendants' motion for summary judgment as to the statute of limitations is DENIED.

Plaintiffs seek partial summary judgment on the following, additional issues:

7. ***Jury Instruction***: Plaintiffs seek an order that, if the jury finds the value of the 50/50 profit split with the no-second-generic provision resulted in a "large, unexplained" reverse payment, then the Settlement Agreement created potential restraints on competition in the U.S. lubiprostone market, and that those restraints in fact occurred. For the reasons explained below, Plaintiffs' motion for partial summary judgment is premature and thus, DENIED.

8. ***Procompetitive Benefits***: Plaintiffs argue that Takeda fails to proffer any legitimate, procompetitive benefits for the reverse payment, and therefore fails to meet the second prong of the rule of reason. For the reasons explained below, there is a triable issue of fact as to whether Defendants have offered evidence of procompetitive benefits. As such, Plaintiffs' motion for partial summary judgment is DENIED.

I. DEFENDANTS' MOTION TO STRIKE

Before detailing the relevant background, I must first address Defendants' Motion to Strike. [Doc. No. 506]. Defendants ask me to strike certain paragraphs set forth in Section XII of Plaintiffs' Statement of Material Facts, in which Plaintiffs provide a list of an additional 158 undisputed facts. *See* [Doc. No. 509]. Alternatively, Defendants ask me to disregard these statements when ruling on Plaintiffs' Motion for Summary Judgment.

Local Rule 56.1 requires a party opposing a motion for summary judgment to "include a concise statement of the material facts of record as to which it is contended that there exists a genuine issue to be tried, with page references to affidavits, depositions and other documentation." L.R. 56.1. Defendants argue that "Plaintiffs' submission of voluminous, uncited statements violates this Rule, burdens the record, and undermines the efficiency of the summary judgment process." [Doc. No. 507 at 1–2]. Defendants further argue that "Plaintiffs' submission of 130 extraneous statements is neither concise nor material, violating both the Rule's letter and its spirit." [*Id.* at 3]. Defendants take issue with the fact that many of Plaintiffs' additional facts are not cited in support of their opposition to Takeda's motion for summary judgment. Plaintiffs respond that although it is correct that not all of their additional facts are cited in support of their

opposition, the facts are "relevant and material to Plaintiffs' arguments," provided to respond to Defendants' material facts to establish that a genuine dispute exists, provide background information that "puts other facts into context, all in one place," and are otherwise relevant to issues presented in Plaintiffs' briefs. *See* [Doc. No. 517 at 2, 6].

District courts enjoy "broad latitude in administering local rules" and are "entitled to demand adherence to specific mandates contained in the rules." *Air Line Pilots Ass'n v. Precision Valley Aviation, Inc.*, 26 F.3d 220, 224 (1st Cir. 1994). "Local Rule 56.1 does not clearly prescribe what form a nonmoving party's opposition must take. It does require that the nonmoving party identify which of the moving party's facts are in dispute, with citations to the record to explain the basis for that dispute." *Kaiser v. Kirchick*, 662 F. Supp. 3d 76, 86 (D. Mass. 2023). I agree that here, Plaintiffs' additional statement of facts "could certainly be more succinct," but "the length is not unreasonable" given the complexities of this antitrust class action. *Id.* While many facts presented in both parties' statement of facts may ultimately be extraneous or may only have been provided to give a detailed background and context for this case, "determining whether the disputed issues are material is the court's basic task at summary judgment, and therefore the purported immateriality of the additional facts is not a ground for excluding them from consideration entirely." *Id.* (citation omitted) (denying motion to strike and instead electing to disregard "additional facts" that are "conclusory or go beyond the task of identifying material facts of record as to which it is contended that there exists a genuine issue to be tried"). As such, I will "give little to no consideration to extraneous factual and legal assertions propounded by either party." *Knidel v. T.N.Z., Inc.*, 189 F. Supp. 3d 283, 285 (D. Mass. 2016). Accordingly, Defendants' Motion, [Doc. No. 506], is DENIED.

II. BACKGROUND

The Court summarizes the following operative facts, "not as they necessarily are, but rather as a jury might reasonably find them to be in favor of . . . the non-movant." *Doe v. Brown Univ.*, 43 F.4th 195, 200 (1st Cir. 2022). This case involves a large body of background facts. The facts below are undisputed unless otherwise noted, and additional facts relevant to my analysis will be set forth in their relevant sections.[2]

A. The Hatch-Waxman Act And The U.S. Pharmaceutical Market

In 1984, Congress enacted the Hatch-Waxman Act, in part, to bring generic drugs to market faster. [Doc. No. 499 at ¶ 1]. "Generic manufacturers make drugs more affordable by bringing to market lower cost generic versions of established drugs." [*Id.* (citing Doc. No. 419-3 at 988, ¶ 10)]. The Hatch-Waxman Act was enacted "in an effort to balance the interests of innovator drug companies and generic drug companies as well as the public's interest in the availability of pharmaceutical products" and "[i]nnovator companies, also known as pioneer

[2] In the interest of brevity, this fact background is limited to the facts that will be most helpful to provide a lay of the land with respect to the parties' cross-motions for summary judgment. However, both parties have submitted statements of facts that contain numerous paragraphs and are heavily disputed on both sides. Many of those disputes, however, take issue with semantics, characterizations, implications, the completeness of the fact, or devolve into legal argument. I will endeavor to parse which disputes are genuine and material. *See Atain Specialty Ins. Co. v. Davester LLC*, 518 F. Supp. 3d 551, 555 (D. Mass. 2021) ("Disputes over facts that are irrelevant or unnecessary will not preclude summary judgment") (citation omitted). To the extent that any facts are not properly disputed, those will be considered undisputed. *See Muniz v. RXO Last Mile, Inc.*, 2023 WL 5353749, at *2 (D. Mass. Aug. 21, 2023) (finding responses to statement of facts obstructive where the dispute merely raises "distinctions without a difference" or "restates legal standards to manufacture a dispute"); *Guerrios Flores v. S.M. Med. Servs., C.S.P.*, 2020 WL 1698993, at *2 (D.P.R. Apr. 7, 2020) ("Responses which do not oppose the truth of the statement offered and are either irrelevant to the matter at hand, provide additional evidence not related to the fact in question and/or failed to contradict it are insufficient to properly controvert a material fact") (citation omitted). "Disputed" facts that are not supported by citations to the record will also be considered undisputed. L.R., D. Mass. 56.1 ("A party opposing the motion shall include a concise statement of the material facts of record as to which it is contended that there exists a genuine issue to be tried, with page references to affidavits, depositions and other documentation").

companies, devote enormous resources to developing and obtaining FDA approval of new drugs." [*Id.* (citing Doc. No. 419-3 at 988, ¶ 10)].

A company seeking to sell a branded pharmaceutical product in the United States, such as Amitiza, must first obtain FDA approval of a new drug application ("NDA"). [Doc. No. 509 at ¶ 7]. Upon approval, the company is required to list any patents it contends cover the branded product in the FDA's "Orange Book." [*Id.*]. Generic drugs, on the other hand, can be marketed and sold in the United States: (i) as an "ANDA generic"; or (ii) as an authorized generic. [Doc. No. 499 at ¶ 3]. ANDA generics are approved by the FDA after review of the manufacturer's Abbreviated New Drug Application ("ANDA"). [*Id.*]. To secure approval, ANDA applicants must demonstrate that the generic drug is bioequivalent to the listed referenced brand drug, include a certification regarding the patent status of the brand drug, and must satisfy other requirements imposed by the FDA. [Doc. No. 509 at ¶ 8].

If the ANDA applicant seeks to market a generic drug prior to expiration of a patent listed for the brand drug in the Orange Book, it must submit a "Paragraph IV certification" asserting that "such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug[.]" [*Id.* at ¶ 9]. Upon FDA's acceptance of a Paragraph IV application, the ANDA applicant must give notice of the Paragraph IV certification to the brand company. [*Id.*]. The filing of a Paragraph IV certification is, by statute, an act of patent infringement, allowing the patent holder to sue. [*Id.*]. If a patent owner sues within 45 days of receiving a Paragraph IV certification, the FDA cannot grant final approval of the related ANDA for 30 months absent a final court decision holding that the patents are invalid or not infringed. [*Id.*]. Expiration of the 30-month litigation stay does not automatically give rise to final ANDA approval, but simply lifts the prohibition against FDA from doing so. [*Id.* at ¶ 10]. Only if FDA approves an ANDA can the

ANDA filer launch (i.e., begin to sell) its generic product. [*Id.*]. If the ANDA filer receives FDA approval and launches its generic product while patent litigation is pending, it does so "at risk," because it may be enjoined from selling the product and be liable for infringement damages should it ultimately lose the patent litigation. [*Id.*].

The first generic manufacturer to file a "substantially complete" ANDA containing a paragraph IV certification is eligible for 180-days of exclusivity from other generic competition. [Doc. No. 499 at ¶ 3; Doc. No. 509 at ¶ 11]. FDA cannot approve other, later-filed ANDAs until the first filer's 180-day exclusivity has run or been forfeited. [Doc. No. 509 at ¶ 11]. This 180-day first-filer marketing exclusivity period does not apply to, or bar the sale of, an authorized generic version of the brand product that is made and sold or licensed by the owner of the brand product. [*Id.*].

Authorized generics, also referred to as "AGs," are marketed and sold under the brand drug's FDA approval; in other words, an AG is the brand drug sold under a generic label, but with no trademark or trade dress or using a different trademark and trade dress other than the brand drug. [Doc. No. 499 at ¶ 4]. A brand drug manufacturer can sell an AG version of its drug whenever it wants, so the first ANDA generic is never guaranteed a time without any generic competition due, in part, to the potential of an AG product launch. [*Id.* at ¶ 5]. Generic drugs are typically less expensive than their branded counterparts, with generic drug discounts increasing as more generic versions become available. [*Id.* at ¶ 6]. While brand name drugs companies compete for market share by clinically differentiating their product to doctors, generic drugs are identical to their brand counterpart (and each other), in that they share the same active ingredient, and so they generally compete for market share based on price. [*Id.* at ¶ 7]. The entrance of the second generic will generally start price competition and result in a price decline as generic

drugs compete on price with each other. [*Id.* at ¶ 8]. In all 50 states and the District of Columbia, there are automatic substitution laws that permit or require pharmacists to substitute branded drugs with generics when available, and as a result, generic substitution occurs rapidly. [*Id.* at ¶ 9 (citing Doc. No. 419-5 at 19–20, ¶ 31)].

Plaintiffs contend that when unrestricted competition begins, consumers often have three purchasing options available in the first 180 days: the brand drug, the first ANDA generic to receive FDA approval, and an AG. [*Id.* at ¶ 10]. Defendants dispute this, noting that consumers of Amitiza or generic Amitiza have more purchasing options because Amitiza is just one of several treatments of chronic constipation and is interchangeable with other chronic constipation drugs ("CCDs") such as Linzess, Relistor, Symproic, Zelnorm, and Motegrity. [*Id.*]. Selling an AG to compete with the first ANDA generic allows the brand company to capture some of what would otherwise have been lost sales/revenue to the ANDA generic. [*Id.* at ¶ 11].

B. Amitiza

Amitiza, which contains the active pharmaceutical ingredient lubiprostone, was developed by Sucampo Pharmaceuticals, Inc. ("Sucampo").[3] [*Id.* at ¶ 12]. Amitiza is a prescription oral capsule that increases fluid secretion in the intestines to help facilitate stool passage. [*Id.* at ¶ 13]. Sucampo made the decision to partner with a company that had the capabilities and commercial infrastructure to commercialize (i.e., promote and sell) Amitiza in the United States. [*Id.* at ¶ 14 (citing Doc. No. 419-3 at 759–760, 13:15-14:9)]. On October 29, 2004, Defendant Takeda Limited Pharmaceutical Company Limited entered into a Collaboration and License Agreement ("CLA") with Sucampo, pursuant to which Sucampo granted Takeda an "exclusive, non-transferable license . . . to co-develop, use, sell, promote, offer for sale, import and distribute the

[3] Defendants dispute this in part stating that Amitiza was co-developed by Sucampo and R-Tech Ueno, Ltd. ("RTU"). [Doc. No. 499 at ¶ 12].

Product" Amitiza and to use the trademarks to "advertise, market, promote and sell" Amitiza. [*Id.* at ¶ 15 (citing Doc. No. 419-6 at 524)].[4] In exchange, Takeda agreed to pay Sucampo an upfront payment of $20 million, and the CLA provided for milestone payments and running royalties contingent on certain conditions outlined in the CLA. [Doc. No. 499 at ¶ 15 (citing Doc. No. 419-6 at 537–538)]. Also, on October 29, 2004, Takeda entered into an intellectual property agreement with Sucampo. [*Id.* at ¶ 16]. This agreement obligated each party to notify the other of any infringement or threatened infringement of the patents related to Amitiza. [*Id.*]. Takeda also had the right to prosecute an infringement action if Sucampo elected not to; and each party was obligated to cooperate with the other if the other were prosecuting the infringement action. [*Id.*]. On January 31, 2006, Amitiza was first approved by the FDA for the treatment of chronic idiopathic constipation in adults. [*Id.* at ¶ 17; *see also* Doc. No. 509 at ¶ 5]. In April 2006, Takeda and Sucampo began jointly selling Amitiza in the United States and in accordance with the parties' CLA. [Doc. No. 499 at ¶ 18; Doc. No. 509 at ¶ 6]. On January 29, 2008, Amitiza was approved by the FDA for the treatment of irritable bowel syndrome with constipation in adult women. [Doc. No. 499 at ¶ 19].

C. The Patents

Sucampo secured seventeen patents covering Amitiza and listed those patents in the Orange Book. [Doc. No. 509 at ¶¶ 12–13]. In August 2012, Par submitted an amended ANDA for generic lubiprostone to the FDA. [Doc. No. 499 at ¶ 20; Doc. No. 509 at ¶ 18]. Par's revised ANDA contained a Paragraph IV certification as to all Amitiza patents then-listed in the Orange

[4] *See also* [Doc. No. 509 at ¶ 14 (Takeda purchases the Amitiza brand product that it sells from R-Tech Ueno, Ltd. ("RTU"). Both Mallinckrodt (which acquired Sucampo) and Par are in or have recently emerged from bankruptcy)].

Book, certifying that they were either invalid or not infringed by Par's product. [Doc. No. 509 at ¶ 18]. The Paragraph IV certification triggered Sucampo's right to sue Par. [*Id.*].

On February 7, 2013, Takeda and Sucampo sued Par for patent infringement (hereafter, the "Par Patent Litigation"). [Doc. No. 499 at ¶ 23]. Takeda asserted seven patents against Par in the Par Patent Litigation: U.S. Patent No. 6,414,016 (the '016 Patent), U.S. Patent No. 8,076,613 (the '613 Patent), U.S. Patent No. 7,795,312 (the '312 Patent), 8,389,542 (the '542 Patent), U.S. Patent No. 8,097,653 (the '653 Patent), U.S. Patent No. 8,016,393 (the '393 Patent), and U.S. Patent No. 8,338,639 (the '639 Patent). [Doc. No. 509 at ¶ 206]. U.S. Patent No. 8,748,481 (the '481 Patent) issued on June 10, 2014, less than a week before the first settlement meeting between Par and Takeda took place on June 16, 2014. [*Id.* at ¶ 209]. U.S. Patent No. 8,779,187 (the '187 Patent) issued on July 15, 2014. [*Id.* at ¶ 210]. Takeda never asserted the '481 or '187 patent against Par, [*Id.* at ¶ 211], however, the final Settlement Agreement between Takeda and Par included a covenant not to sue Par on any other patent purporting to cover Amitiza, including the '481 or '187 patents. [*Id.* at ¶ 212].

Five other generic manufacturers, Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's" or "DRL"); Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. (collectively, "Teva"); Amneal Pharmaceuticals LLC ("Amneal"); Sun Pharmaceutical Industries, Ltd. and Sun Pharmaceutical Industries, Inc. (collectively, "Sun"); and Zydus Pharmaceuticals (USA) Inc. ("Zydus") (collectively, the "Later Filers" and with Par, the "ANDA Filers"), filed ANDAs for generic versions of Amitiza. [*Id.* at ¶ 21]. Sucampo, RTU, and Takeda filed separate infringement lawsuits against each of them. [*Id.*].

On September 25, 2017, Sucampo asserted the '481 Patent against Teva in the Teva Hatch-Waxman litigation, and Teva settled the Teva Hatch-Waxman Litigation effective June 28, 2018.

[*Id.* at ¶ 93]. On October 30, 2018, Sucampo asserted the '481 and '187 Patents against Sun in the Sun Hatch-Waxman litigation, and Sun settled the Sun Hatch-Waxman litigation effective June 4, 2020. [*Id.* at ¶ 94]. On January 28, 2020, Sucampo asserted the '481 and '187 Patents against Zydus in the Zydus Hatch-Waxman litigation, and Zydus settled the Zydus Hatch-Waxman litigation effective October 21, 2020. [*Id.* at ¶ 95]. FDA granted final approval for DRL's lubiprostone ANDA on February 8, 2022. [*Id.* at ¶ 190]. FDA granted tentative approval for Teva's lubiprostone ANDA on March 9, 2021. [*Id.* at ¶ 194]. FDA granted final approval for Amneal's lubiprostone ANDA on November 30, 2021. [*Id.* at ¶ 200].

On April 26, 2013, following the initiation of the Par Patent Litigation, Takeda and Sucampo entered into a Common Interest Agreement. [Doc. No. 499 at ¶ 24]. As part of the agreement, Takeda and Sucampo agreed that each of them, "through various licensing agreements and ownership interests ha[d] Common Interests pertaining to actual and potential patent infringement litigation." [*Id.* (citing Doc. No. 419-7 at 119)].

D. The Settlement Agreement[5]

On October 9, 2014, Takeda signed the settlement agreement (the "Settlement Agreement" or "Agreement") between Sucampo, Takeda, RTU, and Par, effective September 30, 2014. [*Id.* at ¶ 25 (citing Doc. No. 419-3 at 23–26)]. On October 9, 2014, Takeda entered into an amended CLA with Sucampo, effective September 30, 2014. [*Id.* at ¶ 26]. Takeda entered into an extension of the CLA with Sucampo, "so that Takeda and Sucampo may share in the gross

[5] To the extent that facts outlining terms of the Settlement Agreement and other agreements are disputed because the terms of the Settlement Agreement "speak for themselves," those are improper objections that do not create disputes of fact. To the extent that the parties dispute the *interpretation* of certain terms of the contract, that may constitute a dispute of fact. Otherwise, recitations of portions of the agreements as stated in either party's statement of facts will be detailed here as undisputed to the extent they simply state what the agreements say.

profits of Amitiza after the launch of Par's generic lubiprostone." [*Id.* at ¶ 27 (citing Doc. No. 419-7 at 136)].

The Settlement Agreement granted Par a nonexclusive license "with respect to the Sucampo Patents," beginning on January 1, 2021 to make and market either its generic lubiprostone product pursuant to its ANDA, or to market an Amitiza AG product supplied by Sucampo. [Doc. No. 509 at ¶ 22]. At the time of the Settlement Agreement, the FDA had not approved Par's ANDA. [*Id.* at ¶ 26]. Par exercised its option under the Settlement Agreement to market an Amitiza AG beginning in January 2021, which permitted Par to market generic Amitiza without having gained FDA approval of its ANDA and six years before the expiration of Sucampo's patents in 2027. [*Id.* at ¶¶ 27–28]. Par received FDA approval for its ANDA product on June 27, 2022. [*Id.* at ¶ 29]. Several of the Later Filers launched their generic Amitiza (either an AG or an ANDA product) shortly after January 1, 2023. [*Id.* at ¶ 30]. Beyond any AG-launches by the ANDA Filers, Sucampo and Takeda did not launch an additional AG Amitiza product. [*Id.* at ¶ 31].

When entering the Settlement Agreement, the parties acknowledged the "significant future legal expenses and inherent legal risks involved in continuing protracted patent litigation with an uncertain end" and that the settlement of the patent litigation will permit the parties to "avoid the substantial costs, uncertainty and risk involved with prolonged patent-infringement litigation, trial and appeal." [Doc. No. 499 at ¶ 29 (citing Doc. No. 419-3 at 3)]. On November 21, 2014, following their Settlement Agreement, the parties to the patent litigation action filed a joint motion to approve the consent judgment and for the case to be closed, and on December 2, 2014, the judge approved and entered the consent judgment ending the litigation. [*Id.* at ¶ 31].

The license arrangement is set forth in Article 3 of the Settlement Agreement. [*See* Doc. No. 419-3 at 9–14]. Section 3.3 states that "Par and its Affiliates and Related Parties shall not make, have made, import into, distribute, offer to sell or sell in the Territory any Licensed Products prior to the License Effective Date." [*Id.* at 9]. The terms "Licensed Products" and "License Effective Date" are defined in the Settlement Agreement, [*id.* at 5], although the parties dispute the interpretation of these terms or how they impact other sections in the Settlement Agreement. [*See* Doc. No. 499 at ¶ 32]. The term "Licensed Products" is defined as "Par's ANDA Products:"

> "Licensed Products" means Par's ANDA Products, consisting of an 8 mcg soft gelatin capsule for irritable bowel syndrome with constipation and a 24 mcg soft gelatin capsule ANDA Products for chronic idiopathic constipation and opioid-induced constipation as existing on the Effective Date, as described in the Par ANDA that may be amended or supplemented by Par from time to time in the ordinary course of business, provided that any such amendment or [redacted]

[Doc. No. 419-3 at 5]. The term "License Effective Date" means the earliest to occur of the following dates:

> (a) January 1, 2021; or
>
> (b) provided that Par has not forfeited its 180-day exclusivity pursuant to 21 U.S.C. § 355(J)(5)(D), the date of a Final Court Decision in an action brought against or by a Third Party that causes the 75-day period of 21 U.S.C. § 355(J)(5)(D)(i)(I)(bb)(AA) to begin; in the event of such forfeiture, the date following the entry of such Final Court Decision on which such Third Party begins to Commercially Market a Generic Equivalent; or
>
> (c) in the event that Sucampo or any of its Affiliates enters into an agreement with any Third Party that would permit such Third Party to market or sell in the Territory a Generic Equivalent, the date provided for by Section 3.6 of this Agreement; or
>
> (d) in the event that Sucampo or any of its Affiliates, or a Third Party, Commercially Markets or sells an Authorized Generic, the date provided for by Section 3.7 of this Agreement; or
>
> (e) the date on which a Market Decline Event occurs.

[*Id.*]. Additional provisions that relate to market entry include Sections 3.6–3.8, 3.10, and 3.11. [*Id.* at 10–12]. Section 3.1 states that, "[e]ffective upon the License Effective Date, Sucampo and

RTU hereby grant to Par a non-exclusive license with respect to the Sucampo Patents with the right to grant sublicenses to Affiliates, (i) to make, have made, use, promote, offer to sell, sell, import, or otherwise dispose of Licensed Products in the Territory, and (ii) to make and have made the Licensed Products outside the Territory only for use, sale and importation in the Territory." [*Id.* at 9]. Section 3.12 of the Settlement Agreement states that "Par shall have the option to Commercially Market an Authorized Generic, but not earlier than January 1, 2021." [*Id.* at 12]. Specifically, Section 3.12 states:

> Section 3.12 Par's Option to Sell Authorized Generic Products. Par shall have the option to Commercially Market an Authorized Generic, but not earlier than January 1, 2021. In the event that Par or its Affiliates wishes to Commercially Market an Authorized Generic, Par shall first notify Sucampo of its desire to purchase Authorized Generic products to resell, which Authorized Generic products shall be supplied to Par at [redacted] (the "Authorized Generic Supply Cost") and pursuant to such other terms and provisions as set forth in the Manufacturing and Supply Agreement set forth on Exhibit B hereto. Except as stated above in this Section 3.12, all terms in this Agreement that apply to Licensed Products shall apply equally to the Authorized Generic products manufactured for, and supplied to Par, including the payment of royalties pursuant to Section 3.13, as though Par were Commercially Marketing Licensed Products.

[*Id.*]. Section 3.12 specifies that, except for as stated in Section 3.12, "all terms" in the Settlement Agreement "that apply to Licensed Products shall apply equally to the Authorized Generic products manufactured for, and supplied to Par, including the payment of royalties pursuant to Section 3.13, as though Par were Commercially Marketing Licensed Products." [*Id.*]. The royalty structure is outlined in Section 3.13. The relevant portions of the Settlement Agreement governing the royalties are as follows:

Section 3.13(a): "Beginning on the License Effective Date, Par shall pay Sucampo a royalty of [redacted] . . . ." [*Id.*].

Section 3.13(b): "During any period after the License Effective Date where, in addition to Par Commercially Marketing a Generic Equivalent, one Third Party is Commercially Marketing

a Generic Equivalent or Authorized Generic in the Territory (or Sucampo, RTU, and/or Takeda or an Affiliate is Commercially Marketing an Authorized Generic in the Territory) the royalty rate provided for in Section 3.13(a) [redacted] and Sucampo or its Affiliates have the option to supply Par with Authorized Generic products at a negotiated costs plus price." [*Id.* at 13].

Section 3.13(c): If "two or more Third Parties are Commercially Marketing a Generic Equivalent or Authorized Generic in the Territory (or one or more Third Parties is Commercially Marketing a Generic Equivalent and Sucampo, RTU, and/or Takeda or an Affiliate is Commercially Marketing Authorized Generics in the Territory), the royalty rate provided for in Section 3.13(a) shall be [redacted] and Sucampo or its Affiliates have the option to supply Par with Authorized Generic products at a negotiated costs plus price." [*Id.*].

The term "Authorized Generic" is defined in the Settlement Agreement as "8 mcg and 24 mcg lubiprostone products sold in the Territory pursuant to NDA No. 021908 but not under the AMITIZA® trademark." [*Id.* at 4]. The term "Generic Equivalent" is defined in the Settlement Agreement as "a pharmaceutical product that has received FDA approval for marketing in the Territory pursuant to an ANDA (or equivalent regulatory mechanism) as a generic equivalent to the AMITIZA® Products." [*Id.* at 5]. The parties dispute the interpretation of the terms "Authorized Generic," "Generic Equivalent," and "Licensed Products" as they relate to the royalty provisions in the Settlement Agreement. [*See* Doc. No. 499 at ¶¶ 32, 37–39]. Specifically, the parties dispute whether the terms of the royalty provisions apply whether Par launches an ANDA generic or an Authorized Generic. [*See id.* at ¶ 39].

Section 6.15 of the Settlement Agreement states: "This Agreement constitutes the entire agreement between the Parties with respect to the subject matter hereof, and no oral or written

statement that is not expressly set forth in this Agreement may be used to interpret or vary the meaning of the terms and conditions hereof. This Agreement supersedes any prior or contemporaneous agreements and understandings, whether written or oral, between the Parties with respect to the subject matter hereof." [Doc. No. 419-3 at 22; Doc. No. 499 at ¶ 40].

E. Performance Under The Settlement Agreement

In dispute is whether Sucampo was incentivized not to launch an AG based on the 50 percent royalty provision in the Settlement Agreement. [Doc. No. 499 at ¶ 58]. The parties also dispute how exactly Sucampo, Par, or Takeda interpreted the 50/50 profit split to mean in the Settlement Agreement. [*Id.* at ¶¶ 59–61]. Takeda's annual sales of brand Amitiza peaked at [redacted] in 2020. [*Id.* at ¶ 62]. In 2020, the average wholesale price of brand Amitiza was [redacted]. [*Id.* at ¶ 63]. The first generic version of Amitiza became available in January 2021 when Par—relying on product supplied by Sucampo—launched an AG version of Amitiza (as opposed to under an ANDA). [*Id.* at ¶ 64 (citing Doc. No. 419-3 at 679, ¶ 44)]. Par's generic sales quickly captured the majority of brand and generic Amitiza sales. [*Id.* at ¶ 65]. Par's generic sales totaled $144.9 million in 2021 and $150.7 million in 2022. [*Id.* at ¶ 66]. The average wholesale price of Par's generic Amitiza product was $3.83 per pill in 2021 and 2022. [*Id.* at ¶ 67]. Dr. Reddy's, Sun, and Teva all launched generic versions of Amitiza in January 2023, while Amneal launched in March 2023 and Zydus in January 2024. Among these five generic manufacturers, three (Teva, Amneal, and Zydus) launched generic versions of Amitiza under an ANDA. The remaining two (Dr. Reddy's and Sun) launched AG versions of Amitiza like Par—as permitted by their respective patent settlement agreements with Sucampo and Takeda. [*Id.* at ¶ 68 (citing Doc. No. 419-3 at 680, ¶ 45)].

The average generic wholesale price of Amitiza dropped to $1.26 during 2023 as other generic Amitiza products were introduced. [*Id.* at ¶ 69]. As of 2023, Par continued to sell an AG version of Amitiza under Sucampo's NDA. [*Id.* at ¶ 70]. During the two years that Par was on the market as the only generic lubiprostone, Par and Sucampo performed under the Settlement Agreement by splitting Par's gross profits 50/50, though Defendants dispute whether Plaintiffs' cited evidence demonstrates that Par and Sucampo actually did split the gross profits. [*Id.* at ¶¶ 71–72]. Takeda did not launch, and has not launched, an AG lubiprostone product. [*Id.* at ¶ 73].[6]

F. Market Power

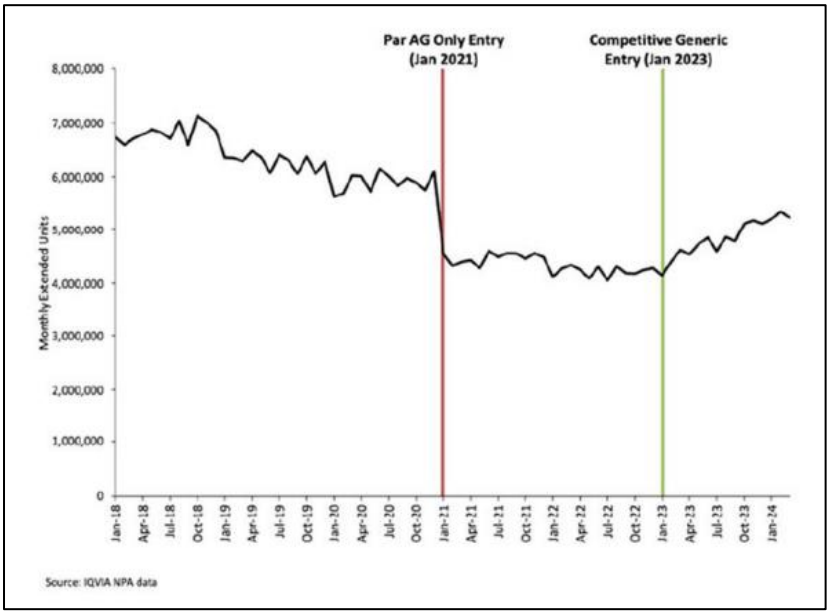
Takeda "switching reports" tracked patient switching between Amitiza, Linzess, and other chronic constipation drugs from 2013 to 2019. [Doc. No. 509 at ¶ 33]. Takeda's Amitiza market definition in October 2014 included Linzess, Relistor, and Movantik, and Takeda planned to increase its Amitiza marketing efforts prior to the launch of Movantik in 2015. [*Id.* at ¶ 34]. In July 2019, October 2019, and April 2020, Takeda's "corporate market definition" documents, which tracked the drugs that Takeda considered Amitiza's competitors, included Linzess, Movantik, Relistor, Symproic, and Trulance. [*Id.* at ¶ 35]. Ironwood Pharmaceuticals, one of the developers and marketers of Linzess, compared Linzess's anticipated market penetration after launching in December 2012 relative to Amitiza and Zelnorm. [*Id.* at ¶ 36]. AstraZeneca, which manufactured Movantik, [redacted]. [*Id.* at ¶ 37]. Takeda cites to testimony from CVS's and Walgreen's corporate representatives to support its statement that Amitiza competed with Linzess, Trulance, Relistor, and Movantik, which Plaintiffs dispute. [*Id.* at ¶¶ 38–39].

[6] Plaintiff's statement of facts states that Mallinckrodt, which acquired Sucampo, has not launched its own AG lubiprostone product. [Doc. No. 499 at ¶ 74]. Defendants dispute this and claim that Sucampo and Mallinckrodt have launched three AG lubiprostone products, distributed by each of Par, DRL, and Sun, but do not cite to record evidence. [*Id.*]

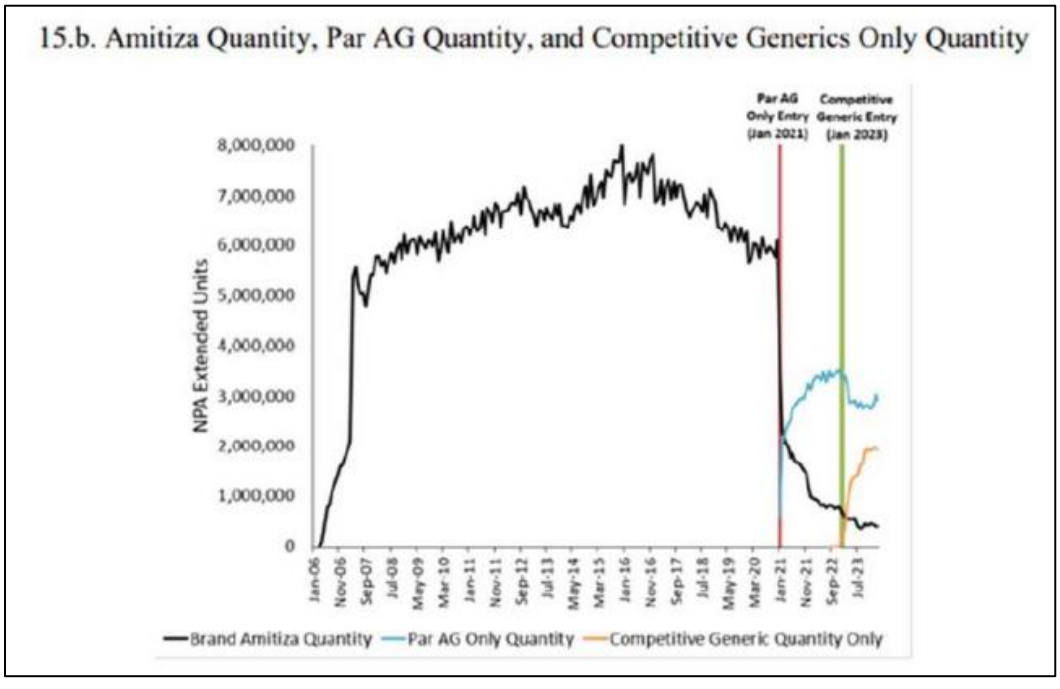
In the month before generic entry, brand Amitiza's wholesale price was $5.74. [Doc. No. 499 at ¶ 76]. Upon entry of the Par AG in January 2021, Par's AG Amitiza was priced lower than brand Amitiza and quickly captured the majority of brand and generic Amitiza sales after entry. [*Id.* at ¶ 77]. In the two years when the Par AG was the only generic on the market, the wholesale price of the Par AG averaged $3.83 per capsule, a 33% decline in price from pre-generic entry. [*Id.* at ¶ 78]. Upon entry of multiple versions of generic Amitiza in January 2023, the generic wholesale price continued to drop rapidly. During 2023, the average generic price was $1.26 per capsule, and by March 2024, the last month of available data, it had dropped to $0.63 per capsule, an 89% decline from the pre-generic entry price. [*Id.* at ¶ 79]. Based upon Takeda's own profit and loss statements for Amitiza, which do not include research and development costs, Takeda's gross margins on Amitiza ranged from [redacted] between 2012 and 2020, with an average gross margin of [redacted] over this period. [*Id.* at ¶ 80].

Plaintiffs state that generic manufacturers' company-wide gross margins over the same period averaged between 36% and 44%. [*Id.* at ¶ 81]. Defendants dispute this and argue that gross margins represent the generic firm's revenue-weighted average margin for all drugs in the company's portfolio across varying therapeutic areas and competitive positions and comparing it to the margins of branded manufacturers does not account for the additional costs that branded manufacturers incur that must be accounted for in an analysis of profitability. [*Id.*]. Plaintiffs also state that the Lerner Index value for Amitiza over this period was between [redacted]. [*Id.* at ¶ 82]. Defendants respond that the Lerner Index is not appropriate for use in pharmaceutical cases as it does not take into account other costs like research & development or marketing. [*Id.*]. Takeda's Lerner Index value for Amitiza translates to a price markup between [redacted]; i.e., Takeda priced Amitiza between [redacted] times its cost of producing Amitiza. [*Id.* at ¶ 83].

Plaintiffs provide the monthly aggregate brand and generic lubiprostone sales in extended units ("EUs") from data vendor IQVIA, as well as IQVIA National Prescription Audit ("NPA") data:



[*Id.* at ¶ 84]. Monthly lubiprostone sales in EUs (IQVIA NPA data), separated into sales of brand Amitiza, Par AG Amitiza, and competitive (non-Par) generic Amitiza:



[*Id.* at ¶ 85]. Plaintiffs state that the only event that caused a dramatic decline in Amitiza sales was the entry of generic Amitiza. [*Id.* at ¶ 86]. Defendants dispute this, citing to (1) changes in Amitiza price influencing sales of Symproic and Relistor, (2) the entry of competitive products like Linzess or Movantik, which also influenced Amitiza sales, (3) Takeda's pricing strategy to minimize its price premium relative to Linzess, and (4) the entry of Par's AG product. [*Id.*].[7]

III. PROCEDURAL HISTORY

On November 19, 2024, Plaintiffs filed their Motion for Partial Summary Judgment, [Doc. No. 416], and Defendants filed their Motion for Summary Judgment, [Doc. No. 421]. That same day, Defendants filed their motions to exclude certain of Plaintiffs' experts. [Doc. Nos. 404, 406, 408, 410, 412, 414]. On December 18, 2024, Plaintiffs filed their motions to exclude certain of Defendants' experts. [*See* Doc. Nos. 457, 459, and 461]. On January 29, 2025, Defendants filed their Motion to strike portions of Section XII of Plaintiffs' Statement of Material Facts. [Doc. No. 506].

IV. DAUBERT MOTIONS

Both parties have filed a number of *Daubert* motions to exclude each other's experts at summary judgment. I will address those motions in turn. I further note that some of the arguments made on the merits for summary judgment depend on the admissibility of certain of these experts' opinions. As explained below, I find that all of the challenged experts are admissible. As such, to the extent that any arguments are premised on the fact that the only evidence either party offers depends on those experts' opinions, summary judgment will be DENIED.

[7] Defendants' statement of facts also cites to opinions and testimony offered by the parties' experts regarding market power. *See* [Doc. No. 509 at ¶¶ 40–64]. The parties do not dispute that these opinions and testimony were given; they dispute their import. Accordingly, such discussion is more appropriate for its relevance to the legal analysis.

Rule 702 of the Federal Rules of Evidence governs testimony by expert witnesses, codifying standards set forth in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). The rule defines an expert witness as "a witness who is qualified as an expert by knowledge, skill, experience, training, or education." Fed. R. Evid. 702. To be permitted to testify, the following four requisites must be met: (1) "the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;" (2) "the testimony is based on sufficient facts or data;" (3) "the testimony is the product of reliable principles and methods; and" (4) "the expert's opinion reflects a reliable application of the principles and methods to the facts of the case." *Id*. *Daubert* also states that to be admissible, an expert's opinion must rest on more than a "subjective belief or unsupported speculation," and that it must be grounded in "appropriate validation" based on what is known. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 590 (1993).

"This rule imposes a gate-keeping role on the trial judge to ensure that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *United States v. Vargas*, 471 F.3d 255, 261 (1st Cir. 2006) (quoting *Daubert*, 509 U.S. at 597)). "Expert testimony must be reliable, such that 'the reasoning or methodology underlying the testimony is scientifically valid and … that reasoning or methodology properly can be applied to the facts in issue.'" *Id.* (quoting *Daubert*, 509 U.S. at 592–93). "The proffered expert testimony must also be relevant . . . in the incremental sense that the expert's proposed opinion, if admitted, likely would assist the trier of fact to understand or determine a fact in issue.'" *Id.* (citation omitted). "The inquiry under Rule 702 is a 'flexible' one." *Id.* (quoting *Daubert*, 509 U.S. at 594). "The trial court enjoys broad latitude in executing its gate-keeping function; there is no particular procedure it is required to follow." *Id.*

V. DEFENDANTS' DAUBERT MOTIONS[8]

A. Susan Marchetti

Defendants move to exclude the opinions of Susan Marchetti, [Doc. No. 404], an expert in Pharmaceutical Supply Chain Management and Manufacturing Operations, who offers "testimony regarding the dates on which Par Pharmaceuticals ("Par"), Amneal Pharmaceuticals ("Amneal"), Teva Pharmaceuticals ("Teva"), and Dr. Reddy's Laboratories ("DRL" and, collectively, the "ANDA Filers") would have been ready to launch their Generic Amitiza products absent the alleged anti-competitive agreement at the center of Plaintiffs' complaints." [Doc. No. 405 at 6]. Defendants argue that Ms. Marchetti's opinions must be excluded because (1) she was improperly asked to "assume" that the ANDA Filers would be ready to launch by the dates selected by Plaintiffs, (2) Ms. Marchetti testified to a list of documents that she would require in the ordinary course to assess a company's ability to launch by a certain date, which she did not rely upon in forming her opinions in this case, and therefore, her opinions were inconsistent with her professional experience, and (3) her opinions lacked foundation due to Plaintiffs' intentional avoidance of obtaining discovery from Par. [*Id.* at 6–7].

a. Whether Ms. Marchetti Assumed Launch Dates

Ms. Marchetti was asked to opine on three questions:

> Did the ANDA filers listed below have the ability to manufacture enough generic Amitiza (lubiprostone) to support a launch by the corresponding dates listed below and continue to support commercial demand volumes going forward?
>
> i. Par Pharmaceuticals – October 2016.
> ii. Amneal Pharmaceuticals – June 2019.
> iii. Teva Pharmaceuticals – March 2021.
> iv. Dr. Reddy's Laboratories – February 2022.

[8] Defendants' Motion to Exclude the opinions of Plaintiffs' Experts on Litigation Success, Probability, Timing, Expenses, and Hypothetical Launch Dates, [Doc. No. 406], is addressed in relevant parts of the opinion below. As explained in those sections, the Motion is DENIED.

[Doc. No. 466 at 8]. Ms. Marchetti concluded:

> Par or a reasonable generic manufacturer in Par's position – e.g., a generic manufacturer with significant resources, facilities, and a claim to generic exclusivity on a drug with large sales – would have been incentivized and able to manufacture sufficient quantities of generic Amitiza to meet market demand, at launch and thereafter, if it had launched its ANDA generic version of Amitiza in 2016 (or 2018). Similarly, reasonable generic manufacturers in the position of subsequent ANDA filers Amneal, Teva and DRL would have had the resources and facilities to manufacture sufficient quantities of generic Amitiza to meet market demand for their generic products, at launch and thereafter, if they had launched in June 2019, March 2021, and February 2022, as Plaintiffs allege would have occurred absent the terms of the Takeda/Sucampo-Par agreement.

[*Id.* at 9]. Plaintiffs argue that Ms. Marchetti's conclusion was based on "a) her 35 years of experience in the pharmaceutical industry in high-level positions (e.g., Head of Supply Chain Operations, Chief Operating Officer, and Executive Board member); b) her review of the evidentiary record in this case; and c) her independent research regarding the abilities, resources, facilities, and sophistication of the Lubiprostone ANDA Filers." [*Id.* at 12]. Plaintiffs clarify that when Ms. Marchetti testified that she was asked to "assume that Par, Teva, Amneal and DRL would be able to launch by a certain date," she was asked to assume that "there were no regulatory or patent impediments to launch by the specified dates provided to her," rather than assume "that the ANDA Filers could manufacture sufficient generic Amitiza to support a launch." [*Id.* at 12, 13]. Defendants argue that this is merely a *post facto* argument unsupported by the record. [Doc. No. 503 at 4].

Even if that is so, Defendants have not shown that Ms. Marchetti's opinions were based only exclusively on assumptions. Ms. Marchetti's opinions are based on her 35 years of experience working in supply chain management, her consideration of "over 100 documents produced by the ANDA filers in this litigation—including regulatory submissions related to drug manufacturing and internal planning documents," and the deposition testimony of the Senior

Director and Head, Strategic Portfolio Management/North America for DRL, who testified that she was not aware of any compliance or manufacturing issues that would prevent DRL from being able to launch. [Doc. No. 466 at 14]. In her opening report, Ms. Marchetti analyzed the capabilities of the ANDA Filers to launch by the dates that Plaintiffs allege, but for the no-second-generic condition, ANDA Filers would have obtained FDA approval. As such, she analyzed Par's marketing materials and public disclosures to conclude that Par was a "large, sophisticated generic company with substantial resources, significant manufacturing capabilities, and a history of successful generic launches, including generic versions of brand drugs with substantial sales, and for which Par enjoyed periods of generic market exclusivity," such that Par had the ability to launch. [*Id.* at 17–18]. These capabilities were enhanced when Par was acquired by Endo in 2015, and Ms. Marchetti further explains that Par partnered with another sophisticated pharmaceutical company, [redacted] that could assist with these capabilities. [*Id.* at 18–19].

As such, I do not find persuasive Defendants' arguments that Ms. Marchetti's opinions should be excluded based on her assumption.

b. Whether Ms. Marchetti's Opinions Are Reliable

Defendants next argue that Ms. Marchetti's opinions should be excluded because, despite testifying to categories of documents and information that may be helpful to her analysis, she did not look at any such information for any ANDA Filer, could not point to any specific documents that were produced by the ANDA Filers that were specific to generic Amitiza, and could not identify a single drug launched by ANDA Filers that was comparable to generic Amitiza in its form, dosage, active ingredients, the manufacturing processes needed to make it, or source materials and requisite lead times. [Doc. No. 405 at 20]. Plaintiffs respond that the types of

documents Ms. Marchetti identifies—"documents regarding available equipment, capacity constraints, lead times for producing the product, lead times for obtaining the required materials, transportation lead times, determinations of the appropriate levels of inventory, lot sizes, and safety stock"—would not have existed in this case due to the fact that Par could not launch a generic version of Amitiza until 2021, and opted to launch an AG instead of its own product. [Doc. No. 466 at 15].

In response to Defendants' arguments that Ms. Marchetti did not consider the ANDA Filers' capabilities of manufacturing drugs with the characteristics of lubiprostone, Plaintiffs argue that Ms. Marchetti discussed evidence demonstrating that Par's finished goods manufacturer, [redacted] had 80 years of experience developing soft-gel capsules. [*Id.* at 19]. Furthermore, Plaintiffs argue that Dr. Christians, not Ms. Marchetti, was responsible for addressing those technical and scientific questions. [*Id.* at 20]. "As *Daubert* makes clear, questions about the strength of 'the factual underpinning of an expert's opinion' are 'matter[s] affecting the weight and credibility of the testimony' and therefore 'a question to be resolved by the jury.'" *Rodriguez v. Hosp. San Cristobal, Inc.*, 91 F.4th 59, 71–72 (1st Cir. 2024) (quoting *Daubert*, 509 U.S. at 595). Further, the First Circuit guides that "*Daubert* does not require that a party who proffers expert testimony carry the burden of proving to the judge that the expert's assessment of the situation is correct. As long as an expert's scientific testimony 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 Puerto Rico Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998) (citing *Daubert*, 509 U.S. at 596).

Defendants' remaining arguments that Ms. Marchetti failed to develop additional evidence or her lack of awareness regarding the content of depositions from two other Par representatives do not merit exclusion. Defendants do not explain what information from those depositions would warrant exclusion of Ms. Marchetti's existing opinions. Plaintiffs have also pointed out the difficulty of obtaining evidence from Par due to Endo's filing of bankruptcy in 2022, resulting in a stay of all litigation proceedings. That Plaintiffs could have filed a relevant motion in bankruptcy court to obtain such discovery does not explain why Ms. Marchetti's opinions are unreliable and warrant exclusion.

As such, Defendants have not shown that Ms. Marchetti's opinions are unreliable or unhelpful to the jury. Defendants' Motion to Exclude Ms. Marchetti, [Doc. No. 404], is DENIED.

B. Dr. Uwe Christians and Todd Clark

Defendants move to exclude Plaintiffs' experts, Dr. Uwe Christians, a pharmacologist, and Mr. Todd Clark, a pharmaceutical industry expert, regarding their opinions that absent the Settlement Agreement, a reasonable company in Par's position would be incentivized and able to obtain FDA approval and come to market earlier. [Doc. No. 410; Doc. No. 467 at 6]. Defendants argue that: (1) "Dr. Christians and Mr. Clark improperly intrude upon the fact-finder's role by speculating about Par's and FDA's motivations and state of mind;" (2) "many of Dr. Christians' and Mr. Clark's opinions rely on improper interpretations or assumptions about the terms and effects of the 2014 Par Settlement;" and, (3) "even if the opinions were proper in scope, both Dr. Christians and Mr. Clark lack the qualifications necessary to reliably opine on Par's motivations, regulatory strategy, or the terms of the 2014 Par Settlement." [Doc. No. 411 at 6].

Plaintiffs oppose, arguing that Dr. Christians and Mr. Clark are well qualified by their experience to offer opinions as to "how an earlier launch opportunity would have impacted the incentives and conduct of a reasonable generic company in Par's position," and "they do not speculate about the state of mind or intent of Par's employees, or FDA." [Doc. No. 467 at 7]. I agree.

a. Dr. Christians' And Mr. Clark's Opinions On State Of Mind

Defendants contend that Dr. Christians and Mr. Clark improperly intrude upon the fact-finder's role because expert testimony on a party's state of mind, intent, or motivations risks "replacing the jury's judgment with unfounded speculation." [Doc. No. 411 at 6]. Courts routinely permit expert testimony about how a reasonable manufacturer would have acted. *See, e.g.*, *In re Solodyn*, No. 14-md-02503, 2018 WL 734655, at *2 (D. Mass. Feb. 6, 2018) (finding that an expert could not be permitted to testify regarding a party's "actual state of mind," but allowing experts to "opine about how a reasonable company sitting in [the party's] shoes may analyze the business context"); *In re Intuniv Antitrust Litig.*, No. 1:16-cv-12396, 2020 WL 5995326, at *16 (D. Mass. Oct. 9, 2020) (expert "permitted to testify as to why his previous experience leads him to believe that a reasonable company would not necessarily introduce an AG and, instead, would consider a number of factors in determining whether to launch an AG").

Dr. Christians did not improperly attempt to determine Par's mental state in failing to act with urgency in seeking FDA approval, but rather opined "based on his decades of experience and review of contemporaneous documents, that…'Par did not act with the urgency that [he] would expect of a reasonable generic manufacturer seeking to come to market as soon as possible.'" [Doc. No. 467 at 13]. Similarly, Mr. Clark assessed how the terms of the Settlement Agreement "impacted the incentives of Par or a reasonable company in Par's position." [*Id*. at

13–14]. Additionally, both expert witnesses explicitly refrained from offering any opinions or speculation about Par's actual state of mind or motivations. [*Id*. at 15].

Similarly, Dr. Christians and Mr. Clark did not improperly opine on the FDA's state of mind but rather were "simply employing [their] extensive experience regarding dissolution testing to educate the jury about the FDA's relevant guidance." [*Id*. at 17]. Because Dr. Christians' and Mr. Clark's testimonies speak to what a "reasonable generic company" would do, and not on the parties' state of mind, intent, or motivations, such opinions do not improperly intrude on the fact-finder's role and need not be excluded.

b. Dr. Christians' and Mr. Clark's Opinions On The Settlement Agreement

Defendants further contend that Dr. Christians' and Mr. Clark's opinions rely on improper assumptions regarding the Settlement Agreement. Specifically, Defendants argue that the experts' interpretations of the contract terms encroach on the court's authority and their opinions are based on an impermissible assumption that an anticompetitive agreement exists. [Doc. No. 411 at 13]. But Dr. Christians and Mr. Clark do not interpret the terms of the Settlement Agreement nor add anything to them. They merely describe the allegations regarding the Settlement Agreement, the public disclosures, and Par's own internal notes regarding those terms. [Doc. No. 467 at 18]. Further, as explained below, I have concluded as a matter of law that there are disputes of material fact as to what the contract terms mean that are best left for resolution by a jury. Defendants seek to offer their own expert's opinion that is based on their interpretation of the Settlement Agreement, which Plaintiffs move to exclude due to their disagreements about that interpretation. [*See* Doc. No. 459]. As I have denied Plaintiffs' motion to exclude on the basis that it is premature given the material disputes of fact regarding the Settlement Agreement, I will also deny Defendants' motion for the same reason here.

Regarding Defendants' issue with Plaintiffs' experts assuming the existence of an antitrust agreement when forming an opinion, it is hard to understand how an opinion regarding causation could be formed without the underlying assumption that a reverse payment exists. *See In re Pork Antitrust Litig.*, 665 F. Supp. 3d 967, 994 (D. Minn. 2023) (holding that "an expert may express an opinion that is based on facts that the expert assumes, but does not know, to be true, and that it then becomes the responsibility of the party calling the expert to introduce other evidence establishing the facts assumed by the expert") (citation omitted). Here, experts are not assuming facts not in evidence, rather, they are forming an opinion regarding causation that is consistent with Plaintiffs' theory of harm arising from the Settlement Agreement at issue. The jury may disagree, but that does not warrant exclusion. If Plaintiffs' experts were not permitted to form opinions based on Plaintiffs' allegations, all expert opinions would be inadmissible.

c. Dr. Christians' And Mr. Clark's Qualifications

Finally, Defendants contend that even if their opinions were proper in scope, Dr. Christians and Mr. Clark lack the qualifications necessary to opine on Par's motivations, regulatory strategy, or the terms of the Settlement Agreement as "Dr. Christians has never worked at FDA and has no experience with ANDA filings, and Mr. Clark's general industry experience does not include the specialized knowledge required to address these issues." [Doc. No. 411 at 6]. I find that both Dr. Christians and Mr. Clark have the knowledge, experience, and education that would qualify them as expert witnesses. Dr. Christians has decades of experience studying and addressing the primary issues at hand including "dissolution testing, stability, and impurities," along with his laboratory having been contracted by both FDA and other generic companies. [Doc. No. 467 at 24]. Mr. Clark has also had decades of experience as a researcher, scholar, and author studying the generic drug industry. [*Id.*]. During these three decades of

experience, Mr. Clark served as an industry consultant, having been "retained to advise companies on Paragraph IV strategy 'many, many times' and has provided market forecasting input to companies negotiating Hatch-Waxman settlements." [*Id.* at 25].

This is enough to qualify these experts' testimonies. "Expert testimony should be excluded only if it is so fundamentally unsupported that it can offer no assistance to the jury." *Sandoe v. Bos. Sci. Corp.*, 333 F.R.D. 4, 10 (D. Mass. 2019) (citation omitted) (finding that 35 years of experience in the relevant industry and previous submitted testimony in federal courts qualified the expert's testimony). The specialized knowledge of both expert witnesses will help the factfinder understand whether Par's conduct in obtaining FDA approval "was consistent with the manner, and the level of urgency, in which a reasonable generic manufacturer in Par's position would be expected to address those issues absent the Agreement." [Doc. No. 467 at 24].

Accordingly, Defendants' Motion to Exclude the Opinions of Dr. Uwe Christians and Todd Clark, [Doc. No. 410], is DENIED.

C. Christopher J. Ruhm

Defendants seek to exclude Plaintiffs' expert Dr. Christopher J. Ruhm, a healthcare economist expert who opines on the anticompetitive effect of the reverse payment in this case; specifically, he opines that the Settlement Agreement reduced Takeda/Sucampo's incentives to launch a second generic product. [Doc. No. 414; Doc. No. 463 at 5]. Defendants seek to exclude Dr. Ruhm's opinions that, "(1) brands 'typically' launch an authorized generic; (2) settlement agreements between branded and generic pharmaceutical companies 'normally' don't include payments from the generic to the brand; and (3) in competitive settlements with AG licenses, the brand 'typically' keeps a low share of the profits." [Doc. No. 415 at 7]. Takeda argues that Dr. Ruhm's experience as a healthcare economist does not qualify him to provide, "opinions

regarding the 'typical' terms of Hatch-Waxman settlement agreements and competition in pharmaceutical markets" which are "highly specialized and specific." [Doc. No. 493 at 4]. Therefore, Takeda claims that, "Dr. Ruhm has no 'knowledge, skill, experience, training, or education' that would permit him to serve as an expert" regarding the testimony in question. [Doc. No. 415 at 13]. Takeda also argues that the opinions of Dr. Ruhm should be excluded for not being "based on the facts of the case." [Doc No. 493 at 7]. Takeda argues this is shown by Dr. Ruhm's reliance on literature and "conversations with others" that were "aimed at compensating for his lack of expertise." [*Id.* at 8]. Takeda argues that Dr. Ruhm's opinions are not reliable because, "Dr. Ruhm expressly admitted . . . that the articles that he relied upon do not support the opinions that he reached." [Doc. No. 415 at 12].

Plaintiffs oppose, arguing that Dr. Ruhm's "40 years of experience as a recognized and respected healthcare economist... 'allow [him] to look at issues within an economic framework.'" [Doc. No. 463 at 10, 12 (citation omitted)]. Plaintiffs argue that an expert "need not be specialized in the subspecialty he renders his testimony in," and therefore "the fact that his research and prior testimony has not specifically focused on Hatch-Waxman settlement agreements does not negate his decades of relevant experience." [*Id.* at 11–12]. Plaintiffs also dispute Takeda's claim that Dr. Ruhm's discussions with Dr. McGuire, Dr. Bradford, and Dr. Drake was an attempt to "'present the expertise of others by proxy.'" [*Id.* at 14 (citation omitted)]. Plaintiffs argue that "none of these conversations . . . have any bearing over the originality of Dr. Ruhm's work or the opinions he formulated for this case." [*Id.* at 14–15]. Lastly, Plaintiffs claim that "Dr. Ruhm's opinions are reliable, [and] supported by decades of economic literature" [*Id.* at 13]. While Takeda argues Dr. Ruhm admitted his sources do not

support his testimony, plaintiffs say this was a mischaracterization of Dr. Ruhm's deposition testimony where he stated that he hadn't "'chosen the best'" sources. [*Id.*]

a. Dr. Ruhm's Qualifications

Takeda claims that Dr. Ruhm's experience does not provide him with the qualifications necessary to provide expert opinions "regarding the 'typical' terms of Hatch-Waxman settlement agreements and competition in pharmaceutical markets." [Doc. No. 493 at 4]. The First Circuit holds that as long as an expert is, "qualified … by knowledge, skill, experience, training or education … he need not have had first-hand dealings with the precise type of event that is at issue." *Microfinancial, Inc. v. Premier Holidays Int'l Inc.,* 385 F.3d 72, 80 (1st Cir. 2004) (citing Fed. R. Evid. 702). Dr. Ruhm's academic and professional qualifications meet this standard for the testimony he offers.

Dr. Ruhm's background is composed of over 40 years as a healthcare economist. [Doc. No. 463 at 12]. Dr. Ruhm earned a bachelor's, master's, and postdoctoral degree in Economics from the University of California in 1978, 1981, and 1984, respectively. [*Id.* at 6]. Dr. Ruhm went on to work as a Professor at Boston University, University of North Carolina, and the University of Virginia. [*Id.*]. Further, Dr. Ruhm is a "Research Associate in the Health Economics, Health Care and Children's programs at the National Bureau of Economic Research," Distinguished Fellow of the Southern Economics Association, and served for three years as an award committee chair for the International Health Economics Association, where he was "tasked with selecting the best articles in the field of health economics." [*Id.* at 6–7]. Additionally, Dr. Ruhm worked as the "Senior Staff Economist on President Bill Clinton's Council for Economic Advisors" where his "primary responsibilities" included health policy. [*Id.* at 7]. Dr. Ruhm has "over 170 publications in the areas of health and labor economics," and

ranks as "one of the top 50 health economics authors." [*Id.*]. These extensive qualifications allow Dr. Ruhm to "look at issues within an economic framework," and thereby testify as an expert on Hatch-Waxman agreements and competition in pharmaceutical markets. [*Id.* at 12].

In *Microfinancial*, the First Circuit found a witness qualified to testify on the tracking of money into and out of lock-box accounts, despite having no experience dealing directly with lock-box accounts. *Microfinancial, Inc.*, 385 F.3d at 80. The court reasoned that "Rule 702 is not so wooden as to demand an intimate level of familiarity with every component of a transaction," and therefore the witness's thirty-three years of experience as a federal agent specializing in financial fraud qualified their testimony. *Id.* Also, in *Gaydar*, the First Circuit found a medical doctor was qualified to testify on ectopic pregnancies despite being a general practitioner without specialty in obstetrics or gynecology. *Gaydar v. Sociedad Instituto Gineco-Quirúrgico y Planificación* 345 F.3d 15, 24–25 (1st Cir. 2003). The court reasoned that "the proffered expert physician need not be a specialist in a particular medical discipline to render expert testimony relating to that discipline." *Id.* at 24. Similarly, here, Dr. Ruhm's extensive background as a healthcare economist is sufficient and he need not be a specialist regarding Hatch-Waxman agreements or competition in pharmaceutical markets to testify on those disciplines within healthcare economics. This includes testimony as to what is typically included in Hatch-Waxman settlements based on his review of independent sources.

Although Takeda argues that Dr. Ruhm's scenario is more like *Wilson* or *Levin*, these cases do not support excluding Dr. Ruhm's testimony. In *Wilson*, the First Circuit found no abuse of discretion in determining a chemist lacked experience to testify regarding "usages and practices in the silk-screening industry" and the "commercial feasibility of printing shirt logos." *Wilson v. Bradlees of New England., Inc.*, 250 F.3d 10, 18 (1st Cir. 2001). The First Circuit

reasoned that the chemist, "had no familiarity with the silk-screening industry, ink manufacture or logo design." *Id*. Dr. Ruhm's scenario is not analogous. Dr. Ruhm is seeking to testify regarding sub-specialties of health economics, of which he has sufficient experience, whereas the expert in *Wilson* was seeking to testify on industrial manufacturing, a distinct subject from their experience in chemistry. *Id*. Furthermore, in *Levin*, although the First Circuit did not find an abuse of discretion in limiting expert testimony, the First Circuit noted that "the court likely could have allowed . . . the challenged opinion," but "it did not abuse its considerable discretion by taking a more conservative tack and excluding the opinion." *Levin v. Dalva Brothers, Inc.*, 459 F.3d 68, 79 (1st Cir. 2006).

I conclude that Dr. Ruhm's experience places him well within the requisite legal bounds to serve as an expert witness.

b. Dr. Ruhm's Opinions Based On References To Other Experts

Takada also argues that Dr. Ruhm's citation to articles by Dr. McGuire and Dr. Drake, along with conversations with Dr. McGuire, Dr. Drake, and Dr. Bradford, renders Dr. Ruhm's opinions a mere "parroting of information . . . to supplement his own lack of expertise." [Doc No. 415 at 14]. While it is true that a witness may not "'parrot' the conclusions of other witnesses . . . an expert may rely on other witness's testimony or other expert conclusions to form an opinion." *Iconics, Inc. v. Massaro*, 266 F. Supp. 3d 461, 469–70 (D. Mass. 2017) (admitting testimony of expert who relied on others to assist him in interpreting code absent evidence expert merely adopted statements of others "wholesale" when forming his opinion); *see also* Fed. R. Evid. 703 (stating that, "an expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed"). Dr. Ruhm has clarified that he did not parrot any expert's information. [Doc. No. 463 at 14]. Dr. Ruhm explained that he spoke

with Dr. Bradford because he will often "pick somebody's brain if they're a knowledgeable person who can be helpful." [*Id.*]. Dr. Ruhm denies discussing the case with Dr. McGuire and explained that Dr. Drake works for the firm helping Dr. Ruhm assemble his reports. Takeda fails to adequately address whether these conversations, or reliance on any articles, have any bearing over the originality of Dr. Ruhm's work. [*Id.* at 14–15].

Therefore, Takeda has not shown that Dr. Ruhm's opinions are not based on his own independent evaluation of the facts of this case or simply a parroting of information from other experts.

c. Dr. Ruhm's Opinions Based On References To Other Experts

Lastly, Takeda argues that Dr. Ruhm's opinion and testimony should be excluded "because they do not rest on a reliable foundation." [Doc No. 415 at 15]. Takeda bases this argument on the notion that Dr. Ruhm made an "express admission that the articles that he cites do not actually support the opinions for which he cites them," and therefore should be excluded. [*Id.*]. To the contrary, Dr. Ruhm never said that his sources do not support his testimony. Dr. Ruhm stated, "'I haven't chosen the best [sources] . . . but I still believe the statement that I make in the report." [Doc. No. 463 at 13]. This statement does not amount to an admission that Dr. Ruhm's opinions are unsupported. Therefore, Takeda has not shown that Dr. Ruhm's testimony is unreliable.

Accordingly, Defendants' Motion to Exclude Certain Opinions and Testimony of Christopher J. Ruhm, [Doc. No. 414], is DENIED.

D. Nicole Maestas

Defendants move to exclude Plaintiffs' expert, Dr. Nicole Maestas, [Doc. No. 408], who has provided expert testimony on whether Takeda possessed market power. Specifically,

Defendants argue that Dr. Maestas lacks the requisite experience to analyze market power in the pharmaceutical market, and that her opinions regarding direct and indirect evidence of market power are based on insufficient facts or data, unreliable principles and methods, or unreliable application of principles and methods to the facts of this case. [Doc. No. 409 at 5]. Plaintiffs oppose, arguing that Dr. Maestas is sufficiently qualified, that her opinions regarding direct evidence is well-supported, and that her opinions regarding indirect evidence are based on several forms of evidence that led to her conclusion that Takeda has substantial market power. *See* [Doc. No. 465].

a. Dr. Maestas's Qualifications

I find that Dr. Maestas's background as a "qualified and experienced economist" with a focus on health economics is sufficient to serve as an expert witness. [Doc. No. 465 at 5, 8]. Dr. Maestas received a PhD in economics from the University of California, "and currently teaches health economics and health policy at Harvard Medical School and Harvard University." [*Id*. at 5]. From Dr. Maestas's academic experience she has developed the skills necessary to "design and analyze complex economic and econometric models." [*Id*. at 8–9] Further, "Dr. Maestas has been published in numerous significant economic and medical journals... has done extensive study of pharmaceutical prescribing and use and has published journal articles on the topic," and has "testified before the U.S. House and Senate." [*Id*. at 8]. These qualifications would allow Dr. Maestas to "assist the jury in evaluating the issue of market power," and therefore are sufficient for her to serve as an expert witness. [*Id*. at 9]. As explained above, given Dr. Maestas's experience with pharmaceuticals and extensive background as a health economist, she need not be a specialist regarding pharmaceutical antitrust markets to testify on that particular discipline within health economics. Further, the fact that Dr. Maestas has never provided an expert opinion

on market definition before is not sufficient to exclude her testimony. *See, e.g., Doe v. Trustees of Dartmouth Coll.*, 699 F. Supp. 3d 171, 176–77 (D.N.H. 2023).

Although Takeda argues Dr. Maestas's scenario is similar to *Virginia Vermiculite* and *Berlyn*, these cases are not analogous. In *Virginia Vermiculite*, the court excluded an expert on antitrust market analysis, because his background lied in geological engineering, and he only took an economics course twenty years prior to providing his opinions in that case. *Virginia Vermiculite Ltd. v. W.R. Grace & Co.-Conn.*, 98 F. Supp. 2d 729, 732 (W.D. Va. 2000). As such, the court held that he "lacks the requisite educational background for an expert witness" and also demonstrated an "apparent failure to understand basic antitrust economic principles." *Id.* at 732, 735. Similarly, in *Berlyn*, the court excluded an expert whose background in engineering and business administration was "completely devoid of specific education, training, or experience in economics or antitrust analysis." *Berlyn, Inc. v. Gazette Newspapers, Inc.*, 214 F. Supp. 2d 530, 537 (D. Md. 2002). Further, at the time that expert was retained in that case, he admitted he was "entirely unaware of how an economist would perform such a study" on market analysis. *Id.* at 537–548.

Therefore, Dr. Maestas experience places her well within the requisite legal bounds to serve as an expert witness.

b. Dr. Maestas's Opinions Regarding Direct Evidence Of Market Power

"Reliability is a flexible inquiry, allowing for consideration of factors like whether the expert's methodology has been objectively tested; whether it has been subjected to peer review and publication; the technique's known or potential error rate; and whether the expert's technique has been generally accepted within the relevant industry." *Lawes v. CSA Architects and Eng'rs LLP*, 963 F.3d 72, 98 (1st Cir. 2020). However, "*Daubert* does not require that a

party who proffers expert testimony carry the burden of proving to the judge that the expert's assessment of the situation is correct," and "so long as an expert's scientific testimony rests upon good grounds, based on what is known . . . it should be tested by the adversarial process, rather than excluded for fear that jurors will not be able to handle the scientific complexities." *Milward v. Acuity Specialty Products Group, Inc.*, 639 F.3d 11, 15 (1st Cir. 2011) (citation omitted). Dr. Maestas opinion meets these standards.

Restricted output may be shown by evidence that after generic competitors entered the market, total output of the drug increased. *See, In re Intuniv*, 496 F.Supp.3d 639, 658 (D. Mass. 2020). Takeda claims that "the undisputed evidence is to the contrary," because "Par first entered the market with generic Amitiza in 2021... [and] sales of lubiprostone did not increase." [Doc. No. 409 at 10]. However, Plaintiffs argue that Takeda focuses on only one time period—2021 to 2022—during which Par essentially partnered with Takeda to launch one generic. During this period, "the price of Amitiza was still significantly higher than it became after full generic entry." [Doc. No. 465 at 10]. For that reason, output was restricted from 2021 to 2022 when Par was the only generic on the market, relative to when prices would decline sharply in 2023. As explained further below in Section VII.B., these arguments mirror the parties' substantive arguments at summary judgment. While this is sufficient to create an issue of material fact, Defendants have not shown that Dr. Maestas' opinions do not rest on good grounds or are unreliable. For instance, Takeda argues that Dr. Maestas failed to "conduct any analysis of potential alternative causes for the sales increase in 2023." [Doc. No. 409 at 11]. However, "[a]s long as the expert opinion meets the requirements of Rule 702, there is no additional requirement that an expert eliminate all alternative possible causes in offering a differential diagnosis."

Pagliaroni v. Mastic Home Exteriors, Inc., No. 12-cv-10164, 2015 WL 5568624, at *7 (D. Mass. Sept. 22, 2015).

Takeda also argues that Dr. Maestas' price decline opinions are unreliable because she failed to account for "prices actually paid by patients and payors for Amitiza." [Doc. No. 409 at 12]. However, "an economist's failure to consider certain data is not fatal to admissibility if the expert sufficiently explains her choice of data for her analysis." *In re Pharmaceutical Indus. Average Wholesale Price Litigation*, 491 F. Supp. 2d 20, 86, 89–93 (D. Mass 2007) (finding reliance on "three surrogates " instead of conducting "a survey of payors" did not render expert inadmissible where expert explained reasoning); *see also, Cummings v. Std. Register Co.*, 265 F.3d 56, 65 (1st Cir. 2001) (finding alleged failure to account for "company-specific data" go to "the weight, not the admissibility" where expert offered "sufficient explanations" and defendant failed to show how data relied on was incorrect or contrary to economist norms). Dr. Maestas explained that she analyzed "the price Takeda actually set for Amitiza." [Doc. No. 465 at 12]. Further, Dr. Maestas explained that "the consumer price is not the relevant standard because patients do not select which drug to receive, and normally only pay a small fraction of the actual price of the drug." [*Id*. at 12–13]. Further, Dr. Maestas did look at the patient prices cited by Dr. Jena in his report and found that patient prices were significantly higher before Par's generic entry, declined upon Par's generic entry, and further upon competitive generic entry. While Takeda offers various reasons why this use of data may be incorrect, they fail to argue that it is inconsistent with the economist profession. [Doc. No. 409 at 11–12; Doc. No. 502 at 6–7].

Defendants also take issue with Dr. Maestas' opinions on high gross margins because she does not account for fixed costs such as marketing and research & development ("R&D"). Plaintiffs argue that Dr. Maestas's calculations accounted for ongoing fixed costs, but correctly

excluded sunk costs because they do not affect pricing and found that the ongoing R&D costs for Amitiza were negligible. [Doc. No. 465 at 16]. I find that Dr. Maestas has sufficiently explained her reasons for excluding sunk costs from her analysis, and any weaknesses in that exclusion may be presented upon cross-examination at trial. Further, Dr. Maestas sufficiently relied on the "Lerner index" to assess market power, which courts have accepted. *See, e.g., In re Opana ER Antitrust Litig.*, 2021 WL 2291067, at *9 (N.D. Ill. June 4, 2021) ("[T]he Lerner [I]ndex is a well-established method implemented in the field of economics to find evidence of market power, although not conclusive in and of itself"); *In re Aggrenox Antitrust Litig.*, 199 F. Supp. 3d 662, 667 (D. Conn. 2016) (citing the Lerner Index as a "generally accepted economic means of analyzing the probability that given prices are supracompetitive using price and marginal cost").

Finally, Takeda argues that Dr. Maestas' opinions on supracompetitive prices are unreliable because she compares "Amitiza-specific margin to generic manufacturers' company-wide gross margins," and "elsewhere in her report, Dr. Maestas herself criticizes the use of company-wide data to evaluate drug pricing." [Doc. No. 409 at 13–14]. However, Plaintiffs argue that this is a misstatement of Dr. Maestas' testimony criticizing Dr. Jena's use of company-wide margins when arguing that fixed costs must be accounted for, and that she otherwise uses company-wide margins as a "conservative" comparator. [Doc. No. 465 at 16–17]. Defendants have not shown that this is a basis to exclude Dr. Maestas' opinions here.

As to Plaintiffs' reverse payment allegations, it is unclear whether Dr. Maestas's opinion is that evidence of a reverse payment *alone* is sufficient to establish market power at summary judgment. As explained further below in Section VII.B.ii., evidence of a reverse payment alone—a fact that is hotly in dispute here—is not sufficient evidence of market power. To the extent that Dr. Maestas's opinion is that such evidence alone is sufficient, those opinions or

testimony must be excluded. However, to the extent that a reverse payment is just one piece of evidence of market power, those opinions or testimony may be allowed.

c. Dr. Maestas's Opinions Regarding Indirect Evidence Of Market Power

Takeda argues that Dr. Maestas' use of the "Hypothetical Monopolist Test" ("HMT") and her "natural experiments" should be excluded as unreliable methodologies.

As to Dr. Maestas' use of the HMT, "in the First Circuit, it remains true that the hypothetical monopolist test is the touchstone of market definition, even in contexts outside of horizontal mergers." *In re Intuniv Antitrust Litig.*, 496 F. Supp. 3d 639, 664 (D. Mass. 2020) (citation omitted) (finding persuasive that the "ABA Model Jury Instructions have also adopted the Hypothetical Monopolist Test in determining whether two products are in the same relevant product market"); *Coastal Fuels of Puerto Rico, Inc. v. Caribbean Petroleum Corp.*, 79 F.3d 182, 198 (1st Cir. 1996) ("The touchstone of market definition is whether a hypothetical monopolist could raise prices"); *Solodyn*, 2018 WL 563144, at *6 ("When products are close economic substitutes, a small change in [the] price of one product will cause consumers to shift and sales to respond accordingly, meaning the cross-elasticity of demand will be high.").

Defendants also argue that Dr. Maestas' natural experiment, in which she "quantif[ies] the impact of Amitiza generic entry on quantity demanded of the potential economic substitutes" for both Par's AG entry in January 2021 and multiple generic entry in January 2023, is unreliable. [Doc. No. 409 at 16–17]. In conducting this analysis, Dr. Maestas relied on a "January control" to negate the effect of a pattern in which the price increases at the start of each calendar year. Defendants argue that the use of this "January control" is unreliable because generic Amitiza entry occurred in both January 2021 and January 2023, and as a result, the "January control" "counteracts the impact of the largest Amitiza price changes on the sales of

other drugs." [Doc. No. 409 at 17]. Defendants argue that Dr. Maestas is "controlling for (i.e., negating the effect of) the very thing she is seeking to measure." [*Id.*]. Additionally, Defendants argue that the "January control" does not account for other factors that may lead to changes in drug sales, including that January is the beginning of an insurance year leading to changes in drug placements and resulting insurance reimbursements. [*Id.*]. But Dr. Maestas responded to this criticism of her January control in her rebuttal report. [Doc. No. 419-1 at 158–163]. Further, the fact that there are other factors that may lead to changes in drug prices is an issue that can be raised on cross-examination. As such, Dr. Maestas' opinions need not be excluded.

d. Dr. Maestas's Reliance On IQVIA Data

Finally, Defendants argue that Dr. Mastas' reliance on price data from IQVIA, specifically its NPA and National Sales Perspective ("NSP") datasets, should be excluded because those datasets exclude rebates, discounts, and coupons. [Doc. No. 409 at 18]. But IQVIA data is considered by economist and pharmaceutical industry personnel to be the "gold standard of prescription data and is widely used for research on the pharmaceutical industry." [Doc. No. 419-1 at 176–177]. And as already discussed, Dr. Maestas has explained why patient-level costs are not the correct framework for her analysis. Accordingly, Defendants have not shown why their disagreements with theses analyses should lead to a total exclusion of Dr. Maestas' opinions, as opposed to a challenge on cross-examination.

For the above reasons, Defendants' Motion to Exclude Nicole Maestas, [Doc. No. 408], is DENIED.

E. Michael F. Johnson

Defendants seek to exclude the opinions of Plaintiffs' expert, Michael Johnson, [Doc. No. 412], a corporate expert on authorized generics, that "several aspects of the Par Settlement

Agreement with Sucampo and Takeda differed from typical authorized generic licensing agreements or settlements of drug patent litigations; the royalty rates in the Par Settlement Agreement were 'below market;' the declining royalty provision of the Par Settlement Agreement created 'a no-second-generic provision,' and; the 'unusual aspects' of the Par Settlement Agreement 'acted to transfer value from Takeda to Par and limited competition for Amitiza.'" [Doc. No. 412 at 1 (citation omitted)].

Defendants argue that Mr. Johnson lacks the necessary "real-world" experience and expertise to offer opinions on the Settlement Agreement. [Doc. No. 413 at 5–13]. Specifically, they argue: (1) Mr. Johnson's opinions are based on limited professional experience involving settlement agreements, leaving him without specialized knowledge necessary to qualify his testimony concerning the terms in a "typical agreement" between branded and generic pharmaceutical companies, and (2) Mr. Johnson's opinions regarding "market" royalty rates should be excluded because they are based on unreliable authorities with questionable methodologies. [*Id*. at 9–10]. Defendants argue that Mr. Johnson improperly relies on an FTC Report that provides a range of percentage royalty compensation from which Mr. Johnson apparently "cherry-pick[ed]" the upper bound of 92%. [*Id*. at 14–15]. Additionally, Defendants claim that "Mr. Johnson never explains how he extrapolates from information about non-settlement AG royalty rates to somehow inform his opinions." [*Id*. at 16].

Plaintiffs respond that Mr. Johnson is qualified to render a reliable opinion on the royalty rate at issue based on his thirty-seven years of work experience in the pharmaceutical industry at Eli Lilly and Company ("Lilly"). [Doc. No. 464 at 6]. Plaintiffs emphasize that Mr. Johnson has been recognized by Lilly as "the corporate expert on authorized generics" and does not "need economic experience to opine on the practices of pharmaceutical companies" when Mr. Johnson

was asked to opine on authorized generic agreements. [*Id*. at 6, 12]. Plaintiffs additionally claim that Mr. Johnson's opinions are reliably based on his analysis of the FTC report, where Mr. Johnson examined rates in standalone authorized generic agreements to form an opinion on the "fair value" compensation rate. [*Id*. at 13–14]. Plaintiffs argue that Defendants' criticisms of Mr. Johnson's opinions are not sufficient to exclude his opinions here.

a. Michael Johnson's Qualifications

First, Defendants contend that Mr. Johnson lacks relevant professional experience in analyzing the Settlement Agreement at issue. [Doc. No. 413 at 5]. As discussed, an expert need not have first-hand experience when opining on a precise issue so long as he has the requisite knowledge, skill, experience, training, or education. *Microfinancial*, 385 F.3d at 80.

Mr. Johnson's educational and employment background position him as a qualified expert witness. He holds a B.S. in Pharmacy from the University of North Carolina School of Pharmacy. [Doc. No. 464 at 6]. His knowledge and experience are a result of thirty-seven years of employment in the pharmaceutical industry at Lilly in multiple capacities, including a ten-year period where he acted as Vice President of Corporate Business Development, leading a group responsible for analyzing and carrying out authorized generic launches. [*Id.*]. Specifically, his responsibilities entailed "le[ading] the group that analyzed each internal authorized generic opportunity – *i.e.*, whether Lilly would launch its own authorized generic," and he "responded to all proposals for partnerships through which Lilly would launch an authorized generic through a third party distributor, solicited proposals from companies qualified to distribute authorized generics as business cases were developed, and negotiated the authorized generic distribution agreements." [*Id.*]. Mr. Johnson routinely "solicited proposals, evaluated the business opportunity, selected the best third-party authorized generic distribution partner, negotiated the

financial terms and all other provisions of the contracts, and made final recommendations to senior management," ultimately allowing Mr. Johnson to review over 75 authorized generic proposals and agreements over the course of his career. [*Id.* at 7].

Based on this extensive experience, Mr. Johnson offers opinions that are relevant to this case and will be helpful to the trier of fact. I find, along with other courts, that "Johnson is qualified to testify as to his expertise in negotiating licensing agreements. The fact that he has not specifically negotiated a Hatch-Waxman settlement agreement goes to the weight of his testimony, not its admissibility." *Intuniv*, 2020 WL 5995326, at *24; *In re Xyrem (Sodium Oxybate) Antitrust Litig.*, No. 20-md-02966, 2024 WL 4023562, at *7 (N.D. Cal. Aug. 26, 2024) ("That Johnson does not have experience negotiating Hatch-Waxman settlement agreements does not justify excluding his opinions").

b. The Reliability Of Mr. Johnson's Opinions

Defendants argue that Mr. Johnson's opinions are unreliable, based on "selective quoting" of the FTC Report. [Doc. No. 413 at 13–14]. Mr. Johnson claims that the industry standard for royalty payments to the brand company from the generic is around 90%. [*Id.* at 14]. He relies on a 2011 FTC report that "cites specific agreements wherein the 'profit split to the brand is 92%,' and . . . notes the increasing acceptance of AGs and competition for AG opportunities.'" [*Id.* (citation omitted)]. Defendants take issue with the fact that Mr. Johnson does not include other portions of the FTC Report that state that an agreement in which the brand received 50% of the profits from a generic company is acceptable and not worthy of anticompetitive scrutiny. [*Id.*]. Defendants also argue that the FTC Report was discussing the context of marketing rights derived from settlements, which generally require a 50–92% profit range, which Defendants argue have nothing to do with the case here. Defendants state that the

FTC Report makes clear that in the settlement context, generics often pay less than 35%. [*Id.* at 14–15 (citation omitted)]. Defendants also argue that Mr. Johnson does not explain how he extrapolates information from non-settlement AG royalty rates to form an opinion in which an AG was granted and a royalty was agreed upon as part of the settlement (which is the case here). [*Id.* at 16]. Defendants take issue with the fact that Mr. Johnson opined that the 50% royalty rate paid from Par to Sucampo was below market, but refused to provide any examples of market royalty rates for AGs and ANDA settlement agreements.

Plaintiffs argue that "Mr. Johnson looked only at the rates in standalone agreements in order to determine that the 10% compensation to the AG distributor 'represents the fair value of goods or services provided in an arm's length business arrangement.'" [Doc. No. 464 at 13–14]. They argue that sections of the report on the royalty rates in settlement agreements were not germane to his opinion, and the single non-settlement distribution agreement that the report states had a 50% royalty at the low end of the range does not negate Mr. Johnson's opinions regarding industry standard. [*Id.*]. Mr. Johnson "explains how he compares the industry-standard royalty rate in standalone AG distribution agreements to the royalty rate in this settlement agreement." [*Id.* at 15]. Finally, Plaintiffs argue that Mr. Johnson's refusal to disclose confidential royalty rates he saw in his experience had already been rejected by another court because the opinion there was also based on the public FTC report. [*Id.* at 16 n.60]. I agree with Plaintiffs that Defendants fail to meet the necessary standard warranting exclusion.

Defendants' challenges to Mr. Johnson's reliance on the FTC report, "while potentially a basis to criticize Johnson's opinions, does not warrant exclusion." *Xyrem*, 2024 WL 4023562, at *7. "Only if the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded." *U.S. v. Zolot*, 968 F. Supp. 2d 411, 417 (D. Mass.

2013); *Int'l Adhesive Coating, Inc. v. Bolton Emerson Int'l, Inc.*, 851 F.2d 540, 545 (1st Cir. 1988) ("When the factual underpinning of an expert's opinion is weak, it is a matter affecting the weight and credibility of the testimony – a question to be resolved by the jury"). I find that Mr. Johnsons' opinions are sufficiently reliable to aid the jury.

Accordingly, Defendants' Motion to Exclude Mr. Johnson, [Doc. No. 412], is DENIED.

VI. PLAINTIFFS' DAUBERT MOTIONS[9]

A. Dr. Anupam B. Jena

Plaintiffs seek to exclude the opinions of Dr. Anupam B. Jena, [Doc. No. 457], Takeda's expert on market power, as contrary to law. Plaintiffs argue that Dr. Jena's opinions should be excluded for the following reasons: (1) Dr. Jena's market power analysis fails to consider the economic impact of patent law, drug approval law, FDA regulations, generic substitution laws, or reverse payment law, (2) his opinions on direct evidence of market power put forth by Dr. Maestas and Dr. Leffler must be excluded because his opinion that generic price cannot be the competitive level for purposes of evaluating market power is contrary to law, and (3) his opinions on indirect evidence of market power must be excluded because he conducts no analysis of cross-price elasticity. *See* [Doc. No. 458]. As explained below, there are genuine disputes of material fact as to whether there is either direct or indirect evidence of market power. Plaintiffs' criticisms go, at most, to the weight of Dr. Jena's opinions, which may be challenged at trial, and I do not find that his opinions are contrary to law.

a. Dr. Jena's Opinions On Direct Evidence Of Market Power

"Market power, sometimes called monopoly power, 'is the abilities (1) to price substantially above the competitive level and (2) to persist in doing so for a significant period

[9] Plaintiffs' Motion to Exclude Celest Saravia, [Doc. No. 459], is addressed in relevant parts of the opinion below. As explained in those sections, the Motion is DENIED.

without erosion by new entry or expansion.'" *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 326 (D.R.I. 2017) (quoting *Aggrenox*, 199 F. Supp. 3d at 665). As explained in further detail below in Section VI.B., Plaintiffs can prove market power through direct or indirect evidence. Direct evidence can be shown through evidence of supracompetitive prices, restricted output, and/or high margins.[10] "Where direct evidence of market power is available . . . a plaintiff need not attempt to define the relevant market." *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 388 n.19 (D. Mass. 2013). Rather, the definition of the relevant market goes to "circumstantial evidence of market power ... [which] show[s] that the defendant has a dominant share in a well-defined relevant 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." *Id.* at 389 (quoting *Coastal Fuels of P.R., Inc. v. Caribbean Petroleum Corp.,* 79 F.3d 182, 197 (1st Cir. 1996)).

Here, Plaintiffs allege that the "competitive level" is "the price that purchasers would have enjoyed with unrestrained availability of generic lubiprostone." [Doc. No. 458 at 17]. "There is no strict prohibition on defining a relevant market as a single-drug market." *Loestrin*, 261 F. Supp. 3d at 327 (citing cases); *see, e.g.*, Eastman *Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 482 (1992) ("This Court's prior cases support the proposition that in some instances one brand of a product can constitute a separate market"); *Nexium*, 968 F. Supp. 2d at 388 (holding a single branded drug and its generic to be a plausible relevant market); *Geneva Pharms. Tech. Corp. v. Barr Labs., Inc.*, 386 F.3d 485, 496–500 (2d Cir. 2004) (defining the relevant market as the generic versions of a particular drug, excluding the branded version of the drug). Dr. Jena, however, opined that "lubiprostone did not form a standalone market, but instead

[10] As explained below in Section VI.B., this "and/or" clause is debated, and I do not resolve that debate here.

was one treatment within the chronic constipation drug market." [Doc. No. 504 at 9]. Accordingly, the debate here is whether the relevant market is the lubiprostone market or the chronic constipation drug market.

I agree with Defendants that the definition of the relevant market goes to indirect evidence, and there is no case that holds that the competitive level as a matter of law is always the generic drug market. Dr. Jena opines that the generic price may not be the appropriate competitive level because it fails to account for the idea that average molecule prices always decline after generic entry, and branded companies invest heavily in research and development ("R&D"), marketing, and promoting their products, so the fact that average prices fall after generic entry does not mean that the branded drug had market power. [Doc. No. 458 at 18; Doc. No. 504]. As explained by another district court:

> [P]roduct market definition matters where *indirect* evidence of market power is being considered; at this juncture the focus is on *direct* evidence. Second, even if product market definition should be considered for purposes of direct evidence, product market definition is only *informed* by what the alleged anticompetitive conduct is; such conduct is not automatically dispositive of the matter. Indeed, as discussed below, ***product market definition typically turns on what products are economic substitutes, and there are factual questions concerning the identification of such substitutes***. Finally, under Plaintiffs' position, in any generic competition case, the competitive price will be the generic price which, in turn, would seem to 'render most brand name pharmaceutical companies ... *per se* monopolists prior to generic entry,' *Kaiser Found. v. Abbott Labs.*, No. CV 02-2443-JFW (FMOx), 2009 U.S. Dist. LEXIS 107512, at *29 (C.D. Cal. Oct. 8, 2009); this is a difficult proposition to embrace.

In re HIV Antitrust Litig., 656 F. Supp. 3d 963, 984 (N.D. Cal. 2023) (emphasis added). Here, Plaintiffs have not shown that Dr. Jena's criticisms of Plaintiffs' market definition are contrary to law, and disputed issues of fact exist as to whether there are economic substitutes, as explained below in Section VI.B.

I also do not find that Dr. Jena's analysis inappropriately conflicts with patent law, FDA law and regulations, generic substitution laws, or reverse payment law. Plaintiffs claim that Dr. Jena "rejects the notion that FDA law shapes market rights for brand companies as well as generics" because when opining that brand companies need to recover their sunk R&D expenses—and therefore generic prices cannot be the measure of competitive level—he ignores that Congress specified the way in which those sunk costs can be accounted for. [Doc. No. 458 at 21]. Dr. Jena's opinions to this effect do not amount to a total rejection that FDA law shapes market rights for brand companies as well as generics. Furthermore, that Plaintiffs argue that the federal government "already struck a balance between compensating brands and promoting generic competition," [*id.* at 22], is a counterargument that potentially undermines Dr. Jena's opinion, not a demonstration that Dr. Jena's opinions are contrary either to FDA or generic substitution laws.

Moreover, Plaintiffs argue that Dr. Jena's opinions regarding R&D sunk costs in the context of direct evidence are contrary to law, citing cases where courts have rejected this theory as a basis for undermining evidence of supracompetitive prices. In *Aggrenox*, 199 F. Supp. 3d at 666, the court held that:

> The defendants argue (perhaps correctly) that brand manufacturers incur enormous fixed costs developing and marketing new drugs, and that they therefore need to charge higher prices in order to recoup those costs. Generic manufacturers are free-riders who do not undertake those investments, and this fact alone is sufficient to account for the price differential. That may be right, but it does not mean that the price of the brand drug is not supracompetitive.

However, in *In re Glumetza Antitrust Litig.*, 2021 WL 3773621, at *3 (N.D. Cal. Aug. 25, 2021), when denying a motion to exclude Dr. Jena in that case, the court declined to adopt *Aggrenox*'s decision to limit discovery to the market of *Aggrenox* and its generic equivalents. The court there found that because the posture of that case was "much farther along than *Aggrenox*—and the

conclusion at summary judgment that left the finding of direct proof of market power in the hands of the jury, this order will not now withhold from that jury relevant expert testimony on this critical issue." *Id.* As explained below, I also leave the finding of direct proof of market power to the jury, and therefore, do not find a basis to exclude Dr. Jena's opinions here.

As to patent exclusivity, Plaintiffs argue that Dr. Jena's refusal to analyze the generic prices that ensue upon the expiration of patents conflicts with patent law. [Doc. No. 458 at 23]. It is unclear what patent law Plaintiffs are referring to. Their brief outlines how patents are designed as an exception to the rule against monopolies, granting brand drugs legal exclusivity for a supracompetitive price for a certain period of time. [*Id.* at 24]. Plaintiffs claim that "Dr. Jena's opinion fails to recognize the economic significance of generic entry upon the expiration of a brand's patents," which appears to be a criticism of the fact that Dr. Jena did not merely accept that the existence of a patent alone is evidence of market power. [*Id.*]. The same goes for Plaintiffs' argument that Dr. Jena fails to accept that a reverse payment is evidence of market power. "To be sure . . . the *Actavis* Court did not hold that a large reverse payment is dispositive of antitrust liability, nor that a patent guarantees market power." *Aggrenox*, 199 F. Supp. 3d at 665.

> Indeed, it is the reward of lawful (albeit temporary) market power that creates the incentive for innovation that patent protection is intended to foster. And the size and circumstances of the reverse payment are suggestive of the market power conferred by the patent: the larger the reverse payment (and the greater its independence from other services for which it might represent compensation), the likelier that the challenged patent in fact confers a high degree of market power—and the stronger the inference that the reverse payment is intended 'to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market.' *Actavis*, 570 U.S. at 157. *Aggrenox*, 199 F. Supp. 3d at 655.

Id. Because there are disputed issues of fact as to the size and circumstances of the reverse payment, Plaintiffs are free to challenge these opinions at trial.

b. Dr. Jena's Analysis Of Indirect Evidence Of Market Power

Finally, Plaintiffs argue that Dr. Jena conducts no analysis of cross-price elasticity to support his opinions that indirect evidence does not establish market power. Plaintiffs argue that Dr. Jena "offers no quantitative calculation of cross-elasticity, and none of the qualitative evidence he identifies suggests that there was substantial cross-elasticity between Amitiza and any drug other than generic Amitiza that constrained its price to a competitive price." [Doc. No. 458 at 30]. Not so. Dr. Jena does conduct an analysis of cross-price elasticity, [*see* Doc. No. 424-74 at 683], which Plaintiffs believe is not evidence of "substantial" cross-price elasticity. [Doc. No. 458 at 32]. Plaintiffs argue that clinical substitutability, pricing comparable to other brands, payment for preferred formulary placement couponing and assistance programs, and promotional expenditures, are not evidence of "substantial" cross-price elasticity. [*Id.* at 30–37].

Defendants explain that clinical substitutability is just one part of Dr. Jena's analysis to determine what products are in the same market; thus, the need to consider interchangeability is relevant to an analysis of the relevant market. [Doc. No. 504 at 17–18]. *See In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-md-02503, 2018 WL 563144, at *9 (D. Mass. Jan. 25, 2018) (denying motion to exclude expert on the basis that "he did not consider Solodyn's cross-price elasticity of demand").

In addition to clinical substitutability, Dr. Jena also analyzed economic substitutability between Amitiza and other chronic constipation drugs. Defendants argue that this evidence was not offered to support his cross-price elasticity analysis, but to opine that Takeda competed on price with other chronic constipation drugs. [Doc. No. 504 at 19]. Dr. Jena also opines that price competition for favorable formulary placement relative to other chronic constipation drugs indicates economic substitutability between Amitiza and those drugs. [*Id.* at 20].

After identifying substantial rebates and discounts that Takeda provided for Amitiza and relevant sources, Dr. Jena concluded that "Takeda and other manufacturers of chronic constipation drugs competed aggressively for preferential formulary tier placement to influence patient-level prices and secure patient prescription share." [*Id.*]. He also opines that there is evidence that Takeda and other drug manufacturers competed on price through discounts, samples, vouchers, and coupons. [*Id.* at 21]. Courts have accepted such evidence of price competition. *Intuniv*, 496 F. Supp. 3d at 664 ("Defendants have put forth evidence of Shire's use of rebates and coupons, which undercuts Plaintiffs' arguments for cross-price elasticity, and also provide evidence that Shire was competing with other non-stimulant ADHD treatments").

Plaintiffs' arguments that Dr. Jena's evidence of Takeda's investment in promotional activities is not evidence of substantial cross-price elasticity does not warrant exclusion of Dr. Jena's opinions at this stage as contrary to law. *Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 437 (3d Cir. 2016) ("Defendants offered unrebutted expert testimony, including detailed statistical analyses, showing that demand for other generics rose in response to certain of Defendants' strategic marketing and sales decisions . . . this evidence demonstrated that Defendants responded to the market's reaction to their prices with sales promotions in an effort to increase their ability to compete").

For the above reasons, Plaintiffs' Motion to Exclude Dr. Jena, [Doc. No. 457], is DENIED.

B. David Engels

Plaintiffs seek to exclude the opinions and testimony of Defendants' expert, David Engels, an expert in the pharmaceutical industry. [Doc. No. 461]. Specifically, they seek to exclude his opinion that, "lubiprostone ANDA filers … would likely have faced significant

challenges in manufacturing generic Amitiza drug product at commercial scaled-up volumes." [Doc. No. 462 at 6]. Plaintiffs argue that: (1) Mr. Engels, "lacks the requisite qualifications and experience to offer the opinions contained in his report;" (2) his opinions do not align with the facts of the case and will fail to assist the jury, and (3) Mr. Engels failed to "consider voluminous record evidence contrary to his opinions." [Doc. No. 462 at 6–8]. Ultimately, Plaintiffs advance that even if the court admits this testimony under Rule 702, it ought to be excluded under Rule 403. They argue that "the minimal probative value of such unsupported opinions would be substantially outweighed by the likelihood that such testimony would unduly prejudice, mislead, and confuse the jury." [*Id.* at 8].

c. Mr. Engels's Qualifications

Plaintiffs argue that Mr. Engels is not qualified to opine about the complexity of lubiprostone, the intricacies of soft gelcaps, or any associated manufacturing challenges. [Doc. No. 462 at 10]. Because Mr. Engels never worked as a pharmacist, does not hold any postgraduate degrees in scientific disciplines, and is not an expert in pharmaceutical formulation, Plaintiffs argue that Mr. Engels lacks the scientific qualifications necessary to form these opinions. [*Id.* at 12]. As discussed above, so long as an expert is, "qualified … by knowledge, skill, experience, training or education … he need not have had first-hand dealings with the precise type of events at issue." *Microfinancial*, 385 F.3d at 80. Mr. Engels' qualifications and fall squarely within these bounds. Mr. Engels has a degree in pharmacy and is a registered pharmacist with over forty years of experience, and, as Plaintiffs acknowledge, has had "direct participation in supply chain, manufacturing, and other decisions by a brand manufacturer about when and whether to launch pharmaceutical products." [Doc. No. 462 at 12]. Mr. Engels "shared responsibility at Pfizer for forecasting product sales and demand, including by taking into

account market conditions, potential sourcing issues, and regulatory concerns from the manufacturing, supply chain, and regulatory departments he interfaced with regarding both brand and generic drug products." [Doc. No. 494 at 11]. As Director/Senior Director of Pfizer's U.S. Diversified Products, Mr. Engels had the responsibility for budgeting and forecasting product sales and units and regularly worked with supply chain and manufacturing sites in forming his conclusions. [*Id.* at 11–12]. Furthermore, Mr. Engels testified that he reviewed the literature regarding the process of manufacturing liquid-filled soft-gel capsules and formed his opinion along with his experience with prostaglandins and gelatin from working on specific drug products he identified at his deposition. [*Id.* at 13]. He further specified that he had knowledge and experience with soft gelatin capsules but wanted to do more in-depth research in preparation for this case. [*Id.*].

I find that Mr. Engels possesses the relevant work experience to offer opinions regarding the potential difficulties with launching lubiprostone.

a. The Relevance Of Mr. Engels's Opinions

Plaintiffs argue that Mr. Engels failed to opine on "whether the lubiprostone ANDA filers (or their CMOs) had the sophistication, resources, and facilities to successfully manufacture commercial quantities of their lubiprostone generic products." [Doc. No 462 at 18]. As such, Plaintiffs argue that his testimony should be excluded because it cannot assist the trier of fact in determining whether Plaintiffs had the ability to overcome any challenges they may have encountered at launch. [*Id.* at 20]. Plaintiffs also argue that Mr. Engels failed to consider evidence from their expert, Dr. Christians, which they claim details voluminous documents that are contrary to Mr. Engels's opinion about the complexity of lubiprostone molecules and challenges to manufacturing them in soft gel capsule form. [*Id.* at 21–23].

First, Mr. Engels is a rebuttal expert whose opinions were offered to respond to the opinions of Plaintiffs' expert, Ms. Marchetti. Plaintiffs do not explain why Mr. Engels, as a rebuttal witnesses, would have been required to opine on the additional question of whether the ANDA Filers would have been able to overcome such difficulties. *See Aviva Sports, Inc. v. Fingerhut Direct Mktg., Inc.*, 829 F. Supp. 2d 802, 834 (D. Minn. 2011) ("A number of other district courts have held that rebuttal expert witnesses may criticize other experts' theories and calculations without offering alternatives"). Indeed, "[a] rebuttal expert, by nature, criticizes the methodology and/or opinions of another. There is no requirement that a rebuttal expert himself offer a competing analysis; his opinions may properly concern criticizing that presented by another party." *In re Aluminum Warehousing Antitrust Litig.*, 336 F.R.D. 5, 29 (S.D.N.Y. 2020). As such, excluding Mr. Engels, a rebuttal witness to Ms. Marchetti, for failing to review the reports of Dr. Christians, is not a solid reason for excluding his opinions here.

In the same vein, I do not find persuasive Plaintiffs' argument that if Mr. Engels's opinion cannot be excluded under Rule 702, it must be excluded under Rule 403. Rule 403 of the Federal Rules of Evidence states that "the court may exclude relevant evidence if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. Plaintiffs argue that if the jury were permitted to consider Mr. Engels's narrow testimony, the jury may "assume that the ANDA filers and their CMOs would not have been able to overcome these challenges and would, therefore, not have been able to manufacture commercial quantities of lubiprostone—the relevant manufacturing question for the jury." [Doc. No. 462 at 23]. There is no reason why the jury would be misled if Plaintiffs have emphasized that their expert, Dr. Christians, has provided his own opinions that

they argue are contrary to Mr. Engels's opinion regarding the complexity of lubiprostone and the ability of ANDA Filers to launch generic versions of Amitiza. As such, the experts can battle it out at trial.

For the reasons stated above, Plaintiffs' Motion to Exclude the Opinions and Testimony of Defendants' Expert David Engels, [Doc. No. 461]. is DENIED.

VII. CROSS-MOTIONS FOR SUMMARY JUDGMENT

Over a decade ago, the Supreme Court addressed the potential anticompetitive effects of so-called "reverse payments," a type of settlement agreement between a patentee company and an infringer company in which the patentee agrees to pay the infringer not to produce the patented product for a certain period of time. *F.T.C. v. Actavis, Inc.*, 570 U.S. 136 (2013). In *Actavis*, the Court held that reverse payments differ from commonplace patent litigation settlements because "[i]n reverse payment settlements . . . a party with no claim for damages (something that is usually true of a paragraph IV litigation defendant) walks away with money simply so it will stay away from the patentee's market." *Id.* at 152. Reverse payments, therefore, may be subject to antitrust scrutiny. *Id.* The Supreme Court discussed five considerations when determining whether such reverse payment settlements should be subject to antitrust scrutiny:

> [1] [A] reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; [2] one who makes such a payment may be unable to explain and to justify it; [3] such a firm or individual may well possess market power derived from the patent; [4] a court, by examining the size of the payment, may well be able to assess its likely anticompetitive effects along with its potential justifications without litigating the validity of the patent; and [5] parties may well find ways to settle patent disputes without the use of reverse payments.

In re Loestrin 24 Fe Antitrust Litig., 814 F.3d 538, 544 (1st Cir. 2016) (citing *Actavis*, at 158); *see also id.* at 551 n.12 ("[T]he five considerations should not overhaul the rule of reason, nor should they create a new five-part framework in antitrust cases"). The

Supreme Court "determined that the potential anticompetitive effects of a reverse payment are subject to the rule of reason test." *Id.* at 544. "The 'rule of reason' is a means of evaluating a restraint on trade and determining 'whether under all the circumstances of the case the restrictive practice imposes an unreasonable restraint on competition.'" *Id.* at 544-45 (citing *Arizona v. Maricopa Cty. Med. Soc'y*, 457 U.S. 332, 343 (1982)). "To satisfy the rule of reason test, the plaintiff must demonstrate 'that the alleged agreement involved the exercise of power in a relevant economic market, that this exercise had anti-competitive consequences, and that those detriments outweighed efficiencies or other economic benefits.'" *Id.* at 545 (citing *Stop & Shop Supermarket Co. v. Blue Cross & Blue Shield of R.I.*, 373 F.3d 57, 61 (1st Cir. 2004)).

The First Circuit applies "a burden-shifting framework to determine whether a restraint violates the rule of reason." *Vazquez-Ramos v. Triple-S Salud, Inc.*, 55 F.4th 286, 299 (1st Cir. 2022). "First, the plaintiff must prove that the challenged restraint has a substantial anticompetitive effect that harms consumers in the relevant market." *Id.* (citation omitted). "Then, the burden shifts to the defendant to demonstrate a procompetitive rationale for the restraint." *Id.* (citation omitted). "Finally, the burden shifts back to the plaintiff to establish that the procompetitive efficiencies could be reasonably achieved through less anticompetitive means." *Id.* (citation omitted). This is a fact intensive inquiry that is generally inappropriate to resolve on the pleadings. *Id.*

A. Whether The Settlement Agreement Contained A Reverse Payment That Acted As An Implicit No-AG Agreement

As discussed above, "[i]n a reverse payment case, the Court applies the rule of reason. First, Plaintiffs must prove anticompetitive effects, by demonstrating a payment for delay, or, in other words, payment to prevent the risk of competition." *Intuniv*, 496 F. Supp. 3d at 667. The

First Circuit has held that reverse payments need not be monetary. *Loestrin*, 814 F.3d 538, 549 (1st Cir. 2016) (holding that the "Supreme Court recognized that a disguised above-market deal, in which a brand manufacturer effectively overpays a generic manufacturer for services rendered, may qualify as a reverse payment subject to antitrust scrutiny and militates against limiting the Supreme Court's decision to pure cash payments"). "For example, a reverse settlement may include an agreement by the brand company not to launch an AG, if the brand company 'give[s] up the valuable right to capture profits' from an AG launch and 'transfers [those profits] to the settling generic.'" *Intuniv*, 496 F. Supp. 3d at 661 (citing *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 405 (3d Cir. 2015)); *In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 42 (1st Cir. 2016) ("Under this functional approach, 'no-AG' provisions—in which the brand-name manufacturer agrees not to market an 'authorized generic' version of the drug for a certain period of time—and other settlement provisions in which some advantage is transferred from the patent holder to the alleged infringer may constitute a reverse payment subject to antitrust scrutiny."); *Loestrin*, 261 F. Supp. 3d at 333 (finding that a no-AG agreement constituted a reverse payment because it transferred payments to the settling generic company that the brand company would have otherwise received by distributing an AG). "No-AG provisions should be treated as a form of reverse payment, the magnitude of which must be estimated on a case-by-case basis." *Intuniv*, 496 F. Supp. 3d at 661 (D. Mass. 2020) (citing Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, The *Actavis* Inference: Theory and Practice, 67 Rutgers U. L. Rev. 585, 598 (2015)).

Here, Plaintiffs challenge the profit split and royalty structure outlined in the Settlement Agreement. The Settlement Agreement explains that in exchange for permitting Par to launch a generic drug by January 1, 2021, Takeda/Sucampo and Par will split the profits from Par's

generic sales 50/50. Upon the entrance of an additional generic drug, the royalty declines such that Takeda/Sucampo only receive 15% of the royalties from the generic sales, and upon the entrance of two or more additional generics, the royalty reduces to 0%. Plaintiffs argue that these provisions disincentivized Takeda from launching its own AG and thus constituted an agreement by Takeda not to launch a second generic in exchange for Par's agreement not to launch generic Amitiza until January 1, 2021. Plaintiffs offer two theories for why these provisions constitute a reverse payment in the form of an implicit "no-AG" agreement. First, the declining royalty structure, in which the royalties decline following the entrance of additional generics, "incentivized the brand not to launch its own authorized generic. If it did, the brand's profits from Par would drop from 50% to 15%. And when a third generic entered, Par would owe the brand no profits at all." [Doc. No. 417 at 52]. Second, "[t]he 50/50 profit split, standing alone, also disincentivized the entry of a second generic . . . because Sucampo would internalize the benefits that it received from sales of Par's generic (in the form of royalties), which outweighed profits from the additional unit sales that Sucampo could have obtained by launching a second AG. In other words, the 50 percent royalty incentivized Sucampo not to launch an AG." [*Id.* (citing Doc. No. 419-3 at 699)].

Defendants contest both theories of reverse payment. First, Defendants argue that the declining royalty structure only applies to the scenario in which Par elected to launch its own ANDA product, as opposed to launching a Sucampo-supplied AG. Defendants argue that "[b]ecause the Agreement's clear terms provide that the declining royalty rate applies only when Par is marketing an ANDA and not AG product, a declining royalty rate structure could not have disincentivized Sucampo and Takeda from launching a competing AG." [Doc. No. 422 at 26]. Second, Defendants argue that Plaintiffs have not proven that the 50/50 profit split on its own,

without a declining royalty structure, was too high or too low to sufficiently disincentivize Sucampo and Takeda from launching its own AG. Specifically, Defendants argue that the 50% profit split reflects a more permissible settlement that allows "the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." *Actavis*, 570 U.S. at 158. Defendants argue that "Par's 50% royalty payment obligation is not a reverse payment because the payment does not flow in the reverse direction, and because the Agreement did not give Par exclusivity." [Doc. No. 422 at 33].

Courts have recognized evidence tending to show that a royalty structure "effectively incentivize[d]" a brand to "stay out of the generic market" where "there is evidence that both companies understood that [the brand] would make more from the royalty agreement than from distributing an AG." *Intuniv*, 496 F. Supp. 3d at 670–671. The FTC has also found that a "common form of possible compensation" in reverse settlements is a "royalty structure" that "may achieve the same effect as an explicit no-AG commitment." *In re Xyrem (Sodium Oxybate) Antitrust Litig.*, 555 F. Supp. 3d 829, 859 (N.D. Cal. 2021) (citing FTC, Overview of Agreements Filed in FY 2016: A Report by the Bureau of Competition at 2 (May 2019) ("2019 FTC Report")). "This *de facto* no-AG agreement may be achieved where a result of the 'brand [manufacturer] launch[ing] an authorized generic' would be that 'the generic [company]'s obligation to pay royalties is reduced.'" *Id.* (citing 2019 FTC Report at 2); *see also id.* at 858 (recognizing theory that royalty structure in which the generic company "will pay increasingly higher percentages of revenue to [the brand] as [the generic's] market share increases" would have "incentivized [the brand] to delay its own AG" and thus constitute a reverse payment).

Summary judgment is not warranted here for two reasons. First, the Settlement Agreement is ambiguous as to whether the declining royalty structure applies regardless of Par

launching either an ANDA or an AG. Second, there is sufficient competing evidence as to whether Takeda/Sucampo and Par agreed to enter into an implicit no-AG agreement based on the 50% profit split alone.

i. Whether The Declining Royalty Structure Applied Regardless Of The Type Of Generic Par Chose To Launch

The Settlement Agreement is governed by Delaware law. [Doc. No. 419-3 at 17]. "Under Delaware law, construction and interpretation of contract language, including the question of whether ambiguity exists, is a question of law." *Barraford v. T & N Ltd.*, 778 F.3d 258, 263 (1st Cir. 2015). In Delaware, "[t]he test for ambiguity is whether terms within an agreement are reasonably susceptible of different meanings." *In re Olympic Mills Corp.*, 333 B.R. 540, 554 (B.A.P. 1st Cir. 2005), *aff'd*, 477 F.3d 1 (1st Cir. 2007). The Delaware Supreme Court has instructed:

> A contract is not rendered ambiguous simply because the parties do not agree upon its proper construction. ***Rather, a contract is ambiguous only when the provisions in controversy are reasonably or fairly susceptible of different interpretations or may have two or more different meanings.*** Ambiguity does not exist where the court can determine the meaning of a contract without any other guide than a knowledge of the simple facts on which, from the nature of language in general, its meaning depends. Courts will not torture contractual terms to impart ambiguity where ordinary meaning leaves no room for uncertainty. The true test is not what the parties to the contract intended to mean, but what a reasonable person in the position of the parties would have thought it meant.

Id. (citing *Rhone–Poulenc Basic Chem. Co. v. American Motorists Ins. Co.*, 616 A.2d 1192, 1195 (Del. 1992)) (emphasis added). "If a contract is unambiguous, extrinsic evidence may not be used to interpret the intent of the parties, to vary the terms of the contract or to create an ambiguity." *Eagle Indus., Inc. v. DeVilbiss Health Care, Inc.*, 702 A.2d 1228, 1232–33 (Del. 1997) (cleaned up). However, if "there is uncertainty in the meaning and application of contract language, the reviewing court must consider the

evidence offered in order to arrive at a proper interpretation of contractual terms." *Id.* "If there are issues of material fact, the trial court must resolve those issues as the trier of fact." *Id.* "[I]n a dispute over the proper interpretation of a contract, summary judgment may not be awarded if the language is ambiguous and the moving party has failed to offer uncontested evidence as to the proper interpretation." *GMG Cap. Invs., LLC v. Athenian Venture Partners I, L.P.*, 36 A.3d 776, 784 (Del. 2012).

The following provisions of the Settlement Agreement are relevant:

Section 1.1 (Definitions):

- "Authorized Generic" is defined as "8 mcg and 24 mcg lubiprostone products sold in the Territory pursuant to NDA No. 021908 but not under the AMITIZA® trademark." [Doc. No. 419-3 at 4].
- "Generic Equivalent" is defined as "a pharmaceutical product that has received FDA approval for marketing in the Territory pursuant to an ANDA (or equivalent regulatory mechanism) as a generic equivalent to the AMITIZA® Products." [*Id.* at 5].
- "Licensed Products" are defined as "Par's ANDA Products." [*Id.*].

Section 3.1 states that, "[e]ffective upon the License Effective Date, Sucampo and RTU hereby grant to Par a non-exclusive license with respect to the Sucampo Patents with the right to grant sublicenses to Affiliates, (i) to make, have made, use, promote, offer to sell, sell, import, or otherwise dispose of ***Licensed Products*** in the Territory, and (ii) to make and have made the Licensed Products outside the Territory only for use, sale and importation in the Territory." [*Id.* at 9 (emphasis added)].

Section 3.12 states that "all terms" in the Settlement Agreement "***that apply to Licensed Products shall apply equally to the Authorized Generic products*** manufactured for, and

supplied to Par, ***including the payment of royalties pursuant to Section 3.13***, as though Par were commercially Marketing Licensed Products." [*Id.* at 12 (emphasis added)].

Section 3.13(a) states that, "Beginning on the License Effective Date, ***Par shall pay Sucampo a royalty of 50% of Gross Profits of the Licensed Products sold during the term of this Agreement*** . . . ." [*Id.* (emphasis added)].

Section 3.13(b) states that, "During any period after the License Effective Date where, ***in addition to Par Commercially Marketing a Generic Equivalent***, ***one Third Party is Commercially Marketing a Generic Equivalent or Authorized Generic*** in the Territory (or Sucampo, RTU, and/or Takeda or an Affiliate is Commercially Marketing an Authorized Generic in the Territory) ***the royalty rate provided for in Section 3.13(a)*** [redacted]% of Gross profits and Sucampo or its Affiliates have the option to supply Par with Authorized Generic Products at a negotiated costs plus price." [*Id.* at 13 (emphasis added)].

Section 3.13(c) states that, if "During any period after the License Effective Date where, ***in addition to Par Commercially Marketing a Generic Equivalent, two or more Third Parties are Commercially Marketing a Generic Equivalent or Authorized Generic*** in the Territory (or one or more Third Parties is Commercially Marketing a Generic Equivalent and Sucampo, RTU, and/or Takeda or an Affiliate is Commercially Marketing Authorized Generics in the Territory), ***the royalty rate provided for in Section 3.13(a)*** [redacted] and Sucampo or its Affiliates have the option to supply Par with Authorized Generic Products at a negotiated costs plus price." [*Id.* (emphasis added)].

Defendants argue that "Because Section 3.12 states that 'all terms . . . that apply to Licensed Products shall apply equally to the Authorized Generic products . . . including the payment of royalties,' Par was required to pay a 50% royalty on its sale of AG product pursuant

to Section 3.13(a). But the terms that could trigger a reduction of the royalty rate—specifically Sections 3.13(b) and (c)—apply only when Par markets a 'Generic Equivalent' product, i.e., 'a pharmaceutical product that has received FDA approval for marketing in the Territory pursuant to an ANDA[.]'" [Doc. No. 422 at 29 (citing Doc. No. 419-3 at 5, 12–13)]. Defendants argue that accordingly, "Sections 3.13(b) and (c) cannot be triggered by a Par-distributed AG, even though the parties could have easily included such a trigger in the Agreement." [*Id.* at 29]. Plaintiffs, on the other hand, argue that because all terms that apply to "Licensed Products shall apply equally to the Authorized Generic products," [Doc. No. 419-3 at 12], "the unambiguous meaning of the language is that all terms that apply to Par's ANDA product apply equally to Par's authorized generic product, as though Par was marketing the ANDA product." [Doc. No. 417 at 44].

The ambiguity here is not in the definition of the terms "Licensed Products," "Authorized Generic," or "Generic Equivalent." Here, it is unambiguous that "Licensed Products" are ANDA products, "Generic Equivalent" are ANDA products, and "Authorized Generic" are Authorized Generic products. Instead, the apparent conflict lies in three sections: (1) Section 3.12's provision that "all terms that apply to Licensed Products shall apply equally to the Authorized Generic products . . . , including the payment of royalties pursuant to Section 3.13, as though Par were Commercially Marketing Licensed Products," (2) Section 3.13(a)'s provision that "Par shall pay Sucampo a royalty of 50% of Gross Profits of the Licensed Products," and (3) Section 3.13(b) and (c)'s provisions that say that the royalty decline gets triggered upon the entrance of additional generic drugs, "in addition to Par Commercially Marketing a Generic Equivalent."

A reasonable person could accept both parties' readings of the contract. For example, Defendants are correct that Sections 3.13(b) and (c), the royalty decline provisions, by their plain language, describe that the royalty reductions are triggered only when Par is commercially

marketing a "Generic Equivalent," i.e., an ANDA product. However, Plaintiffs are also correct that Section 3.12's provision can be read to broaden the royalty decline provisions to include a decline if Par launches an Authorized Generic product. Section 3.12 states that "all terms that apply to Licensed Products shall apply equally to the Authorized Generic products . . . including the payment of royalties pursuant to Section 3.13." In other words, Section 3.12 states that all terms that apply to Licensed Products (which is defined as an ANDA) apply equally to Authorized Generic products. But the language in Section 3.12 can be read to apply generally to the "payment of royalties pursuant to Section 3.13." Section 3.12 does not specify whether Licensed Products = Authorized Generics in all the subsections of Section 3.13, including the declining royalty provisions. As such, a reasonable person could read Section 3.12's provision to encompass not only Section 3.13(a), which provides for the 50/50 profit split as to Par's Licensed Products—such that the profit split applies regardless of whether Par's product is an ANDA or an AG—but also to Sections 3.13(b) and (c), such that the royalty decline provisions would apply upon the entrance of additional generics regardless of whether Par's generic is an ANDA or an AG. Thus, "sufficient ambiguity exists to warrant the use of extrinsic evidence to interpret the meaning and intent of the alleged No-AG provision." *In re Zetia (Ezetimibe) Antitrust Litig.*, 655 F. Supp. 3d 406, 419 (E.D. Va. 2023).

Plaintiffs point to testimony from Sucampo's CEO, Peter Greenleaf, who testified that when a second generic enters the market, the 50/50 profit split declines to [redacted]. [Doc. No. 417 at 45 (citing Doc. No. 419-3 at 836-837, 90:21–91:1)]. They also point to testimony from Par's in-house counsel, Gina Gencarelli, who testified that the profit split would drop to [redacted] with an additional generic entrant and explained that this provision existed because when other generics enter the market, "Par would not be able to sustain paying a 50 percent royalty when competition

enters. So in order to remain competitive in the market, we would need a reduced royalty." [Doc. No. 419-3 at 107–110; *id.* at 110, 77:16–22]. Plaintiffs argue that this "rationale obviously applies whether Par sold an authorized generic product or an ANDA product. Whichever product was sold, when additional generics entered the market, the price would drop and the profit split would drop as well." [Doc. No. 417 at 46]. Plaintiffs also point to testimony from Takeda's in house counsel, Mark Buonaiuto, who testified that the agreement [redacted] but also testified that [redacted] [Doc. No. 419-3 at 403, 117:5–19]. Defendants respond that this testimony only shows that the witnesses understood that a declining royalty provision exists but does not confirm whether they understood those provisions to apply regardless of whether Par launched an ANDA or AG drug. [Doc. No. 470 at 36]. Defendants also point to evidence that the course of negotiations show that Par "understood the difference between 'Generic Equivalent' and 'Authorized Generic,' but chose not to amend the trigger to have it apply the royalty reduction when Par was 'Commercially Marketing a Generic Equivalent or Authorized Generic.'" [*Id.* at 37].

Plaintiffs argue that forecasts by Sucampo and Par show that they specifically reference reductions in the profit split as additional generics entered the market, but without referencing any specific reason why that profit split would decline. [Doc. No. 417 at 46]. Plaintiffs provide evidence of various forecasts from Par, including forecasts in scenarios where Par assumed it would launch alone, [Doc. No. 499 at ¶¶ 45–47], which Defendants dispute. The parties also dispute whether Sucampo and Takeda forecasted that Par would possess market exclusivity upon launch of its generic product and neither Sucampo nor Takeda would launch its own AG. [*Id.* at ¶¶ 48–57]. Defendants argue that these forecasts are unpersuasive as they do not facially predict

Par launching an AG product as opposed to an ANDA product. Rather, the forecasts predict a "Par Generic," which do not specify whether it was launching an ANDA or AG product. [Doc. No. 470 at 38–39]. Defendants point to evidence from Par that [redacted] [*Id.* at 39; *see also* Doc. No. 499 at ¶ 39].

Next, Plaintiffs cite to Dr. Ruhm's report criticizing Dr. Saravia's interpretation of the contract language, in which he opined that in 2023, when later filers started selling Amitiza, Par continued to sell its AG option but stopped paying royalties. [Doc. No. 419-4 at 92 n.38 ("Mallinckrodt (which acquired Sucampo) told investors in its Q3 2022 Earnings Call: 'We expect to lose roughly $75 million in net sales in 2023 due to the loss of the U.S. royalty with Endo as the market fully converts to a generic marketplace with multiple entries.'")]. Defendants respond that this is not evidence that the royalty decline provisions applied to Par's AG sales after 2021, but rather the effect of the operation of a "most favored nation" ("MFN") clause in Section 3.6 of the Settlement Agreement, which states that: "In the event that Sucampo, RTU, and/or Takeda is a party to or enters into an agreement with any Third Party . . . (ii) providing [redacted] and to be effective only for the remaining term of this Agreement." [Doc. No. 470 at 40–41; Doc. No. 419-3 at 10]. Takeda, Sucampo, and RTU reached settlement agreements with the other ANDA Filers, with DRL receiving a [redacted] royalty rate, and Amneal and Teva receiving [redacted]. [Doc. No. 470 at 41]. Defendants argue that under this provision of the Settlement Agreement, "as soon as any of the generic

competitors launched their ANDA or AG Amitiza product at a zero percent royalty rate, Par's royalty obligation also went to zero." [*Id.* at 41–42]. Plaintiffs respond that the Mallinckrodt SEC disclosure does not specify that the double-digit royalty ended by operation of the MFN, and that an alternative interpretation is that "the subsequent agreements included lower royalty rates than the Agreement because the subsequent generic manufacturers knew that Par's profit split would decline when they entered, and they would not agree to a higher rate than Par." [Doc. No. 495 at 18].

Neither party has presented such one-sided extrinsic evidence that can lead me to grant summary judgment regarding the meaning of this ambiguous contract. *See GMG Cap. Invs., LLC*, 36 A.3d at 784. Accordingly, I find that "the parties' Agreement is susceptible to two equally reasonable, but conflicting, interpretations. That gives rise to an unresolved issue of material fact that renders summary judgment inappropriate. Extrinsic evidence, such as prior communications and course of dealing, must be considered by the factfinder to resolve the ambiguity." *Id.*

I also note that Plaintiffs have moved to exclude Defendants' expert, Dr. Celeste Saravia, on the basis that her opinions are erroneously based on instruction from counsel that the declining royalty provision of the Settlement Agreement only applies to Par's ANDA product. [Doc. No. 459]. Plaintiffs argue that if I conclude as a matter of law that the declining royalty provision applies to both Par's ANDA product and Par's AG product, then Dr. Saravia's opinions to the contrary must be excluded. Because I have found that the declining royalty provision is ambiguous and that material disputes of fact exist as to the appropriate interpretation of the contract. Excluding Dr. Saravia's opinions at this stage is premature. As such, Plaintiffs' Motion to Exclude the opinions of Dr. Saravia on this basis is DENIED.

ii. Whether The 50/50 Profit Split Alone Constitutes A Reverse Payment

Defendants next argue that Plaintiffs' theory that the 50% profit split alone constitutes a reverse payment is wrong. Defendants first take issue with Plaintiffs' theory that "the Agreement's 50% royalty was sufficiently high (irrespective of any decline in rate) to keep Sucampo and Takeda from launching a second AG because Sucampo would earn more from royalties on sales of Par's AG than by launching a competing AG product." [Doc. No. 422 at 31; Doc. No. 419-4 at 95, ¶ 47 (describing the opinion of Dr. Ruhm that "the 50/50 profit split does not resemble royalty rates that are typically included in competitive agreements" because in the typical case, the brand and generic company "would usually keep most if not all of the profits from its product")]. Defendants argue that Par "managed to secure an early date-certain to bring a generic version of a patented product—including a potential AG—to market pursuant to a license by offering to pay the patent holder (Sucampo) a 50% royalty," [Doc. No. 422 at 32], the type of settlement that is "squarely protected by *Actavis*." *Mayor & City Council of Baltimore v. AbbVie Inc.*, 42 F.4th 709, 715 (7th Cir. 2022). According to Defendants, because the royalty runs from the patent challenger Par to the patentee Sucampo, there is no reverse payment.

Defendants argue that this case is like *AbbVie*, which affirmed the dismissal of a reverse payment claim. There, AbbVie settled numerous patent suits by permitting "biosimilar drugs" to enter the U.S. market in 2023, even though the patents lasted well beyond 2023. *Id.* at 714. The plaintiffs did "not contend that there is anything fishy or anticompetitive about the settlements allowing entry in 2023 without any payment from AbbVie to the potential entrants—if those settlements are viewed by themselves." *Id.* Rather, the plaintiffs argued that patent litigation in the European Union was settled with an October 2018 entry date, and as such, "AbbVie gifted the biosimilar makers with 4+ years of profits in Europe, in exchange for their agreement not to

enter the U.S. market in 2023." *Id.* The Seventh Circuit rejected this theory, holding that both the U.S. and European settlements were a "normal settlement without any payment to the entrants, a settlement of the kind that *Actavis* says is not problematic." *Id.* at 715. "In each AbbVie agreed to entry before the last patents expired and didn't pay anyone to delay entry. As the district judge saw things, 0 + 0 = 0." *Id.* That is not the case here, where Plaintiffs allege that that the 50% profit split is essentially a "no-AG" agreement from Takeda, in which the 50% royalties are so profitable on its own that there is no incentive to launch an independent AG drug.

Likewise in *Fed. Trade Comm'n v. Endo Pharms. Inc.*, the D.C. Circuit Court of Appeals held that "a valid patent holder's grant of a nearly exclusive license to a single potential competitor in exchange for royalty payments" did not violate antitrust law because that "nearly exclusive license restrains trade only to an extent traditionally recognized by patent law as reasonable." 82 F.4th 1196, 1204 (D.C. Cir. 2023). The court explained that "while *Actavis* held that the unexplained 'reverse payment' at issue in that case was subject to antitrust scrutiny, it did not disturb the long-standing principle that a single patentee may set conditions in granting a single licensee the right to use its valid patents." *Id.* The court emphasized that the FTC did not allege that the agreement at issue in that case "was an 'unusual' settlement in which Endo paid Impax to drop a legitimate challenge against potentially weak or invalid patents." *Id.* at 1206. However, that is precisely what Plaintiffs allege here.

Similarly, in *Revlimid*, the plaintiffs alleged that a settlement agreement contained a reverse payment in the form of "a volume limited, royalty-free generic license before full generic competition began, equating to hundreds of millions of dollars in payment" to the generic company." *In re Revlimid & Thalomid Purchaser Antitrust Litig.*, No. 19-7532, 2024 WL 2861865, at *7 (D.N.J. June 6, 2024). The court dismissed the claim because although the

plaintiffs alleged that "the volume-limited license transferred value to Natco by allowing it to sell its generic [drug] at allegedly supracompetitive prices, it is not plausible that the volume limited nature of the license, standing on its own, could have ensured that Natco could sell its generic [drug] 'at multiples higher' than it could have if Natco had not been volume capped." *Id.* at 59. Specifically, there was no allegation that "Celgene granted Natco an exclusive license during the entire relevant license period. Accordingly, at the time Celgene settled with Natco, it was still possible that other generics could enter the market with generic versions of [the drug] before patent expiry and during the term of Natco's volume limited license." *Id.* That is not the case here either.

Accordingly, none of these cases support a finding that, as a matter of law, the 50% royalty on its own is the type of traditional patent settlement that *Actavis* approves of.

Next, Defendants challenge what they believe is Plaintiffs' conflicting theory of the case, that the 50% royalty is too low such that Par is being improperly compensated for its delayed generic entry. [Doc. No. 28 at ¶ 219 ("The Takeda/Sucampo-Par 2014 agreement required only a 50% royalty. This far-below market rate royalty was an effective large payment to Par, designed to get Par to agree to a long delay in generic entry for Takeda's benefit, and to agree not to challenge the weak patents on Amitiza")]. Defendants argue that a royalty cannot be "too low" where *Actavis* has recognized that companies can settle a patent litigation without requiring any royalty, and as such, "Plaintiffs fail to explain why it is actionable for Sucampo and Takeda to do in part (license Par to use the Amitiza patents for a royalty prior to the expiration of the patents) what they unquestionably were entitled to do in full (license those same patents for no royalty)." [Doc. No. 422 at 35].

Plaintiffs' expert Michael Johnson opined that the royalty rate that Par pays under the Settlement Agreement is "very low" because "the industry standard for a royalty payment to the brand company in a stand-alone, arms-length AG agreement is ~90%." [Doc. No. 419-5 at 307, ¶ 98]. Plaintiffs explain that "the profit split in the Agreement allowed Par to keep 40% more than if this were a standalone deal in which Takeda/Sucampo simply sought distribution services for its AG." [Doc. No. 469 at 19]. Plaintiffs argue that it is this additional 40% granted to Par that constitutes the reverse payment.

Plaintiffs further argue that there is no inconsistency between the opinions of Dr. Ruhm and Dr. Leffler, as Defendants contend. Both Dr. Ruhm and Dr. Leffler opine that the 50% profit split disincentives the brand from launching its own AG because it would earn more from the royalty itself. [Doc. No. 469 at 19]. Plaintiffs also point to the opinions of Takeda's expert, Dr. Saravia, who agreed that a 50% profit split on its own made it unprofitable for Takeda/Sucampo to launch a second generic. [*Id.*]. Additionally, both Dr. Ruhm and Dr. Leffler compare the 50% profit split to independent AG distribution deals where the brand typically keeps 85% or more of the profits from the AG and find the difference to be evidence of a reverse payment. [*Id.* at 20]. Plaintiffs argue that Dr. Ruhm also points out that most ANDA litigation can be settled without any profit split at all, but "[t]here is nothing inconsistent between this observation and using an industry standard for standalone AG agreements to measure the reverse payment to Par." [*Id.*].

Based on my reading, I do not find anything conflicting in either theory premised on the 50% royalty alone, as a reverse payment. Whether the 50% royalty was so high to Takeda as to disincentivize Takeda from launching its own AG, or so low to Par as to constitute an effective payment from Takeda to Par in exchange for Par to delay its entry into the generic market,

Plaintiffs have created a material dispute of fact as to whether the 50% profit split alone constitutes a reverse payment.

B. Market Power

Both parties seek summary judgment as to whether Takeda had market power. Plaintiffs argue that the following undisputed direct evidence proves that Takeda had market power over Amitiza: (1) supra-competitive prices (i.e., prices exceeding those that would prevail with unrestrained generic entry), (2) high gross margins, and (3) restricted output. [Doc. No. 417 at 18]. Plaintiffs also provide indirect evidence that they believe establishes that Takeda had market power, however, they do not move for summary judgment on the basis of this indirect evidence. [*Id.* at 26]. Defendants argue that neither the direct nor indirect evidence is sufficient to establish market power, and that Takeda's market share in a properly defined market is insufficient to establish market power as a matter of law. I find that genuine issues of fact exist to preclude summary judgment on whether Takeda had monopoly power over Amitiza.

"To successfully prove a monopolization offense, a plaintiff must show that defendant (1) has monopoly power and (2) the defendant has engaged in impermissible exclusionary practices with the design or effect of protecting or enhancing its monopoly position." *In re Ranbaxy Generic Drug Application Antitrust Litig.*, 573 F. Supp. 3d 459, 470 (D. Mass. 2021) (citing *Coastal Fuels of P.R., Inc. v. Caribbean Petroleum Corp.*, 79 F.3d 182, 195 (1st Cir. 1996)). "To prove attempted monopolization, a plaintiff must similarly prove predatory or anticompetitive conduct but need only demonstrate that there was 'a dangerous probability of achieving monopoly power' and 'a specific intent to monopolize.'" *Id.* (citing *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993)). "With regard to both claims, '[m]onopoly power is the power to control prices or exclude competition.'" *Id.* (citing *United States v. E. I. du Pont de*

Nemours & Co., 351 U.S. 377, 391 (1956)). "Market power may be established through direct evidence or indirect evidence." *Intuniv*, 496 F. Supp. 3d at 658.

As an initial matter, the parties dispute what the law says regarding which direct evidence is sufficient to prove market power. Plaintiffs argue that any of its direct evidence—supra-competitive prices, high gross margins, and restricted output—on its own, is sufficient to establish market power, citing primarily to a holding in *Ohio v. Am. Express Co.*, in which the Supreme Court held that "[d]irect evidence of anticompetitive effects would be proof of actual detrimental effects on competition . . . such as reduced output, increased prices, *or* decreased quality in the relevant market." 585 U.S. 529, 542 (2018) (citation omitted) (emphasis added). Defendants argue that evidence of high prices must be combined with restricted output, citing *Amex*'s holding that "Market power is the ability to raise price profitably *by restricting output*." *Id.* at 549 (citation omitted) (emphasis in original). Courts have interpreted and applied *Amex*'s holding differently, and the First Circuit has not weighed in on whether high prices must be combined with restricted output, or whether a showing of either one alone is sufficient. *Contrast Solodyn*, 2018 WL 563144, at *12 (holding that both are needed: "Absent any evidence of restricted output, Plaintiffs' evidence of high margins is insufficient direct evidence as a matter of law to demonstrate market power"), and *Intuniv*, 496 F. Supp. 3d at 657–658 (same), *with Ranbaxy*, 573 F. Supp. 3d at 470 (holding that either one alone may suffice: "Plaintiffs may prove such power with two kinds of evidence: direct, such as super-competitive prices or restricted output, or circumstantial"), *and In re Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d 274, 299 (D.R.I. 2019) (same), *and CoStar Grp., Inc. v. Com. Real Est. Exch., Inc.*, No. 23-55662, 2025 WL 2573045, at *7 (9th Cir. Sept. 5, 2025) (holding that "a plaintiff need not allege

both output restrictions and supracompetitive pricing to plead direct evidence of monopoly power").

As the Northern District of California explained, there are convincing arguments why either interpretation is correct. *See HIV*, 656 F. Supp. 3d at 982. On the one hand, both supracompetitive prices and restricted output might be necessary because "in the pharmaceutical context, there may be reasons to be cautious about finding market power based on supracompetitive pricing alone – *i.e.*, because, presumably, a brand drug will always be more expensive than a generic one, often for reasons which are not anticompetitive." *Id.* ("If a firm can profitably raise prices *without causing competing firms to expand output and drive down prices*, that firm has monopoly power") (citation omitted) (emphasis in original). On the other hand, "it could be argued that, under traditional microeconomic principles, raising prices (whether by a monopolist or other competitor) would naturally tend to diminish demand (and hence output) relative to that market participant, and thus absolute categorical approach may not be appropriate." *HIV*, 656 F. Supp. 3d at 982; *see also Loestrin*, 433 F. Supp. 3d at 300 n.2 ("Economic theory holds that an increase in price restricts output . . . because of the consequent demand decrease . . . [t]his is known in economics as the law of demand, . . . and arguably obviates the need for Plaintiffs separately to prove output restriction where it has shown supracompetitive prices.").

As explained below, I "need not resolve the "and/or" dichotomy at this juncture because, for the reasons discussed below, there are factual questions as to each element which preclude summary judgment." *HIV*, 656 F. Supp. 3d at 982.

i. Direct Evidence

1. Supracompetitive Prices

Plaintiffs argue that undisputed evidence shows that Takeda charged supra-competitive prices for Amitiza and that Takeda's gross margins were extremely high. As for supracompetitive prices, Plaintiffs argue that prior to Par's generic entry in 2021, the brand Amitiza wholesale price was $5.74 per capsule, but that after entry of multiple other generic products in January 2023, the generic price decreased rapidly so that by March 2024, Amitiza was available at $0.63 per capsule, an 89% decline from the pre-generic entry price. [Doc. No. 417 at 19]. Furthermore, in the two years during which the only generic on the market was Par's authorized generic—from 2021 to 2023—the generic price averaged $3.83, a 33% decline in price from pre-generic entry. [*Id.*]. Plaintiffs argue this "steep price decline from the supra-competitive prices during the period of generic delay is undisputed" and therefore sufficient to establish supra-competitive prices. [*Id.*]. Plaintiffs rely on *Actavis*'s holding that market power is "the power to charge prices higher than the competitive level." 570 U.S. at 157. Plaintiffs argue that the competitive level here is the price that such competition would have generated, [*Id.* at 17]; i.e., the price purchasers would pay for generic lubiprostone once it launched. [Doc. No. 495 at 8].

Defendants respond that Plaintiffs' theory is "overly simplistic." [Doc. No. 470 at 19]. In other words, merely because Amitiza prices went down after generic entry is not evidence that prices prior to generic entry must have been supra-competitive. [*Id.*]. "[I]n any generic competition case, the competitive price will be the generic price which, in turn, would seem to render most brand name pharmaceutical companies *per se* monopolists prior to generic entry . . . this is a difficult proposition to embrace." *HIV*, 656 F. Supp. 3d at 984 (citation omitted).

Plaintiffs argue that they do not present evidence that Takeda's pricing was merely more than the generic price, but rather, it was "*an order of magnitude more*." [Doc. No. 495 at 8 (emphasis in original)]. Plaintiffs' expert put forth evidence that in the three years before generic entry, Takeda priced Amitiza at nearly ten times the competitive price, which is evidence of Takeda's ability to charge supra-competitive prices. [*Id.*]. Takeda's expert argues that the generic price of lubiprostone is not the appropriate benchmark because generic prices do not take into consideration the brand company's investments into research & development ("R&D") and therefore, ignores that a monopolist does not set prices based on these "sunk costs." [Doc. No. 417 at 20]. I find that there is a dispute as to whether this pricing demonstrates market power or simply reflects "incentives provided to brand manufacturers in the pharmaceutical industry." *Intuniv*, 496 F. Supp. 3d at 660.

2. High Gross Margins

Plaintiffs argue that Takeda's high gross margins on Amitiza is undisputed evidence that Takeda "set and maintained Amitiza's prices far above its marginal cost." [Doc. No. 417 at 20–21]. A product's "gross margin" is its net sales minus the total cost of goods sold, divided by net sales. [*Id.* at 21]. Amitiza's gross margins ranged from [redacted] between 2012 and 2020, with an average gross margin of [redacted] over the period. [*Id.*]. Plaintiffs then compared Takeda's gross margins for Amitiza to the company-wide margins of generic manufacturers and found that the company-wide gross margins for generic manufacturers averaged 36% to 44% while Takeda's average gross margin for Amitiza was [redacted], indicating a supra-competitive profit level. [*Id.*]. Plaintiffs also rely on the "Lerner Index," which is the ratio of a product's gross margin to its price and ranges from 0, indicating no market power, to close to 1, which indicates a very high presence of market power. [*Id.*]. Plaintiffs' expert, Dr. Nicole Maestas, calculated the

Lerner Index value for Amitiza to be between [redacted]. [*Id.*]. Plaintiffs argue that this value translates to Takeda pricing Amitiza between [redacted] times the cost of producing Amitiza. [*Id.* at 21–22]. Plaintiffs compare this to the average U.S. pharmaceutical industry gross margin, which is 65.3%, corresponding to a price markup to [redacted] times the cost of production. [*Id.* at 22].

Defendants respond that Dr. Maestas' analysis is flawed because it fails to account for total costs. [Doc. No. 470 at 20]. Defendants offer their own expert Dr. Anupam Jena's testimony that the margins are high because they fail to consider Takeda's research and development costs, and that the margins are improperly based on a comparison to company-wide margins. [*Id.*]. Plaintiffs respond that Dr. Maestas has explained why these arguments are incorrect, but that even if research & development costs were considered or if Dr. Maestas had compared Amitiza's margins to generic-product specific margins, the gross margins would have remained high. [Doc. No. 469 at 38–39]. I find that this is a "battle of the experts" that "cannot be resolved at summary judgment." *HIV*, 656 F. Supp. 3d at 985.

3. Restricted Output

Plaintiffs present evidence from Dr. Maestas that Takeda restricted output of Amitiza. Data from IQVIA National Prescription Audit show that after competitive generic entry in January 2023, sales abruptly began to rise to meet the amount of sales predicted by the pre-Par authorized generic sales trends. [Doc. No. 417 at 23–24]. Further, the data shows that during the period where Par AG was the only generic, there was substantial output restriction but that after the entry of multiple generics in January 2023, sales abruptly rose from the Par AG sales trend. [*Id.* at 24–25]. Overall, the increased output over the Par AG sales trend is [redacted] extended units from January 2023 through March 2024. [*Id.* at 25 (citing Doc. No. 419-1 at 27–28, ¶ 52)].

Defendants respond that during the period of January 2021 through December 2022 when Par was the only generic on the market, output did not increase, which necessarily shows that output was not restricted prior to Par's entry. [Doc. No. 470 at 21]. Takeda argues that the fact that Par's generic sales quickly captured a majority of brand and generic Amitiza sales shows that after Par's entry in January 2021, Takeda only had a small share of lubiprostone sales and could not have had market power. [*Id.*]. Defendants' expert, Dr. Jena, has also provided alternative reasons as to why output increased following the entry of multiple generics in January 2023, including that patients switched from other drugs to generic Amitiza after entry. [Doc. No. 424-74 at 672].

Plaintiffs argue that Defendants incorrectly limit the output period to when Par was the only generic on the market, from January 2021 to December 2022. [Doc. No. 495 at 7]. Plaintiffs claim that the issue is whether output expanded once the anticompetitive conduct ended, and that Takeda does not dispute that output expanded after Par launched its generic. [*Id.*]. Further, Plaintiffs' expert, Dr. Maestas, provides reasons as to why Dr. Jena's arguments regarding output restriction following multiple generic entry in January 2023 is flawed. [*Id.*]. Again, this is a battle of experts that presents material issues of fact for the jury.

ii. Indirect Evidence

Plaintiffs do not move for summary judgment with respect to their indirect evidence of market power, but Defendants move for summary judgment on their argument that Plaintiffs have neither direct nor indirect evidence of market power. Defendants argue that Takeda could not have had market power because it competed with other chronic constipation drugs ("CCDs") and had only a [redacted] market share, which is insufficient to show market power. *See* [Doc. No. 422 at 45–49]. Defendants also argue that Plaintiffs cannot rely on their own reverse payment

theory to show market power. [*Id.* at 44]. I find that there are material disputes of fact as to whether evidence of competition and Takeda's [redacted] market share demonstrate that Takeda lacked market power. However, I agree with Defendants that the reverse payment itself cannot form the basis for establishing market power at the summary judgment stage.

"Indirect evidence of a company's market power includes evidence 'that the defendant has a dominant share in a well-defined relevant market and that there are significant barriers to entry in that market and that existing competitors lack capacity to increase their output in the short run.'" *Intuniv*, 496 F. Supp. 3d at 662 (citing *Coastal Fuels*, 79 F.3d at 197). "With regard to the relevant product market, 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." *Id.* (citations omitted). "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 to define the relevant market." *Id.* (citation omitted).

"Products are in the same relevant product market only where there is cross-elasticity of demand, i.e. if customers would switch to alternatives in response to a price increase in the alleged monopolist's product." *Id.* (citation omitted). Plaintiffs argue that no drug other than generic Amitiza constrained Takeda's ability to price Amitiza at supracompetitive levels. [Doc. No. 417 at 26]. Plaintiffs argue that Dr. Maestas' natural experiments show that there was no large-scale switching from other drugs to generic Amitiza after Par's entry in 2021 and the entry of other generic drugs in 2023. [*Id.* at 27]. Plaintiffs further rely on a hypothetical monopolist test performed by Dr. Maestas that shows "Takeda would only need to control branded Amitiza and generic Amitiza in order to profitably impose a price increase of 5% for at least a year."

[*Id.*]. The fact that "Takeda imposed repeated price increases without leading to meaningful substitution to other drugs," Plaintiffs argue, is indirect evidence that the relevant market was limited to Amitiza and generic Amitiza, which Taked had market power over. [*Id.*]. Defendants argue that because Amitiza is therapeutically interchangeable with other chronic constipation drugs ("CCDs"), such as Linzess, Relistor, Symproic, Zelnorm, and Motegrity, the relevant product market cannot be limited to just brand Amitiza and generic Amitiza. [Doc. No. 422 at 46]. Takeda offers evidence from Dr. Jena as well as contemporaneous evidence from Takeda and other companies that demonstrates that Amitiza competed with other CCDs during the relevant time and evidence of patient switching between Amitiza and other drugs. [*Id.*].

"Therapeutic interchangeability is, on its own, insufficient to establish the relevant market." *Intuniv*, 496 F. Supp. 3d at 664–65. However, Defendants have also presented evidence that Amitiza did compete with other CCDs during the relevant time period. As such, I find that disputed issues of fact exist as to whether there is indirect evidence of Takeda's market power.

Takeda also argues that its market share was less than [redacted] in the relevant time period in which it was competing with other CCDs, [Doc. No. 422 at 48], which is insufficient to establish market power. *Grappone, Inc. v. Subaru of New England, Inc.*, 858 F.2d 792, 797 (1st Cir. 1988) (noting that 30% market share may not be sufficient to show market power). Plaintiffs respond that Takeda's market share analysis is not based upon cross-price elasticity but is instead dependent on clinical guidelines which are not the equivalent of a cross-price elasticity analysis. [Doc. No. 469 at 42]. I find that this is a triable issue for the jury.

Finally, I find that evidence of a reverse payment, when presented along with other evidence of market power, is sufficient. However, evidence of a reverse payment on its own is insufficient to prove market power. *Actavis* recognized that "where a reverse payment threatens

to work unjustified anticompetitive harm, the patentee likely has the power to bring about that harm in practice. The size of the payment from a branded drug manufacturer to a generic challenger is a strong indicator of such power." 570 U.S. at 138. However, in *Solodyn*, the court held that allegations of a reverse payment alone are insufficient to survive summary judgment. There, the court acknowledged "the logic of the interconnectivity of market power and a sizable reverse payment," but concluded that "it would be inappropriate to equate the two at the summary judgment phase." 2018 WL 563144, at *5. The court held that while an allegation of a large, unjustified reverse payment is sufficient to state a claim, "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." *Id.* As in *Solodyn*, here, Defendants dispute the existence of a reverse payment, and therefore, it would be inappropriate to rely on this evidentiary dispute alone to find market power. Accordingly, both parties' motions as to market power are DENIED.

C. Evidence Of Anticompetitive Agreement

Defendants move for summary judgment that Plaintiffs have failed to adduce evidence of an anticompetitive agreement. "To prevail on a conspiracy claim under Section 1 of the Sherman Act, 15 U.S.C. § 1, the Plaintiffs must prove the existence of a single agreement, tacit or express, in restraint of trade." *Nexium*, 42 F. Supp. 3d at 249–50. "Independent decisions by individual firms, even if they constitute parallel business behavior and 'lead to the same anticompetitive result as an actual agreement among market actors,' are not prohibited by the federal antitrust laws." *Id.* at 250 (citing *White v. R.M. Packer Co.*, 635 F.3d 571, 575 (1st Cir. 2011)). "Conscious parallelism is a phenomenon of oligopolistic markets in which firms might in effect share monopoly power, setting their prices at a profit-maximizing, supracompetitive level by

recognizing their shared economic interests and their interdependence with respect to price and output decisions." *White*, 635 F.3d at 576 (citation omitted). "Each producer may independently decide that it can maximize its profits by matching one or more other producers' price, on the hope that the market will be able to maintain high prices if the producers do not undercut one another." *Id.* "A tacit agreement—one in which only the conspirators' actions, and not any express communications, indicate the existence of an agreement—is distinguished from mere conscious parallelism by 'uniform behavior among competitors, preceded by conversations implying that later uniformity might prove desirable or accompanied by other conduct that in context suggests that each competitor failed to make an independent decision.'" *Id.* (citing *Brown v. Pro Football, Inc.*, 518 U.S. 231, 241 (1996)).

"Because supracompetitive prices—prices above what they would be in a perfectly competitive market—can result from both lawful conscious parallelism and an unlawful agreement to fix prices, antitrust doctrine has developed evidentiary standards to minimize the risk that legal conduct will be chilled or punished." *Id.* at 577. "Plaintiffs must establish that it is plausible that defendants are engaged in more than mere conscious parallelism, by pleading and later producing evidence pointing toward conspiracy, sometimes referred to as 'plus factors.'" *Id.* To survive summary judgment, "plaintiffs must produce direct or circumstantial evidence that is not only consistent with conspiracy, but 'tends to exclude the possibility of independent action.'" *Id.* (citing *Monsanto Co. v. Spray-Rite Service Corp*., 465 U.S. 752 (1984)). In other words, Plaintiffs "must show that the inference of conspiracy is reasonable in light of the competing inferences of independent action or collusive action that could not have harmed" Plaintiffs. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 588 (1986).

Defendants argue that Plaintiffs have not offered any direct evidence that the Settlement Agreement constitutes an anticompetitive, no-AG agreement with Par. They point to (1) DPPs' expert Dr. Ruhm's opinion that both Takeda and Par may not have known with 100% certainty what Takeda would eventually decide to do in 2021 when they entered into the Settlement Agreement in 2014, [Doc. No. 419-5 at 61 n.224], and (2) Par's post-settlement forecasts that modeled an AG launch by Sucampo, [Doc. No. 509 at ¶ 32]. Plaintiffs respond that the Settlement Agreement itself is direct evidence that the "natural effect of the 50/50 profit split was to disincentivize Takeda from launching a second generic." [Doc. No. 469 at 30]. I disagree.

While it is true that some courts have found that the agreement itself constitutes evidence of an antitrust conspiracy, those cases are inapposite. In *Wellbutrin*, the court held that the existence of the settlement itself was sufficient evidence for a reasonable jury to find that the defendant engaged in the alleged conspiracy. *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 770 (E.D. Pa. 2015) (cleaned up). But there, unlike here, the defendant expressly waived its rights to launch an AG. *Id.* at 747, 770. In *King Drug*, the court held that plaintiffs presented direct evidence of a concerted action through the settlement agreements, but also noted that defendants did not challenge plaintiffs' ability to meet the standard for concerted action. *King Drug Co. of Florence v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 410 (E.D. Pa. 2015). In *Eli Lilly*, the court held that an explicit agreement between two alleged co-conspirators not to supply in bulk an antibiotic to anyone other than to the other co-conspirator was direct evidence of an agreement illegally restraining trade. *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 172 F. Supp. 2d 1060, 1065 (S.D. Ind. 2001).

None of these cases are like the antitrust conspiracy alleged here, which highly depends on the effects of the anticompetitive agreement. Indeed, the Settlement Agreement here does not

contain an explicit no-AG agreement or any explicit agreement from Takeda/Sucampo waiving their right to launch their own AG. The theory here is that the structure of the profit split and royalty provisions make it economically irrational for Takeda/Sucampo to launch their own AG. I find that "[t]hese pieces of evidence are not analogous to the types of express threats or communications that other courts have treated as direct evidence." *Nexium*, 42 F. Supp. 3d at 252 (citing cases); *see e.g.*, *Monsanto*, 465 U.S. at 765 (regarding a supplier's advice to distributors that they would be terminated if they did not maintain suggested price levels); *Mayor & City Council of Baltimore v. Citigroup, Inc.*, 709 F.3d 129, 136 (2d Cir. 2013) ("[Direct] evidence would consist, for example, of a recorded phone call in which two competitors agreed to fix prices at a certain level.").

The Settlement Agreement itself, and what the parties understood, is circumstantial evidence of a conspiracy at best. To exclude the possibility of independent action, "[c]ircumstantial evidence meeting this standard may demonstrate, for example, 'parallel behavior that would probably not result from chance, coincidence, independent responses to common stimuli, or mere interdependence unaided by an advance understanding among the parties.'" *Nexium*, 42 F. Supp. 3d at 250–251 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 n.4 (2007)). Plaintiffs have put forth certain evidence of "plus factors." In *Nexium*, the court considered the Defendants' "strong motives to coordinate the actions they took." *Id.* at 256. Here, Plaintiffs have put forth evidence that Defendants would be motivated to delay generic entry in order to avoid patent litigation costs and maintain supra-competitive prices. While "agreeing to delay market entry is contrary to a generic competitor's interests, because of the potentially lucrative market for generic [Amitiza]," Par would be incentivized to do so where the Settlement Agreement effectively disincentivized Takeda/Sucampo from competing with Par. *Id.*

While this may be flimsy circumstantial evidence, a reasonable jury may still find that there is an implicit no-AG agreement, which could not have resulted from the independent actions of either Par or Takeda/Sucampo. Accordingly, Defendants' motion for summary judgment as to antitrust agreement is DENIED, to the extent that Plaintiffs may be permitted to present their circumstantial evidence to a jury.

D. Causation

"In order for judgment to be entered in his or her favor, an antitrust plaintiff must prove that he or she suffered damages from an antitrust violation and that there is a causal connection between the illegal practice and the injury." *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 267 (D. Mass. 2014), *aff'd*, 842 F.3d 34 (1st Cir. 2016) (internal citation omitted). Defendants argue that Plaintiffs have failed to establish that the Settlement Agreement caused the antitrust violation—here, the generic delay—for three reasons.

First, Defendants argue that Plaintiffs have not put forth evidence that Par would have been able to lawfully launch its ANDA product with full patent clearance. Around the time of settlement, Sucampo issued two additional patents: the '481 patent issued on June 10, 2014, set to expire in September 2025, and the '187 patent issued on July 15, 2014, set to expire in January 2027. [Doc. No. 422 at 49–51]. According to Defendants, Plaintiffs have not put forth evidence that Par would have won a subsequent patent litigation as to the '481 and '187 patents—which were not a part of the Par Patent Litigation that resulted in the Settlement Agreement here—and therefore cannot establish that Par would have received the requisite patent clearance to be able to lawfully launch its ANDA product.

Second, Defendants argue that Plaintiffs have not put forth evidence that the FDA would have approved Par's ANDA such that Par could have entered the market with its own generic

Amitiza by any of Plaintiffs' assumed launch dates in their but-for scenarios. Defendants provide evidence that Par did not obtain FDA approval of its ANDA until June 2022, despite evidence that Par persistently pursued FDA approval, because of the FDA's stringent requirements and regulatory barriers that Par faced during the process of obtaining ANDA approval. [*Id.* at 54–59].

Third, Defendants argue that there is no evidence that the other ANDA Filers would have been launch ready by the time of any of Plaintiffs' but-for scenarios. Specifically, Plaintiffs rely solely on the opinions of their expert who Defendants argue has offered inadmissible and unreliable opinions about the ability of these companies to launch their generics. [*Id.* at 62–66].

"Plaintiffs need not prove that the antitrust violation was the sole cause of their injury, but only that it was a material cause." *Nexium*, 42 F. Supp. 3d at 267. "Complicating matters is the fact that in disputes like this one, an injury can have multiple independent causes—some stemming from, as alleged in this case, FDA regulatory actions, some from manufacturing problems, and some from anticompetitive behaviors." *Id.* In *Nexium*, Judge Young outlined several key guideposts to determine whether the act of a third party was an independent act of causation: "First, drawing from the common law principles of proximate cause, courts have held that intervening conduct does not sever the chain of causation where that [third-party] conduct was a foreseeable consequence of the original antitrust violation. Second, injuries that are caused almost exclusively by the actions of government regulators do not give rise to antitrust liability." *Id.* at 268 (citation omitted). "In cases where governmental influence is not so pervasive, however, and the intervening governmental act followed from a defendant's conduct in some way, liability may still attach." *Id.*

In sum, "summary judgment on questions of causality is not appropriate where the plaintiff was injured by intervening conduct proximately caused by the defendant's antitrust

action, or where such intervening conduct was a foreseeable consequence of the defendant's antitrust action. Summary judgment is appropriate, however, where there is insufficient proof of causation, or where the intervening conduct was independently caused by a government actor." *Id.* at 269. However, it is worth noting that these issues are fact-heavy, and the "issues of proximate causation and superseding cause involve application of law to fact, which is left to the factfinder, subject to limited review." *Id.* (citing *Exxon Co., U.S.A. v. Sofec, Inc.*, 517 U.S. 830, 840–41 (1996)). As the First Circuit has held, "[c]ausation questions of this sort are normally grist for the jury's mill." *Peckham v. Continental Cas. Ins. Co.*, 895 F.2d 830, 837 (1st Cir.1990).

I find that for each of the issues pertaining to causation here, Plaintiffs have established a dispute of material fact.

i. Whether Par Would Have Obtained The Necessary Patent Clearance To Launch Its Own ANDA Product

For Plaintiffs to show that Par would have launched its own generic drug but-for the anticompetitive agreement, Plaintiffs "must also show that the launch would have been legal. "After all, if the launch were stopped because it was illegal, then the [Plaintiffs' injury] . . . would be caused not by the settlement but by the patent laws prohibiting the launch." *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 165 (3d Cir. 2017) (cleaned up). Defendants argue that the evidence shows that Par would have had to clear the two additional Orang Book patents, the '481 patent and the '187 patent, before Par could launch its own generic Amitiza product. Defendants point to the testimony of Par's 30(b)(6) witness, Gina Gencarelli, who testified that the Settlement Agreement not only covered the seven patents that were asserted in the Par Patent litigation, but also contained a broad covenant not to sue for future patents, and that Par was aware that Sucampo had additional patents or patent applications. [Doc. No. 422 at 52 (citing Doc. No. 509 at ¶¶ 84–87)]. Takeda's experts who have

experience as Hatch-Waxman attorneys, Mr. Jonathan Singer and Dr. Josephine Liu, also testified that the two additional Sucampo patents would substantially increase the likelihood that Par might face another lawsuit, which had the potential to create more uncertainty. [*Id.* (citing Doc. No. 509 at ¶ 99)]. Defendants argue that even though Plaintiffs' expert, Dr. Michael Davitz, opined on the likelihood that Par would have succeeded at trial as to the seven patents asserted in the Par Patent litigation, he did not provide any opinion as to Par's chances of overcoming Sucampo's newly-issued patents. [Doc. No. 422 at 53].

Plaintiffs respond that they have presented evidence of two alternative causation benchmarks for the launch date of Par's generic drug absent the reverse payment: (1) an alternative settlement with no reverse payment and an earlier agreed launch date, and; (2) a generic launch by Par after winning the patent litigation. I will address each in turn.

1. Benchmark For Causation #1: Alternative Settlement Agreement

Courts have recognized a no-payment settlement as a theory of but-for causation. *Solodyn*, 2018 WL 563144, at *21; *Wellbutrin*, 133 F. Supp. 3d at 757 (accepting the theory of an alternative settlement scenario but granting summary judgment in favor of defendants where there was clear evidence that the brand manufacture would have refused to settle absent the anticompetitive provision of the settlement); *see also United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Teikoku Pharma USA*, 296 F. Supp. 3d 1142, 1163 (N.D. Cal. 2017) (denying summary judgment where experts provided sufficient evidence to posit an alternative settlement theory).

In *Solodyn*, the court accepted the opinions of plaintiffs' experts—one of whom is Plaintiffs' expert here, Dr. Leffler—in finding that plaintiffs presented sufficient factual support for their alternative settlement causation theory. *Solodyn*, 2018 WL 563144, at *23. There, the

court accepted Dr. Leffler's opinions regarding "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." *Id.* at *22. Plaintiffs present similar evidence here, including economic models from plaintiffs' economists that "each identify an alternative earlier entry date that would have been economically rational for the parties absent the reverse payment . . . by comparing the expected value to Takeda and Par of continued patent litigation to the expected value of a settlement without the reverse payment." [Doc. No. 469 at 47]. Based on his analysis, Dr. Leffler identified an August 2019 entry date had Par settled without a reverse payment and Dr. Ruhm identified an October 2019 alternative settlement entry date. [*Id.*].

Defendants respond that there is no evidence that such an alternative settlement would have been reached, but courts have held that providing such evidence is almost impossible. *In re Zetia (Ezetimibe) Antitrust Litig.*, No. 2:18-MD-2836, 2021 WL 6690351, at *6 (E.D. Va. Aug. 17, 2021), *aff'd*, 566 F. Supp. 3d 509 (E.D. Va. 2021) ("Even if it were the case that there is no testimony or documentation to support Plaintiffs' hypothetical earlier entry date, an issue which the Court is not reaching here, this would not be surprising, as such an analysis addresses a but-for world, rather than the one in which the parties were acting.") (citation omitted). As such, "[a]ny criticism the Defendants have of the experts' methodologies or conclusions are best handled through cross-examination and the production of contrary evidence." *In re Androgel Antitrust Litig. (No. II)*, No. 1:09-cv-955, 2018 WL 2984873, at *17 (N.D. Ga. June 14, 2018).

Under this benchmark for causation, Plaintiffs argue that the alternative settlement would have been legal and not blocked by the '187 and '481 patents because the Settlement Agreement contained a covenant not to sue on any patent covering Amitiza, which would remain in even in the alternative settlement scenario where the challenged restraints would be removed. [Doc. No.

469 at 49]. Dr. Leffler and Dr. Ruhm assessed the alternative no-payment entry date as of the date of the Settlement, and Plaintiffs argue that at that time, the two additional patents had not been asserted against any generic manufacturer, Par was aware of those patents, and Takeda/Sucampo agreed to give Par a covenant not to sue with respect to all of its patents. [*Id.* at 50]. Plaintiffs argue that these same factors would have motivated Takeda/Sucampo to grant a covenant not to sue Par in the but-for world, citing to deposition testimony that it was Par's typical practice to include such covenants when licensing other patents and that Takeda/Sucampo agreed to such a covenant during the settlement negotiations, without any pushback. [*Id.*]. Defendants respond that this argument is a red herring. They argue that even if the alternative settlement would have included such a covenant, that does not explain the failure of Plaintiffs' experts to address the litigation success, probability, and timing for the '481 and '187 patents, and how those factors would impact the alternative settlement and entry date. [Doc. No. 508 at 17–18].

If a covenant not to sue on any of the patents would have existed in an alternative scenario, it is unclear why Plaintiffs' experts would have to put forth additional evidence covering these two additional patents in the context of this particular benchmark for causation. Even so, Plaintiffs *have* put forth such evidence in the context of their second benchmark for causation in which Par wins the patent litigation, as explained further below.

I further find that *Wellbutrin* and *Nexium* are inapposite. In *Wellbutrin*, "the expert provided no testimony that an alternate settlement would have been reached nor described what that settlement would have looked like." *Teikoku Pharma*, 296 F. Supp. 3d at 1163. Further, there was evidence that "the generic manufacturers regarded the no authorized generic agreement as an essential term." *Wellbutrin*, 133 F. Supp. 3d at 738. In *Nexium*, the First Circuit affirmed

the trial court's denial of plaintiffs' motions for a permanent injunction and for a new trial following a jury verdict for defendants, where Plaintiffs did not present evidence of either an alternative no-payment settlement or a patent litigation victory. *See Nexium*, 842 F.3d at 61–65.

2. Benchmark For Causation #2: Patent Litigation Victory

Plaintiffs' next theory of causation is based on Par's ability to prevail in the patent litigation. Plaintiffs argue that two scenarios may have occurred: "(1) Par wins the Par Patent Litigation, [redacted], obtains FDA approval of its ANDA, and launches by October 2016; and (2) Par wins the Par Patent Litigation, [redacted], obtains FDA approval, and launches by April 2018." [Doc. No. 469 at 52–53]. Dr. Davitz, a patent lawyer with extensive experience in Paragraph IV Hatch-Waxman litigation, estimated that Par had at least a 60% chance of prevailing on all of the patents asserted in the Takeda-Par litigation. [*Id.* at 53]. Dr. Davitz opined that "the '187 Patent claims are directed to gel capsules incorporating lubiprostone," and that the '187 patent was "a continuation of the '393 Patent," which he analyzed in detail in his report. [*Id.* at 54 (citing Doc. No. 424-74 at 409, ¶ 651)]. Dr. Davitz concluded that the '187 patent "would likely also be susceptible to the same types of validity challenges based on the same prior art relied upon by Par in its arguments against the validity of the '393 and '639 Patents." [*Id.* (citing Doc. No. 424-74 at 409, ¶ 651)]. Similarly, he concluded that the '481 patent is also directed toward long term treatment of chronic constipation using lubiprostone, and detailed his analysis of the '613, '016, '653, and '542 patents, which all relate to the use of lubiprostone to treat constipation in different dosages. [*Id.*]. He concluded that the additional patents did not alter his assessment of the likelihood of Par's litigation success. [Doc. No. 424-74 at 409, ¶ 653]. Plaintiffs also provide

evidence that Par certified to the FDA that all claims of the '187 and '481 patents were either invalid or not infringed, and that those invalidity arguments significantly overlapped with the seven patents asserted in the Par Patent Litigation, as well as evidence that Takeda/Sucampo did not assert the additional patents against subsequent generic Amitiza filers. [Doc. No. 469 at 55–56].

While Defendants may disagree with these arguments as speculative, I find that Plaintiffs have provided enough support to overcome summary judgment as to causation with respect to the two additional patents. As such, it is best left to a jury to decide whether the two additional patents would have been an independent bar to Par's ability to launch a generic drug earlier.

Before moving on, I note that Defendants have moved to exclude the opinion of Dr. Davitz, as well as the opinions of Mr. Clark, Dr. Leffler, Dr. Ruhm, and Dr. Conti, that proffer hypothetical launch scenarios based on Dr. Davitz's opinions. [Doc. No. 406]. Many of these arguments parallel the arguments that Defendants make here at summary judgment, as Defendants claim that Dr. Davitz's opinions are unreliable for his failure to consider the outcome, timing, and expenses of the Par Patent Litigation as well as the two additional patents. Defendants argue that there are "significant 'analytical gap[s] between the data and the opinion proffered.'" [Doc. No. 407 at 12]; *Doucette v Jacobs*, 106 F.4th 156, 169 (1st Cir. 2024) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)) (modification in original). As already explained above, I agree with Plaintiffs that what Defendants are referring to are not "analytical gaps," but rather material that their experts do not have to address. As explained, the alternative no-payment settlement scenario would have contained a similar covenant not to sue as in the Settlement Agreement, Dr. Davitz did consider the '481 and '187 patents and opined that "given their similarity to the subject matter of the asserted patents, the existence of the non-asserted

patents did not alter his opinions on the likelihood of success of the parties in the Takeda-Par litigation," [Doc. No. 468 at 23], and there is evidence that Takeda did enter into such covenants not to sue with later filing generics and did not sue on those patents in some cases. Defendants do not meet the standard for exclusion under Rule 702 here. As such, Defendants' Motion to Exclude the opinions of Plaintiffs' Experts on Litigation Success, Probability, Timing, Expenses, and Hypothetical Launch Dates, [Doc. No. 406], is DENIED.

ii. Whether Par Would Have Obtained FDA Approval To Launch Its ANDA Product By The Time Of Plaintiffs' But-For Scenarios

Next, Defendants argue that there is no genuine dispute of material fact that Par would not have been able to launch any generic product by January 1, 2021, absent the Settlement Agreement. Defendants point to the following evidence that the FDA would have posed an independent regulatory bar to Par's ability to obtain an approved ANDA product that would be ready to launch by 2021: (1) post-settlement evidence that Par was motivated to pursue FDA approval of its own ANDA notwithstanding that Par had the ability to launch an AG under the Settlement Agreement; (2) extensive record evidence of Par's correspondences with the FDA that details the difficulty that Par was facing in meeting the FDA's requirements; (3) incentives baked into the Settlement Agreement for Par to get FDA approval, and; (4) Plaintiffs' lack of evidence based on the opinions of two experts, Dr. Christians and Mr. Clark, who Defendants say only offer speculative opinions that Par delayed approval efforts due to is ability to distribute an AG under the Settlement Agreement. [*See* Doc. No. 422 at 54–62]. These arguments essentially boil down to two questions: "absent the [Takeda/Sucampo and Par] Settlement, did [Par] have the "will" to enter the market before [2021], and was there a "way" for it to enter had the agreement allowed for earlier entry, considering both manufacturing and FDA approval requirements?" *Nexium*, 42 F. Supp. 3d at 270.

As explained above in Section V.C., I find the opinions of Dr. Uwe Christians and Mr. Todd Clark to be admissible, and Takeda can challenge the sufficiency of those opinions at trial.

As to Par's "will" to pursue its own ANDA, Plaintiffs argue that their experts analyzed the financial incentives that motivate generic companies to prioritize ANDAs, and opined that when a company has the option to launch an AG that does not require FDA approval, those companies are incentivized to allocate their resources to other ANDAs with earlier launch dates. [Doc. No. 469 at 58]. Plaintiffs' experts concluded that a reasonable generic company in Par's position would have been incentivized to obtain approval and launch its ANDA product as early as October 2016. [*Id.*]. Plaintiffs further argue that the evidence shows that Par did act with urgency to obtain ANDA approval before February 20, 2015, but that once Par agreed not to launch generic Amitiza until 2021 and obtained the option to launch an AG, Par lacked urgency to seek final approval. [*Id.* at 59]. Plaintiffs argue that this "before and after" evidence creates a dispute of fact such that a jury is entitled to agree with Plaintiffs' experts regarding whether Par's motivation to pursue approval of its ANDA decreased following the Settlement Agreement. [*Id.*].

Further, Plaintiffs dispute that the Settlement Agreement itself incentivized Par to get FDA approval. Defendants argue that the royalty provision only declined if Par were selling its own FDA-approved product, and the Settlement Agreement provided no guarantees that Par would be the first generic to enter on January 1, 2021, due to the possibility of forfeiture of Par's 180-day exclusivity period or the possibility that the market decline event or license effective date acceleration terms of the Settlement Agreement could be triggered at any point prior to January 1, 2021. [Doc. No. 422 at 58]. If another generic were to enter before Par, Par would not have had the option to market its AG and thus had the incentive to continue diligently pursuing ANDA approval. [*Id.* at 59]. Plaintiffs primarily dispute these arguments given that they are

premised on the assumption that the royalty rate only declined if Par were selling an ANDA rather than an AG. As already discussed, this is a disputed fact regarding the terms of the Settlement Agreement that jury must resolve. I find that both parties have presented evidence sufficient to create a material dispute of fact as to Par's motivations to pursue ANDA approval.

Finally, as to whether Par had the "way" to gain FDA approval, Defendants point to evidence that from 2014 to 2022, Par responded to multiple demands from the FDA, including seven complete response letters, FDA's responses to multiple requisite amendments to Par's ANDA, information requests, a revised FDA Product Specific Guidance for lubiprostone, and requests stemming from the FDA's inspectional findings for Everlight's drug manufacturing facilities. [*See* Doc. No. 422 at 75–76]. Plaintiffs respond that there is evidence that (1) issues the FDA raised [redacted]. [Doc. No. 469 at 61]. I find that this evidence is sufficient to create a material dispute of fact as to whether Par would have faced roadblocks from the FDA to be able to launch a generic, absent any settlement agreement, before January 1, 2021.[11]

[11] Defendants accuse Plaintiffs of intentionally failing to develop any evidence of Par's post-settlement so that they can fill the void with their own speculative opinions from their experts as to Par's motivations. [Doc. No. 422 at 59–60]. Plaintiffs respond that it was difficult to obtain certain discovery from the companies that acquired Sucampo and Par, who were in bankruptcy during the discovery period. [Doc. No. 469 at 62]. Whether the parties were diligent in their discovery efforts do not impact my opinion regarding whether there is a triable issue of fact as to causation here.

iii. Whether The ANDA Filers Were Launch Ready By The Time Of Plaintiffs' But-For Scenarios

Lastly, Takeda argues that there is no evidence that the ANDA Filers would have been ready to produce and launch sufficient quantities of generic Amitiza at the times that Plaintiffs' experts assume. Plaintiffs rely on the opinions of their expert, Susan Marchetti, who opines that ANDA Filers had the sophistication, resources, facilities, and know-how to manufacture sufficient quantities to meet market demand for generic Amitiza by the dates specified in her reports. Defendants' arguments here parallel the arguments raised in their motion to exclude Ms. Marchetti. As explained in Section V.A., I find Ms. Marchetti's opinions admissible. Any weaknesses in her opinions may be properly challenged at trial. Furthermore, Plaintiffs have also put forth evidence of launch readiness from Mr. Clark. As both experts have been properly admitted, there is no basis to grant summary judgment in favor of Defendants at this stage.

E. Injury To Ten Brand-Only Purchasers

Defendants seek summary judgment that ten DPP class members suffered no injury and therefore lack standing. Although I considered and rejected similar arguments at class certification, [Doc. No. 616 at 22], I will briefly discuss this argument here.

There is evidence that three purchasers purchased only brand Amitiza throughout the entire class period, including after Par's entry in 2021, and seven purchasers ceased purchases of brand Amitiza entirely prior to Par's generic entry, and did not purchase any brand or generic Amitiza after Par's entry. [Doc. No. 422 at 67–69]. Defendants argue that the behavior of these brand-only purchasers in the "actual world" do not comport with DPPs' theory of injury: specifically, that purchasers of brand Amitiza, prior to generic entry, would have switched to generic Amitiza if it was available. Defendants argue that there is no evidence that such purchasers would have switched to generic Amitiza in the "but-for" world, given the evidence

that they did not switch to generic Amitiza in the actual world. Further, Defendants argue that contrary to Plaintiffs' beliefs, injury is only complete at the time the brand purchase is made *if* an entity purchased at a higher price in the actual world than they would have in the but-for world, which DPPs cannot prove.

Again, Defendants conflate injury and damages. As Plaintiffs note, it is irrelevant whether brand-only direct purchasers actually purchased generic Amitiza when it became available, or whether brand Amitiza would have been cheaper absent the illegal conduct. Several courts have affirmed that "antitrust injury occurs the moment the purchaser incurs an overcharge." *In re Nexium Antitrust Litig.*, 777 F.3d 9, 27 (1st Cir. 2015); *see also Meijer, Inc. v. Warner Chilcott Holdings Co. III*, 246 F.R.D. 293, 304 (D.D.C. 2007) ("[A]ntitrust injury occurs and is complete when the defendant sells at the illegally high price."). As such, "if a class member is overcharged, there is an injury, even if that class member suffers no damages." *Nexium*, 777 F.3d at 27; *In re Celebrex Antitrust Litig.*, 2017 WL 3669604, at *8 (E.D. Va. July 28, 2017) ("[T]he 'overcharge' is the difference between what they actually paid and what they would have paid after generic entry") (emphasis in original). Plaintiffs correctly note that the "measure of *damages* may depend on calculating the difference between the price absent anticompetitive conduct and the price actually paid, but *injury* does not." [Doc. No. 469 at 68 (emphasis in original)]. Plaintiffs have put forth evidence from their expert that an overcharge did occur here, which is sufficient to survive summary judgment. As such, Defendants' motion for summary judgment as to the brand-only purchasers is DENIED.

F. Statute Of Limitations

Defendants move for summary judgment that DPPs and Retailer Plaintiffs[12] cannot recover certain damages because they fail to plead or prove fraudulent concealment. DPPs filed their first complaint on June 25, 2021, [Doc. No. 28], and Retailer Plaintiffs filed their complaints on December 13, 2023, [23-cv-13061 Doc. No. 1], and January 29, 2024, [24-cv-10223 Doc. No. 1]. In each of those complaints, Plaintiffs allege that the statute of limitations should be tolled under the doctrine of fraudulent concealment and thus seek damages beginning at hypothetical alternative generic entry dates as early as October 2016. Defendants argue that Plaintiffs have not put forth evidence of fraudulent concealment and therefore, the DPPs and Retailers' recovery should be limited to sales after June 25, 2017, within four years of the filing of DPPs' complaint. [Doc. No. 422 at 71].

Federal antitrust enforcement actions are subject to a four-year statute of limitations. 15 U.S.C. § 15b. Any such action that is not brought "within four years after the cause of action accrued" is deemed "forever barred." *Id.* "Generally, a cause of action accrues under the Sherman Act when the plaintiff suffers an injury that is traceable to the defendant's conduct." *Nexium*, 968 F. Supp. 2d at 399. However, the statute of limitations may be equitably tolled if the plaintiff demonstrates fraudulent concealment. A claimant can establish fraudulent concealment when it shows the following elements: "1) wrongful concealment by defendants of their actions; and 2) failure of the claimant to discover, within the limitations period, the operative facts which form the basis of the cause of action; 3) despite the claimant's diligent efforts to discover the

[12] Defendants only move for summary judgment as to the statute of limitations against DPPs' and Retailers' claims because EPPs do not assert federal claims. [Doc. No. 508 at 26 n.103 (acknowledging that "applying a ruling to EPPs may vary depending on state law")]. Recently, Defendants filed their Motion for Partial Summary Judgment as to statute of limitations issues that pertain specifically to the EPPs' state-specific claims. [Doc. No. 604]. I will address those arguments in a separate decision.

facts." *Álvarez-Maurás v. Banco Popular of Puerto Rico*, 919 F.3d 617, 626 (1st Cir. 2019) (citation omitted).

Defendants bear the burden of proof when it "moves for summary judgment on the basis of an affirmative defense -- like the statute of limitations . . . ." *Ouellette v. Beaupre*, 977 F.3d 127, 135 (1st Cir. 2020). Defendants "cannot attain summary judgment unless the evidence that [they] provide[] on that issue is conclusive." *Id.* (citation omitted). "If the defendant produces such conclusive evidence, the burden shifts to the plaintiff to establish that the statute of limitations does not apply." *Id.* (citation omitted). While questions of when plaintiffs knew or should have known of their cause of action are typically questions of fact, when those facts are undisputed, the issue may be decided as a matter of law. *Orbusneich Med. Co. v. Bos. Sci. Corp.*, No. 09-cv-10962, 2011 WL 1086015, at *3 (D. Mass. Mar. 21, 2011)

Plaintiffs' allegations of fraudulent concealment are premised on their theory that "Takeda and Sucampo paid Par in the form of a functional no-authorized generic promise (or "one generic only" agreement) [that] was not fully revealed until after Par launched its authorized generic Amitiza product on January 4, 2021, and neither Takeda nor any other licensed third party launched another authorized generic version of Amitiza." [Doc. No. 28 at ¶ 316]. Plaintiffs allege that "[a]t that point, it became clear that there would not be competition for generic Amitiza and that Takeda/Sucampo-Par 2014 agreement was the reason for that." [*Id.*].

Although there was an October 9, 2014 press release announcing the Settlement Agreement, Plaintiffs allege that the press release was misleading because it stated that Par was granted a non-exclusive license to market par's generic version of Amitiza, even though that is

not what the Settlement Agreement conferred.[13] [*Id.* at ¶¶ 320–321]. Defendants argue that Plaintiffs' experts have now put forth a theory that the 50/50 profit split itself is a no-AG agreement, independent of any declining royalty, and as such, Plaintiffs would have been on notice of this harm at least as of the date the Settlement Agreement were made public. [Doc. No. 422 at 71]. However, Plaintiffs counter that the press release did not disclose that the profit split was a *50/50* division. [Doc. No. 469 at 69–70; Doc. No. 28 at ¶ 321]. Additionally, although the Settlement Agreement was publicly disclosed on November 7, 2014, the royalty rates were redacted, which Plaintiffs allege were "intended to, and did, obscure the true nature of the overall anticompetitive agreement" while misleadingly leaving unredacted "Takeda's (illusory) reservation of its ability to launch a competing authorized generic product." [Doc. No. 28 at ¶¶ 322–323]. Plaintiffs also allege that a subsequent court filing falsely proclaimed that the Settlement Agreement had "procompetitive" effects. [*Id.* at ¶ 324]. Defendants argue that Takeda had no duty to disclose the Settlement Agreement's terms, that the press release was not misleading, and Plaintiffs have not provided evidence that they made diligent efforts to uncover the operative facts necessary for their claims. [Doc. No. 508 at 26].

While I agree with Defendants that Plaintiffs have not put forth evidence that they could not uncover the harm absent diligent efforts, it is unclear what evidence Plaintiffs can provide. Indeed, it is Defendants' right not to disclose the "intimate details" of an anticompetitive agreement for suspicion to arise. *Donahue v. Pendleton Woolen Mills, Inc.*, 633 F. Supp. 1423, 1443 (S.D.N.Y.1986). That does not change the fact that without key information—the 50/50 profit split and the declining royalty—Plaintiffs could not have known of their claims. Further,

[13] To be clear, the Settlement Agreement explicitly grants a non-exclusive license, but the argument appears to be that based on the function of the Settlement Agreement (and Plaintiffs' theory of the case), the license was not actually non-exclusive. [Doc. No. 419-3 at 9].

Defendants' cases are inapposite. In *Niaspan*, plaintiffs did not plead reasonable diligence. *Id.* at 748–749. Further, in both *Niaspan* and *In re: Lamictal Indirect Purchaser & Antitrust Consumer Litig.*, 172 F. Supp. 3d 724, 746 (D.N.J. 2016), the relevant terms were disclosed in other sources. *See Niaspan*, 42 F. Supp. 3d at 748 (The relevant "dollar amounts *were* disclosed in 2007—only two years after the settlement agreements were executed and six years before the filing of the Complaints.") (emphasis in original); *Lamictal*, 172 F. Supp. 3d at 746 ("Plaintiffs acknowledge that the terms of the No-AG Commitment were publicly disclosed in a 2008 lawsuit in the District of New Jersey between Teva and GSK.").

As these material facts are not in dispute, I find as a matter of law that the statute of limitations is equitably tolled for DPPs' and Retailer Plaintiffs' claims. Accordingly, Defendants' motion for summary judgment as to the statute of limitations is DENIED.

G. Pro-Competitive Effects

Plaintiffs argue that partial summary judgment should be granted in their favor because Takeda fails to proffer any legitimate, procompetitive benefits of the reverse payment, as required under the second prong of the rule of reason. Specifically, Plaintiffs argue that (1) any procompetitive benefits must be specific to the challenged restraint—here, the 50/50 profit split and declining royalty—rather than the Settlement Agreement as a whole, and (2) Defendants have not offered any procompetitive benefits for the reverse payment at issue here because the reverse payment was not necessary to achieve the procompetitive benefits that Defendants claim have been achieved by the Settlement Agreement. [Doc. No. 417 at 53–59]. I follow the other courts in this district that hold that procompetitive benefits need not be limited to the challenged restraint. Further, I find that Takeda has proffered evidence of procompetitive benefits that creates a dispute of fact.

Under the First Circuit's rule of reason, after the plaintiff proves that the challenged restraint has a substantial anticompetitive effect that harms consumers in the market, "the burden shifts to the defendants to demonstrate a procompetitive rationale for the restraint." *Vazquez-Ramos*, 55 F.4th at 299 (internal citation omitted). Plaintiffs rely on several cases that they believe establishes that Defendants must demonstrate a procompetitive rationale for the challenged restraint itself, as opposed to any other aspect of the agreement. I will address the two that are binding on me.

First, in *Actavis*, the Supreme Court held that "[a]n antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason." 570 U.S. at 156. Plaintiffs read this holding to mean that the defendants must provide justifications that relate to the challenged terms, otherwise those justifications will not explain the term's presence in the agreement. [Doc. No. 417 at 55]. However, I agree with Defendants that *Actavis* does not bind lower courts to limiting its consideration of procompetitive rationales only to the challenged restraint. Another fair reading of *Actavis* could be that defendants have the burden to show that procompetitive benefits justify the *presence* of the challenged term, even if those rationales implicate other aspects of the agreement. This is precisely the view that courts in this district have taken. *See Solodyn*, 2018 WL 734655, at *4 (D. Mass. Feb. 6, 2018) (rejecting plaintiffs' argument that the "proffered justifications focus, improperly, upon the settlement agreements as a whole, rather than justifying the payment itself" and declining "to take such a narrow view, such that the payment would be divorced from its business context"); *In re Intuniv Antitrust Litig.*, No. 16-cv-12396, 2021 WL 10362709, at *5 (D. Mass. Mar. 3, 2021) ("Despite Plaintiffs' contention, Defendants are not limited to asserting procompetitive justifications for the alleged

no-AG Agreement specifically."); *In re Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d 274, 317 (D.R.I. 2019) (same).

Second, Plaintiffs rely on *Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of Univ. of Oklahoma*, 468 U.S. 85 (1984), where the Supreme Court reviewed whether the National Collegiate Athletic Association's ("NCAA") plan for televising college football claims violated the Sherman Act. There, the Court held that "[t]he interest in maintaining a competitive balance that is asserted by the NCAA as a justification for regulating all television of intercollegiate football is not related to any neutral standard or to any readily identifiable group of competitors." *Id.* at 118. As such, the television plan was "not even arguably tailored to serve such an interest." *Id.* at 119. Plaintiffs argue that this case supports the proposition that "procompetitive benefits must relate to the challenged restraint to hold any weight." [Doc. No. 417 at 55]. Defendants respond that the Court in *University of Oklahoma* "did not require the NCAA to tie any justification to any individual aspect of the plan." [Doc. No. 470 at 48]. The Supreme Court's holding in this case, which challenged the television plan as a whole, does not stand for a general rule that lower courts assessing procompetitive rationales must only assess those rationales as they relate to a challenged restraint.

Finally, Plaintiffs cite to *United States v. Am. Airlines Grp. Inc.*, where the First Circuit credited the Supreme Court's holding that "anticompetitive restraints of trade may wind up flunking the rule of reason to the extent the evidence shows that substantially less restrictive means exist to achieve any proven procompetitive benefits." 121 F.4th 209, 226 n.10 (1st Cir. 2024) (quoting *NCAA v. Alston*, 594 U.S. 69, 100 (2021)). But this holding goes to the weight that any potential procompetitive explanations may have, rather than to a bright-line rule that defendants are limited to offering procompetitive justifications as to the challenged restraint. At

trial, a jury may very well find that there are less restrictive means to achieve the procompetitive benefits Defendants offer—but they should nevertheless be permitted to hear any rationales Defendants have to offer.[14]

At trial, Defendants will offer evidence from their expert, Dr. Celeste Saravia, that "the Par Settlement Agreement (1) allowed Par onto the market earlier than was justified by the strength of the patents (thus adding a generic to the market much earlier than was otherwise possible), (2) provided Par an AG supply option that allowed Par to enter the market despite lacking approval of its own ANDA product, and (3) allowed Sucampo to allocate more resources to research and development for new products to benefit the market." [Doc. No. 470 at 47]. Defendants argue that even if Plaintiffs' narrow construction of the rule of reason analysis regarding procompetitive benefits were adopted, Defendants' evidence directly relates to the challenged provisions of the Settlement Agreement. Plaintiffs, of course, dispute this, and respond that to achieve these supposed benefits, "a royalty need not be structured as a 50/50 profit split with a no-second-generic provision, and a profit split is not required at all." [Doc. No. 495 at 24]. Further, they argue that "[b]ecause the profit split and no-second-generic condition were not necessary to the Agreement (and Takeda's experts agree), they are not related to the entry date. The same is true of the ability to launch an AG and investment in R&D (which has nothing to do with the Agreement at all)." [*Id.*]. This is a dispute of fact ripe for a jury.

I also note that Plaintiffs have moved to exclude the opinions offered by Dr. Saravia on the procompetitive benefits of the Settlement Agreement, [Doc. No. 459]. There, Plaintiffs raise largely the same arguments as they do here, that Dr. Saravia improperly opined on the benefits of the agreement as a whole as opposed to the benefits of the challenged term. Based on my finding

[14] Plaintiffs' remaining cases do not persuade me to adopt their position and are otherwise not binding.

that Defendants are permitted to offer such evidence and such evidence is not contrary to law, Plaintiffs' Motion to Exclude is DENIED.

H. Jury Instruction

Plaintiffs seek an order that, if the jury finds the value of the 50/50 profit split with the no-second-generic provision resulted in a "large, unexplained" reverse payment, then the Settlement Agreement created potential restraints on competition in the U.S. lubiprostone market, and that those restrains in fact occurred. [Doc. No. 417 at 49]. Defendants respond that such jury instructions are premature, and that there are still several disputes in play that must be resolved before the court can decide on jury instructions at this stage. [Doc. No. 470 at 44–47]. For instance, the parties still dispute (1) the terms of the Settlement Agreement, (2) whether there was a reverse payment at all, and (3) whether there were anticompetitive consequences. [*Id.*]. I agree with Defendants that a finding that there was a large, unexplained reverse payment does not alleviate Plaintiffs' duty of proving anticompetitive effects and a request for this jury instruction is premature at summary judgment.

Plaintiffs argue that though Takeda may have created a triable issue of fact as to the value of the reverse payment, there are other features of the restraints that cannot be disputed and therefore justifies a finding as a matter of law that there was a potential for anticompetitive effects, and that those anticompetitive effects occurred, if the jury were to find a large, unexplained reverse payment. For instance, the Settlement Agreement helped Takeda avoid the risk of losing the patent litigation and an at-risk launch by Par, delayed Par's entry by seven years, and ultimately disincentivized Takeda and Sucampo from launching a second-AG, the type of anticompetitive harm that *Actavis* seeks to avoid. [Doc. No. 417 at 50]. However, *Actavis* does not seek to avoid all settlements that resolve patent litigation, but rather settlements that

have unjustified, anti-competitive consequences that outweigh any pro-competitive benefits. *See Watson Lab'ys, Inc.*, 101 F.4th 223, 238 (2d Cir. 2024) ("An overly restrictive interpretation of *Actavis* would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive.") (citation omitted). Further, Defendants dispute that the Settlement Agreement contained a no-AG provision or otherwise disincentivized Takeda or Sucampo from launching its own AG.

Plaintiffs also cite to evidence of the parties' post-settlement conduct and forecasts that Plaintiffs argue show the anti-competitive potential of the Settlement Agreement. [Doc. No. 417 at 52–53]. However, these facts that Plaintiffs argue support anti-competitive consequences are, in fact, in dispute. [*See, e.g.*, Doc. No. 499 at 41, ¶ 50 (disputes regarding the implications of the forecasts)]. If I cannot decide whether these facts establish, as a matter of law, the anti-competitive potential or effects of the Settlement Agreement at the summary judgment phase, I certainly cannot instruct the jury to *assume* the anti-competitive potential or effects based solely on a finding of a large, unexplained reverse payment. *Intuniv*, for example, explains that under the rule of reason, "Plaintiffs must 'prove anticompetitive effects,' by demonstrating 'a payment for delay, or, in other words, payment to prevent the risk of competition' . . . [i]n assessing whether the payment had anticompetitive effects, the Court must consider 'its size, its scale and relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.'" 496 F. Supp. 3d at 667 (citing *Loestrin III*, 261 F. Supp. 3d at 329); *see also In re Xyrem (sodium oxybate) Antitrust Litig.*, 2024 WL 4023561, at *17–18 (N.D. Cal. Aug. 26, 2024) (denying summary judgment and leaving it up to the jury to "determine whether and to what extent the Agreements were anticompetitive").

Accordingly, Plaintiffs' motion for partial summary judgment seeking an order regarding a jury instruction on potential restraints is DENIED.

VIII. CONCLUSION

For the above reasons, Plaintiffs' Motion for Partial Summary Judgment, [Doc. No. 416], is GRANTED in part and DENIED in part. Defendants' Motion for Summary Judgment, [Doc. No. 421], is DENIED. Plaintiffs' motions to exclude certain of Defendants' experts, [*see* Doc. Nos. 457, 459, and 461], are DENIED. Defendants' motions to exclude certain of Plaintiffs' experts, [*see* Doc. Nos. 404, 406, 408, 410, 412, 414], as well as Defendants' Motion to strike portions of Section XII of Plaintiffs' Statement of Material Facts, [Doc. No. 506], are DENIED.

SO ORDERED.

/s/ Myong J. Joun
United States District Judge