UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
Norfolk Division

In re:
ZETIA (EZETIMIBE) ANTITRUST LITIGATION

MDL NO. 2:18md2836

OPINION

This matter comes before the court on Defendants'[1] Objections, ECF No. 1732, ("Objections" or "Def. Obj.") to Magistrate Judge Douglas E. Miller's Report and Recommendation, ECF No. 1717, ("R&R"). In his R&R, Judge Miller recommended that this court deny Defendants' Motions for Summary Judgment, ECF Nos. 1037, 1067, on all claims. See R&R at 73. For the reasons stated below, the court hereby **OVERRULES** Defendants' Objections; **AFFIRMS** the findings and recommendations set forth in the R&R; and **DENIES** Defendants' Motions for Summary Judgment.

I. BACKGROUND

The record is replete with recitations of the relevant facts.[2] However, the court provides the following background

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[1] Defendants in this case consists of Merck & Co., Inc.; Merck Sharp & Dohme Corp.; Schering-Plough Corp.; Schering Corp.; and MSP Singapore Co. LLC (collectively, "Merck"); Glenmark Pharmaceuticals, Ltd. and Glenmark Pharmaceuticals Inc., USA (collectively, "Glenmark").

[2] See, e.g., R&R at 5-24, n.3.

information and a selected timeline of relevant events for purposes of addressing Defendants' Objections to the R&R.

A. ANDA Process

In order to market and sell a pharmaceutical product, a firm must file a New Drug Application ("NDA") with the Food and Drug Administration ("FDA"). Seeking approval under the NDA process is "a long, comprehensive, and costly testing process." Fed. Trade Comm'n v. Actavis, 570 U.S. 136, 142 (2013). To incentivize the entrance of lower-priced, generic versions of previously approved, "listed drugs," the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act") provides for the Abbreviated New Drug Application ("ANDA") process. Pub. L. No. 98-417, 98 Stat. 1585 (1984).

Under the ANDA process, a pharmaceutical company may request approval from the FDA to market and sell a generic version of a listed drug. The first generic manufacturer to obtain ANDA approval (the "first filer") is granted an "exclusivity" period, which lasts 180 days. See 21 U.S.C. § 355(j)(5)(B)(iv). During this exclusivity period, no other generic product may enter the market, except for one produced by the patent holder. A patent holder's generic, if produced, is referred to as an "authorized generic" ("AG"), and is defined as a drug "marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the

listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the listed drug." 21 U.S.C. § 355(t)(3)(B)

In an ANDA filing, an applicant must make certain assurances and certifications, designed to ensure that the brand-name manufacturer and the generic manufacturer "resolve intellectual property disputes." In re Wellbutrin XL Antitrust Litig, 868 F.3d 132, 144 (3d Cir. 2017). One such certification, referred to as a "Paragraph IV certification," claims that the manufacturer's patent is either invalid or will not be infringed by the generic drug. See 21 U.S.C. § 355 (j)(2)(A)(vii), (IV). If an ANDA filer includes the Paragraph IV certification, the patent holder must be notified. 21 U.S.C. § 355 (j)(2)(B). A patent infringement suit is likely to follow.

B. Actavis Reverse Payment

Plaintiffs' theory in this case relies on the foundational reverse payment case, Actavis. See 570 U.S. 136. In Actavis, the patent holders of a pharmaceutical drug sued two generic manufacturers for patent infringement, after the generics had filed Paragraph IV ANDA applications. After years of litigating their patent dispute, the parties settled. As a part of the settlement agreement, the patent holders paid millions of dollars to the generic manufacturers, who agreed to a particular date on

which their generic versions of the patented drug could enter the market.

The Court found this reverse payment settlement "unusual," since the patent holders faced no potential liability to the generics. Id. at 147-48. The payees were situated as plaintiffs in the patent infringement suit and were further shielded by the protection of their patents. Id. After analysis of the parties' dispute and consideration of the tension between patent and antitrust law,[3] the Court identified its central concern with reverse payment arrangements, generally: The possibility that the "unusual" payment reflected the patent holder's "desire to maintain and to share patent-generated monopoly profits" by entering into the settlement agreement with the generic manufacturer. Id. at 158. That kind of arrangement, the Court exclaimed, could thus be the result of the improper wielding of the patent power rather than simply the avoidance of future litigation costs; a type of conduct that "the antitrust laws are likely to forbid." Id.

The Court identified that an "unexplained large reverse payment" of the type paid in Actavis, "would normally suggest that

[3] As the Eleventh Circuit had stated in its opinion, before cert was granted: "The difficulty at the heart of this case is in deciding how to resolve the tension between the pro-exclusivity tenets of patent law and the pro-competition tenets of antitrust law." Fed. Trade Comm'n v. Watson Pharmaceuticals, Inc., 677 F.3d 1298, 1306 (11th Cir. 2012).

the patentee has serious doubts about the patent's survival." Id. at 157.[4] In response to the doubt about its patent's ability to survive the infringement suit, the patent holder may "prevent the risk of competition" by paying off the generic challenger to settle the suit, and thereby control the date on which the generic enters the market. Id. Thereby, the patent holder chooses to exchange "a share of its monopoly profits" for a delay in competition. Id. at 154. The precise delay obtained, in this context, spans between *Date X*, the risk-adjusted date of patent invalidation,[5] and *Date Y*, the settlement's agreed generic entry date.

This delay, potentially obtained by the improper use of the patent power, leaves consumers with a relatively longer period without generic competition in the market, and higher prices as a result. Accordingly, the Court's decision in Actavis addresses the "concern that settlements taking this form tend to have significant adverse effects on competition," by declaring that these agreements may be subject to antitrust scrutiny. Id. at 137.

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[4] If the patent holder thought it was sure to win the infringement suit, why would they pay the generic a sum larger than future litigation costs to end the dispute?

[5] To illustrate, unless there is a certainty that the patent would be invalidated, the risk-adjusted date of patent invalidation must be some time later than the projected end of the patent infringement litigation. This date is also necessarily before the settlement agreement allows generic entry and before patent expiry.

Ultimately, the Court found that the familiar rule of reason framework should apply to reverse payment arrangements, but left up to lower courts the method for effectuating the framework in the context of reverse payment cases. Id. at 160. While the payment in Actavis was strictly monetary, lower courts have since extended its holding to apply to other, non-monetary "transfers of value," such as a patent holder's agreement to not produce an AG. See King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp. ("Lamictal"), 791 F.3d 388, 394 (3d Cir. 2015).

C. Timeline of the Merck-Glenmark Litigation

In the 1990s and early 2000s, Merck applied for and obtained various patents and reissued patents related to the compound ezetimibe. See ECF No. 128 at 37-43 ("DPPs Am. Compl."). On October 25, 2002, Merck obtained approval from the FDA to market and sell Zetia, a cholesterol drug which contained ezetimibe as its active ingredient. See DPPs Am. Compl. at 45. On October 25, 2006, Glenmark filed an ANDA for Zetia, certifying that the patents covering Zetia were either invalid or would not be infringed by Glenmark's generic. See DPPs Am. Compl. at 48.

On March 22, 2007, after receiving notice of Glenmark's ANDA filing, Merck sued Glenmark in the District of New Jersey, alleging that Glenmark's generic would infringe U.S. Patent No. RE37,721 (the "RE'721 Patent"), one of Merck's patents covering ezetimibe. See DPPs Am. Compl. at 49. In mid-2009, Merck and

Glenmark began settlement negotiations. See ECF No. 1085 at 15-17 ("Merck Statement of Facts" or "Merck SOF").

On November 5, 2009, a second generic drug manufacturer, Mylan, notified Merck that it had submitted an ANDA for Vytorin. Merck SOF at 20. Vytorin was also a drug marketed and sold by Merck, which contained a mix of ezetimibe and a second compound, called simvastatin. See Merck SOF at 12. On December 16, 2009, Merck filed a patent infringement suit against Mylan in the District of New Jersey, alleging that Mylan's ANDA application for Vytorin *also* infringed the RE '791 Patent. See Merck SOF at 20.

On May 10, 2010, Merck and Glenmark signed a settlement agreement. ECF No. 398-21 ("Settlement Agreement" or "Sett. Agr."). The Settlement Agreement provided, inter alia:

- Merck would reimburse Glenmark for up to $9 million in attorneys' fees, already incurred. Id. § 7.3.

- During its period of exclusivity, Glenmark was granted the exclusive right to market "Generic Ezetimibe," id. § 5.3, elsewhere defined as:

> [A] drug product containing ezetimibe as its sole active ingredient (a) that refers to the Approved Zetia Product as the reference-listed drug in an ANDA . . . or (b) that is sold pursuant to NDA No. 21-445 but is not sold under the trademark Zetia® or another trademark or trade name of Schering, MSP or their Affiliates.

id. § 1.14.[6]

[6] Plaintiffs allege that these provisions amount to a so-called "No-AG agreement," which prohibits Merck from launching an

- Glenmark could launch its generic version of Zetia on December 12, 2016. Id. §5.4.

- Merck and Glenmark would execute a consent judgment, ending their dispute. Id. § 2.1.

On June 14, 2011, the RE'721 Patent was reissued by the Patent and Trademark Office ("PTO") as U.S. Patent No. RE42,461 (the "RE'461 Patent"), which Merck then asserted against Mylan. See Merck SOF at 21. On December 5, 2011, the trial between Merck and Mylan began. See Merck SOF at 21. On April 27, 2012, the District Court for the District of New Jersey, Judge Linares, held that the RE'461 Patent was valid and enforceable. See Merck SOF at 21. This decision was subsequently affirmed by the Federal Circuit. See Merck, Sharp & Dohme Corp. v. Mylan Pharms., Inc., 496 F. App'x 87 (Fed. Cir. 2013).

In or about January 2014 is the date on which Plaintiffs' patent expert, Robert Hrubiec, opines that the litigation between Merck and Glenmark would have ended, after exhaustion of all appeals to the Federal Circuit. See ECF No. 1083-18 at 30 ("Hrubiec Rpt.").[7] In or about early-2015 is the date on which Plaintiffs'

AG during Glenmark's period of exclusivity; Defendants adamantly disagree. This dispute is discussed, at length, infra Part III.A.1.

[7] Thus, January 2014 constitutes the date on which Glenmark's generic might have entered the market, if the parties continued to litigate their patent dispute, and Glenmark prevailed. The court notes that this date and its underlaying opinion is heavily

economic experts, Drs. Thomas McGuire and Keith Leffler, opine that Merck and Glenmark would have agreed to allow entry of Glenmark's generic version of Zetia, had the Settlement Agreement not included § 5.3.[8] See ECF Nos. 1130-9 at 26 ("McGuire Rbt. Rpt."), 1130-4 at 54-55 ("Leffler Rpt."). December 12, 2016, is the date on which the Settlement Agreement, by its explicit terms, allowed entry of Glenmark's generic version of Zetia. See Sett. Agr. § 5.4. On April 25, 2017, Merck's period of pediatric exclusivity for Zetia ended, terminating Merck's exclusive rights to ezetimibe.[9] See Merck SOF at 12, 13.

D. Defendants' Motions for Summary Judgment

Plaintiffs'[10] and Defendants have been engaged in extensive litigation concerning Merck and Glenmark's Settlement Agreement.

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disputed by Defendants. It is included in this timeline to illustrate the relevant events, as alleged by Plaintiffs.

[8] Thus, early 2015 constitutes the date on which Plaintiffs' alternate settlement theory relies. See infra Parts III.B.1.ii. (discussing alternate settlement theory as it relates to anticompetitive effect), III.C.2 (same, as it relates to causation). Again, the court notes that this date and its underlaying opinion is heavily disputed by Defendants. It is included in this timeline to illustrate the relevant events, as alleged by Plaintiffs.

[9] Thus, April 25, 2017 constitutes the date on which Glenmark's generic might have entered the market, if the parties continued to litigate their patent dispute, and Merck prevailed.

[10] "Plaintiffs" refers to all plaintiffs in this multi-district litigation, which consists of a class of End Payor Plaintiffs ("EPPs"), jointly litigating Direct Purchaser Plaintiffs ("DPPs"), and several large insurance companies and pharmaceutical retailers.

Plaintiffs claim that Defendants conspired to delay the introduction of generic ezetimibe to the market, in violation of Sections 1 and 2 of the Sherman Act. DPPs Am. Compl. at 11, 29; See 15 U.S.C. § 1, 2. The Settlement Agreement, Plaintiffs allege, included an "unexplained large reverse payment," which violates the antitrust laws, according to the Supreme Court's opinion in Actavis, 570 U.S. 136. This prolonged multidistrict litigation is now on the eve of trial, which is scheduled to begin on April 17, 2023. See ECF No. 1765.

On August 10, 2020, Glenmark, ECF No. 1037, and Merck, ECF No. 1067, filed their Motions for Summary Judgment. On September 2, 2022, Judge Miller issued his R&R, recommending that this court deny Defendants' Motions. See ECF No. 1717. In consolidated filings, Defendants objected, ECF No. 1732 ("Def. Obj."), and Plaintiffs responded, ECF No. 1739 ("Pls. Resp."). Shortly thereafter, on October 6, 2022, Defendants requested leave to file a reply,[11] ECF No. 1742, which the court granted, ECF No. 1766. Defendants also requested that this court hold a hearing on the matter. See ECF No. 1751. On December 15, 2022, counsel for the parties convened before the court and argument was heard. See ECF No. 1791. Thus, having been extensively briefed and argued

[11] The impetus for Defendants' request for leave to reply is discussed in greater detail. Infra Part III.B.1.

before the court, this matter is now ripe for judicial determination.

II. STANDARD OF REVIEW

A. Review of Magistrate Judge's R&R

Pursuant to Rule 72(b) of the Federal Rules of Civil Procedure, the court, having reviewed the record in its entirety, must make a de novo determination of those portions of the R&R to which the parties have specifically objected. Fed. R. Civ. P. 72(b). "[A]s part of its obligation to determine de novo any issue to which proper objection is made, a district court is required to consider all arguments directed to that issue, regardless of whether they were raised before the magistrate." See United States v. George, 971 F.2d 1113, 1118 (4th Cir. 1992) (emphasis added).

For unchallenged portions, the court "must 'only satisfy itself that there is no clear error on the face of the record in order to accept the recommendation.'" Diamond v. Colonial Life & Accident Ins. Co., 416 F.3d 310, 315 (4th Cir. 2005) (quoting Fed. R. Civ. P. 72 advisory committee's note). The court may accept, reject, or modify, in whole or in part, the recommendation of the Magistrate Judge, or recommit the matter to him with instructions. 28 U.S.C. § 636(b)(1).

B. Summary Judgment

Summary judgment is appropriate when the court, viewing the record as a whole and in the light most favorable to the nonmoving party, finds there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law. Austin v. Clark Equip. Co., 48 F.3d 833, 835-36 (4th. Cir. 1995). "Thus, it is the burden of the moving party to show the court that no material factual issues exist for trial." Id. at 835.

If the moving party carries its burden, the court should grant summary judgment if the nonmoving party has failed to establish, after adequate time for discovery, the existence of an essential element of that party's case. Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986). At a minimum, the nonmoving party must present "evidence on which the [trier of fact] could reasonably find" for the nonmoving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986). The nonmoving party must go beyond the facts alleged in the pleadings, and rely instead on affidavits, depositions, or other evidence to show a genuine issue for trial. See Celotex, 477 U.S. at 324; M & M Med. Supplies & Serv., Inc. v. Pleasant Valley Hosp., Inc., 981 F.2d 160, 163 (4th Cir. 1992).

III. DEFENDANTS' OBJECTIONS

Defendants raise several objections to the R&R, which map generally to the various elements of Plaintiffs' antitrust claim.

Each objection concludes that the R&R was in error regarding the finding of triable issues of fact related to an antitrust element. Defendants challenge the characterization and valuation of the reverse payment in this case and submit that no reasonable juror could conclude that (1) the Settlement Agreement had anticompetitive effects, (2) Defendants' conduct caused Plaintiffs an antitrust harm, or (3) Plaintiffs suffered an antitrust injury. These objections are addressed, in turn, below.

A. Reverse Payment

The initial question in any reverse payment case is straightforward: What was the reverse payment, and how much was it worth? Here, Plaintiffs allege that the reverse payment from Merck to Glenmark consisted of two components: (1) a "No-AG provision," valued at $25.5 million (*or more*); and (2) the reimbursement for Glenmark's attorney's fees, up to $9 million. See ECF Nos. 1130-8 at 53 ("McGuire Rpt."), 1130-4 at 47 ("Leffler Rpt."). Contrary to Defendants' objections, the R&R correctly concluded that there are disputes of material fact concerning both the nature and value of the reverse payment in this case. See R&R at 29.

1. Existence of an Alleged No-AG Provision

Defendants object to the R&R's finding that "Plaintiffs have established triable issues regarding *the existence* of a No-AG agreement." R&R at 29 (emphasis added). Defendants argue that any

reasonable juror would find at trial that the alleged No-AG provision in the Settlement Agreement merely constituted a "limited exclusive license provision under which Merck would not launch an *unbranded* AG during a portion of Glenmark's period of exclusivity." Def. Obj. at 9 (emphasis added). Defendants submit that the plain language of the Settlement Agreement makes clear that Merck maintained the right to launch a *branded* AG, defined succinctly in the R&R as "a generic that is sold under some 'trademark or trade name' of Merck that is not Zetia," R&R at n. 15, and thus the provision cannot be reasonably interpreted as a No-AG agreement. Def. Obj. at 10.

Because they claim that the language of the provision is unambiguous, Defendants submit that the R&R ran contrary to New Jersey rules of contract interpretation[12] when considering extrinsic evidence that contradicts what Defendants assert is the plain meaning of the Settlement Agreement. Def. Obj. at 11 (citing Conway v. 287 Corp. Ctr. Assocs., 187 N.J. 259, 269 (2006)).

The court agrees with the R&R's conclusion that Plaintiffs have established triable issues of fact related to the appropriate characterization of the alleged No-AG provision. First, the language of the provision is sufficiently ambiguous to turn to extrinsic evidence. See Conway, 901 A.2d at 346. This court

[12] The Settlement Agreement is controlled by New Jersey law. See Sett. Agr. ¶ 10.3 (ECF No. 398-1, at 23).

meticulously analyzed the language of the relevant provisions in the Settlement Agreement when ruling on Defendants' Motions to Dismiss, ECF Nos. 157, 160, 162. See ECF No. 489 at 15-21. In that Opinion, this court reasoned that:

> Because the Settlement Agreement allowed Merck to sell ezetimibe under a "trade name," or brand name, and not under the generic name "ezetimibe," the Settlement Agreement [plausibly] did not allow Merck to sell a generic product, including an AG.

Id. at 20.

At that time, the court explicitly identified an ambiguity in the definition of "Generic Ezetimibe," due to Defendants' reasonable, "competing interpretation" of the phrase "trade name." Id. That ambiguity, and its effect on whether Merck retained the ability to launch an AG, remains at this juncture, even after numerous briefings, hearings before the court, and after review of the Objections and R&R. Thus, sufficient ambiguity exists to warrant the use of extrinsic evidence to interpret the meaning and intent of the alleged No-AG provision. Put simply, the R&R correctly concluded that "the Settlement Agreement language is not so clear that summary judgment could be awarded to either party based on the textual argument alone." R&R at 32.

Alternatively, Defendants object to the R&R's finding that the antitrust nature of Plaintiffs' claim independently justifies the availability of extrinsic evidence to interpret the provision's meaning. Def. Obj. at 12. Plaintiffs' arguments, ECF

No. 1156 at 58-59, and the R&R's conclusion to this effect, R&R at 32, rely on the proposition by relying on the Eighth Circuit's opinion in In re Wholesale Grocery Prods. Antitrust Litig., 752 F.3d 728, 734 (8th Cir. 2014). In that case, the Eighth Circuit found that extrinsic evidence was available to interpret the meaning of a non-compete agreement between the defendants. Id. The court reasoned that the antitrust nature of the plaintiffs' claim broadened the scope of the court's inquiry beyond the text of the agreement itself:

> [T]his is not a contracts case in which the scope of the alleged anticompetitive agreement is cabined by the four corners of the written document. Not confined by the parol evidence rule, [the plaintiffs] could use all manner of extrinsic evidence to persuade a jury that what the [defendants] actually agreed to was a naked division of territory and customers.

Id. The Eighth Circuit then looked to the extrinsic evidence proffered by the plaintiffs and held that the "the record contains enough evidence, viewed in the light most favorable to [the plaintiffs]" to present "a factual dispute about the real terms of the [defendants'] agreement." Id. at 734-35.

Here, Defendants attempt to distinguish Wholesale Grocery by arguing that a necessary prerequisite to considering extrinsic evidence in an antitrust case is an allegation by the plaintiffs that an "alternate agreement," distinct from the written one, exists. Def. Obj. at 12. Defendants deny that Plaintiffs have made such an allegation, nit-picking that Plaintiffs' theory focuses

on interpreting the true meaning of the No-AG provision, rather than alleging the existence of a side-agreement, not evinced by Defendants' written agreement itself. See id.[13] The court disagrees with this reading of Wholesale Grocery. The Eighth Circuit's concern with "aspiring monopolists . . . sealing their true anticompetitive agreement," surely includes, as the R&R described, disguising the true meaning of the agreement with carefully crafted, iterative, ambiguous text. See R&R at 33. As the R&R noted, Plaintiffs have "consistently" theorized and produced evidence substantiating that the true nature of Defendants' agreement was disguised in this fashion. Id.

Turning then to the evidence submitted by Plaintiffs, the court agrees with the R&R that Plaintiffs have established triable issues of fact regarding whether Defendants intended the Settlement Agreement to prevent Merck from launching a generic version of Zetia during Glenmark's period of exclusivity. Plaintiffs have offered "extensive evidence that Glenmark sought a no-AG agreement during negotiations," as well as extensive evidence that "both Merck and Glenmark made post-settlement

[13] Defendants overemphasize the significance of the fact that the defendants in Wholesale Grocery had explicitly acknowledged that the "'basis of the deal' was a broader agreement" that the defendants wouldn't compete in a particular geographical region, rather than simply over their former customers, as the written agreement specified. Def. Obj. at 12 (citing Wholesale Grocery, 752 F.3d at 730).

decisions reflecting Defendants' mutual understanding that the settlement restricted Merck's ability to launch an AG." R&R at 31. Therefore, as in Wholesale Grocery, "this case presents a factual dispute about the real terms of [Defendants'] agreement." 752 F.3d at 735.

2. Value of the Reverse Payment

Defendants also object to the R&R's determination that triable issues of fact exist regarding the value of both components of the reverse payment. Def. Obj. at 13-14. Here, the court finds no error.

First, Defendants reject the opinion of one of Plaintiffs' economists, Dr. McGuire, because his analysis did not consider a provision with the type of restriction Defendants' claim the alleged No-AG provision imposes. Def. Obj. at 13. Still eschewing the suggestion that the provision could, in fact, outright prevent Merck from launching an AG, Defendants claim that Dr. McGuire's analysis was flawed because it did not account for the value of Merck's ability to launch a "product that had a trademark or tradename of Merck on it during [Glenmark's exclusivity period']." Id. (citing ECF No 1082-19 at 70:11-71:14, "McGuire Dep.").

However, Defendants can cross-examine Dr. McGuire and argue their points to the jury. Moreover, Plaintiffs may offer expert testimony based on a disputed version of the facts. See ECF No. 1649 at 18 (Magistrate Judge's Order denying Defendants'

Motion to Exclude). Further, Plaintiffs have supported their experts' valuation of the No-AG agreement. Plaintiffs' experts testify that there would be "no sound economic reason" for a pharmaceutical company to launch a branded generic. See ECF No. 1154-4 at 7-16 ("Rosenthal Dep."); McGuire Dep. at 3-4. Consistent with those opinions, Merck's own product history illustrates that Merck routinely launched unbranded AGs for its drugs, but never a second branded drug. See ECF No. 1156 at 33-34 ("Pls. Res. to SJ"). This appears to be industry convention, as only three percent of generics are branded. See id. at 33.

While Defendants contend that these arguments rely, to some extent, on what Merck was likely to do, rather than what Merck might have been permitted to do under the plain language of the Settlement Agreement, the court agrees with the R&R's finding that industry custom and economic feasibility are "probative of how [Merck and Glenmark] valued the alleged carveout for a branded generic when it was drafted." R&R at 38. The valuation of the provision at the time of settlement is the proper inquiry. Accordingly, even cabining the possibility that Merck retained the ability to launch a branded generic, triable issues of fact regarding the true value of the provision to Merck remain. A reasonable juror may resolve these issues in Plaintiffs' favor.

Second, Defendants object to the R&R's finding that the $9 million payment from Merck to reimburse Glenmark for its

attorney's fees may be considered alongside the approximately $25.5 million (or more) valuation of the No-AG provision.[14] Def. Obj. at 14. Defendants cite to Actavis itself, claiming that the $9 million reimbursement falls under the "safe harbor" of a payment provided for "traditional settlement considerations, such as avoided litigation costs." Def. Obj. at 14 (citing Actavis, 570 U.S. at 156). However, as the R&R noted, the $9 million reimbursement was not provided for "avoided litigation costs;" it was "expressly denominated as reimbursement for Glenmark's attorney's fees already incurred." R&R at 44. Thus, there was no error in concluding that a reasonable juror could find that the $9 million payment for incurred litigation costs was a component of the large and unjustified payment. This determination is consistent with several lower court decisions following Actavis. See e.g., King Drug, 88 F. Supp. 3d at 418; In re Aggrenox Antitrust Litig., 94 F. Supp. 3d 224, 243 (D. Conn. 2015).

B. Anticompetitive Effect

After identifying the nature and value of the reverse payment, the next inquiry is whether the payment had an anticompetitive effect, under the principles outlined in Actavis and its progeny. See Lamictal, 791 F.3d at 412 ("[T]o prove

[14] As the R&R noted, Drs. McGuire and Leffler "estimate that a Zetia AG was worth at least $25.5 million but could have been markedly more valuable." See R&R at 42.

anticompetitive effects, the plaintiff must prove payment for delay, or, in other words, payment to prevent the risk of competition."). Defendants object to various aspects of the R&R's findings related to the anticompetitive effects of the Settlement Agreement. See Def. Obj. at 15-22. Defendants claim that Judge Miller's analysis of the anticompetitive effects of the Settlement Agreement relied on a theory of harm that Plaintiffs were not alleging. Def. Obj. at 15-17. Further, Defendants argue that no disputes of material fact exist concerning whether the No-AG provision was given in exchange for the entry date of Glenmark's generic nor whether Merck actually avoided the risk of patent invalidation. Def. Obj. at 17-22. For the reasons stated below, the court finds that Plaintiffs have sufficiently produced evidence such that a reasonable juror could conclude that the Settlement Agreement had anticompetitive effects of the type contemplated by the Court in Actavis. See In re Nexium (Esomeprazole) Antitrust Litig., 42 F. Supp. 3d 231, 287 (D. Mass. 2014) ("Plaintiffs bear the burden of evincing evidence that would enable a reasonable jury to find each core element of an antitrust claim").

1. Theory of Anticompetitive Effect

In support of their claim that Judge Miller erred when "basing his recommendation on a theory of anticompetitive harm that Plaintiffs are not alleging," Defendants point out that:

> The R&R treats Plaintiff's theory of anticompetitive harm as being that Defendants' settlement avoided the risk of competition *because it avoided the risk of patent invalidation* in the Glenmark litigation itself.

Def. Obj. at 15-16 (emphasis added). This characterization of the R&R's analysis is partially correct.[15] The R&R, at various points, described the "risk of competition" avoided by settling the patent infringement suit as the possibility that Merck's RE'721 Patent would be invalidated. See R&R at 47, 51, 53. Had the RE'721 Patent been invalidated at the resolution of the patent dispute, Glenmark's generic could have entered the market, as soon as feasible. This line of reasoning results in the avoidance of one type of risk of competition, which may be referred to as the patent invalidation theory. As described above,[16] the patent invalidation theory of risk of competition effectuates an anticompetitive harm in the market because it results in a "delayed" generic entry. To reiterate, the "delay," in that context, is between the risk-adjusted patent invalidation date and the settlement's agreed entry date.[17]

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[15] However, aside from the R&R's references to Merck's avoidance of patent invalidation, the R&R *also* cites Plaintiffs' causation argument, the alternate settlement theory, as contributing to the dispute of material fact around anticompetitive effect. R&R at 53; see infra Part III.C.2. (discussing alternate settlement theory).

[16] See supra Part I.B.

[17] See id. (discussing how avoiding the risk of patent invalidation leads to a "delay" in generic entry).

Defendants' Objections contend that the patent invalidation theory of risk of competition is inconsistent with Plaintiffs' broader theory of what happened in this case:

> Plaintiffs have abandoned any theory that, but for the [alleged No-AG] provision, the Glenmark case would have proceeded to trial in 2010 and the patent would have been invalidated . . . . Instead, under Plaintiffs' actual theory, the case was always going to settle, either with the [alleged No-AG] provision and a December 2016 entry date . . . or without the [alleged No-AG] provision and a January-May 2015 entry date.

Def. Obj. at 16. This is correct. The "actual theory" referred to by Defendants here is the theory on which Plaintiffs focus when arguing that triable issues regarding causation exist.[18] This theory of risk of competition is called the "alternate settlement" theory.[19]

Pursuant to the alternate settlement theory, Plaintiffs' experts contrast the real-world settlement - in which Defendants' Agreement contained the alleged No-AG provision and a generic entry date of December 2016 - with a hypothetical world in which the Settlement Agreement *did not* contain a No-AG provision, and had an agreed entry date of sometime between January and May 2015.[20] Juxtaposed as such, Plaintiffs' causation argument, and

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[18] See infra Part III.C.2. (discussing Plaintiffs' alternate settlement theory of causation).

[19] Id.

[20] Id.

broader theory of the case, is that the No-AG provision was given in exchange for a delay in generic competition from January - May 2015 (which may be called the "competitively-balanced generic entry date") to December 2016 (the allegedly anticompetitive generic entry date).

The issue is glaring. If Plaintiffs' hypothetical world *without* a No-AG provision results in Merck and Glenmark settling the patent infringement suit, the No-AG provision could not have been given in exchange for settlement. Thus, Defendants are correct to the extent they exclaim that, by Plaintiffs' own causation theory, Merck's patent was never at risk of being invalidated by the Glenmark litigation. Therefore, Plaintiffs' theory of anticompetitive effects is in tension with their theory of causation.

In response to this section of Defendants' Objections, Plaintiffs' essentially doubled-down on their shape-shifting argument, asserting that they "have consistently contended that Merck's No-AG commitment was exchanged for Glenmark's commitment to drop its patent challenge . . . ." Pls. Resp. at 14-15. Plaintiffs propose that Defendants' argument to this effect "confuses liability with causation," and suggests that "the purchasers' evidence of an antitrust violation" is separate from the "benchmark that they have presented to establish that the violation caused them some injury." Id. Plaintiffs argue that

their "election not to pursue a causation benchmark based on Glenmark's success in the patent litigation absent the Defendants' No-AG agreement says nothing about whether the No-AG agreement was anticompetitive." Id. at 17. The court agrees with Plaintiffs' proposition that "[t]he question of causation arises only *after* the purchasers prove that the payment was anticompetitive." Id. However, Plaintiffs inappropriately diminish the significance of the fact that their theory of anticompetitive effects conflicts with their theory of causation.[21]

With Plaintiffs' conflicting theories laid bare, Defendants jolted in response and requested leave from the court to reply, alleging that "Plaintiffs have presented a new purported theory of anticompetitive harm . . . [that] is inconsistent with its alternative settlement theory of causation and damages, which is improper as a matter of law." ECF No. 1742 at 2 (citing Comcast Corp. v. Behrend, 569 U.S. 27, 35 (2013); In re Opana ER Antitrust Litig., No. 14 C 10150, 2021 WL 2291067, at *15 (N.D. Ill. June 4, 2021)). In their objection to that request, Plaintiffs backtracked, retreating to the cover of general terminology, and claimed that their theory of anticompetitive effect is, and always has been, that "Merck paid Glenmark to avoid the *risk of competition*." ECF No. 1746 at 3 (emphasis added).

[21] See infra Part III.B.1.i-ii.

The problem, of course, is that the phrase "risk of competition" is too vague to squarely address the nuance of the conflict Defendants expose. During argument regarding anticompetitive effect and causation, respectively, it must be clear whether the "risk of competition" referred to is (1) the risk of patent invalidation; or (2) generic entry at the competitively balanced entry date, set forth by an alternate settlement without a reverse payment.

For the reasons stated below, the court finds that, despite Plaintiffs' conflicting and oftentimes overly vague statements throughout their briefings, Plaintiffs have produced evidence and argument sufficient to establish a theory of anticompetitive effect that is consistent both with Actavis *and* with their theory of causation. As such, Defendants are not entitled to summary judgment as a matter of law. The jury ultimately must decide this matter of fact based on the law as instructed by the court.

i. Plaintiffs' Inconsistent Theories

Defendants cite to two different cases to support their claim that "[i]t is clear as a matter of law" that Plaintiffs' "mix and match" theories entitle Defendants to summary judgment. ECF No. 1742-1 at 10 ("Def. Reply"). The court disagrees and finds that neither case, nor the principle of law they evince, so clearly leads to the conclusion that Plaintiffs' case should be cut down at this juncture.

Defendants first cite to Comcast, 569 U.S. 27. Comcast was an antitrust class action case in which the Supreme Court granted cert to determine "whether class certification was appropriate under Fed. R. Civ. P. 23(b)(3)." Id. at 29. The respondents' expert in that case used two different models; one to establish anticompetitive effects and one to establish damages. Id. at 31. On appeal, the petitioners argued that the class was improperly certified because the expert's damages model relied on a different theory of what happened in the case than the theory supporting the liability model. Id. at 32.

The precise holding of Comcast was that the lower courts erred by granting and affirming class certification. Id. at 39. However, the Court more broadly reasoned that "a model purporting to serve as evidence of damages in this class action must measure only those damages attributable to that theory." Id. at 35. Accordingly, the Court required that "at the class-certification stage (as at trial), any model supporting a 'plaintiff's damages case must be consistent with its liability case, particularly with respect to the alleged anticompetitive effect of the violation.'" Id. (quoting ABA Section of Antitrust Law, Proving Antitrust Damages: Legal and Economic Issues 57, 62 (2d ed. 2010)).

The impact of this rationale has caused considerable confusion among lower courts, particularly in interpreting its effect on the Rule 23(b)(3) predominance inquiry. See e.g., Alex

Parkinson, Comcast Corp. v. Behrend and Chaos on the Ground, 81 U. Chi. L. Rev. 1213, 1225-38 (2014) (describing the wide-ranging lower court interpretations of Comcast). As applied to the instant case, the impact of the Court's statements in Comcast is further muddied by the fact that this case is not a class action subject to Rule 23's predominance requirement: This case is proceeding as an MDL, with the parties joined individually. See ECF No. 1770 at 3-4, n.6 (outlining the procedural history of this case, resulting in the MDL structure). Further, the posture of Comcast was not a ruling on a motion for summary judgment, as here.

Defendants' second citation to Opana, a case in the Northern District of Illinois, more squarely applies to the case at bar, as Opana also dealt with a reverse payment MDL case. See Opana, 2021 WL 2291067. In Opana, the expert's theory of causation was the "continued litigation" theory (i.e., absent the reverse payment, the parties would have continued to litigate the patent dispute to the end, with the generic challenger emerging victorious). Id. at *15. But there was a wrinkle in the facts of Opana: the patent holder subsequently acquired new patents, which it then enforced against other generic manufacturers. Id. Thus, even if the parties had continued to litigate their patent dispute, the introduction of an additional set of patents served as an intervening event. To compensate for that disruption, the expert's damages model was truncated to extend only through the

date on which the patent holder acquired the additional patents. Id.

The district court in Opana ultimately rejected the expert's damages model, citing the Court's reasoning in Comcast. Id. However, like Comcast, Opana's ruling was not in response to a motion for summary judgment, but rather in response to the defendants' Daubert motion seeking to reject the expert's testimony. Id. at 14. Accordingly, neither Comcast nor Opana directly control the limited issue of whether inconsistent theories of anticompetitive effect and causation entitle a defendant to summary judgment in a reverse payment case.

When pressed at the hearing, Defendants eventually clarified that they viewed the application of the Comcast "principle" in the summary judgment context as exposing a factual issue. See ECF No. 1797 at 14-15. Defendants argue that, viewed through the Court's reasoning in Comcast, an antitrust plaintiff "cannot survive summary judgment by presenting a case that is factually inconsistent" by presenting one theory of anticompetitive effect and another of causation, which "are not based on the same [factual] premises." Id. Essentially, Defendants highlight that Plaintiffs' case requires the fact finder to determine that the reverse payment was exchanged to obtain settlement, on one hand, and to obtain an alternate settlement, on the other. Id.

Defendants assert that no reasonable juror could find both facts to be true. Id.

Defendants' briefing also alludes to another potential connective tissue between the Court's reasoning in Comcast and the instant case: Antitrust standing. See Def. Reply at n.3. Antitrust standing, distinct from Article III standing, is a prudential doctrine of which antitrust injury is a component. See Brunswick Corp. v. Pueblo Bowl-O-Mar, Inc., 429 U.S. 477, 489 (1977); Bell v. Dow Chem. Co., 847 F.2d 1179, 1182 (5th Cir. 1988); Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application, Ch. 3, ¶ 335 (5th ed. 2022) (discussing and identifying generally the elements of antitrust standing). "To establish antitrust standing, a plaintiff must show that it has suffered an antitrust injury – that is, an injury of the type the antitrust laws were intended to prevent *and that flows from that which makes the defendants' acts unlawful.*" Wellbutrin, 868 F.3d at 164 (citations and internal quotations omitted) (emphasis added).

Through this lens, the principle outlined in Comcast may also support the conclusion that Plaintiffs lack antitrust standing if a disconnect between the theory of liability and injury prevents the plaintiffs' from establishing that their injury "flow[ed] from that which [made] the defendants' acts unlawful." Brunswick, 429 U.S. at 489. If Defendants' conduct is *only* unlawful if Merck's

patent avoided the risk of invalidation, yet Plaintiffs' injury stems from an alternate settlement, Plaintiffs would appear to not have antitrust standing, which is "properly viewed as an element of an antitrust claim that can be resolved at summary judgment." Wellbutrin, 868 F.3d at 164 (citations omitted). However, for the reasons stated below, the court finds that Plaintiffs have offered evidence and argument under their theory of alternate settlement sufficient to establish a theory of anticompetitive effects that is consistent with Actavis and thus capable of surviving summary judgment.

ii. Alternate Settlement as a Theory of Anticompetitive Effect

At bottom, Plaintiffs' alternate settlement theory itself serves as a valid theory of anticompetitive effect under Actavis. To show anticompetitive effect in a reverse payment case, the plaintiff must show "payment for delay."[22] Lamictal, 791 F.3d at 412. The alternate settlement theory does just that.

While the specific delay in Actavis was based on the avoidance of the risk of patent invalidation, it was the alleged conduct resulting in the that delay which led the Court to subject reverse payments to antitrust scrutiny. The Court granted

[22] See In re Loestrin 24 Fe Antitrust Litig., 814 F.3d 538, 542 (1st Cir. 2016) ("[A] reverse payment typically arises when a brand-name manufacturer pays the generic manufacturer to delay entry of its generic equivalent, thereby protecting the brand's market from generic competition.")

certiorari to review Actavis after the Eleventh Circuit ruled "that a reverse payment settlement agreement generally is 'immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.'" Actavis, 570 U.S. at 141 (quoting Fed. Trade Comm'n v. Watson Pharmaceuticals, Inc., 677 F.3d 1298, 1312 (11th Cir. 2012)). By rejecting this holding and finding instead that "reverse payment settlements . . . can sometimes violate the antitrust laws," the decision of the Court in Actavis was a broad correction of the lower court's subjugation of antitrust law to patent law protections. Actavis, 570 U.S. at 141. Thus, the Court's attention in Actavis was focused not simply on the possibility that a patent holder avoided the risk of its patent being invalidated, but instead on the possibility that the patent holder was exploiting its advantage in the market to "maintain and share patent-generated monopoly profits." Id. at 158. As such, albeit briefly, the Court in Actavis suggested "those interested . . . to examine" the legislative history of the Hatch-Waxman Act. See id. at 152-53 (quoting remarks of Sens. Hatch and Waxman, plainly stating that the intent of the Act was not to allow collusive deals that delayed generic entry).

Courts interpreting Actavis have similarly identified this broader concern. For example, when finding that a No-AG agreement was consistent with the Courts' idea of a reverse payment

potentially subject to antitrust scrutiny, the Third Circuit identified that:

> The thrust of the Court's reasoning is not that it is problematic that money is used to effect an end to the patent challenge, but rather that the patentee *leverages some part of its patent power* (in Actavis, its supracompetitive profits) to cause anticompetitive harm – namely, elimination of the risk of competition.

Lamictal, 791 F.3d at 406 (emphasis added). That is to say, the through-line in any reverse payment case is whether the settlement agreement, "without justification, [] delay[s] competition for longer than the patent's strength would otherwise permit." Id. at 409. The Third Circuit later reinforced this broad reading of Actavis, explaining that "[w]hile there is language in Actavis that describes premature termination of litigation as an anticompetitive harm . . . the Supreme Court's holding was not so narrow." Wellbutrin, 868 F.3d at n.50 ("In other words, the Court took issue with reverse payments not simply because they could lead to the premature termination of litigation, but rather because they eliminate the risk of competition.").

The alternate settlement theory is clearly based on the idea that the patent holder improperly wielded its patent power to obtain a settlement different than one that is competitively balanced based on the "patent's strength" alone. Lamictal, 791 F.3d at 409. To reiterate, in an alternate settlement, the patent holder avoids entering into a settlement agreement that stipulates

the competitively balanced generic entry date by inducing the challenger to agree to a later generic entry date with some form of payment. This kind of delay is, in a sense, even more direct than the delay obtained in risk of patent invalidation cases, such as Actavis. In risk of patent invalidation cases, the delay effectuated may never have actually materialized in the but-for world, if the patent's validity would have been affirmed as a result of the infringement suit.[23] In contrast, in alternate settlement cases, the entry date of the generic is *certain* to have been delayed, as the patent holder obtains the guaranteed avoidance of competition between the competitively balanced entry date and the alternate settlement's entry date.[24]

Broadly interpreting Actavis' conception of the relevant anticompetitive conduct also finds support in the fact that the Court consistently explained that the patent's actual validity was not a concern. See Actavis, 570 U.S. at 157 ("[I]t is normally not necessary to litigate patent validity to answer the antitrust question . . . ."). Instead, the Court emphasized that its concern

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[23] As a result of settlement, this contingency is fundamentally unknowable. See Androgel, 2018 WL 2984873, *12 ("[D]etermining the ultimate outcome of the underlying patent litigation is both fundamentally unknowable and procedurally impossible.").

[24] This assertion is, of course, contingent on the finding that the economic experts' calculation of the alternate settlement date is correct.

was with the patent holder's successful avoidance of the *risk* of patent invalidation itself. Id. The anticompetitive conduct contemplated by the Court thus centered on whether the patent holder *perceived* that its patent could be invalidated and thereafter used its patent power to avoid the possibility of that occurrence.[25] Id. at 157-158. Actavis's holding simply suggests that improper use is anticompetitive.

Accordingly, the court concludes that even though Plaintiffs' causation theory admits that Merck and Glenmark would have settled the infringement suit regardless of the No-AG provision, it is consistent with the anticompetitive conduct contemplated by the court in Actavis. As a practical matter, if the alternate settlement theory was insufficient to show anticompetitive effect at summary judgment, then any case based on that theory for purposes of causation would surely have the same Comcast issue that Defendants now raise. However, courts have consistently found that alternate settlement is a valid theory of causation. See R&R

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[25] In fact, the key rationale of the so-called "Actavis Inference" is that "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." Actavis, 570 U.S. at 158. The size of the payment and the patent holder's perceived risk of patent invalidation share a direct relationship. For purposes of identifying the risk-adjusted patent invalidation date, necessary for calculating damages, this reasoning also relies on the idea that the patent holder's perceived risk of invalidation is the best approximation of the actual risk. Who better to understand the patent's vulnerability than the patent holder itself?

at 62 (citing In re Androgel Antitrust Litig. (No. II), No. 1:09-CV-955-TWT, 2018 WL 2984873, at *16 (N.D. Ga. June 14, 2018) (collecting cases)). Although Defendants' correctly point out that the R&R makes several references to the avoidance of the risk of patent invalidation as the anticompetitive conduct in this case, see Def. Obj. at 15-16, the R&R also indicated that Plaintiffs' alternate settlement theory displayed anticompetitive effect per Actavis. See R&R at 53 ("Plaintiffs' argument that the No-AG agreement compensated Glenmark for generic delay is amply supported by their causation arguments . . . .").[26]

Ultimately, at this juncture, the court finds that even in the face of Plaintiffs' vague and potentially conflicting arguments, it is appropriate to deny summary judgment on anticompetitive effect. This case involves a complex area of law, applied to a novel set of facts. See 10A C. Wright, A. Miller, & M. Kane, Fed. Prac. and Proc.: Civ., § 2725.3 (1983) ("[A]lthough complex or novel issues of law do not preclude summary judgment, their presence in the action may suggest that a fuller development of the facts would be helpful to their resolution. In those circumstances, the court may deny summary judgment."). The parties have engaged in multiple years' of discovery, thousands of pages

[26] The R&R also accurately framed the anticompetitive conduct question by stating: "[T]o succeed on its claims, Plaintiffs must prove that Glenmark's delay was given in exchange for Merck's no-AG agreement: that is Actavis." R&R at 48 (citations omitted).

of briefings, and numerous hearings before the court. As a result, Plaintiffs have submitted evidence and argument sufficient to establish a dispute of material fact regarding anticompetitive effect that is consistent with the type of "pay for delay" contemplated by Actavis. The court, "not confined to the particular propositions of law advanced by the parties on the summary-judgment motion," accordingly finds that Defendants are not entitled to judgment as a matter of law on this point. Wright & Miller, supra, § 2725.3.

2. Link Between Payment and Generic Entry Date

Defendants claim that the R&R was in error "in concluding the jury could find a link between the [alleged No-AG agreement] and the [generic] entry date." Def. Obj. at 17. Defendants submit that Plaintiffs have offered "no facts to meet their burden of proving such a connection," and submit that "Plaintiffs' two economists admitted that they had not seen any documents or testimony suggesting any *quid pro quo* relating to the entry date or that the entry date was tied to the presence of the alleged No-AG provision." Id. Pointing to other record evidence, Defendants submit that the negotiators for Merck and Glenmark "testified that there was no link between the request for a No-AG provision and the early entry date." Id. at 18 (citations omitted).

Nevertheless, the court finds no error when finding triable issues of material fact regarding whether the reverse payment was linked to the generic entry date. First, Defendants crucially overlook the fact that the R&R identified record evidence exposing inconsistencies across the negotiators' testimony. See R&R at 54 (citing ECF No. 1156 at 60-61) (Plaintiffs' Response to Motion for Summary Judgment). Second, as stated in the R&R, Plaintiffs may appropriately rely on their economic experts' testimony that "the settlement agreement itself was evidence of an exchange." R&R at 54 (citations omitted). This finding is rooted in the reasoning of Actavis, which provided that an inference may be drawn between an "unexplained large reverse payment" and the "desire to maintain and to share patent-generated monopoly profits." Actavis at 157-58; see Aaron Edlin et al., The Actavis Inference: Theory & Practice, 67 Rutgers U. L. Rev. 585, 589 (2015) ("[A] fact-finder may properly infer that such a large and unexplained payment was made to delay generic entry, and hence is anticompetitive.") (internal quotations omitted).

Therefore, the inconsistent testimony of Defendants' negotiators paired with Plaintiffs' economists' testimony is sufficient to create a dispute of material fact around the link between the alleged No-AG provision and the entry date. Accordingly, the court finds no error in the conclusion that Plaintiffs' evidence "can reasonably support a jury's inference .

. . that the Agreement included a reverse payment and avoided the risk of competition." R&R at 55. See Androgel, 2018 WL 2984873, at *12 ("Plaintiffs have provided enough evidence for a reasonable jury to find that, by overvaluing these side agreements in the settlement, the Defendants were able to reach agreements that left them better off than any party would have been [had no anticompetitive conduct occurred].")

3. Risk of Patent Invalidation

Defendants' last objection to the R&R's findings related to anticompetitive effect is that "the Magistrate Judge erred in permitting plaintiffs to proceed without proof that Merck avoided the risk of patent invalidation." Def. Obj. at 20. Central to this proposition is the fact that, at the time of the settlement with Glenmark, Merck was also litigating its infringement suit against Mylan. See id. As such, Defendants claim that Merck's settlement with Glenmark achieved no reduction in risk because "even after settling with Glenmark, Merck still faced the same risk that its patent would be invalidated" by the Mylan decision. Id.

The R&R found that the existence of the pending Mylan litigation did not mitigate the anticompetitive effect of the Settlement Agreement with Glenmark for two reasons. First, Judge Miller found that Actavis does not require that "the settlement close the door on all potential risk." R&R at 56. Defendants request that this court "not be the first to extend Actavis to

this sharply different circumstance." Def. Obj. at 21. Second, Judge Miller found that unpredictable developments unfolded after the Glenmark settlement, causing the Mylan case to proceed to trial "under a very different record" and thus under a different risk-profile. R&R at 57. In particular, the R&R highlights the fact that, after settling its dispute with Glenmark, Merck "obtained reissue of the RE'721 patent omitting compounds 4E and F," "designated a new export on inventorship," and "benefitted from the Federal Circuit's tightening of the inequitable conduct standard" in Therasense, Inc. v. Becton, Dickinson and Co., 649 F.3d 1276 (Fed. Cir. 2011). See R&R at 57. The court agrees with the R&R's determination that these events create a dispute of material fact whether the risk of patent invalidation faced by Merck in the Mylan litigation was different than that faced in the Glenmark litigation.

Nevertheless, both of Defendants' challenges here are inapposite. As outlined previously,[27] the court now finds that Plaintiffs' alternate settlement theory, and the supporting evidence, independently serves a basis for showing that Settlement Agreement had anticompetitive effects, consistent with Actavis. Accordingly, Defendants are not entitled to summary judgment as a matter of law based on these arguments.

[27] See supra Part III.B.1.ii.

C. Causation

To succeed in their antitrust action, Plaintiffs must show that Defendants' "allegedly anticompetitive conduct was the actual and proximate cause" of their antitrust injury." In re Wellbutrin XL Antitrust Litig., 133 F. Supp. 3d 734, 762 (E.D. Pa. 2015) (citing 15 U.S.C. § 15). Defendants have three objections to the conclusions in the R&R with respect to causation. Def. Obj. at 22-31. Defendants first argue that the R&R erred when recommending that the district court preclude Plaintiffs from arguing two abandoned theories of causation at trial, rather than recommending the district court to grant summary judgment on those theories. Id. at 22-23. Next, Defendants argue that the R&R erred by finding disputes of material fact regarding Plaintiffs' remaining "alternate settlement" theory of causation. Id. at 23-29. Third, the R&R erred in finding disputes of material fact regarding whether Glenmark had the manufacturing capacity to launch its generic in time for the alternate settlement's generic entry date. Id. at 29-31. For the reasons stated below, the court finds no error.

1. Abandoned Theories of Causation

In the initial stages of this litigation, Plaintiffs proposed three different theories of causation: the "continued litigation" theory, the "at-risk" theory, and the "alternative settlement" theory. See ECF No. 315 at 67 ("DPPs Am. Class Action Compl.").

Under the continued litigation theory, Plaintiffs alleged that Glenmark would have continued to fight its patent challenge against Merck, eventually winning the litigation and launching their generic following that victory. Id. Under the at-risk theory, Plaintiffs alleged that Glenmark would have launched its generic shortly following the expiration of the 30-month stay imposed by the Hatch-Waxman Act after being triggered by Glenmark's ANDA filing. Id.; see 21 U.S.C. § 355(j)(5)(B)(iii). However, discovery and various rulings from the court have shaped the parties' dispute, and Plaintiffs have since abandoned the "continued litigation" and "at risk" theories. See R&R at 61. Instead, Plaintiffs now rely solely on the alternate settlement theory of causation. Accordingly, Defendants submit that they are entitled to summary judgment on the two abandoned theories. Def. Obj. at 23. The court disagrees.

As the R&R indicated, the "continued litigation" and "at risk" theories of causation are, as defined, merely theories. They are methods of showing a causal connection between a defendant's anticompetitive conduct and a plaintiff's injury. It is the causal connection itself, not the method of establishing that connection, which constitutes the antitrust element. Plaintiffs adequately rebutted Defendants' objection in this regard by pointing out Defendants' misplaced reliance on Wellbutrin, 868 F.3d at 167-170. Defendants proposed that the Third Circuit's ruling on

causation in Wellbutrin supported their position that they are entitled to summary judgment on the abandoned theories. Def. Obj. at 23. However, as Plaintiffs pointed out, see Pls. Resp. at n. 85, the Third Circuit in Wellbutrin did not grant summary judgment to the defendants on the plaintiffs' various *theories* of causation, but rather on the antitrust *element* of causation, after determining that none of the plaintiffs' theories established a dispute of material fact. See Wellbutrin, 868 F.3d at 167-170.

Here, Plaintiffs do have a remaining theory of causation (the alternate settlement theory) which, for the reasons explained below, see infra Part III.C.2., does establish disputes of material fact. Thus, the R&R's recommendation that "Plaintiffs are precluded at trial from presenting these theories to the jury," R&R at 62, is the appropriate conclusion. See In re Solodyn Antitrust Litig., Civ. No. 14-md-2503, 2018 WL 563144, at *13 (D. Mass. Jan. 25, 2018) (denying summary judgment on the plaintiffs' abandoned theory of causation as moot).

2. Evidence of Alternate Settlement

Defendants here object on the grounds that "the Magistrate Judge erred in finding that Plaintiffs have created a genuine question of fact on causation" via their alternate settlement theory. Def. Obj. at 23. The alternate settlement theory states that, had Merck and Glenmark's Settlement Agreement not included the reverse payment, the Agreement would have stipulated that

Glenmark's generic could enter the market sometime between January and May 2015, rather than in December 2016. See ECF Nos. 1130-9 at 26 ("McGuire Rbt. Rpt."), 1130-4 at 54-55 ("Leffler Rbt. Rpt."). In particular, Defendants claim that: (1) Plaintiffs can point to no evidence in the record indicating that Merck and Glenmark would have agreed to an earlier generic entry date; (2) Plaintiffs' only evidence (economic experts' opinions) are fatally flawed; and (3) record evidence actually contradicts the experts' opinions. Def. Obj. at 23-29.

Regarding the lack of record evidence, the court agrees with Plaintiffs' characterization that they are "not required to show a 'paper trail' . . . showing what [Defendants] would have done had they not violated the antitrust laws." Pls. Res. At 26. Instead, the R&R appropriately concluded that the expert opinions of Drs. McGuire and Leffler were "adequate to support Plaintiffs' arguments against summary judgment." R&R at 65. Contrary to Defendants' claim that the opinions are "completely speculative," Def. Obj. at 24, the conclusions are clearly based on the experts' thorough analysis of "estimates regarding the strength of Glenmark's patent challenges," Merck's "expected profits from offering an [AG] during Glenmark's period of exclusivity, as well as the cost to Glenmark from facing such competition," ECF No. 1649 at 4, 11.

Numerous courts have also found that expert opinions based on this type of analysis were sufficient to establish triable issues of fact and thus capable of surviving summary judgment. See, e.g., Androgel, 2018 WL 2984873, at *16; Solodyn, 2018 WL 563144 at *23; United Food & Commer. Workers Local 1776 v. Teikoku Pharma USA ("Lidoderm"), 296 F. Supp. 3d. 1142, 1163 (N.D. Cal. 2017). Nevertheless, Defendants attempt to divert the court's attention away from this robust line of precedent, and again towards the Wellbutrin line of cases. See Def. Obj. at 24. It is true that the district court in Wellbutrin "found that there was no evidence that a settlement without a No-AG provision 'was ever contemplated, much less that it would have resulted in an earlier entry date.'" Id. (citing 133 F. Supp. 3d at 738). However, the circumstances leading to that decision are clearly distinguishable.

In Wellbutrin, the district court's ruling relied on the fact that the plaintiffs' expert did not "try to answer the question of what specifically some alternative form of settlement would have looked like." 133 F. Supp. 3d at 757-58. Not so here. Further, when affirming the lower court's ruling, a critical component of the Third Circuit's analysis highlighted the tangential nature of the patent holder's incentives in that case, since the patent holder was not a party to the reverse payment. 868 F.3d at 166-67. Here, the experts' opinions regarding the competitively

balanced entry date, absent the reverse payment, are squarely the result of the payor's incentives and expectations, not some third parties' position.

Next, regarding whether Plaintiffs' economic experts' opinions are flawed, Defendants again seek to undermine Dr. Hrubiec's opinion, on which Drs. McGuire and Leffler's alternate settlement dates were based. Def. Obj. at 26-29. Dr. Hrubiec opined, in part, that Glenmark had a "'65 to 75%' chance of prevailing against Merck in the patent litigation." Def. Obj. at 26 (citing ECF No. 1083-18 ("Hrubiec Rpt."). Defendants claim that Dr. Hrubiec's opinion is "arbitrary and unconnected to any facts or data" and is negated by the fact that Merck subsequently won its patent litigation against Mylan. Def. Obj. at 27.

In the R&R, Judge Miller dispensed with these arguments by deferring to his previous analysis, when denying Defendants' Daubert motions regarding Plaintiffs' experts. R&R at 64; see ECF Nos. 1648 (Order denying Defendants' Daubert Motion with respect to Dr. Hrubiec), 1649 (same, with respect to Drs. McGuire and Leffler). Defendants propose that "the Magistrate Judge erred in concluding that his decision *admitting* those opinions in and of itself sufficed to preclude summary judgment." Def. Obj. at 24. However, the court interprets this reasoning in the R&R differently. Instead, the court finds that Judge Miller's deferral to the Daubert orders was appropriate: The substance of

Defendants' challenge to the experts' opinions has not changed and Judge Miller's previous rejection of those arguments supports the conclusion that the opinions maintain a dispute of material fact. See R&R at 64.

Judge Miller's previous rulings reject the argument that Dr. Hrubiec's opinion was "arbitrary and unconnected to any facts or data." Def. Obj. at 27. As Judge Miller stated, aside from his "25 years of experience in the field of pharmaceutical patents," Dr. Hrubiec's opinion was based on his review of "'relevant pleadings, briefing, expert reports, discovery materials, and court orders/opinions from the underlying patent cases,' as well as the expert report of Plaintiffs' chemistry expert . . . ." ECF No. 1648 at 10, 13 (citing Hrubiec Rpt. at 15). Further, Dr. Hrubiec's opinion was based on his review of "statistical studies that were publicly available in 2009-2010, each of which showed that generic companies generally prevailed in infringement suits." Id. at 13.

Judge Miller's previous rulings also reject the argument that Dr. Hrubiec's opinion is negated by Merck's eventual victory against Mylan. As noted in the Daubert ruling, Dr. Hrubiec's "decision not to consider the eventual outcome of the Mylan litigation" was based on his finding that the outcome of the Mylan litigation was not "reasonably foreseeable by the parties or their counsel in May 2010" and was affected by "intervening changes to

the legal and factual landscape." Id. at 12, 41. Ultimately, in addition to contributing to the admissibility of Dr. Hrubiec's opinion, this basis also creates a dispute of material fact sufficient to survive Defendants' summary judgment challenge.

Defendants also attack Drs. McGuire and Leffler's opinions because "[t]hey assume that Merck's settlement with Glenmark eliminated *all* risk to Merck of having its Zetia patent invalidated." Def. Obj. at 28. Defendants claim that, since at the time of settlement, the Mylan litigation was ongoing, the experts' opinions are flawed for not discounting the value of the settlement by "the percentage chance that Merck would lose the Mylan case." Def. Obj. at 28. Judge Miller's Daubert ruling responded to this same argument by crediting the experts' argument that the Mylan risk need not be discounted it "would impact settlement profits and litigation risk equally." ECF No. 1649 at 31. Put differently, there is a dispute of material fact whether "the [Mylan] risk was immaterial," considering the experts' stance that the risk affected the value of the litigation and settlement in equal and opposite amounts, effectively cancelling out. Id.

Finally, regarding the supposedly contradictory record evidence, Defendants point to the negotiations between Merck and Glenmark. Def. Obj. at 25-26. Defendants exclaim that, of the various proposed entry dates, none were earlier than six-months, nor were any expressly contingent upon a particular payment. Id.

The court finds that this evidence does not so clearly negate the evidence Plaintiffs have submitted. Plaintiffs have consistently alleged that all entry dates proposed in negotiations were already colored through the lens of the parties' understanding that "Merck would provide substantial compensation to Glenmark in some form." Pls. Res. at 28. Thus, the record evidence of negotiations highlighted by Defendants actually contributes to the dispute of material fact; it does not undermine Plaintiffs' experts' opinions to the extent that Defendants are entitled to summary judgment.

Ultimately, none of Defendants' critiques of Plaintiffs' causation evidence entitles them to summary judgment, but rather "goes to the weight of the testimony and should be explored in cross-examination." ECF No. 1649 at 31.

3. Manufacturing Capacity

In order to establish causation, Plaintiffs must also show that Glenmark had the ability to launch its generic by the time of the alternate settlement's earlier entry date. See Wellbutrin, 868 F.3d at 166; Lidoderm, 296 F. Supp. 3d. at 1164-65. To do so, Plaintiffs rely on the expert opinion of Susan Marchetti, see ECF No. 1148-13 ("Marchetti Rpt."), and submit that Glenmark would have been able to launch its generic "on November 15, 2014, or any time later" by contracting with a third-party supplier, MSN Labs. See ECF No. 1084-06 at 63 ("McGuire Rpt."); 1084-13 at 25 ("Leffler Rpt."). The R&R found that "Marchetti's testimony is

sufficiently reliable to create a dispute of material fact on this issue." R&R at 66. Defendants object, claiming that "there is no evidence in the record" that Glenmark could have launched its generic by the alternative entry date and thus that Marchetti's opinion is "overly speculative." Def. Obj. at 29-30. The court disagrees and finds no error. It will be up to the jury to determine the reliability and weight of Marchetti's testimony in its role of assessing the credibility of witnesses at trial under the factors outlined by the court in its instructions

In this regard, Marchetti's opinion was based, in part, on her review of various certificates of analysis ("COAs") from 2013, which display MSN Labs' production of various batches of ezetimibe, measured by active pharmaceutical ingredient ("API"). See Marchetti Rpt. at 37. Marchetti concluded based on these COAs that "MSN had the manufacturing capacity to produce *at least* three lots of API (150kg) within a two-week period," at that time. Marchetti Rpt. at 37 (emphasis added). Defendants reject this reasoning because Marchetti's analysis was not based on any underlying facts relating to the structure of MSN Labs' COA, its facilities or other resources. See Def. Obj. at 30. However, as noted in the R&R, "Marchetti also testified that she did not need this information" because her understanding of COAs within the industry was backed by extensive experience, which includes "over 35 years . . . at brand and generic pharmaceutical companies" and

assisting with "the launch of more than 60 generic products." R&R at 67-68. Defendants and Plaintiffs can argue these matters to the jury.

Marchetti's opinion was also based on her review of a June 30, 2015 email, in which MSN Labs responded to Glenmark's inquiries about manufacturing rates as a variable of several order lead times. Marchetti Rpt. at 37. Based on this email, Marchetti identified that, with six-months of lead time, MSN Labs was capable of manufacturing at a rate of 250kg per month. Marchetti Rpt. at 38. Defendants object to this conclusion and claim that the email only supports the proposition that "MSN's capacity differed depending on the timing of Glenmark's request." Def. Obj. at 31. However, Marchetti has clearly stated that, based on her wide-ranging experience in the industry, the kind of statement in the June 30, email stands as a sort of certification that MSN Labs could sustainably meet that rate of output. ECF No. 1139-5 at 6-7 ("Marchetti Dep."). Again, these arguments are for the jury.

In sum, the court agrees with the R&R's conclusion that Marchetti's opinion is sufficient for a reasonable juror to conclude that Glenmark had the ability to launch its generic in time for the alternate settlement's entry date. See R&R at 61. The court reiterates, Defendants' critiques of Marchetti's opinion are appropriately reserved for cross-examination to challenge the

weight of the testimony and credibility of the witness. Defendants are not entitled to summary judgment on this matter.

D. Antitrust Injury

Finally, Defendants submit that Judge Miller "erred in finding that Plaintiffs have created a genuine question of fact on antitrust injury." Def. Obj. at 31. As stated previously, the antitrust injury must reflect the anticompetitive effect of the violation. See Brunswick, 429 U.S. at 489. In this case, Plaintiffs must do so by showing that "they suffered an injury in the form of higher drug prices because of the delay in generic entry caused by the reverse payment settlement." Androgel, 2018 WL 2984873, at *12; see Wellbutrin, 868 F.3d at 164-165. Plaintiffs' alternate settlement theory makes this showing and is sufficient to survive summary judgment.[28]

Nevertheless, Defendants argue that Plaintiffs are precluded from establishing antitrust injury because Merck's patent was valid and infringed and "exclusion from the market of an undisputedly infringing product cannot serve as the basis for antitrust injury." Def. Obj. at 31. Essentially, Defendants argue that any early entry for Glenmark's generic was procompetitive, and the allegation that the competitive generic entry date should

[28] See supra Part III.C.2.

have been earlier amounts to complaining that the Settlement Agreement was not "procompetitive enough." Def. Obj. at 32.

However, as the R&R correctly noted, "[t]he question is not one of patent law, but of antitrust law which prohibits the improper use of a patent monopoly." R&R at 72 (citing Lamictal, 791 F.3d at 407; Actavis, 570 U.S. at 148). The unlawful wielding of the patent power is of such interest to the antitrust laws that, even when the theory of risk of competition is the avoidance of patent invalidation, courts have found that "the actual validity of the patent is irrelevant to the question of whether the reverse payments violated the antitrust laws." Androgel, 2018 WL 2984873 at *11.

Even more so in the alternate settlement context, the fact that Merck won its patent litigation against Mylan does not weigh on the question of whether an antitrust injury resulted from the "improper use of a patent monopoly." R&R at 72 (citing Lamictal, 791 F.3d at 407; Actavis, 570 U.S. at 148). Thus, Judge Miller did not err in finding a dispute of material fact regarding antitrust injury and Defendants are not entitled to summary judgment in this regard.

IV. CONCLUSION

For the reasons stated above, and after a de novo review, the court overrules Defendants' objections and accepts the R&R's recommendation, see ECF No. 1717 at 73, that Defendants Motions

for Summary Judgment, ECF Nos. 1037, 1067, be denied. See Fed. R. Civ. P 72(b). There are disputes of material fact regarding the nature and value of the reverse payment in this case, whether the Settlement Agreement had anticompetitive effects, whether Defendants' allegedly anticompetitive conduct caused Plaintiffs' injury, and whether the injury suffered by Plaintiffs is the type of harm that the antitrust laws are meant to prevent. See Fed. R. Civ. P. 56(a). Accordingly, Defendants are not entitled to judgment as a matter of law; Judge Miller's thorough and well-reasoned R&R is **AFFIRMED**; and Defendants' Motions for Summary Judgment are **DENIED**.

The Clerk is **DIRECTED** to send a copy of this Opinion to counsel for all parties.

IT IS SO ORDERED.[29]

/s/
Rebecca Beach Smith
Senior United States District Judge

Rebecca Beach Smith
Senior United States District Judge

February 10, 2023

[29] For reference purposes, an Index of this Opinion is attached hereto as Exhibit A.