## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF KANSAS

IN RE: EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litigation

**MDL No: 2785** 

**Case No. 17-md-2785-DDC-TJJ** 

(This Document Applies to the Sanofi Case)

### MEMORANDUM AND ORDER

This Order applies to the *Sanofi* case—one of two litigation tracks in this MDL. Here, the court addresses the parties' motions seeking to exclude expert opinions filed contemporaneously with their dispositive motions in the *Sanofi* case. As explained more fully below, the court rules the parties' motions as follows:

Plaintiff/Counterclaim Defendant Sanofi Aventis U.S. LLC's:

- Motion to Exclude the Expert Reports and Testimony Offered By Gary
   Zieziula (<u>Doc. 1666</u>) is granted in part and denied in part.
- Motion to Exclude the Expert Reports and Testimony Offered by Thomas
   Varner (Doc. 1675) is denied.

Defendant Mylan Inc. and Defendant/Counterclaim Plaintiff Mylan Specialty L.P.'s:

- Motion to Exclude Opinion Testimony of Fiona M. Scott Morton, Ph.D.
   (Doc. 1682) is granted in part and denied in part.
- Motion to Exclude Opinion Testimony of Mary Ann Michelis, M.D. (Doc. 1683) is granted in part and denied in part.

- Motion to Exclude Opinion Testimony of Eduardo Schur (<u>Doc. 1684</u>) is denied.
- Motion to Exclude Opinion Testimony of Steven N. Wiggins, Ph.D. (Doc. 1685) is granted in part and denied in part.

With this Order, the court rules each issue presented by the parties' motions to exclude expert opinions. The court recognizes that some of the expert opinions that the parties seek to exclude are not germane to the court's summary judgment analysis in the contemporaneously-filed Order ruling the parties' dispositive motions. And, because the court grants summary judgment against Sanofi's Sherman Antitrust Act claims against Mylan, as well as Mylan's Counterclaim alleging Lanham Act and unfair competition claims against Sanofi, no trial is needed to resolve the parties' legal claims. So, the court's gatekeeping function here is limited to deciding what evidence the court properly can consider on summary judgment.

But, before the court can address the parties' summary judgment arguments, it must decide which evidence is admissible and thus part of the admissible evidence available to determine the summary judgment facts. So, it considers all of the parties' arguments about the challenged experts' opinions because the parties have presented them for decision. The court takes up this task, below.

## I. Factual Background

The Sanofi litigation track in this MDL involves just one case: Sanofi-Aventis U.S. LLC v. Mylan Inc. Plaintiff Sanofi-Aventis U.S. LLC ("Sanofi") is a pharmaceutical company who purportedly competes with defendants Mylan Inc. and Mylan Specialty L.P. (collectively "Mylan"). Mylan is the distributor of the EpiPen, an epinephrine auto-injector ("EAI") used to treat anaphylaxis. Sanofi alleges that Mylan engaged in a variety of anticompetitive conduct

designed to prevent Auvi-Q—a rival EAI once sold by Sanofi—from gaining access to the EAI market, and to prevent consumers from acquiring Auvi-Q. Sanofi asserts three claims against Mylan under Section 2 of the Sherman Antitrust Act, <u>15 U.S.C. § 2</u>. The three claims are: (1) monopolization through exclusive dealing, (2) deceptive conduct to further monopolization, and (3) an overall scheme to monopolize.

In response to Sanofi's Complaint, Mylan filed an Answer and Counterclaim. <u>Doc. 112</u>. Mylan Specialty L.P., as counterclaim plaintiff, alleges that Sanofi, as counterclaim defendant, made false and misleading statements about Auvi-Q's equivalence and superiority to the EpiPen, causing confusion within the marketplace. Also, Mylan Specialty L.P. alleges that Sanofi competed unfairly in the market by offering illegal cash payments to healthcare providers in exchange for prescriptions and sales of Auvi-Q. Based on these allegations, Mylan Specialty L.P.'s Counterclaim asserts two claims against Sanofi: (1) commercial disparagement and false advertising violating the Lanham Act, <u>15 U.S.C. § 1125(a)</u>, and <u>(2)</u> common law unfair competition. *Id.* at 49, 52.<sup>1</sup>

Both Sanofi and Mylan have designated witnesses to provide expert testimony to support either their claims or defenses. Relevant to the motions here, Sanofi has designated as expert witnesses: (1) Dr. Fiona M. Scott Morton, (2) Dr. Mary Ann Michelis, (3) Dr. Steven N. Wiggins, and (4) Eduardo Schur. Docs. 1443, 1519. Mylan has designated as expert witnesses: (1) Gary Zieziula, and (2) Dr. Thomas R. Varner. Docs. 1442, 1515. Contemporaneously with filing cross-motions for summary judgment, the parties have filed motions seeking to exclude

To the extent the court refers to the Counterclaim as asserted by "Mylan," it makes this reference for ease. The court recognizes that only Mylan Specialty asserts the Counterclaim as the Counterclaim Plaintiff. Mylan, Inc. is not a party to the Counterclaim.

these experts' opinions from the court's consideration of the dispositive motions. This Order rules those motions to exclude.

## II. Legal Standard

The court has a "gatekeeping obligation" to determine whether expert testimony is admissible. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999) (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993)). When performing this gatekeeping role, the court has broad discretion. *Kieffer v. Weston Land, Inc.*, 90 F.3d 1496, 1499 (10th Cir. 1996) (citing *Orth v. Emerson Elec. Co.*, 980 F.2d 632, 637 (10th Cir. 1992)). Courts exercise this discretion under Fed. R. Evid. 702. It provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) 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;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

## Fed. R. Evid. 702.

The Tenth Circuit has directed trial judges to apply a two-part test when determining admissibility of expert testimony under *Daubert* and Rule 702. *Conroy v. Vilsack*, 707 F.3d 1163, 1168 (10th Cir. 2013). First, the court must determine "whether the expert is qualified 'by knowledge, skill, experience, training, or education' to render an opinion." *United States v. Nacchio*, 555 F.3d 1234, 1241 (10th Cir. 2009) (quoting Fed. R. Evid. 702). Second, the court "must satisfy itself that the proposed expert testimony is both reliable and relevant, in that it will

assist the trier of fact, before permitting a jury to assess such testimony." *Id.* (quoting *United States v. Rodriguez-Felix*, 450 F.3d 1117, 1122 (10th Cir. 2006)).

To qualify as an expert witness, the witness must possess "such skill, experience or knowledge in that particular field as to make it appear that his opinion would rest on substantial foundation and would tend to aid the trier of fact in his search for truth." *LifeWise Master Funding v. Telebank*, 374 F.3d 917, 928 (10th Cir. 2004) (citation and internal quotation marks omitted). Then, to determine whether the expert's testimony is reliable, the court must assess "whether the reasoning or methodology underlying the testimony is scientifically valid and . . . whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93.

In *Daubert*, the Supreme Court identified four factors that—though not exhaustive—trial courts should consider when determining the reliability of proffered expert testimony under Fed. R. Evid. 702. They are: (1) whether the theory used can be and has been tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error; and (4) the theory's general acceptance in the scientific community. *Id.* at 593–94. The Supreme Court has emphasized, however, that these four factors are not a "definitive checklist or test," and that a court's gatekeeping inquiry about reliability "must be tied to the facts of a particular case." *Kumho Tire*, 526 U.S. at 150 (citations and internal quotation marks omitted).

But, in some cases, "the relevant reliability concerns may focus upon personal knowledge or experience," rather than the *Daubert* factors and scientific foundation. *Id.* For such testimony to satisfy the reliability standard, it "must be 'based on actual knowledge, and not mere "subjective belief or unsupported speculation."" *Pioneer Ctrs. Holding Co. Emp. Stock*Ownership Plan & Tr. v. Alerus Fin., N.A., 858 F.3d 1324, 1341–42 (10th Cir. 2017) (quoting

Mitchell v. Gencorp, Inc., 165 F.3d 778, 780 (10th Cir. 1999) (quoting Daubert, 509 U.S. at 590)). "When expert opinion 'is not supported by sufficient facts to validate it in the eyes of the law, or when indisputable record facts contradict or otherwise render the opinion unreasonable, it cannot support a jury's verdict' and will be excluded." Id. at 1342 (quoting Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 242 (1993)).

"The proponent of expert testimony bears the burden of showing that the testimony is admissible." *Conroy*, 707 F.3d at 1168 (citing *Nacchio*, 555 F.3d at 1241). "[R]ejection of expert testimony is the exception rather than the rule." Fed. R. Evid. 702 advisory committee's notes to 2000 amendments. While *Daubert* makes the court the gatekeeper for expert testimony, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof" remain "the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596 (citation omitted).

The court has discretion to determine how to perform its gatekeeping function under Daubert. Bill Barrett Corp. v. YMC Royalty Co., LP, 918 F.3d 760, 770 (10th Cir. 2019). "The most common method for fulfilling this function is a Daubert hearing, although such a process is not specifically mandated." Goebel v. Denver & Rio Grande W. R.R., 215 F.3d 1083, 1087 (10th Cir. 2000) (citations omitted); see also United States v. Charley, 189 F.3d 1251, 1266 (10th Cir. 1999) ("The trial judge is granted great latitude . . . in deciding whether to hold a formal [Daubert] hearing."). Alternatively, the district court may satisfy its gatekeeping role without a formal Daubert hearing "so long as the court has sufficient evidence to perform 'the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." Goebel, 215 F.3d at 1087 (quoting Daubert, 509 U.S. at 597). Here, exercising its discretion, the court concludes that it need not conduct a separate Daubert hearing to rule the

parties' motions to exclude. The court has reviewed the parties' filings and attached exhibits carefully. And the court finds that the parties have provided a sufficient record for the court to decide these motions without a hearing.

#### **III.** Sanofi's Motions

Sanofi has filed motions seeking to exclude the opinions and testimony of two of Mylan's experts: (1) Gary Zieziula, and (2) Dr. Thomas Varner. The court addresses each motion, separately, below.

#### A. Motion to Exclude Opinions of Gary Zieziula

Sanofi asks the court to exclude the testimony and opinions of Mylan's expert, Gary Zieziula. Mr. Zieziula is a retired pharmaceutical executive. Mr. Zieziula once served as the President and Managing Director of a pharmaceutical company, and he has more than 40 years of experience in the pharmaceutical industry. Mylan has retained Mr. Zieziula to provide expert opinions supporting Mylan's counterclaims for Lanham Act violations and unfair competition. Specifically, Mr. Zieziula offers opinions about Sanofi's promotional claims to payors, physicians, and consumers when it was marketing Auvi-Q. Doc. 1669-4 at 5 (Zieziula Expert Report). Mr. Zieziula opines that Sanofi's promotional claims are not consistent with industry best practices, lack the substantiation required by regulatory standards, and are at odds with the data that Sanofi actually possessed. *Id.* 

Mr. Zieziula also submitted a rebuttal expert report in response to the expert report and damages analysis submitted by Sanofi's expert, Dr. Fiona Scott Morton. Mr. Zieziula disagrees with Dr. Scott Morton's antitrust analysis and opinions about why Auvi-Q didn't succeed in the EAI market. Mr. Zieziula opines that Auvi-Q failed to achieve its projected EAI market share because of "Sanofi's own conduct and decision-making . . . and not [because of] any anti-

competitive conduct that Professor Scott Morton attributes to Mylan." Doc. 1669-5 at 8 (Zieziula Mar. 25, 2019 Expert Report).

Sanofi asserts that the court should exclude Mr. Zieziula's opinions for three reasons:

(1) Mr. Zieziula is not qualified to offer his opinions, (2) Mr. Zieziula's opinions about Sanofi's marketing practices are fundamentally unreliable, and (3) Mr. Zieziula's testimony will not assist the trier of fact. The court addresses each argument, in turn.

## 1. Is Mr. Zieziula qualified to provide expert opinion?

Sanofi asserts that Mr. Zieziula is not qualified to offer his expert opinions because he's not an expert in any of the areas in which he opines. Mylan responds that Mr. Zieziula's decades of experience in pharmaceutical sales and marketing and product commercialization qualify him to offer the challenged expert opinions here. Sanofi's motion identifies three of Mr. Zieziula's opinions that, Sanofi contends, he is not qualified to offer because he is not an expert in the particular field relevant to the opinion.

First, Sanofi argues that Mr. Zieziula is not qualified to offer his opinion that Sanofi made unsupported "comparative claims and [patient] preference claims . . . without the appropriate data to substantiate those claims," Doc. 1669-4 at 5 (Zieziula Expert Report), because he's not a expert in regulatory affairs or FDA compliance. But, Mylan responds, Mr. Zieziula's opinion is about industry best practices for commercializing pharmaceutical products, not regulatory law.

Mylan concedes that Mr. Zieziula testified that the question whether a claim about a pharmaceutical product is a comparative claim "is a regulatory question that [he is] not an expert in answering." Doc. 1669-3 at 4 (Zieziula Dep. 47:8–15). But, Mylan argues, Mr. Zieziula isn't offering opinions about whether Sanofi complied with FDA regulatory standards. Instead, Mr.

Zieziula opines that Sanofi did not comply with *pharmaceutical industry* standards when developing and using a patient preference study and responding to FDA feedback. *See*, *e.g.*, Doc. 1669-4 at 9 (Zieziula Expert Report) (opining that Sanofi made comparative claims that "were not in line with industry best practices" because they "were not supported by the kind of data the FDA requires to make such claims"). Mylan argues that Mr. Zieziula is qualified to provide these opinions based on his extensive experience in the pharmaceutical industry which includes launching new products in the market, developing and overseeing marketing campaigns, participating in the decision whether to conduct certain studies to support a marketing campaign, and monitoring whether sales and marketing personnel were complying with the rules and regulations governing promotional practices. *See* Doc. 1669-4 at 4-5 (Zieziula Expert Report) (describing Mr. Zieziula's qualifications). The court agrees with Mylan.

Mr. Zieziula offers opinions about Sanofi's purported failure to comply with pharmaceutical industry standards when making claims about Auvi-Q, as compared to EpiPen, without the FDA's support. As a former pharmaceutical executive with more than 40 years of experience in the pharmaceutical industry—experience that includes bringing new products to market and developing marketing campaigns for those products—Mr. Zieziula is qualified to offer opinions whether Sanofi's marketing of Auvi-Q complied with pharmaceutical industry standards and best practices. *See, e.g., F & H Coatings, LLC v. Acosta, 900 F.3d 1214, 1223* (10th Cir. 2018) (concluding that an expert witness was qualified under Fed. R. Evid. 702 and *Daubert* to offer opinions about safety procedures used to support steel pressure vessels and tanks during sandblasting and painting based on his "professional experience, certifications, and awareness of industry standards relating to the elevation and placement of heavy objects on various support structures in industrial settings" even though he was not an engineer, never had

studied mechanical or civil engineering, and had no expertise with designing or fabricating pressure vessels); *John McClelland & Assocs., Inc. v. Med. Action Indus., Inc.*, No. 04-2545-CM, 2006 WL 3333061, at \*3 (D. Kan. Nov. 15, 2006) (holding that an expert witness who had 18 years of experience in the "healthcare-products industry" including directing and managing sales and sales representatives was qualified to offer an opinion about "the customs and practices in the healthcare-products industry, primarily regarding the compensation of independent sales representatives serving in the industry" (citations and internal quotation marks omitted)).

Second, Sanofi argues that Mr. Zieziula is not qualified to opine whether the types of comparative and preference claims that Sanofi used "can have a significant impact on payers, prescribing physicians, and consumers' purchasing decisions." Doc. 1669-4 at 5 (Zieziula Expert Report). Sanofi says he's not qualified to render this opinion because he isn't a member of any of these groups—not a doctor, not an EAI consumer, not a payor or payor employee—and because he's not an expert in EAI devices, Doc. 1669-3 at 7, 21 (Zieziula Dep. 67:2–4, 401:10–402:3).

Mylan responds to this argument by asserting that an expert need not fall within the target audience of a marketing campaign to offer an opinion about the effect that a pharmaceutical promotional message could have on physicians or consumers. Instead, Mylan argues, courts routinely allow marketing experts to offer opinions about the likely effects of a marketing strategy on the target audience.

For example, Mylan quotes a portion of a Pennsylvania case where the court noted: "[W]hen an issue before the court pertains to the effect of a marketing an[d] advertising campaign on a potential consumer, courts regularly permit expert testimony to aid the jury on the precise topic of marketing strategies." *Merisant Co. v. McNeil Nutritionals, LLC*, 515 F. Supp.

2d 509, 541 (E.D. Pa. 2007). In *Merisant*, the court never allowed the expert to opine about a marketing campaign's actual effect on consumers. Instead, in this Lanham Act case involving false and misleading advertising claims, the proffered expert was "expected to testify generally [about] the standards and customs in the marketing industry and specifically [about] the application of certain advertising and marketing techniques and strategies to [defendant's] campaigns for [its product]." Id. at 539-40. When it concluded that the expert's testimony about brand positioning strategy was admissible, the court relied on Schwab v. Philip Morris USA, Inc., No. CV 04-1945(JBW), 2005 WL 2401647 (E.D.N.Y. Sept. 29, 2005). Merisant, 515 F. Supp. 2d at 541. The Merisant court explained that, in Schwab, "one of the issues was the design and intent of the tobacco industry in promoting 'light' or 'low tar' cigarettes[,]" so the Schwab court admitted testimony from a marketing expert about "both what defendants knew and intended and how their activities were designed to influence the beliefs and activities of consumers." Id. (quoting Schwab, 2005 WL 2401647, at \*5). Thus, the Merisant court allowed the expert to testify about "advertising, marketing and brand positioning" because his "education, experience, analytical techniques and expert report compl[ied] with all elements of Daubert and Rule 702 of the Federal Rules of Evidence." Id.

Similarly, other courts have permitted marketing experts to opine about the design and *intended* effect of marketing materials on consumer—*i.e.*, from the perspective of a marketer who creates marketing materials with the purpose of reaching a target audience. *See*, *e.g.*, *Select Comfort Corp. v. Tempur Sealy Int'l, Inc.*, No. 13-2451 (DWF/SER), <u>2016 WL 5496340</u>, at \*18 (D. Minn. Sept. 28, 2016) (allowing marketing expert to opine about "the *expected* impact of the alleged false advertising on consumers" (emphasis added)); *Goldberg v. 401 N. Wabash Venture LLC*, No. 09 C 6455, <u>2013 WL 212912</u>, at \*3–6 (N.D. Ill. Jan. 18, 2013) (recognizing that

"[c]ourts regularly permit expert testimony pertaining to *the designed effect* of marketing materials on a potential consumer" and permitting an expert to testify about "how [real estate] developers design [marketing] materials, and opine on the significance of the [marketing] materials having been designed in a certain way, based on the customs and practices of the industry" (emphasis added)).

But, in contrast, courts tend to prohibit marketing experts from testifying about the *actual* effects of a marketing campaign on the intended audience because that kind of opinion is speculative. *See, e.g., Goldberg,* 2013 WL 212912, at \*3–6 (allowing a marketing expert to opine about "the designed effect of marketing materials on a potential consumer" but prohibiting the expert from testifying about "what reasonably prudent buyers would conclude, or what they in fact did conclude" from the marketing materials because such testimony "would be too speculative to be admissible"); *Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 439–40 (D.N.J. 2009) (excluding expert testimony about alleged implicit messages contained in defendant's advertising because the expert "relied primarily on his own belief of what customers would understand and expect" from the advertisements and his belief was "legally irrelevant because he is not a member of the relevant purchasing group, did not rely on a survey of this group, and is unqualified to opine on the issue of how physicians would evaluate and act upon scientifically oriented ads or promotions for x-ray contrast media").

The parties do not cite, and the court's research did not reveal, any Tenth Circuit case law governing this issue. But, the court finds persuasive the cases discussed above. And, the court predicts the Tenth Circuit would follow their guidance when deciding whether to admit a marketing expert's opinion in a Lanham Act case.

Here, Mr. Zieziula opines that Sanofi's "marketing messages compared Auvi-Q to Mylan's EpiPen product, suggested that Auvi-Q was the new EpiPen, and that Auvi-Q was a better device which patients preferred." Doc. 1669-4 at 5 (Zieziula Expert Report). And, he asserts, "[i]n [his] experience, the use of these types of misleading comparative messages in pharmaceutical advertising *can have* a significant impact on payers, prescribing physicians, and consumers' purchasing decisions." *Id.* (emphasis added). Thus, the court concludes, Mr. Zieziula's opinion does not testify about the *actual* effects of Sanofi's marketing of Auvi-Q. Instead, Mr. Zieziula offers an opinion about the *expected* or *intended* effect of the marketing messages. That type of opinion is admissible. And, Mr. Zieziula's many years of experience marketing products in the pharmaceutical industry qualify him to render these opinions.

Also, the court finds that Mr. Zieziula is qualified to offer these opinions even though he's not an expert in EAI devices. As Mylan asserts, "a lack of specialization does not affect the admissibility of the opinion, but only its weight." *Wheeler v. John Deere Co.*, 935 F.2d 1090, 1100 (10th Cir. 1991). Thus, courts permit experts to testify on topics within their fields of expertise, even if the expert doesn't have specialized knowledge about a particular area in that field. *See id.* at 1100–01 (holding that expert testimony about consumer expectation for the dangerousness of a product that was offered by a "mechanical engineer with special expertise in the safe design of farm equipment" was admissible because "[i]nherent in the safe design of mechanical equipment is some anticipation of how such equipment will be perceived and used by consumers"); *see also Corr v. Terex USA, LLC*, No. 08-1285-MLB, 2011 WL 976718, at \*4–5 (D. Kan. Mar. 17, 2011) (holding that "an engineer with some expertise in safety and human factors" was qualified to testify that a machine used to pave asphalt was dangerous as designed

even though he had no experience with the machine at issue or other pavers because his opinions still fell within the realm of his expertise).

Sanofi argues that the court shouldn't apply these cases because they are products liability cases and neither involved Lanham Act violations. But Sanofi doesn't explain why that distinction matters. Sanofi also doesn't explain why the marketing of an EAI device is different than marketing any other pharmaceutical product. The court thus rejects Sanofi's argument that Mr. Zieziula isn't qualified to opine about the marketing of EAI devices. Instead, the court finds that Mr. Zieziula's general knowledge and experience with marketing products in the pharmaceutical industry qualifies him to provide his expert opinion about Sanofi's marketing of Auvi-Q.

Last, Sanofi argues that Mr. Zieziula is not qualified to offer the opinions in his rebuttal expert report. Mr. Zieziula submits his rebuttal in response to Dr. Scott Morton's expert report. Dr. Scott Morton is the Theodore Nierenberg Professor of Economics at the Yale School of Management, where she has taught since 1999. Doc. 1680-4 at 6 (Scott Morton Expert Report ¶ 1). Dr. Scott Morton holds a Ph.D. in Economics from MIT. Id. And, from May 2011 through December 2012, she served as the Deputy Assistant Attorney General for Economic Analysis with the Antitrust Division of the Department of Justice. Id. (Scott Morton Expert Report ¶ 3). Dr. Scott Morton opines that "Mylan successfully engaged in exclusionary anticompetitive conduct so as to maintain its monopoly in the EAI market." Id. at 8 (Scott Morton Expert Report ¶ 10). She asserts that Mylan's anticompetitive conduct, in turn, "ensured that Sanofi's competing product—Auvi-Q—would never have a chance to gain a foothold in the U.S. EAI market, thereby preventing it from obtaining significant market share and placing a meaningful competitive constraint on the EpiPen." Id. And, she opines, "no pro-competitive justifications

for Mylan's actions" exist. *Id.* at 11 (Scott Morton Expert Report ¶ 10.j.). Dr. Scott Morton concludes that Mylan's actions "harmed consumers, the competitive process, and Sanofi" and caused Sanofi to sustain monetary damage. *Id.* at 8 (Scott Morton Expert Report ¶ 10).

Mr. Zieziula's rebuttal report offers a different reason why Auvi-Q failed in the EAI market. Mr. Zieziula opines that Sanofi's own conduct and decision-making caused Auvi-Q's failure. Mr. Zieziula provides several reasons for his conclusion. Mr. Zieziula asserts that (1) Sanofi's ability to compete was adversely impacted by its cost structure, (2) Sanofi ignored the evolving environment in the EAI market, (3) Sanofi implemented a conservative rebate strategy that was inconsistent with the recognized market environment, (4) Sanofi failed to implement a robust marketing campaign directed at key decision makers, and (5) Sanofi's eventual recall of Auvi-Q had negative consequences. <u>Doc. 1669-5 at 4</u>–8, 10, 14, 17–18 (Zieziula Mar. 25, 2019) Expert Report). For all these reasons, Mr. Zieziula concludes that "Sanofi's failure to meet its pre-launch forecasts [for Auvi-Q] cannot be attributed to any 'exclusionary conduct' by Mylan." Id. at 19; see also id. at 8 ("[T]here are many potential explanations for Sanofi's failure to achieve its pre-launch ambitions for Auvi-Q that are based on Sanofi's own conduct and decision-making, which ran counter to industry best practices for a successful product launch, and not on any anti-competitive conduct that Professor Scott Morton attributes to Mylan."). Instead, he opines, "the evidence shows competition between Mylan and Sanofi that is consistent with standard industry practices . . . . " *Id.* at 19.

Sanofi argues that Mr. Zieziula is not qualified to rebut Dr. Scott Morton's opinions about Mylan's alleged anticompetitive conduct because he is not an antitrust expert. The court agrees with Sanofi. Mr. Zieziula, as a pharmaceutical executive, is not qualified to opine whether Mylan engaged in exclusionary or anticompetitive conduct. Mr. Zieziula testified that

he has had no antitrust training. Doc. 1669-3 at 19 (Zieziula Dep. 356:14–19). Also, he concedes, he's "not qualified to comment" about what qualifies as anticompetitive behavior. *Id.* at 12 (Zieziula Dep. 156:17–23); *see also id.* at 19 (Zieziula Dep. 355:22–356:12). So, to the extent Mr. Zieziula opines that Auvi-Q's failure was not caused by any anticompetitive conduct on Mylan's part, the court excludes that part of his opinions.

But, Mr. Zieziula's many years of experience in the pharmaceutical industry, particularly with launching new products to market, qualify him to analyze Sanofi's launch of Auvi-Q and identify purported flaws in its marketing of the product. Thus, the court allows Mr. Zieziula to offer his rebuttal opinions but only to the extent that they address Sanofi's conduct when launching and marketing its Auvi-Q product. He cannot opine whether Mylan engaged in anticompetitive conduct or whether that alleged conduct adversely affected Auvi-Q's success in the EAI market.

Sanofi makes one final argument in the section of its motion asserting that Mr. Zieziula is not qualified to offer his opinions. Sanofi contends that the court should exclude Mr. Zieziula's opinions because he generated them just for this lawsuit. Sanofi argues that his opinions don't come from his own independent research. Instead, Sanofi contends, Mr. Zieziula crafted his opinions only because Mylan paid him to do so. To support its argument, Sanofi relies on the Ninth Circuit's opinion in *Daubert* after remand from the Supreme Court, *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311 (9th Cir. 1995). There, the court instructed that "[o]ne very significant fact to be considered [when deciding whether expert opinion is admissible] is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying." *Id.* at 1317. But, the court also recognized: "That an

expert testifies for money does not necessarily cast doubt on the reliability of his testimony, as few experts appear in court merely as an eleemosynary gesture." *Id.* Still, the Ninth Circuit found, when "determining whether proposed expert testimony amounts to good science, [a court] may not ignore the fact that a scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office." *Id.* 

When considering this fact on a motion seeking to exclude expert opinion, our court has noted that it "may have significance in those cases involving scientific or technical methodologies," if the expert didn't develop the methodology independent of the litigation.

\*Raytheon Aircraft Co. v. United States\*, No. 05-2328-JWL, 2008 WL 627488, at \*10 (D. Kan. Mar. 4, 2008) (citations omitted). But, the court doesn't find this factor significant here, where Mr. Zieziula developed his opinions based on his experience in the pharmaceutical industry. See id. (rejecting defendant's argument that expert's testimony was unreliable because "it was not prepared independently from the litigation" because this factor had "little application" to expert testimony about costs plaintiff incurred to clean up a contaminated site—a topic that "does not lend itself to independent research").

Indeed, Rule 702 permits an expert to base his opinions on his experience, as Mr.

Zieziula has done here. *See* Fed. R. Evid. 702 advisory committee's note to 1972 proposed rules (explaining that an expert's testimony is "not limited merely to the 'scientific' and 'technical' but extend[s] to all 'specialized' knowledge" and includes testimony offered by "a person qualified by 'knowledge, skill, experience, training or education." (quoting Fed. R. Evid. 702)); *see also* Fed. R. Evid. 702 advisory committee's note to 2000 amendments ("Nothing in this amendment is intended to suggest that experience alone—or experience in conjunction with other knowledge, skill, training or education—may not provide a sufficient foundation for expert

testimony. To the contrary, the text of Rule 702 expressly contemplates that an expert may be qualified on the basis of experience."). And, the court finds, Mr. Zieziula's experience as a former executive in the pharmaceutical industry qualifies him to render the expert opinions that he offers about Sanofi's marketing of Auvi-Q. Sanofi's criticisms of Mr. Zieziula because he formed his opinions just for this litigation attack the weight of those opinions, but not their admissibility. *See, e.g., United States v. Kelley*, 6 F. Supp. 2d 1168, (D. Kan. 1998) ("An expert witness's bias goes to the weight, not the admissibility of the testimony, and should be brought out on cross-examination." (citation and internal quotation marks omitted)).

Also, Sanofi attacks Mr. Zieziula's qualifications because he doesn't have a marketing degree and hasn't published any papers about marketing. These criticisms also go to the weight that a factfinder should give his testimony, not its admissibility. *See Burton v. R.J. Reynolds Tobacco Co.*, 183 F. Supp. 2d 1308, 1312 (D. Kan. 2002) ("Any alleged gap in [an expert's] qualifications goes to the weight of his expert opinion and can be adequately addressed by cross-examination."). Thus, the court rejects Sanofi's argument that the court should exclude Mr. Zieziula's opinions simply because he formed his opinions for this litigation.

In sum, the court concludes Mr. Zieziula is qualified to provide his opinions about Sanofi's advertising and marketing of Auvi-Q.

#### 2. Are Mr. Zieziula's opinions reliable?

Next, Sanofi argues the court should exclude Mr. Zieziula's opinions because they are unreliable. Sanofi offers three arguments to support this assertion.

First, Sanofi argues that Mr. Zieziula's opinion that Sanofi's advertisements were "misleading" is unreliable because his opinion is supported only by "his own say-so" and not consumer surveys. Doc. 1669 at 18. Mylan responds, arguing that Mr. Zieziula's Expert Report

never opines that Sanofi's advertisements are false or misleading. <u>Doc. 1803 at 21</u>. And, Mylan asserts, Mr. Zieziula won't offer any opinions about the falsity of Sanofi's advertisements at trial. *Id.* Sanofi's Reply brief doesn't respond to this argument. Thus, it appears that Sanofi has abandoned it. In any event, the court agrees with Mylan. Mr. Zieziula's Expert Report opines that Sanofi's marketing of Auvi-Q was not consistent with pharmaceutical industry standards and best practices. *See generally* <u>Doc. 1669-4</u> (Zieziula Expert Report). He doesn't offer an opinion whether Sanofi's advertisements were false or misleading in a way that violated the Lanham Act. So, the court rejects Sanofi's first argument about the reliability of Mr. Zieziula's opinions.

Second, Sanofi asserts that Mr. Zieziula's opinion that Sanofi's promotional messages "were widespread in the marketplace" is unreliable because it isn't based on any scientific or statistical analysis. Doc. 1669-4 at 5 (Zieziula Expert Report). Sanofi argues that Mr. Zieziula bases his opinion on Awareness Trial and Usage ("ATU") studies conducted by Sanofi to "track awareness, trial and usage of launch brands, and message recall from physicians" about Auvi-Q. Id. at 7. Sanofi contends that, because these ATU studies don't specify the type of product comparisons the physicians recalled, they don't show reliably that Sanofi had a widespread practice of making comparisons that were false or misleading. Also, Sanofi argues, the ATU studies are not surveys designed to provide statistically-significant data about Sanofi's promotional practices at large, and thus, they aren't trustworthy. So, Sanofi asserts, Mr. Zieziula's opinion is unreliable because it is based on unreliable ATU studies.

Mylan responds that Mr. Zieziula formed his opinions about the prevalence of Sanofi's promotional messages based on his pharmaceutical marketing and leadership experience. Using that experience, Mylan asserts, Mr. Zieziula concluded from the record evidence that Sanofi widely disseminated comparative promotional messages. According to Mylan, Mr. Zieziula

reached his conclusion after reviewing several sources of evidence—not just the ATU studies. *See, e.g.*, Doc. 1669-3 at 26 (Zieziula Dep. 439:19–440:11) (explaining that his "conclusions and opinions were based on the totality of information that [he] was able to gather from a variety of documents and feedback from the reps and feedback from competitive intelligence reports"); *see also* Doc. 1669-6 at 4, 8 (Zieziula Rebuttal Report) (explaining the various sources Mr. Zieziula relied on to form his opinions including a public statement made by Sanofi's President of North America, the use of a "catch phrase" throughout the organization, and competitive intelligence reports). And, Mylan contends, Mr. Zieziula relied on the ATU studies to form his opinions because, based on his industry experience, they are the types of documents that a pharmaceutical company uses to determine the messages the sales force is conveying in the market. *See* Doc. 1669-4 at 7 (Zieziula Expert Report) (explaining that ATU studies "assist pharmaceutical companies in determining which messages are working in the field"); Doc. 1669-6 at 4 (Zieziula Rebuttal Report) (asserting that ATU studies are "relied upon by companies to assess what's happening in the field").

Sanofi's Reply takes issue with each evidentiary source that Mr. Zieziula relies on to reach his conclusion. Sanofi argues that each source doesn't show widespread dissemination of *false* claims that violate the Lanham Act. Each of these attacks go to the weight of Mr. Zieziula's opinion. But they do not warrant excluding his opinion as unreliable. Instead, the court finds, Mr. Zieziula's opinion about the prevalence of Sanofi's promotional messages is sufficiently reliable because he properly bases it on his experience in the pharmaceutical industry. *See* Fed. R. Evid. 702 advisory committee's note to 2000 amendments ("If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and

how that experience is reliably applied to the facts."); see also Metavante Corp. v. Emigrant Sav. Bank, 619 F.3d 748, 761 (7th Cir. 2010) ("An expert's testimony is not unreliable simply because it is founded on his experience rather than on data; indeed, Rule 702 allows a witness to be 'qualified as an expert by knowledge, skill, experience, training, or education." (quoting Fed. R. Evid. 702)); Bitler v. A.O. Smith Corp., 400 F.3d 1227, 1235 (10th Cir. 2005) (affirming trial court's conclusion that expert's "personal experience, training, method of observation, and deductive reasoning [was] sufficiently reliable to constitute 'scientifically valid' methodology" used by the expert to reach his opinion).

Finally, Sanofi argues that Mr. Zieziula's opinion that Sanofi's advertising harmed Mylan is unreliable. According to Sanofi, this opinion is unreliable because Mr. Zieziula bases it on his own speculation and no scientific analysis. Mylan responds, conceding that Mr. Zieziula hasn't performed any analysis about the *quantity* of harm sustained by Mylan. But, Mylan asserts, Mr. Zieziula offers two opinions that are grounded in his industry experience and will help the trier of fact decide whether Sanofi's conduct caused harm to Mylan.

Mr. Zieziula's first causation opinion is that comparative and preference claims—like the ones Sanofi made—"can have a significant impact on how physicians, payers and patients make decisions on which products to use." Doc. 1669-4 at 5 (Zieziula Expert Report). Mr. Zieziula testified that he reached this conclusion based on his experience and the documents he reviewed. Doc. 1669-3 at 21–22 (Zieziula Dep. 402:20–405:25). But, he never estimated how much effect Sanofi's promotional claims had on the intended audience or how much they damaged Mylan. See id. Mr. Zieziula's second causation opinion is that Sanofi's promotion of Auvi-Q as "the 'new EpiPen' would be harmful to Mylan and the brand equity of EpiPen . . . ." Doc. 1669-4 at 11 (Zieziula Expert Report). Mr. Zieziula opines that "[b]rand equity is built over time based on

a brand delivering the desired results consistently with patients." *Id.* And, in his experience, "the brand equity of a pharmaceutical product plays a big role in a physician's willingness to prescribe that product." *Id.* Thus, Mr. Zieziula concludes, Sanofi's promotion of Auvi-Q as "the 'new EpiPen'" when the two products "are not the same" "would be harmful to Mylan and the brand equity of EpiPen[.]" *Id.* 

Sanofi argues that these opinions are not reliable causation opinions because they opine whether promotional messages "can" or "would" have a particular effect. But, the Lanham Act requires a plaintiff to prove *actual* harm. Doc. 1874 at 14 (quoting *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 228–29 (3d Cir. 1990) (explaining that "[a] Lanham Act plaintiff... is not entitled to the luxury of deference to its judgment" but must shoulder "the burden of proving actual deception by a preponderance of the evidence[,]" and "[h]ence, it cannot obtain relief by arguing how consumers *could* react; it must show how consumers *actually do* react")). And, Sanofi argues, Mr. Zieziula can't opine about the actual effects of Sanofi's advertising because he's not a member of the relevant purchasing group and he hasn't conducted any independent research or analysis on that question.

The argument that Sanofi makes here is similar to the one discussed in the above-section—*i.e.*, that Mr. Zieziula is not qualified to opine about the intended effects of promotional claims because he's not a member of the intended audience. *See supra* Part III.A.1. For the same reasons already discussed, the court rejects this argument. Other courts have permitted marketing experts to opine about the intended effects of promotional messages, finding such opinions reliable when grounded in the expert's marketing or industry experience. *See, e.g.*, *Brighton Collectible, LLC v. Believe Prod., Inc.*, No. 2:15-cv-00579-CAS (ASx), 2017 WL 440255, at \*9 (C.D. Cal. Jan. 30, 2017) (noting, in a Lanham Act case, that "[c]ourts regularly

permit marketing experts to testify to the role of branding, distinctiveness, and design in consumer behavior as well as what effects they would expect based upon the facts of any particular case" and finding expert opinion admissible because it was "sufficiently grounded in the evidence of this case" and although the expert had "fail[ed] to conduct a consumer study consistent with practice in the field of marketing," that failure didn't "undermine the reliability of [the] opinion" which was "not that [defendant's] actions did cause damage to [plaintiff]" but that "based on [the expert's] expertise in marketing and branding, she would expect certain injuries" (citations omitted) (emphasis added)); Goldberg v. 401 N. Wabash Venture LLC, No. 09 C 6455, 2013 WL 212912, at \*3–6 (N.D. Ill. Jan. 18, 2013) (recognizing that "[c]ourts regularly permit expert testimony pertaining to the designed effect of marketing materials on a potential consumer" and finding reliable expert testimony about the "purpose and design" of marketing materials that the expert reached after "appl[ying] his experience to the facts at hand" (emphasis added)).

Here, the court finds that Mr. Zieziula's experience in the pharmaceutical industry, particularly his experience developing marketing strategies and launching new products, provides a reliable methodology for forming his opinions about the intended effects of Sanofi's promotional messages. But, the court agrees with Sanofi in one respect. To prevail on the Lanham Act claim, Mylan must come forward with evidence proving that Sanofi's promotional messages caused it actual harm. *See Lexmark Int'l, Inc. v. Static Control Components, Inc.*, <u>572</u> U.S. 118, 140 (2014) ("To invoke the Lanham Act's cause of action for false advertising, a plaintiff must plead (and ultimately prove) an injury to a commercial interest in sales or business reputation proximately caused by the defendant's misrepresentations."). Mr. Zieziula's opinions—alone—won't satisfy that burden because he doesn't quantify any actual harm

sustained. He just opines on the potential harmful effects that certain promotional messages "can" or "would" cause. But, this shortcoming provides no reason for the court to exclude his opinions as unreliable.

For all these reasons, the court rejects Sanofi's arguments attacking the reliability of Mr. Zieziula's opinions.

## 3. Will Mr. Zieziula's opinions assist the trier of fact?

Last, Sanofi argues that the court should exclude Mr. Zieziula's opinions because they will not "help the trier of fact to understand the evidence or to determine a fact in issue," as Fed. R. Evid. 702(a) requires. Sanofi asserts two arguments why Mr. Zieziula's opinions will not assist the trier of fact.

First, Sanofi contends that Mr. Zieziula just offers expert testimony about the facts of the case. And, Sanofi asserts, that kind of expert opinion usurps the jury's role. See Parker v. Wal-Mart Stores, Inc., 267 F.R.D. 373, 376–77 (D. Kan. 2010) (excluding expert opinion that "involve[d] the determination of facts and the drawing of inferences" because that function "is exclusively the province of the jury" and refusing to "permit [the expert] to usurp the jury's function by asserting facts in the form of 'expert' opinion"). To support this argument, Sanofi selects one portion of Mr. Zieziula's deposition testimony where he was asked about the opinion offered in his Expert Report that "Sanofi's ability to effectively compete was impacted" by Auvi-Q's high costs. Doc. 1669-5 at 4 (Zieziula Mar. 25, 2019 Expert Report). Mr. Zieziula's Expert Report explains that he reached his opinion based on his experience with "P&L responsibility" in the pharmaceutical industry and from reviewing the evidence in the case. Id. at 6–7. When asked about this opinion at his deposition, Mr. Zieziula agreed with counsel who asked him whether he was "basically an expert on the facts of the case, not an expert on royalty rates?"

Doc. 1669-3 at 14 (Zieziula Dep. 193:15–194:3). And, Sanofi relies on this testimony to argue Mr. Zieziula's opinion usurps the jury's role.

But, as Mylan argues, Mr. Zieziula's single admission that he tied this one opinion to evidence about royalty rates doesn't mean that he simply is offering expert opinion on the facts. Indeed, the Supreme Court has explained that Fed. R. Evid. 702 requires that an expert's testimony must "fit" the facts of the case so that it can assist the trier of fact when deciding the facts in issue. Daubert, 509 U.S. at 591; see also id. (instructing courts to consider "whether expert testimony proffered in the case is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute" (quoting United States v. Downing, 753 F.2d 1224, 1242 (3d Cir. 1985)); see also United States v. Garcia, 635 F.3d 472, 476 (10th Cir. 2011) (explaining that "[r]elevant expert testimony must . . . be 'sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute" (quoting Daubert, 509 U.S. at 591)). Here, the court finds, Mr. Zieziula's Expert Report sufficiently explains how his experience leads him to form the conclusions that he reaches. Doc. 1669-5 at 6-7 (Zieziula Mar. 25, 2019 Expert Report).

And, Mr. Zieziula's opinions about pharmaceutical cost structure will assist the trier of fact when understanding the evidence about Auvi-Q's performance in the EAI market.

Sanofi's Reply argues that Mr. Zieziula's deposition admission when discussing his opinion about Auvi-Q's high cost and its effect on Sanofi's ability to compete isn't the only opinion where Mr. Zieziula provides expert testimony about the facts of the case. The Reply cites several examples from Mr. Zieziula's Expert Report where, Sanofi contends, Mr. Zieziula simply summarizes facts. Doc. 1874 at 16 (citing Doc. 1669-4 (Zieziula Expert Report)). The court normally doesn't address arguments asserted for the first time in a reply brief. *See Guang Dong Light Headgear Factory Co. v. ACI Int'l, Inc.*, 521 F. Supp. 2d 1153, 1173 n.70 (D. Kan.

2007) (citing *Hutton Contracting Co. v. City of Coffeyville*, 487 F.3d 772, 788 (10th Cir. 2007)). But the court makes an exception here because doing so will serve the aim of Fed. R. Civ. P. 1. And, in any event, Mr. Zieziula's Expert Report does more than simply summarize the cited evidence. The Expert Report sufficiently explains how Mr. Zieziula formed his opinions by reviewing the evidence in the case and how he reached certain conclusions about that evidence based on his experience. *See* Fed. R. Evid. 702 advisory committee's note to 2000 amendments ("If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts."). For these reasons, the court rejects Sanofi's argument that Mr. Zieziula's opinions offer improper expert testimony about the case's facts.

Second, Sanofi argues that Mylan uses Mr. Zieziula as a conduit to introduce inadmissible evidence, including hearsay and unauthenticated documents. Sanofi's motion doesn't explain specifically what evidence, it contends, is inadmissible. But, it points the court to the parties' summary judgment briefing. Mylan responds that its summary judgment briefing adequately addresses the admissibility of its proffered evidence. And, Mylan asserts, the Federal Rules of Evidence allow an expert to rely on inadmissible evidence to form an opinion, "[i]f experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject . . . ." Fed. R. Evid. 703; see also United States v. Pablo, 696 F.3d 1280, 1288 (10th Cir. 2012) (explaining that "Federal Rule of Evidence 703 authorizes an expert to testify to an opinion even if that opinion is based on otherwise inadmissible facts or data, which at times may include out-of-court testimonial statements" and this Rule allows "disclosure [of the inadmissible evidence] to the jury if 'the court determines that [its] probative value in

assisting the jury to evaluate the expert's opinion substantially outweighs [its] prejudicial effect" provided that "the disclosure of this otherwise inadmissible information is to assist the jury in evaluating the expert's opinion, not to prove the substantive truth of the otherwise inadmissible information"). The court will address more fully Sanofi's evidentiary objections in its Order ruling the summary judgment motions. But, here, Sanofi's largely undefined arguments about inadmissible evidence don't justify excluding Mr. Zieziula's opinions in their entirety.

#### 4. Conclusion

In sum, the court grants Sanofi's Motion to Exclude the Expert Reports and Testimony Offered By Gary Zieziula (Doc. 1666), but only in part. The court grants Sanofi's request to exclude the opinions in Mr. Zieziula's Rebuttal Report that opine whether Mylan engaged in anticompetitive conduct or whether that alleged conduct adversely affected Auvi-Q's success in the EAI market. As Sanofi argues, Mr. Zieziula, as a pharmaceutical executive, is not qualified to offer antitrust expert opinion. But, the court denies Sanofi's motion seeking to exclude Mr. Zieziula's opinions in all other respects.

## **B.** Motion to Exclude Opinions of Dr. Thomas Varner

Next, Sanofi asks the court to exclude the testimony and opinions of Mylan's expert, Dr. Thomas Varner. Dr. Varner is an economics consultant. Doc. 1677-3 at 3 (Varner Expert Report ¶¶ 1, 4). Mylan has retained Dr. Varner to provide an expert opinion about the amount of damages Mylan sustained from Sanofi's alleged false and misleading advertising that violated the Lanham Act. *Id.* at 4 (Varner Expert Report ¶ 6). Sanofi argues that the court should exclude Dr. Varner's opinions for two reasons: (1) Dr. Varner's estimates for lost profits and unjust enrichment damages are unreliable; and (2) Dr. Varner is not qualified to testify about

EpiPen manufacturing capacity and his testimony on this subject is unreliable. The court addresses each argument, separately, below.

## 1. Are Dr. Varner's opinions about lost profits and unjust enrichment damages reliable?

Sanofi argues that Dr. Varner's opinions about Mylan's lost profits and unjust enrichment damages fail to consider whether Sanofi's alleged conduct actually caused Mylan harm. Sanofi argues that without the necessary causal link between Sanofi's actions and Mylan's damages Dr. Varner's entire damages analysis is unreliable. Specifically, Sanofi argues that Dr. Varner's analysis is unreliable because it: (1) relies on an unsupported and incorrect assumption that Sanofi's alleged conduct caused all of Auvi-Q's sales; (2) fails to establish a causal link between Sanofi's alleged conduct and any Auvi-Q sales or any lost EpiPen sales; and (3) doesn't consider alternative causes for Auvi-Q's sales.

Mylan responds that it hasn't designated Dr. Varner as a causation expert. Instead, Mylan offers his expert testimony only on the issue of damages. Mylan concedes that it bears the burden to prove causation to prevail on its Lanham Act claim. *See, e.g., Sally Beauty Co., Inc. v. Beautyco, Inc.*, 304 F.3d 964, 980 (10th Cir. 2002) (listing the elements of a false advertising claim under the Lanham Act); *see also Gen. Steel Domestic Sales, LLC v. Chumley*,

Sanofi never argues that Dr. Varner isn't qualified to provide his damages analysis. Dr. Varner's Expert Report explains that he is the Executive Vice President of an economics consulting company. Doc. 1677-3 at 3 (Varner Expert Report ¶ 1). He has a B.S. in Architecture from California Polytechnic State University, an M.S. in Civil Engineering (Structural Engineering and Structural Mechanics) from the University of California at Berkeley, an M.B.A. from the University of California at Berkeley, an M.S. in Engineering-Economic Systems from Stanford University, and a Ph.D. in Engineering-Economic Systems & Operations Research from Stanford University. *Id.* (Varner Expert Report ¶ 2). Dr. Varner has taught microeconomics, econometrics, and financial economics courses in the Economics Department of the University of California at Davis. *Id.* (Varner Expert Report ¶ 3). And, he specializes in economic, financial, and statistical analysis. *Id.* Dr. Varner has served as a consulting or testifying expert on legal matters including intellectual property, Lanham Act claims, antitrust, and general business litigation. *Id.* (Varner Expert Report ¶ 4). Based on his education and professional experience, the court finds that Dr. Varner is sufficiently qualified to render the damages opinions he offers in his Expert Report.

627 F. App'x 682, 683–84 (10th Cir. 2015) ("To win a false advertising claim under the Lanham Act, a plaintiff generally must establish among other things that the defendant's commercial advertising contained a false or misleading representation of fact that was likely to cause confusion about the defendant's products or services and that injured the plaintiff." (citing 15 U.S.C. § 1125(a)). And, Mylan asserts, it can satisfy this burden by relying on other record evidence, and not expert testimony.

Dr. Varner's analysis thus assumes causation and he only opines about the amount of damages Mylan allegedly sustained. There is nothing wrong with this approach. Indeed, our court has recognized that a damages expert "is permitted to presume causation, which is a prerequisite to recovery that will have to be established at trial by evidence other than [the damages expert's] testimony." *RMD*, *LLC* v. *Nitto Americas*, *Inc.*, No. 09-2056-JAR-DJW, 2012 WL 5398345, at \*10 (D. Kan. Nov. 5, 2012); see also U.S. Accu-Measurements, *LLC* v. Ruby Tuesday, *Inc.*, Civ. No. 2:10-5011 (KM), 2013 WL 1792463, at \*8 (D.N.J. Apr. 26, 2013) (denying motion to exclude expert who made "assumptions regarding liability on which [the expert] based his calculation of damages" because "[e]xpert opinions on damages commonly assume liability, which must be established independently"); *Sys. Dev. Integration, LLC* v. Comput. Scis. Corp., 886 F. Supp. 2d 873, 882 (N.D. III. 2012) ("It is entirely appropriate for a damages expert to assume liability for the purposes of his or her opinion. To hold otherwise would be illogical.").

The cases cited by Sanofi don't persuade the court otherwise. In each case, the expert offered opinions *both* on causation and on damages. And, in each case, the court excluded the expert opinion as unreliable because it opined that defendant's conduct caused plaintiff's damages without any reliable evidence to support that conclusion. *See, e.g., Verisign, Inc. v.* 

XYZ.COM LLC, 848 F.3d 292, 300–01 (4th Cir. 2017) (affirming trial court's exclusion of expert testimony that opined "that [defendant's] statements sapped [plaintiff's] profits" because the opinion "assumes rather than demonstrates that every [sale defendant made] during the relevant time period was the result of [defendant's] allegedly false statements"); Dependable Sales & Serv., Inc. v. TrueCar, Inc., 311 F. Supp. 3d 653, 660 (S.D.N.Y. 2018) (excluding expert's opinion about the "chain of causation" because it was unsupported by the record); Bracco Diagnostics, Inc. v. Amersham Health, Inc., 627 F. Supp. 2d 384, 443–44 (D.N.J. 2009) (concluding expert's opinion about "causation is not admissible because he assumed causation"); First Savings Bank, F.S.B. v. U.S. Bancorp, 117 F. Supp. 2d 1078, 1084 (D. Kan. 2000) (prohibiting plaintiff from offering expert opinion that was based "on the assumption that plaintiff's loss in business was caused by confusion created in the marketplace by defendants" because plaintiff couldn't use that testimony "to prove that the fact assumed by [expert] is true" (i.e., to establish causation) when his "estimates [were] based—without any evidentiary or even statistical support—on an assumption that defendants caused all declines suffered by plaintiff" that "infect[ed] his basic methodology" (emphasis added)). Dr. Varner hasn't done that here. Mylan doesn't offer Dr. Varner's opinions to prove causation. Indeed, Mylan expressly disclaims that Dr. Varner will testify about causation. Doc. 1804 at 7 n.2 ("To the extent any of Dr. Varner's testimony or reports could be read to offer an affirmative opinion on causation or quantify the portion of damages attributable to Sanofi's conduct, Mylan represents that Dr. Varner will not offer such an opinion at trial."). Instead, Dr. Varner offers only a damage opinion that assumes causation based on Mylan's representation that it will prove that requisite element of its Lanham Act claim through other record evidence. As discussed above, that approach is consistent with the case law.

Dr. Varner offers two damages opinions. The court summarizes his two damages opinions in greater detail, below. And, it finds each of these opinions sufficiently reliable, and thus admissible expert opinions under <u>Fed. R. Evid. 702</u>.

First, Dr. Varner calculates Mylan's claim for unjust enrichment damages in the form of disgorgement of Sanofi's profits. A plaintiff who prevails on a Lanham Act claim is entitled to recover "defendant's profits." 15 U.S.C. § 1117(a). And, when "assessing profits the plaintiff shall be required to prove defendant's sales only; defendant must prove all elements of cost or deduction claimed." Id.; see also Gen. Steel, 627 F. App'x at 686–87 (affirming district court's calculation of disgorgement using "a burden-shifting framework that required [plaintiff] to prove [defendant's] gross profits during the period in question and [defendant] to prove which portion of those profits wasn't attributable to its Lanham Act violations"); cf. Covertech Fabricating, Inc. v. TVM Bldg. Prods., Inc., 855 F.3d 163, 177 (3d Cir. 2017) (explaining that "the Lanham Act's burden-shifting framework" requires a plaintiff to "prov[e] the infringer's sales before the burden of proof shifts to the defendant to show costs and deductions" but, even so, "a bare showing of gross sales is not sufficient to fashion an equitable award without some anchor in the record to support a reasonable estimation of actual profits").

Here, Dr. Varner calculates Sanofi's profits from its Auvi-Q sales. He summarizes Auvi-Q's sales in dollar amounts, units sold, doses, and the average sales price per dose. <u>Doc. 1677-3</u> at 15–16 (Varner Expert Report ¶ 32). And, from that information, Dr. Varner calculates Mylan's alleged unjust enrichment damages. *Id.*; *see also id.* at 41, 43 (Varner Expert Report Exs. 1 & 2.1). This opinion will assist the trier of fact when determining unjust enrichment damages, if it finds Sanofi liable for Lanham Act violations. Dr. Varner's disgorgement calculation is reliable and relevant, and thus admissible.

Second, Dr. Varner calculates Mylan's alleged lost profits damages. His analysis begins with the assumption that "all of Sanofi's Auvi-Q® sales are sold as a result of the false and misleading representations made by Sanofi." Doc. 1677-3 at 16 (Varner Expert Report ¶ 34). But he recognizes that it's Mylan's burden under the Lanham Act "to identify and apportion those sales that are attributable to the false and misleading representations." Id. (Varner Expert Report ¶ 33). Next, Dr. Varner calculates the percentage of Auvi-Q sales that, but-for Sanofi's alleged false and misleading advertising, would have been EpiPen sales made by Mylan. Id. at 16–17 (Varner Expert Report ¶¶ 35–37). Then, he determines how many of those sales Mylan had the capacity to make. Id. at 17–19 (Varner Expert Report ¶¶ 38–42). Finally, Dr. Varner uses a regression model to determine Mylan's incremental profit margin on these sales, which he then uses to calculate Mylan's lost profits on those lost sales. Id. at 20 (Varner Expert Report ¶¶ 43–44). In a Supplemental Expert Disclosure, Dr. Varner describes his lost profits calculation as "provid[ing] a benchmark for the maximum potential recovery of Mylan's 'damages sustained."

Doc. 1677–12 at 4 (Varner Supplemental Expert Disclosure ¶ 5).

<sup>3</sup> 

In a footnote, Sanofi's Memorandum in Support of its Motion to Exclude asks the court to strike Dr. Varner's Supplemental Expert Disclosure under Fed. R. Civ. P. 37. Doc. 1677 at 8 n.2. Sanofi argues that the court should strike the disclosure because it is an improper rebuttal report disclosed in an untimely fashion. Mylan responds that Fed. R. Civ. P. 26(e) required Dr. Varner to submit his Supplemental Expert Disclosure. See Fed. R. Civ. P. 26(e)(1)(A) ("A party who has made a disclosure under Rule 26(a) . . . must supplement or correct its disclosure or response . . . in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect . . . . "). Mylan explains that the Supplemental Expert Disclosure properly makes a correction based on counsel's revised instructions to Dr. Varner about the parties' burdens when proving or defending against Lanham Act damages claims. See Doc. 1677-12 at 3 (Varner Supplemental Expert Disclosure ¶ 2–3 (describing revised legal instructions from counsel)). Importantly, Mylan asserts, Dr. Varner's Supplemental Expert Disclosure doesn't change or supplement his opinion in any way. See Doc. 1677-12 at 3 (Varner Supplemental Expert Disclosure ¶ 4 (explaining that his "calculation of 'Mylan's lost profits' in [his Expert Report does not change based on this revised legal instruction, remains a reliable methodology, and [his] opinion accurately represents 'Mylan's lost profits'")). The court agrees with Mylan. Dr. Varner's Supplemental Expert Disclosure simply corrects the legal standard counsel provided to him. It doesn't change his opinions or his damage calculations.

Mylan asserts that this calculation provides a helpful tool to the jury when determining lost profit damages. Mylan explains that Dr. Varner's assumption that Sanofi's alleged wrongful conduct caused all of its Auvi-Q sales results in an analysis that provides the "upper ranges of Sanofi's revenues and Mylan's lost profits." Doc. 1804 at 8. Using his analysis, the "jury can then multiply those numbers by the percentage of sales it finds were caused by Sanofi's conduct." *Id*.

For support, Mylan cites *Brunswick Corp. v. Spinit Reel Co.*, 832 F.2d 513 (10th Cir. 1987). The *Brunswick* plaintiff based its Lanham Act damages claim "on the theory that [plaintiff] lost one sale of [its product] as a result of each [defendant product] sold." *Id.* at 526. The Tenth Circuit didn't "necessarily believe that each [product] sale [by defendant] resulted in a corresponding loss of sale by [plaintiff]." *Id.* But, it found plaintiff's "theory provides an upper range for an award of damages." *Id.* It directed the district court on remand to consider other evidence, like "the difference in the decline of [plaintiff product's] sales as compared with the decline in sales of [plaintiff's other products]" from which "it may arrive at a fair, if not precise, amount with which to compensate" plaintiff. *Id.* Similarly, when deciding a post-trial motion seeking judgment as a matter of law against a Lanham Act plaintiff's lost profits damage claim, Judge Lungstrum rejected defendant's argument that plaintiff's damage calculation was too

Sanofi urges the court to strike Dr. Varner's supplemental disclosure under the same reasoning the court applied in *Paliwoda v. Showman*, No. 12-2740-KGS, 2014 WL 3925508, at \*5 (D. Kan. Aug. 12, 2014). The supplemental disclosure at issue in *Paliwoda* is not like Dr. Varner's supplemental disclosure here. *Paliwoda* recognized that Fed. R. Civ. P. 26(e) allows a party to supplement a disclosure to correct inaccuracies or add new information. *Id.* at \*2. But, it observed, the Rule doesn't allow a party to submit a supplement containing new opinions. *Id.* at \*3. After reviewing the supplemental expert disclosure, the court concluded that three of its opinions did not correct inaccuracies or provide new information. *Id.* at \*3–5. Instead, the three opinions were entirely new. *Id.* And, for that reason, the court struck those opinions from the supplemental disclosure. *Id.* at \*5. Unlike the improper new opinions offered in *Paliwoda*, Dr. Varner's Supplemental Expert Disclosure merely corrects an inaccuracy. It doesn't offer any new opinions. So, the court denies Sanofi's request that the court strike Dr. Varner's Supplemental Expert Disclosure.

speculative because it relied on certain assumptions. *Marten Transp.*, *Ltd. v. Plattform Advert.*, *Inc.*, No. 14-2464-JWL, 2016 WL 4000927, at \*10 (D. Kan. July 26, 2016). Instead, Judge Lungstrum relied on *Brunswick* and found that plaintiff's lost profits damage claim "set[] an upper range for possible damages" from which the jury may determine "by approximation and some degree of speculation." *Id.* 

Although neither of these cases involved the admissibility of expert testimony, they provide useful guidance about how a jury properly can use a proffered damage calculation when determining lost profit damages. Like the damage claims in *Brunswick* and *Marten Transport*, Dr. Varner's calculation provides an upper range for Mylan's purported lost profits damages. A trier of fact can use that analysis as a helpful tool when determining damages. If the jury finds that the evidence at trial supports the finding that Sanofi's conduct caused all of its Auvi-Q sales, it can rely on Dr. Varner's analysis to award Mylan's lost profit damages that he calculates Mylan sustained from Sanofi's conduct. But, if the jury finds that the evidence establishes that Sanofi's conduct caused only a portion of Auvi-Q sales,<sup>4</sup> the jury can adjust Dr. Varner's calculation downward consistent with its findings. Because Dr. Varner's analysis will aid the trier of fact in this determination, the court finds it admissible.

In sum, the court finds reliable Dr. Varner's opinions about Mylan's unjust enrichment and lost profits damages.

In its Opposition, Mylan cites record evidence, it contends, the trier of fact may rely on to determine the percentage of Auvi-Q's sales that Sanofi's allegedly false and misleading advertising caused in the market. Doc. 1804 at 11–12. Sanofi replies that Dr. Varner's analysis isn't helpful to the trier of fact because it asks the jury to "fill the critical gaps" in his analysis using this other record evidence. Doc. 1869 at 11. Sanofi misconstrues Mylan's argument. Again, Mylan doesn't proffer Dr. Varner's opinions to establish causation. Mylan represents that other evidence—such as the evidence described in its Opposition—will establish the causation element. Maybe it will; maybe it won't. But, if a trier of fact finds that the record evidence establishes that Sanofi's misleading statements caused some portion of Auvi-Q sales, a jury then can use Dr. Varner's analysis—proffered by Mylan only as expert opinion on damages—as a tool to calculate any damages sustained.

# 2. Is Dr. Varner qualified to opine about EpiPen manufacturing capability and is his opinion on this topic reliable?

Next, Sanofi argues that the court should exclude Dr. Varner's opinions because he's not qualified to testify about EpiPen manufacturing capacity. Also, Sanofi contends, his opinions on this same subject are unreliable.

First, Sanofi argues that Dr. Varner is not qualified to opine that Meridian—Mylan's EpiPen supplier—had the ability to manufacture and supply Mylan with the quantity of EpiPens equal to the number of Auvi-Q sold by Sanofi. Specifically, Sanofi relies on Dr. Varner's deposition testimony where he conceded that he's not an expert in pharmaceutical manufacturing or the FDA regulations governing pharmaceutical manufacturing. Doc. 1677-5 at 12–13 (Varner Dep. 260:23–262:3). But, Mylan responds, Dr. Varner offers an opinion as an economist—not as an expert on pharmaceutical manufacturing. To reach his opinion on EpiPen manufacturing capacity, Dr. Varner relied on Mylan's sales data, documents showing Meridian's manufacturing capacity, and interviews with Chris Benson, a Mylan employee who is responsible for EpiPen supply-chain logistics. Doc. 1677-3 at 17–19 (Varner Expert Report ¶¶ 38–41); see also Doc. 1674-3 at 17–19 (Sealed Varner Expert Report ¶¶ 38–41); Doc. 1674-4 at 27 (Sealed Varner Expert Rebuttal Report ¶ 46). Mylan argues that this kind of information and data is precisely the type of information that an economist would use to reach conclusions about EpiPen manufacturing capacity.

Indeed, Federal Rule of Evidence 703 allows an expert to base his opinion on "facts or data in the case . . . [i]f experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject . . . ." Fed. R. Evid. 703. "The Advisory Committee Notes accompanying Rule 703 explain that in practice experts commonly seek the statements of others when forming their opinions." *U.S. Fid. & Guar. Co. v. Sulco, Inc.*, 171

F.R.D. 305, 307 (D. Kan. 1997); see also Fed. R. Evid. 703 advisory committee's notes to 1972 proposed rules (recognizing that a physician "bases his diagnosis on information from numerous sources and of considerable variety, including statements by patients and relatives . . . . "). Thus, courts routinely permit experts to rely on fact witness interviews to support their opinions, if that is the kind of information an expert in the field reasonably would rely on to form an expert opinion. See, e.g., Int'l Adhesive Coating Co. v. Bolton Emerson Int'l, Inc., 851 F.2d 540, 545 (1st Cir. 1988) (holding that an accountant and damages expert who reached his opinion based on a company's "business and financial records and through interviews with company personnel" was admissible because "it [is] obvious that these are sources of information normally and reasonably relied upon by accountants"); United States v. Affleck, 776 F.2d 1451, 1457 (10th Cir. 1985) (holding that an expert accountant properly relied on "conversations with defendant's employees" to form an opinion because this information was "of the type reasonably relied on by other experts in the accounting field in a case such as this"); *Inline Connection* Corp. v. AOL Time Warner Inc., 470 F. Supp. 2d 435, 442–43 (D. Del. 2007) (denying motion to exclude accountants' expert damages opinion that relied on "information . . . obtained through interviews with defendant's employees" because "the type of information and manner in which it was acquired is reasonably relied upon by experts within their field").

Sanofi argues that the Tenth Circuit's opinion in *Affleck* only considered whether an expert accountant's witness interview was the type of information reasonably relied on by other accountants when forming expert opinion. Thus, Sanofi contends that this case doesn't hold that quantitative sales data reviewed by an economist is the type of information reasonably relied on by economists—which is the issue here. The court is not persuaded that this distinction matters here. In one of the cases cited above, the First Circuit held that an accountant properly relied on

business and financial records, as well as interviews with company personnel, to form his damages opinion. Int'l Adhesive Coating Co., 851 F.2d at 545. Although Dr. Varner is an economist—not an accountant—he has performed a similar analysis here. Also, other courts have found that a damages expert may rely on company data and employee interviews to determine manufacturing capacity as part of an expert damages opinion. See Packgen v. Berry Plastics Corp., 46 F. Supp. 3d 92, 109 (D. Me. 2014) (holding that an expert accountant's damage calculation was supported by the facts and information he reviewed including plaintiff's "financial statements, sales history, and tax returns, consulting with [plaintiff's] bookkeeper on financial issues, and gathering information from [plaintiff's] company president regarding factors such as the company's manufacturing capacity and expectation of sales . . . . "); see also Roll-Rite, LLC v. Shur-Co, LLC, No. 12-cv-11150, 2014 WL 2217014, at \*9 (E.D. Mich. May 29, 2014) (finding admissible an accountant's expert damages opinion about plaintiff's manufacturing capacity that was based on information about plaintiff's "production and manufacturing strategy"). And, Sanofi has not directed the court to any case holding that an economist is unqualified to offer opinions similar to those of an accountant that courts have found admissible in the cases discussed. Thus, the court finds, Dr. Varner is qualified to offer his opinions about EpiPen manufacturing capacity. He is qualified to testify as an economist, and the facts and data he relied on to form his opinions are the kinds of information reasonably relied upon by other experts in the field.

Second, Sanofi argues that Dr. Varner's opinion about EpiPen manufacturing capacity is not reliable because he based his opinion on documents and conversations with Mr. Benson but that information is contradicted by other record evidence. Sanofi argues that one of Dr. Varner's own exhibits shows that, in some months, EpiPen and Auvi-Q combined sales exceeded Dr.

Varner's estimates of Meridian's manufacturing capacity. <u>Doc. 1677-3 at 19</u>, <u>58</u> (Varner Expert Report ¶ 41 & Ex. <u>10.1</u>); *see also* <u>Doc. 1674-3 at 19</u>, <u>58</u> (Sealed Varner Expert Report ¶ 41 & Ex. 10.1). But, Mylan responds, Dr. Varner's Expert Report explains that Mylan holds several weeks' worth of additional supply in its EpiPen inventory. <u>Doc. 1677-3 at 19</u> (Varner Expert Report ¶ 41); *see also* <u>Doc. 1674-3 at 19</u> (Sealed Varner Expert Report ¶ 41). So, Dr. Varner concludes, Mylan had the manufacturing capacity to meet the demand, even in months when combined EpiPen and Auvi-Q sales exceeded EpiPen production, because Mylan could rely on its reserve supply. *Id*.

Still, Sanofi contends Dr. Varner's opinions are unreliable because he failed to consider other evidence when he formed his opinion about manufacturing capacity, including a Warning Letter that the FDA sent to Meridian about serious quality issues with the EpiPen and the testimony from Meridian's General Manager and President about Mylan's decision not to issue an EpiPen recall despite the FDA's Warning Letter. These challenges about facts that Dr. Varner didn't consider when forming his opinion go to the weight the trier of fact should assign to his opinion—but not its admissibility. See In re Urethane Antitrust Litig., MDL No. 1616, No. 04-1616-JWL, 2012 WL 6681783, at \*3 (D. Kan. Dec. 21, 2012), aff'd 768 F.3d 1245 (10th Cir. 2014) (refusing to exclude expert testimony because expert had considered only certain evidence when forming his opinion because "[t]he extent to which [the expert] considered the entirety of the evidence in the case is a matter for cross-examination"); see also Stecyk v. Bell Helicopter Textron, Inc., 295 F.3d 408, 414 (3d Cir. 2002) (affirming trial court's admission of expert testimony and noting that "the burden of exploring the facts and assumptions underlying the testimony of an expert witness" rests "on opposing counsel during cross-examination"); Krys v. Aaron, 112 F. Supp. 3d 181, 195 n.15 (D.N.J. 2015) ("[A]n expert may base his opinion on a

particular version of disputed facts and the weight to be accorded to that opinion rests with the jury, and presents [a] proper subject for cross-examination." (citation and internal quotation marks omitted)). Sanofi's challenges are proper subjects for cross-examination. But this argument provides no reason for the court to exclude Dr. Varner's opinions as unreliable.

Finally, Sanofi argues that the court should exclude Dr. Varner's opinion in its entirety because he relies on his interviews with Mr. Benson to form his opinions but Mylan never disclosed Mr. Benson as a fact witness. Thus, Sanofi argues, Mylan has violated Fed. R. Civ. P. 26(a)(1). That Rule requires the parties to disclose the witnesses and documents that the disclosing party "may use to support its claims or defenses . . . . " Fed. R. Civ. P. 26(a)(1)(A)(i)— (ii). But, Mylan argues, Rule 26(a)(1) doesn't require a party to disclose the facts used to support expert opinion. Instead, Rule 26(a)(2) governs expert opinions. And, Mylan asserts it complied with this Rule by disclosing Dr. Varner's written report to Sanofi on February 4, 2019. Doc. 1442. The court agrees. Our court has noted that "[s]triking expert testimony is an extreme sanction disfavored by the court." Sibley v. Sprint Nextel Corp., No. 08-2063-KHV, 2012 WL 13027064, at \*3 (D. Kan. Dec. 13, 2012) (citing Gillum v. United States, 309 F. App'x 267, 270 (10th Cir. 2009)). And, other courts have refused to exclude expert reports in their entirety based on the argument that Rule 26(a)(1) required the party to disclose the underlying data the expert used to reach the opinion. See, e.g., In re Mercedes-Benz, No. 99-4311(WHW), 2006 WL 2129100, at \*10 (D.N.J. July 26, 2006) (finding it "questionable whether the subjects of [an expert's] interviews are used 'to support [a defendant's] claims or defenses,' and must be disclosed under Rule 26(a)(1)" but "[e]ven if the rule applies . . . the non-disclosure of [the expert's] interview subjects" was "substantially harmless and of limited surprise and prejudice to plaintiffs" because defendant served the expert report on plaintiffs more than a year before they

filed the motion to exclude and "[h]ad plaintiffs raised the issue at an earlier date, any prejudice could have been readily cured by the opportunity to depose the interview subjects" so the court refused to impose the "extreme sanction" of excluding the expert report) (quoting Fed. R. Civ. P. 26(a)(1)) (further citation and quotation marks omitted)); *United States v. Dentsply Int'l Inc.*, No. Civ.A. 99-5 MMS, 2000 WL 654378, at \*5–7 (D. Del. May 10, 2000) (holding that Rule 26(a)(1) didn't require a party to disclose "the identities of individual survey respondents and their completed survey questionnaires relating to a survey conducted by a party's expert").

The case that Sanofi cites to support its request that the court exclude Dr. Varner's expert opinion doesn't apply here. In *Ford Motor Co. v. Thermoanalytics, Inc.*, plaintiffs had served discovery requests seeking documents about defendant's finances. No. 14-cv-13992, 2016 WL 1465015, at \*2 (E.D. Mich. Apr. 14, 2016). Defendant refused to produce the documents. *Id.*But later, defendant served an expert report that relied on the financial documents. *Id.*Defendant eventually produced the documents, but conceded that it had "not immediately disclos[ed] the documents upon becoming aware of their relevance." *Id.* at \*3. The court found that defendant had violated Rule 26(a) because, it explained, a party must produce "any documents in that party's possession relied upon by the expert . . . under Rule 26(a)." *Id.* The court also found that the late disclosure was neither justified nor harmless. *Id.* at \*3–4.

Nevertheless, the court refused to exclude the expert report under Rule 37(c) because it was "too severe of a sanction." *Id.* at \*4. Instead, it ordered defendant to pay costs and attorneys' fees for plaintiffs to depose witnesses about the documents. *Id.* 

Unlike *Ford Motor*, Mylan didn't refuse to produce documents in its possession that are relevant to its claims. And, even if Mylan's failure to name Mr. Benson as a witness in its Rule 26(a)(1) disclosures amounted to a violation of that Rule, Sanofi hasn't shown any prejudice

resulting from its purported violation. Indeed, Sanofi learned about Dr. Varner's interviews with Mr. Benson when Mylan disclosed his Expert Report on February 4, 2019. Sanofi has had plenty of time to bring this issue to the court's attention, if it believed that it needed to conduct additional discovery about Mr. Benson's conversations with Dr. Varner. It didn't. Sanofi hasn't shown that the "extreme sanction" of excluding Dr. Varner's Expert Report is appropriate under the facts here. *Sibley*, 2012 WL 13027064, at \*3.

In sum, the court concludes that Dr. Varner is qualified to opine about EpiPen manufacturing capacity and his opinions on this subject are sufficiently reliable.

#### 3. Conclusion

For all the reasons explained, the court denies Sanofi's Motion to Exclude the Expert Reports and Testimony Offered by Thomas Varner.

# IV. Mylan's Motions

Mylan has filed motions seeking to exclude the opinions and testimony of four of Sanofi's experts: (1) Dr. Fiona M. Scott Morton, (2) Dr. Mary Ann Michelis, (3) Eduardo Schur, and (4) Dr. Steven N. Wiggins. The court addresses each motion, separately, below.

# A. Motion to Exclude Opinions of Dr. Fiona M. Scott Morton

Mylan asks the court to exclude the opinions of Dr. Fiona M. Scott Morton. Sanofi has retained Dr. Scott Morton as an expert witness to:

(1) provide an overview of the economics of competition in the pharmaceutical industry generally, and in the Epinephrine Auto-Injector ("EAI") market more specifically; (2) determine the appropriate relevant market within which to assess the extent of Mylan's market power arising from its marketing and sale of the EpiPen along with the competitive consequences of its actions; (3) assess Mylan's market power in that market; (4) assess the competitive consequences of Mylan's actions on consumers and the competitive process in that market; (5) evaluate the extent to which procompetitive benefits (if any) outweigh any competitive harm caused by Mylan's actions; and (6) quantify the injury suffered by Sanofi (if any) from Mylan's anticompetitive conduct.

Doc. 1680-4 at 7 (Scott Morton Expert Report  $\P 8$ ).

Mylan's Motion to Exclude Dr. Scott Morton's opinions just attacks the reliability of her opinions about antitrust liability and damages. Mylan doesn't challenge Dr. Scott Morton's qualifications to offer expert opinion. In Part.III.A.1., supra, the court discussed some of Dr. Scott Morton's qualifications. As mentioned, she is the Theodore Nierenberg Professor of Economics at the Yale School of Management, where she has taught since 1999. Id. at 6 (Scott Morton Expert Report ¶ 1). She also has taught at the business schools of Stanford University and the University of Chicago. Id. Dr. Scott Morton holds a Ph.D. in Economics from MIT. Id. She teaches courses "in the area of competitive strategy and competition economics and policy." Id. (Scott Morton Expert Report ¶ 2). Her research focuses on "the area of empirical Industrial Organization, the sub-field of microeconomics that includes competition economics and the study of firm behavior." Id. Dr. Scott Morton has authored or co-authored almost 50 scholarly articles about economics and law published by leading scholarly and professional journals. *Id.* Her work has appeared in the American Economic Review, the RAND Journal of Economics, the Journal of Industrial Economics, the Quarterly Journal of Economics, the Antitrust Law Journal, and the Yale Law Journal. *Id*.

Dr. Scott Morton previously served as the Deputy Assistant Attorney General for Economic Analysis with the Antitrust Division of the Department of Justice. *Id.* (Scott Morton Expert Report ¶ 3). In this role, she served as the chief economist in the Antitrust Division, where she advised the Assistant Attorney General for Antitrust on enforcement matters and competition policy issues. *Id.* Dr. Scott Morton also has served as an economic consultant for private clients and the Federal Trade Commission, providing both consulting and expert testimony. *Id.* (Scott Morton Expert Report ¶ 4). She has served as an economic expert and has

testified before the International Trade Commission, as well as in federal and state courts and other venues. *Id.* Dr. Scott Morton also has expertise in the area of pharmaceutical markets. *Id.* (Scott Morton Expert Report ¶ 5). She has published papers, testified before Congress, and provided economic expert testimony in federal and state courts about pharmaceutical pricing, innovation, and marketing practices. *Id.* at 6–7 (Scott Morton Expert Report ¶ 5).

Based on her background, education, and experience, the court finds that Dr. Scott Morton is qualified to offer her expert opinions in this case. So, the court now turns to Mylan's arguments for why the court should exclude some of Dr. Scott Morton's opinions as unreliable. Mylan asserts four arguments to support its request to exclude. *First*, Mylan argues that Dr. Scott Morton's damages opinions are unreliable and speculative because she bases them on unreliable data. *Second*, Mylan contends that Dr. Scott Morton's "Effective Entrant Burden" ("EEB") calculations aren't reliable because EEB is a novel theory not accepted by courts or relied on by other economists. *Third*, Mylan argues that Dr. Scott Morton's calculation of entrenched share is not supported by the record. *Finally*, Mylan asserts that Dr. Scott Morton improperly opines about the state of mind of various parties. The court addresses each of these four arguments, below.

# 1. Are Dr. Scott Morton's damages opinions unreliable and speculative?

Dr. Scott Morton offers expert opinions estimating the antitrust injury Sanofi sustained from Mylan's alleged anticompetitive conduct. *See* Doc. 1680-4 at 117–133 (Scott Morton Expert Report ¶¶ 197–226); *see also* Doc. 1680-6 at 74–94 (Scott Morton Expert Reply Report ¶¶ 161–209). Dr. Scott Morton's Expert Reports estimate damages that Sanofi sustained during two distinct time periods. *See* Doc. 1680-4 at 118 (Scott Morton Expert Report ¶ 200); *see also id.* at 118–132 (Scott Morton Expert Report ¶¶ 201–225); Doc. 1680-6 at 81–94 (Scott Morton

Expert Reply Report ¶¶ 173–207). The first period, from 2013 to 2015, is "the period during which Sanofi sold Auvi-Q, up through the voluntary recall of Auvi-Q." Doc. 1680-4 at 118 (Scott Morton Expert Report ¶ 200). The second period, from 2017 to 2029, starts "with the point in time at which Sanofi would have relaunched Auvi-Q were it not for Mylan's anticompetitive conduct" and runs through "the first half of 2029—when the Auvi-Q patent was set to expire." *Id.* Mylan's motion refers to the damage calculation for the first period as "Pre-Recall Damages" and the one for the second period as "Post-Recall Damages." The court adopts that same convention in this Order.

Mylan argues that Dr. Scott Morton's opinions for both Pre-Recall Damages and Post-Recall Damages are unreliable. The court addresses the two damages models, separately, below.

# a. Pre-Recall Damages Model

To calculate Pre-Recall Damages, Dr. Scott Morton "construct[ed] a 'but-for' world" where she predicted how Auvi-Q would have performed in the EAI market "but-for" Mylan's alleged unlawful conduct. Doc. 1680-4 at 118–19 (Scott Morton Expert Report ¶ 199, 201). Dr. Scott Morton's calculations start by relying on a 2012 Sanofi pre-launch forecast ("Sanofi 2012 Forecast") that projected Auvi-Q's market share, sales, costs, and profits. *Id.* at 119 (Scott Morton Expert Report ¶ 201); *see also* Doc. 1680-10 (Sanofi 2012 Forecast). Then, Dr. Scott Morton compared those projections to Auvi-Q's actual profit and loss statement. Doc. 1680-4 at 126 (Scott Morton Expert Report ¶ 210–11). Finally, she calculated the difference between the Sanofi 2012 Forecast's "but-for" profits and what Sanofi actually earned from Auvi-Q sales to reach her calculation of Pre-Recall Damages. *Id.* (Scott Morton Expert Report ¶ 211).

Mylan argues that Dr. Scott Morton's Pre-Recall Damages Model is unreliable for two reasons. *First*, Mylan contends that Dr. Scott Morton improperly relied on the Sanofi 2012

Forecast when forming her opinion. *Second*, Mylan asserts that Dr. Scott Morton attributed all Auvi-Q losses to Mylan instead of isolating just those losses attributable to Mylan's alleged unlawful conduct. For either reason, Mylan argues the court should exclude Dr. Scott Morton's Pre-Recall Damages Model.

#### i. Reliance on Sanofi 2012 Forecast

Mylan contends that Dr. Scott Morton's Pre-Recall Damages Model is unreliable because she never validated independently the Sanofi 2012 Forecast that she relied on to calculate damages. Mylan argues that Dr. Scott Morton "knows virtually nothing about the Sanofi 2012 Forecast, so she cannot account for, let alone cure, its inherent unreliability, rendering her model unreliable." Doc. 1680-2 at 12–13.

Mylan correctly argues that the Tenth Circuit prohibits expert opinion that "merely parrot[s] the opinions of other experts whose conclusions are not themselves in the record."

Beck's Office Furniture & Supplies, Inc. v. Haworth, Inc., Nos. 95-4018, 95-4029, 94 F.3d 655

(table), 1996 WL 466673, at \*7 (10th Cir. Aug. 16, 1996). The Circuit held in Beck's Office that the trial court erred by admitting expert opinion about the value of a business because "[t]he numbers underlying [the expert's] opinion were merely an averaging of the two . . . reports . . . that were prepared by business brokers." Id. And thus, the expert had not "provide[d] an independent opinion of the value of the business." Id. The Circuit reached a similar conclusion in TK-7 Corp. v. Estate of Barbouti, 993 F.2d 722 (10th Cir. 1993). There, the Tenth Circuit affirmed the trial court's exclusion of an expert's damages opinion that relied on another individual's sales projections because "the expert failed to demonstrate any basis for concluding that another individual's opinion on a subjective financial prediction was reliable, other than the fact that it was the opinion of someone he believed to be an expert who had a financial interest in

making an accurate prediction." *Id.* at 732. The Circuit explained that the expert's "lack of familiarity with the methods and the reasons underlying [the other individual's] projections virtually precluded any assessment of the validity of the projections through cross-examination of [the expert]." *Id*.

Sanofi responds that, unlike the experts in these cases, Dr. Scott Morton independently has validated the reliability of the Sanofi 2012 Forecast. Thus, Sanofi contends, it was proper for her to rely on the Sanofi 2012 Forecast to form her opinions. Specifically, Dr. Scott Morton testified that she knew the Auvi-Q Brand Team prepared the Sanofi 2012 Forecast for the purpose of launching Auvi-Q. Doc. 1796-4 at 17-18 (Scott Morton Dep. 273:17-274:13). She testified that the Auvi-Q Brand Team based the Sanofi 2012 Forecast on their research and expertise. Id. at 17–18 (Scott Morton Dep. 273:20–274:13, 276:9–19). She further testified that the Sanofi 2012 Forecast's assumptions for Wholesale Acquisition Cost ("WAC") prices and rebates were "relatively conservative" and consistent with Mylan's projections for how Auvi-Q would perform in the EAI market. Id. at 19 (Scott Morton Dep. 290:19–292:15). Dr. Scott Morton conceded she did not know "what components or assumptions" go into the sales numbers of the Sanofi 2012 Forecast, but she knows they reflect "the experts at Sanofi's best estimate of the demand curve." Doc. 1680-5 at 58 (Scott Morton Dep. 280:3-9). Also, she testified that she relied on the Sanofi 2012 Forecast because the Auvi-Q Brand Team created it based on their "knowledge of how to run [Sanofi's] business" and thus, they included "assumptions in this forecast of normal operating procedure." *Id.* at 60–61 (Scott Morton Dep. 282:12–283:20).

Also, Dr. Scott Morton spoke with Bryan Downey, a former Sanofi Vice President and the Auvi-Q brand leader, "[t]o ensure" she was relying on "the most appropriate forecast." Doc. 1680-4 at 119 (Scott Morton Expert Report ¶ 201 n.392). According to Dr. Scott Morton's

Expert Report, Mr. Downey "confirmed that this forecast was Sanofi's best and most reliable forecast for how Auvi-Q was expected to perform at the time of launch." *Id.*; see also Doc. 1680-6 at 82 (Scott Morton Expert Reply Report ¶ 175). Dr. Scott Morton also compared the Sanofi 2012 Forecast to Mylan's forecasting for Auvi-Q in the "but-for" world. Doc. 1680-4 at 118–19 (Scott Morton Expert Report ¶¶ 199–201). She found that Mylan's forecasts were "remarkably similar" to Sanofi's projections, and she explained that "provid[ed] [her] with confidence that the but-for world" she had constructed "is reasonable." Id. at 118 (Scott Morton Expert Report ¶ 199); see also id. at 119 (Scott Morton Expert Report ¶ 201) (noting the similarities between Mylan's projections for Auvi-Q and Sanofi's).<sup>5</sup>

Finally, Dr. Scott Morton corroborated the data from the Sanofi 2012 Forecast by looking at two other sets of data. Specifically, Dr. Scott Morton analyzed (1) Auvi-Q's performance in Canada, and (2) Auvi-Q's performance on two formularies where Dr. Scott Morton found that the effects of Mylan's exclusionary conduct weren't as great compared to other parts of the market. Mylan argues that neither data set supports Dr. Scott Morton's independent verification

Mylan asserts that Sanofi mischaracterizes Mylan's forecast for Auvi-Q's 2016 market share. Doc. 1866-1 at 11 (citing Doc. 1866-12 at 5 & Doc. 1866-13 at 6). But neither of these two Mylan forecasts is the one that Dr. Scott Morton relied on to conclude that the two companies' forecasts for 2016 were "remarkably similar." Compare Doc. 1680-4 at 119 (Scott Morton Expert Report ¶ 201 n.390 (citing MYEP01209503)) with Doc. 1866-12 at 5 (MYEP00088248) & Doc. 1866-13 at 6 (MYEP00152802). Dr. Scott Morton relied on the latter two forecasts when concluding that Sanofi and Mylan's projections for Auvi-Q by 2015 were "remarkably similar." Doc. 1680-4 at 119 (Scott Morton Expert Report ¶ 201 n.391 (first citing MYEP00088189 at 246, 248; then citing MYEP00152753 at 800, 802)). And, indeed, the forecasts in these two Mylan documents for 2015 are similar to the projections made by the Sanofi 2012 Forecast. See id. (Scott Morton Expert Report ¶ 201 n.392); Doc. 1680-10 at 4 (Sanofi 2012 Forecast). Mylan hasn't submitted the forecast with Bates number MYEP01209503—the document Dr. Scott Morton relied on to conclude that Mylan and Sanofi's 2016 forecasts were similar because, according to her Expert Report, both forecasts predicted that Auvi-Q would achieve about a 40% market share by then. Doc. 1680-4 at 119 (Scott Morton Expert Report ¶ 201 n.390 (citing MYEP01209503)); see also id. (Scott Morton Expert Report ¶ 201 n.392). Since this document isn't part of the record, the court can't conclude that Sanofi has mischaracterized Mylan's 2016 forecast, as Mylan asserts.

of the Sanofi 2012 Forecast. To answer the question, the court takes a closer look at each set of data.

First, Dr. Scott Morton compared the Sanofi 2012 Forecast to Auvi-Q's performance in Canada where Auvi-Q and EpiPen received the same treatment on drug formularies. See Doc. 1680-4 at 119 (Scott Morton Expert Report ¶ 202) (explaining that she examined "Auvi-Q's share of the Canadian market" where "Auvi-Q and EpiPen competed on a relatively level playing field"). Dr. Scott Morton explained she found "it is reasonable to look to the Canadian experience" for "the limited purpose of assessing the market share that Auvi-Q would have obtained in the United States absent Mylan's conduct" because the Canada sales "serve[] as a good guidepost for assessing market shares" in the but-for world. Id. at 120 (Scott Morton Expert Report ¶ 203). And, she demonstrated that this "additional, real-world evidence" "corroborated" the market share projections made in the Sanofi 2012 Forecast. Id. at 119 (Scott Morton Expert Report ¶ 202).

Mylan argues that Dr. Scott Morton's comparisons to Canada aren't reliable because, as she conceded in her deposition, Canada is a "different market" that involves making "different business decisions," the "details" of which she did "not consider[]...." Doc. 1680-5 at 148–49 (Scott Morton Dep. 381:25–382:14). But, as Sanofi correctly asserts, Dr. Scott Morton's Expert Report acknowledges those differences and explains that she was "look[ing] to the Canadian experience only for the limited purpose of assessing Auvi-Q's market share in the but-for world." Doc. 1680-4 at 120–21 (Scott Morton Expert Report ¶ 203). Indeed, courts have approved this type of comparison to a product's performance in another market when assessing antitrust damages. See, e.g., Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 124–25 (1969) (holding the trial court could "infer" from "circumstantial evidence" that, but for the

antitrust violation, plaintiff would have "secur[ed] a share of the market [in Canada] comparable to that which it enjoyed in the United States"); *Nat'l Farmers' Org. v. Associated Milk*Producers, 850 F.2d 1286, 1297–98 (8th Cir. 1988) (approving use of the market share achieved in a test market "as a yardstick against which to measure . . . performance" in other markets even though the "test market theory is not perfect"). Dr. Scott Morton's comparison of Auvi-Q's market share in Canada to corroborate her use of the Sanofi 2012 Forecast was an appropriate comparison here. Dr. Scott Morton adequately explained why she looked to the Canadian data, while recognizing the limitations of that data, to verify reliability of the market share projections found in the Sanofi 2012 Forecast. And, she concluded, the Canadian data corroborated the Sanofi 2012 Forecast's market share projections that she used when calculating the Pre-Recall Damages.

Second, Dr. Scott Morton corroborated the Sanofi 2012 Forecast with Auvi-Q's performance on "two formularies" where "Auvi-Q secured equal treatment to EpiPen, and for which there is reason to believe that the spillover effects [from Mylan's alleged exclusionary conduct] were not as strong as they were in other parts of the country." Doc. 1680-4 at 121–25 (Scott Morton Expert Report ¶ 204–07). Mylan asserts that Dr. Scott Morton's selection of these two formularies was an "arbitrary" choice. Doc. 1680-2 at 13. Mylan contends that other formularies covered Auvi-Q and EpiPen equally but had lower Auvi-Q market shares. *Id.* But, Dr. Scott Morton's Expert Reports explain why she chose these two formularies and her methodology for determining that they would have lesser spillover effects. See Doc. 1680-4 at 121–22 (Scott Morton Expert Report ¶ 204–05) (explaining that she reached her conclusion that the spillover effects for the two formularies were not as great as they were in other places because the Horizon Blue Cross Blue Shield formulary was "a relatively large formulary in New

Jersey" and the University of Michigan formulary was "a formulary that is used by a university population, with access to a university hospital"); see also Doc. 1680-6 at 83–84 (Scott Morton Expert Reply Report ¶ 180).

Based on all of the above, Sanofi argues that Dr. Scott Morton adequately verified the Sanofi 2012 Forecast. The court agrees. Dr. Scott Morton's independent verification of the Sanofi 2012 Forecast makes her Pre-Recall Damages calculation—an opinion that relies on that forecast—reliable. As discussed above, an expert opinion cannot "merely parrot the opinions of other experts whose conclusions are not themselves in the record." Beck's Office, 1996 WL 466673, at \*7. But, an expert may rely on data produced by another expert so long as the testifying expert sufficiently evaluates the validity and confirms the reliability of the information produced by the other expert. See, e.g., In re SemCrude L.P., 648 F. App'x 205, 213–14 (3d Cir. 2016) (holding that "this is one of those cases where an expert may rely on the estimates of others" because the expert "explained the reasons for his reliance on the . . . analysis; and [he] then adjusted the . . . valuation based on his own analysis and judgment while giving cogent reasons to support his conclusions"); In re Namenda Direct Purchaser Antitrust Litig., 331 F. Supp. 3d 152, 180–82 (S.D.N.Y. 2018) (holding that expert opinion that relied on defendant's forecasts was admissible because the experts had "analyz[ed] and evaluat[ed] [the] forecasts for reliability" and noting that "use of [d]efendants' own forecasts to model a but-for world has been held to be a sound economic methodology"); Apotex, Inc. v. Cephalon, Inc., 321 F.R.D. 220, 233 (E.D. Pa. 2017) (finding that a damages expert properly relied on a company's internal business projections to form his opinion because he "demonstrate[d] that he considered the reliability of the market projections, that he understood how they were created, and that he will be able to provide detailed explanations as to why he found their use appropriate," and noting the question

"[w]hether [the expert] relied on the best data in forming his opinions is a question for the jury"); In re Syngenta AG MIR 162 Corn Litig., No. 14-md-2591-JWL, 2017 WL 1738014, at \*14 (D. Kan. May 4, 2017) (refusing to exclude expert opinion that was based on "certain insect fact sheets" because the expert "was sufficiently familiar with the source of the data in those sheets, and he further testified that he confirmed the information by checking additional sources"); Nat'l Credit Union Admin. Bd. v. UBS Sec., LLC, Nos. 12-2591-JWL, 12-2648-JWL, 2016 WL 7496106, at \*6 (D. Kan. Dec. 30, 2016) (refusing to exclude defendants' expert opinion that relied on a third party's analysis because plaintiff "has not cited to any authority suggesting that defendants' experts must be able to replicate the analysis on which they rely; rather, Rule 703 merely requires that the experts reasonably rely on their underlying facts and data," and, under the facts there, "the experts' use of the [third party's] analysis was not without basis"); In re Chocolate Confectionary Antitrust Litig., No. 1:08-MDL-1935, 2013 WL 11305184, at \*4 (M.D. Pa. May 10, 2013) (holding that a damages expert reasonably relied on a company's profit and loss data to form his opinions because, the expert explained, it was "data that [company] executives rely upon in the normal course of business to analyze product profitability" and, the court concluded, was "far from speculative").

Mylan cites several cases that, it contends, require the court to exclude Dr. Scott Morton's testimony because she relied on the Sanofi 2012 Forecast to form her damages opinions. For example, in *ZF Meritor*, *LLC v. Eaton Corp.*, 696 F.3d 254 (3d Cir. 2012), the Third Circuit affirmed the district court's exclusion of an expert's damages opinion based on "a one-page set of profit and volume projections" because the expert did not know "the circumstances under which such projections were created or the assumptions on which they were based." *Id.* at 292. The Circuit recognized, however, that "[i]n some circumstances, an expert

might be able to rely on the estimates of others in constructing a hypothetical reality, but to do so, the expert must explain why he relied on such estimates and must demonstrate why he believed the estimates were reliable." *Id.* (first citing Fed. R. Evid. 702; then citing *Daubert*, 509 U.S. at 592–95 (further citation omitted)). But, the Third Circuit concluded, the expert hadn't demonstrated the reliability of the projections at issue in *ZF Meritor*. *Id.* at 292–93. Instead, the expert "was generally aware of the circumstances under which the [projections were] created and the purposes for which it was used" but, importantly, "he lacked critical information that would be necessary for [defendant] to effectively cross-examine him" because "he did not know who initially calculated the . . . figures," "whether the . . . projections were calculated by [plaintiff's] management, lower level employees at [plaintiff], or came from some outside source," or "the methodology used to create the [projections] or the assumptions on which the [projections'] price and volume estimates were based." *Id.* at 293.

In contrast, here, Dr. Scott Morton has supplied more than a "general[] aware[ness]" about how the Sanofi 2012 Forecast was created. *Id.* As discussed above, Dr. Scott Morton testified that she knew the Auvi-Q Brand Team created the Sanofi 2012 Forecast for the purpose of launching Auvi-Q and that the Brand Team based the data and assumptions in that forecast on its research and expertise. Dr. Scott Morton also corroborated the data in the Sanofi 2012 Forecast by comparing it to Mylan's forecasting for Auvi-Q, as well as Auvi-Q's performance in Canada and on two drug formularies that treated Auvi-Q the same as EpiPen. Also, unlike the one page set of profit and volume projections at issue in *ZF Meritor*, the Sanofi 2012 Forecast is a multi-page document that contains background information about Sanofi's rationale for the projections, including that Sanofi based its pricing forecasts "on multiple rounds of research from payer, physician and patient perspectives." <u>Doc. 1680-10 at 2</u> (Sanofi 2012 Forecast). On

this record, Dr. Scott Morton adequately has "explain[ed] why [s]he relied on such estimates" and has "demonstrate[d] why [s]he believed the estimates were reliable." *ZF Meritor*, 696 F.3d at 292. And, unlike the expert at issue in *ZF Meritor*, Dr. Scott Morton possesses the "critical information that would be necessary for [Mylan] to effectively cross-examine" her. *Id.* at 293.

Similarly, the other cases Mylan relies on to support its argument that Dr. Scott Morton hasn't validated the reliability of the Sanofi 2012 Forecast have very different facts from the ones presented here. In each case, the expert based opinions on unverified or unreliable information, thus rendering the expert opinion unreliable and inadmissible. See, e.g., Carbo Ceramics, Inc. v. Keefe, 166 F. App'x 714, 724 (5th Cir. 2006) (concluding that expert's damages model "based on speculative revenues and operating profit from an unbuilt plant" made the damages model "itself, inherently speculative"); Zenith Elecs. Corp. v. WH-TV Broad. Corp., 395 F.3d 416, 420 (7th Cir. 2005) (recognizing that, although experts "commonly extrapolate from existing data," the expert's reliance on a company's "internal projections" didn't "provide a reliable estimate" on which to base expert opinion because it "rest[ed] on [the company's] sayso" and represented its "hopes rather than the results of scientific analysis" (citations and internal quotation marks omitted)); Elorac, Inc. v. Sanofi-Aventis Canada, Inc., No. 14 C 1859, 2017 WL 3592775, at \*14 (N.D. Ill. Aug., 21, 2017) (excluding plaintiff's proffered expert damages opinion because it relied on a Sanofi sales forecast and the expert hadn't demonstrated that it "was the product of a sufficiently reliable forecasting process, rather than a hopeful sales target," and as a consequence, "the expert opinion [was] not a permissible extrapolation from existing data but an exercise in speculation that is connected to existing data only by the *ipse dixit* of the expert" (citation and internal quotation marks omitted)); Fail-Safe L.L.C. v. A.O. Smith Corp.,

The court recognizes that Sanofi was on the other side of this argument in *Elorac*. But, in *Elorac*, the expert used Sanofi's forecasting to form his opinions but never verified Sanofi's forecasts

744 F. Supp. 2d 870, 887–88 (E.D. Wisc. 2010) (excluding expert opinion that failed to "independently verif[y]" or "seriously scrutinize" the data the expert relied on to form his opinion because, without such analysis, the expert failed to show that the numbers he relied on were "anything more than a hopeful projection" instead of "reliable sources of information" (citations and internal quotation marks omitted)); *In re Universal Serv. Fund Tel. Billing Practices Litig.*, No. 02-MD-1468-JWL, 2008 WL 4382141, at \*7–8 (D. Kan. Sept. 26, 2008) (granting motion to exclude experts' damages opinion because it relied on a spreadsheet and the experts did "not know how or when or why or by whom the spreadsheet was created, or anything else about the reliability of the figures contained therein" so "the reliability of the data on that spreadsheet cannot be assessed at trial" by the opposing party); *Diabetes Ctrs. of Am., Inc. v. Healthpia Am., Inc.*, No. H-06-3457, 2008 WL 375505, at \*2 (S.D. Tex. Feb. 11, 2008) (finding expert "simply accepted" projections and "fail[ed] to show any basis for believing someone else's projections" when forming his opinion, and thus excluding the opinion as "speculative and unreliable").

Because Dr. Scott Morton has explained sufficiently why she relied on the Sanofi 2012 Forecast to form her damages opinion and why she found its projections reliable, the court declines to exclude Dr. Scott Morton's Pre-Recall Damages opinion simply because she based them on the Sanofi 2012 Forecast.

independently. *Elorac*, 2017 WL 3592775, at \*14. The Illinois federal court held that the expert couldn't just rely on "someone's say-so" but instead must "rest [the expert opinion] on a scientific analysis." *Id.* (citation and internal quotation marks omitted). And, because the expert hadn't done that analysis, the *Elorac* court excluded the opinion. *Id.* at \*16. In contrast, here, Dr. Scott Morton has verified the Sanofi 2012 Forecast independently, explaining why she relied on those projections and why she finds them reliable.

#### ii. Accounting for Mylan's Lawful Behavior

Mylan next argues that Dr. Scott Morton's Pre-Recall Damages Model is unreliable because she attributes all of Auvi-Q's losses to Mylan's alleged misconduct but fails to account for other, lawful conduct that could have affected Auvi-Q's performance in the EAI market. This kind of attack on an expert's opinion in a recognized one. Many courts—including this one—have excluded expert damages opinions that don't "incorporate all aspects of the economic reality of [a particular] market" and don't "separate lawful from unlawful conduct." Concord Boat Corp. v. Brunswick Corp., 207 F.3d 1039, 1057 (8th Cir. 2000); see also Blue Cross & Blue Shield United of Wisc. v. Marshfield Clinic, 152 F.3d 588, 593 (7th Cir. 1998) (holding that a damages analysis "that fail[s] to correct for salient factors, not attributable to the defendant's misconduct, that may have caused the harm of which the plaintiff is complaining do not provide a rational basis for a judgment"); Pound v. Airosol Co., Inc., No. 02-2632-CM, 2005 WL 6429719, at \*5 (D. Kan. Mar. 31, 2005) (excluding expert's damages opinion in a Lanham Act case because she failed to consider factors unrelated to defendants' alleged unlawful conduct, like the price differential between two products, when calculating lost profits); First Savings Bank, F.S.B. v. U.S. Bancorp, 117 F. Supp. 2d 1078, 1084 (D. Kan. 2000) (excluding lost profits damages opinion that "improperly attributed all of plaintiff's losses to the defendants' allegedly illegal acts, despite the presence of significant other factors"). Mylan asserts that Dr. Scott Morton's opinion is just like the expert opinions excluded in the cited cases. That is, Mylan argues that Dr. Scott Morton improperly has attributed the entire difference between the Sanofi 2012 Forecast and Auvi-Q's actual profit and loss statement to Mylan's alleged unlawful activity "without a serious effort to address differences not attributable to Mylan's alleged misconduct." Doc. 1680-2 at 15.

More specifically, Mylan identifies several factors that, it contends, Dr. Scott Morton failed to consider when performing her damage analysis. The court summarizes Mylan's arguments to support excluding Dr. Scott Morton's damages analysis for this reason. Then, it explains why it denies Mylan's Motion to Exclude Dr. Scott Morton's Pre-Recall Damages opinions on this basis.

First, Mylan asserts that Dr. Scott Morton's damage calculation for 2013 is flawed because she attributes Auvi-Q's failure to reach the projections of the Sanofi 2012 Forecast to Mylan's alleged anticompetitive behavior. But, Mylan contends, this conclusion conflicts with Dr. Scott Morton's own analysis and with other evidence in the case about Auvi-Q's performance in 2013. For example, Dr. Scott Morton's Expert Reply Report recites that 2013 was "before most of Mylan's exclusionary contracts with [pharmacy benefit managers] took effect." Doc. 1680-6 at 82 (Scott Morton Expert Reply Report ¶ 177); see also id. at 28 (Scott Morton Expert Reply Report ¶ 2013, Sanofi was gaining formulary access, momentum, and market share" and "Sanofi's initial success only halted when Mylan's exclusionary agreements went into effect.")). Also, Sanofi witnesses testified that Auvi-Q performed well in 2013. See, e.g., Doc. 1680-14 at 6 (Downey Dep. 2:1–7); Doc. 1680-13 at 8 (Barry Dep. 24:2–5).

But, Sanofi responds, Dr. Scott Morton recognized that, after Auvi-Q's launch, it was "on track to achieve even more success than originally forecasted" because it was "outperforming" forecasts and this success "alarmed" Mylan. Doc. 1680-6 at 27 (Scott Morton Expert Reply Report ¶ 47). Also, Dr. Scott Morton identified anticompetitive activity that Mylan initiated well before 2013, in an effort to exclude Auvi-Q from the EAI market. *Id.* at 46–47 (Scott Morton Expert Reply Report ¶¶ 97–98) (describing meetings where Mylan discussed exclusionary

strategy "as early as 2011" and describing the changes Mylan made to its contracting strategies in anticipation of Auvi-Q's launch). Dr. Scott Morton's Expert Reply Report also describes exclusionary contracts that Mylan put into place throughout 2013. *Id.* at 50 (Scott Morton Expert Reply Report ¶ 104). And, it highlights Mylan's internal document reciting that Mylan had secured exclusionary contracts "that blocked Auvi-Q from close to 1/3 of the US population by the end of 2013 alone." *Id.* 51–52 (Scott Morton Expert Report ¶ 106) (internal quotation marks omitted). So, Sanofi contends, Dr. Scott Morton's analysis adequately explains why she found it appropriate to attribute all of the difference between Auvi-Q's actual performance in 2013 and the Sanofi 2012 Forecast for that same year to Mylan's alleged anticompetitive conduct.

Second, Mylan argues that Dr. Scott Morton didn't consider whether Sanofi's failure to anticipate higher rebate percentages caused Auvi-Q's underperformance. But, Sanofi responds, Dr. Scott Morton's Expert Reports attribute the higher rebate percentages for Auvi-Q specifically to Mylan's exclusionary conduct. Dr. Scott Morton explains that, after Auvi-Q's launch, Mylan "offered significantly higher rebates (along with price protection) that were conditioned not only on EpiPen getting preferred placement on the formulary, but also on Auvi-Q being placed at a significant disadvantage to the EpiPen—either by being excluded altogether or through the imposition of a step edit or prior authorization." Doc. 1680-4 at 34 (Scott Morton Expert Report ¶ 43). Dr. Scott Morton's damages calculation includes losses incurred for "additional rebates that Sanofi was forced to give to Third Party Payors just to secure access to formularies." Id. at 126 (Scott Morton Expert Report ¶ 210). Dr. Scott Morton explains that Sanofi's initial "rebates were consistent with its goal of gaining formulary access" but by "mid-2013, Sanofi quickly increased its initial rebate offers for access based upon payer and [pharmacy benefit manager]

feedback." <u>Doc. 1680-6 at 30</u> (Scott Morton Expert Reply Report ¶ <u>53</u>). Thus, Sanofi argues, the higher rebate percentages weren't lawful conduct that Dr. Scott Morton failed to consider in her analysis. Instead, Dr. Scott Morton specifically attributes the higher rebate percentages to Mylan's anticompetitive conduct.

Finally, Mylan contends that Dr. Scott Morton failed to account for other factors that affected Auvi-Q sales including consumer awareness, sales force performance, marketing costs, manufacturing costs, and quality issues and returns. Sanofi responds that Mylan's criticisms go to factors that occurred in the real world (as opposed to her constructed "but-for" world), and thus "fail to account for Sanofi's success when unencumbered by Mylan's exclusionary conduct." Doc. 1795 at 17. To measure Sanofi's success in the but-for world, Dr. Scott Morton relies on the Sanofi 2012 Forecast because, as she has explained and the court already has discussed, she believes it's a reliable estimate for how Sanofi would have performed but-for Mylan's anticompetitive conduct.

On this *Daubert* motion, Sanofi doesn't need to establish that Dr. Scott Morton's opinions are "undisputably correct." *Etherton v. Owners Ins. Co.*, 829 F.3d 1209, 1217 (10th Cir. 2016) (citation and internal quotation marks omitted). Instead, the court must determine whether "the method employed by the expert in reaching the conclusion is scientifically sound and that the opinion is based on facts which sufficiently satisfy Rule 702's reliability requirements." *Id.* at 1217–18 (citations and internal quotation marks omitted). In other words, are her opinions sufficiently reliable that a jury should hear them? Dr. Scott Morton's opinions satisfy that standard here. She adequately explains why she attributes all of Auvi-Q's losses to Mylan's alleged misconduct. And, she explains why she didn't account for other, lawful conduct

in her analysis: She doesn't believe it affects the analysis. Dr. Scott Morton's analysis thus provides a reliable basis for her damages calculation.

Other courts have refused to exclude expert opinions in similar circumstances—i.e., when an expert's analysis hasn't accounted for other factors but still the expert provides a reliable basis for the opinion notwithstanding the omission. See, e.g., McCov v. Whirlpool Corp., 258 F. App'x 189, 196 (10th Cir. 2007) (reversing trial court's exclusion of expert testimony that failed to address competing expert's opinion about alternative causes of a fire because the fire's cause was "very much disputed, and it was the jury's province to decide this issue based on its assessment of the evidence and the credibility of [the experts'] conflicting testimony"); In re Universal Serv. Fund Tel. Billing Practices Litig., No. 02-MD-1468-JWL, 2008 WL 4382141, at \*8–9 (D. Kan. Sept. 26, 2008) (rejecting argument that damages experts "failed to consider alternative explanations for over-recovery, such as forecasting errors" because the calculations did "not lack an underlying basis" and a "dispute among the experts concerning whether other events caused over-recoveries . . . must be left for the jury"); In re Linerboard Antitrust Litig., 497 F. Supp. 2d 666, 678–79 (E.D. Pa. 2007) (rejecting defendants' argument that damages expert's "model did not account for legitimate factors affecting price such as costs, capacity constraints, or increase in demand" after defendants conceded that "conflicts between parties or experts over which variables are the proper variables to include in a model or which variables should be given more weight are simply issues of fact to be considered by juries" (internal quotation marks omitted)).

Mylan cites four cases that, it argues, require the court to exclude Dr. Scott Morton's opinion. The court finds these cases unavailing. In each case, the expert made assumptions that contradicted the record or ignored evidence without adequately explaining why the evidence

wasn't factored into the analysis. See, e.g., Concord Boat Corp., 207 F.3d at 1056 (excluding expert's damages opinion that "ignored inconvenient evidence" and "failed to account for market events that both sides agreed were not related to any anticompetitive conduct"); Blue Cross & Blue Shield United of Wisc., 152 F.3d at 593 (excluding experts' damages opinions that "attribute[d] the entire difference between [defendant's] prices . . . and the prices of other Wisconsin providers of medical services to the division of markets, with no correction for any other factor except differences in the treatment mix"); First Savings Bank, 117 F. Supp. 2d at 1084 (excluding expert opinion that was "based—without any evidentiary or even statistical support—on an assumption that defendants caused all declines suffered by plaintiff" which "infect[ed] [the expert's] basic methodology"); In re Aluminum Phosphide Antitrust Litig., 893 F. Supp. 1497, 1504–05 (D. Kan. 1995) (excluding expert opinion that assumed "any price increase between 1993 and the [price-fixing] conspiracy period was caused solely by the alleged conspiracy" because expert didn't explain why the assumption was "scientifically or economically valid"). Dr. Scott Morton hasn't made the same mistake here. As discussed, she has explained adequately her reasons for basing her opinion on the Sanofi 2012 Forecast and attributing all of the difference between that forecast and Auvi-Q's actual performance to Mylan's conduct.

Also, Sanofi need not prove that Dr. Scott Morton's damages calculations are correct. Whether her conclusions are right or wrong is a question for the trier of fact. *See In re Universal Serv. Fund Tel. Billing Practices Litig.*, 2008 WL 4382141, at \*9 (explaining that a "dispute among the experts concerning whether other events caused over-recoveries . . . must be left for the jury"); *see also ZF Meritor LLC v. Eaton Corp.*, No. 06-623-SLR, 2013 WL 6729509, at \*5 (D. Del. Dec. 20, 2013) (recognizing that a damages expert "did not factor into his econometric

model all the potentially relevant variables that defendant identifies, and bases his projections as much on defendant's success in the market as plaintiffs' lack luster track record before dissolution" but holding nonetheless that defendant's challenges to the admissibility of the opinion "can be vetted through discovery and are fodder for cross-examination at trial"). Dr. Scott Morton's decision to attribute all of Auvi-Q's losses to Mylan's conduct is a proper subject for cross-examination. But that decision doesn't require the court to exclude her opinions altogether. For reasons explained, Mylan hasn't persuaded the court that Dr. Scott Morton's opinions are unreliable, and thus inadmissible, because, it contends, Dr. Scott Morton's analysis failed to consider other factors in her analysis.

## b. Post-Recall Damages Model

Next, Mylan asserts that the court should exclude Dr. Scott Morton's opinion calculating Sanofi's Post-Recall Damages. Dr. Scott Morton's Post-Recall Damages opinion calculates "the damages for the 2017–2029 period—starting with the point in time at which Sanofi would have relaunched Auvi-Q [after its voluntary recall] were it not for Mylan's anticompetitive conduct, and going through the first half of 2029—when the Auvi-Q patent was set to expire." Doc. 1680-4 at 118 (Scott Morton Expert Report ¶ 200). To calculate Post-Recall Damages from 2017 to 2029, Dr. Scott Morton again relied on the Sanofi 2012 Forecast to estimate the "but-for profits that Sanofi would have earned from the reintroduction of Auvi-Q." *Id.* at 131 (Scott Morton Expert Report ¶ 224); *see also* Doc. 1680-6 at 89–90 (Scott Morton Expert Reply Report ¶ 193–94). Dr. Scott Morton opines that her calculation represents the profits that Sanofi "lost out on" in every year following Auvi-Q's relaunch in 2017 through 2029 "as a result of Mylan's exclusionary strategy." Doc. 1680-4 at 132 (Scott Morton Expert Report ¶ 225).

Mylan provides three reasons why, it contends, Dr. Scott Morton's Post-Recall Damages Model is unreliable. *First*, Mylan argues that the Post-Recall Damages Model is flawed because—like the Pre-Recall Damages Model—it relies on the Sanofi 2012 Forecast. *Second*, Mylan asserts that the Post-Recall Damages Model is based on the flawed assumption that Auvi-Q would have increased its price by five percent every year through 2029. *Finally*, Mylan contends that the Post-Recall Damages Model fails to account for other factors that would have affected Auvi-Q sales. The court addresses all three arguments, below.

#### i. Reliance on Sanofi 2012 Forecast

Mylan argues that Dr. Scott Morton's Post-Recall Damages Model is unreliable because she used the Sanofi 2012 Forecast to formulate her damage calculation. The Sanofi 2012 Forecast projected Auvi-Q's performance for just four years—starting in 2013 and running through 2017. Mylan contends it was improper for Dr. Scott Morton to rely on the Sanofi 2012 Forecast when calculating damages well beyond those four years—all the way through 2029. Mylan asserts that Dr. Scott Morton's decision to rely on the Sanofi 2012 Forecast to calculate Post-Recall Damages is not based on "sufficient facts or data." Fed. R. Evid. 702(b). So, Mylan argues, the court should exclude Dr. Scott Morton's Post-Recall Damages calculation.

Sanofi responds that Dr. Scott Morton didn't adopt the Sanofi 2012 Forecast blindly when she used it to compute Post-Recall Damages. Instead, Sanofi argues, Dr. Scott Morton's Expert Report adequately explains why she used the Sanofi 2012 Forecast to calculate Post-Recall Damages and why she found that data reliable when estimating damages through 2029. First, Dr. Scott Morton explained why she concluded that it was viable for Sanofi to relaunch Auvi-Q. Doc. 1680-4 at 128 (Scott Morton Expert Report ¶ 215 & n.408). She based that conclusion, among other things, on a conversation she had with Dr. Phillip Huang at Sanofi. *Id.* 

Next, she used the Sanofi 2012 Forecast to calculate but-for profits but she "adjust[ed] the start date and conditions to 2017 when kaléo re-launched Auvi-Q" and then she "projected sales and profits through the expiration of the Auvi-Q patent in the first half of 2029." Doc. 1680-6 at 89 (Scott Morton Expert Reply Report ¶ 193); see also Doc. 1680-4 at 130 (Scott Morton Expert Report ¶ 220–22, 24). Dr. Scott Morton "assume[d] that Auvi-Q would have continued to ramp up sales in much the same way that Mylan and Sanofi projected it would have before Mylan introduced its exclusionary strategy." Doc. 1680-4 at 130 (Scott Morton Expert Report ¶ 222). And, she corroborated the Sanofi 2012 Forecast with Mylan's own forecasts of Auvi-Q performance in 2017. *Id.* at 130–31 (Scott Morton Expert Report ¶ 220–22, 224).

Dr. Scott Morton's Expert Reports provide a reliable basis for relying on the Sanofi 2012 Forecast to calculate Post-Recall Damages. Sanofi argues that Mylan's disagreements with Dr. Scott Morton's Post-Recall Damages are questions for the jury but don't require the court to exclude her opinion. The court agrees. Mylan's criticisms of Dr. Scott Morton's use of the Sanofi 2012 Forecast go to the weight of her opinion, but they don't render her Post-Recall Damages Model inadmissible. *See In re Urethane Antitrust Litig.*, MDL No. 1616, No. 04-1616-JWL, 2012 WL 6681783, at \*3–4 (D. Kan. Dec. 21, 2012), aff'd 768 F.3d 1245 (10th Cir. 2014) (rejecting argument that expert improperly relied on models and opinions of another expert when forming his opinion "without independently determining that such opinions are sound or reliable" because the expert had "not merely adopted [the other expert's] opinion, but ha[d] instead formed his own opinion," and concluding that "complaints about [the expert's] analysis go to weight, not admissibility, and are more appropriately explored in cross-examination at trial"); see also Stecyk v. Bell Helicopter Textron, Inc., 295 F.3d 408, 414 (3d Cir. 2002) (explaining that "the burden of exploring the facts and assumptions underlying the testimony of

an expert witness" rests "on opposing counsel during cross-examination"). The court thus rejects Mylan's request to exclude Dr. Scott Morton's Post-Recall Damages Model because she relied on the Sanofi 2012 Forecast to form her opinions.

#### ii. Five Percent Annual Price Increase

Next, Mylan argues that Dr. Scott Morton's Post-Recall Damages opinion is unreliable because, as her Expert Reply Report explains, she bases her calculation on Sanofi imposing a five percent annual price increase for Auvi-Q. *See* Doc. 1680-6 at 93 (Scott Morton Expert Reply Report ¶ 205) (explaining that Dr. Scott Morton "revised [her] damages model to reflect annual price growth of 5%"). Mylan asserts that Dr. Scott Morton has no basis for this assumption. And, it contends, Dr. Scott Morton revised her opinion to include the five percent price increase just to increase the total amount of damages. Mylan argues that this decision is not grounded in any economic methodology.

Sanofi responds that Dr. Scott Morton reliably based the five percent increase on a December 2015 Sanofi forecast ("Sanofi 2015 Forecast") and a Mylan forecast. *See id.* Her Expert Reply Report explains that she revised her calculations to reflect this increase because she was "unaware" of "this additional information" when she wrote her original Expert Report. Mylan argues Dr. Scott Morton's assertion can't be true because she cited the Sanofi 2015 Forecast in her original Expert Report; so, she was aware of it. *See* Doc. 1680-9 at 41–42 (Scott Morton Dep. 439:17–440:18). But Dr. Scott Morton also testified that the case has "a voluminous record" and that she was "open to new information and to valid criticisms" from Mylan's experts. *Id.* at 13–14 (Scott Morton Dep. 406:25–407:15). And, her Expert Reply Report explains that she revised her calculations to include the five percent price increase based

on forecasts Mylan's expert discussed in his Expert Report. <u>Doc. 1680-6 at 93</u> (Scott Morton Expert Reply Report ¶ 205).

Mylan also argues that Dr. Scott Morton knows nothing about the Sanofi 2015 Forecast. But Dr. Scott Morton testified that she knew it was made by the Sanofi team when they were trying to decide whether to relaunch Auvi-Q. Doc. 1680-9 at 44-45 (Scott Morton Dep. 442:14-443:15). Also, Dr. Scott Morton testified that she believes the five percent price increase is "extremely conservative" because it's at the "very low end of what brands" increase in price over time in the United States. *Id.* Mylan contends that the five percent price increase doesn't account for increasing rebates which drive down the price. But Dr. Scott Morton testified that she projected the percentage of any discounts to price would be the same; so, the net price would continue to rise at five percent each year. *Id.* at 27, 45–46 (Scott Morton Dep. 425:5–18, 443:16–444:7). And, as discussed, she found the five percent increase was a conservative estimate because it's on the low end of price increases for branded pharmaceutical products. *Id.* at 44–45 (Scott Morton Dep. 442:14–443:15). Finally, Mylan contends that Dr. Scott Morton's price increase doesn't account for the fact that EpiPen's list price hasn't increased since Mylan introduced an authorized generic in December 2016. But Dr. Scott Morton explained that real world pricing choices weren't relevant to her "but-for" analysis because, in the real world, Mylan's market power allowed it to impose large price increases every year leading up to 2016. Id. at 52–54 (Scott Morton Dep. 450:13–452:5). And, she contends, after 2016, Mylan's pricing choices were affected by negative publicity it received from allegations that Mylan had engaged in unlawful activity. Id.

All of Mylan's objections to Dr. Scott Morton's use of the five percent price increase go to the opinion's weight, but not its admissibility. In response to Mylan's attacks against the price

increase assumption, Dr. Scott Morton adequately explains why she included a price increase in her calculation and why she believes the five percent increase is a reliable estimate. The court refuses to exclude her Post-Recall Damages Model on this basis.

# iii. Accounting for Other Factors

Finally, Mylan argues that Dr. Scott Morton's Post-Recall Damages opinion is unreliable because it doesn't account for other factors that would have affected Auvi-Q sales, including the reputational effects of Auvi-Q's recall or the introduction of generic and other competition in the EAI market. Dr. Scott Morton explains, however, that her model "accounts for [the] costs [associated with relaunching Auvi-Q] in estimating Auvi-Q's post-relaunch profits in the but-for world and has Sanofi effectively start over, by assuming that Auvi-Q would grow exactly as it was projected to have grown at launch in the but-for world." Doc. 1680-6 at 76 (Scott Morton Expert Reply Report ¶ 163). Dr. Scott Morton also asserts that her model appropriately accounts for the "reputational impact of the voluntary recall" because EpiPen has undergone similar recalls but it hasn't affected its marketability. *Id.* at 76–77 (Scott Morton Expert Reply Report ¶ 164).

Also, Dr. Scott Morton asserts that her opinion appropriately accounts for other competition entering the market. Her Expert Report describes several Mylan forecasts predicting that introduction of generics wouldn't affect Auvi-Q sales. Doc. 1680-4 at 128–131 (Scott Morton Expert Report ¶ 217–23). And so, she assumed that generic competition wouldn't change Auvi-Q pricing. *Id.* at 131 (Scott Morton Expert Report ¶ 223). Nevertheless, Dr. Scott Morton says her model accounts for other competition in the market because it includes a "conservative" growth assumption of the EAI market based on U.S. population growth that assumes that "[a]s new products come into the market, the overall EAI market will grow and

new products will take share away from Auvi-Q." *Id.* at 131 (Scott Morton Expert Report ¶ 224.d.); Doc. 1680-6 at 92 (Scott Morton Expert Reply Report ¶ 202).

Like the arguments already addressed, Mylan's objections that Dr. Scott Morton's Post-Recall Damages Model fails to consider other factors go to the weight of her opinion but don't require the court to exclude her Post-Recall Damages calculations. *See In re Urethane Antitrust Litig.*, 2012 WL 6681783, at \*8–9 (holding that arguments about the data an expert chose to use when forming his opinions went to the weight of the opinions but not admissibility); *see also Krys v. Aaron*, 112 F. Supp. 3d 181, 195 n.15 (D.N.J. 2015) ("[A]n expert may base his opinion on a particular version of disputed facts and the weight to be accorded to that opinion rests with the jury, and presents [a] proper subject for cross-examination." (citation and internal quotation marks omitted)). The court thus denies Mylan's motion to exclude Dr. Scott Morton's opinion calculating Post-Recall Damages.

#### 2. Are Dr. Scott Morton's EEB calculations reliable?

Next, Mylan argues that Dr. Scott Morton's "Effective Entrant Burden" ("EEB") calculations aren't reliable. Dr. Scott Morton uses her EEB calculation to support her opinion that Mylan successfully foreclosed Auvi-Q from the EAI market by offering exclusionary rebates that Sanofi could not overcome. Doc. 1680-4 at 97–104 (Scott Morton Expert Report ¶¶ 155–69). Dr. Scott Morton explains that EEB calculates the rebate that Sanofi must offer a pharmacy benefit manager ("PBM") to match the "same total discount" offered by Mylan for exclusive formulary placement. *Id.* at 101 (Scott Morton Expert Report ¶ 161). She uses the following formula to calculate EEB:

$$EEB = \frac{(exclusionary rebate \%) x (share with exclusion)}{(contestable share)}$$

Id. Dr. Scott Morton's Report provides a table that computes the EEB using various assumptions and under different scenarios. Id. (Scott Morton Expert Report ¶ 161, Table 3). For example, she assumes that if Mylan offers a 30% discount for exclusivity, the contestable share of the EAI market is 50%, and EpiPen's market share when Auvi-Q is excluded is 100%, then the EEB is 60%. Id. According to Dr. Scott Morton, this means that Sanofi has to offer a 60% rebate to match the same discount Mylan has offered. Id. Dr. Scott Morton opines that her EEB analysis shows that "Sanofi would have to sell Auvi-Q at a price at or very close to zero (clearly not covering its costs) before the [PBM] would consider replacing Mylan's exclusionary offer with an offer from Sanofi." Id. at 101–102 (Scott Morton Expert Report ¶ 162).

Dr. Scott Morton proposed her EEB theory in a 2017 co-authored article. *See* Fiona M. Scott Morton & Zachary Abrahamson, *A Unifying Analytical Framework for Loyalty Rebates*, 81 Antitrust L.J. 777 (2017). The article describes the EEB as "calculat[ing] the burden that the rebate contract imposes on the entrant—the amount by which the entrant must lower its own price below the market price to counteract the impact of the rebate contract on customer incentives." *Id.* at 777. And, it explains that EEB is a "single metric" that "measures the extent to which the dominant firm leverages non-contestable demand into anticompetitive exclusion." *Id.* 

Mylan asks the court to exclude Dr. Scott Morton's EEB calculations for two reasons:

(1) Mylan argues that Dr. Scott Morton's EEB analysis lacks empirical validation, and (2) Mylan contends that her EEB opinions directly conflict with the factual record. Exercising its discretion at this gatekeeping stage, the court agrees with Mylan. The court excludes Dr. Scott Morton's EEB calculations for each of these two and independent reasons.

First, Mylan contends that Dr. Scott Morton's EEB analysis is unreliable because it lacks empirical validation. Mylan correctly argues that Daubert instructs the court to consider "whether the theory or technique has been subjected to peer review and publication" and whether the theory enjoys a "general acceptance" in the scientific community because "a known technique which has been able to attract only minimal support within the community may properly be viewed with skepticism." Daubert, 509 U.S. at 593–94 (citations and internal quotation marks omitted). Mylan urges the court to follow Cochrane v. Schneider National Carrier, Inc., where our court excluded an expert's opinion that was based on a "novel methodology" that "had not been subjected to any empirical research" and "[had] been published, but only by [the expert] a short time ago" and thus was not the subject of "any positive peer review." 980 F. Supp. 374, 379–80 (D. Kan. 1997).

Sanofi responds that, unlike *Cochrane*, where the expert's theory merely was self-published, Dr. Scott Morton's co-authored article was published by the American Bar Association's ("ABA") *Antitrust Law Journal*. According to Sanofi, before publication, the *Antitrust Law Journal* subjects articles to review by the Board of Editors and to peer-review by selected scholars and practitioners. Doc. 1795-10 (*Antitrust Law Journal* Publication Procedures). But the document Sanofi cites provides just general guidelines about the ABA's *Antitrust Law Journal*'s publication procedures. It provides no information describing any peer review to which the *Antitrust Law Journal* subjected Dr. Scott Morton's article before publication. Instead, the record includes just one reference to peer review of Dr. Scott Morton's theory. And, in that review, the author described the EEB theory as having "extremely limited usefulness in determining whether a particular loyalty discount program is anticompetitive."

Roger Ware, *The Economics of Multiproduct Loyalty Programs*, 30 Revue Canadiene du Droit de la Concurrence 112, 125–26 (2017), <a href="https://bit.ly/2Yke8XJ">https://bit.ly/2Yke8XJ</a>.

Sanofi argues that the article goes on to explain: "What is required is a full competitive effects analysis of the program in question, with consideration given to the role of contestable and uncontestable markets, and there do not appear to be any simple screens available that would avoid a full investigation in some cases." *Id.* at 126. And, Sanofi contends, Dr. Scott Morton's Expert Reports provide this "full competitive effects analysis." According to Sanofi, her EEB calculation is just one part of her analysis, and it's not dispositive. But, Sanofi, as the proponent of expert testimony, bears the burden to show that Dr. Scott Morton's EEB analysis is reliable—even if it's just one opinion within her Expert Reports—before the court can admit it into evidence. *United States v. Nacchio*, 555 F.3d 1234, 1241 (10th Cir. 2009) ("The proponent of expert testimony bears the burden of showing that its proffered expert's testimony is admissible."). And, the court finds, Sanofi hasn't shouldered that burden here.

Applying the *Daubert* factors to Dr. Scott Morton's EEB theory, the court finds that the record lacks information showing that her theory is reliable. Indeed, Dr. Scott Morton's EEB theory lacks any empirical validation. No one ever has tested it, and there is not a "known or potential rate of error." *Daubert*, 509 U.S. 593–94. Dr. Scott Morton has published her theory, but only in one publication, and the record contains no evidence of other "positive peer review." *Cochrane*, 980 F. Supp. at 379–80 (citing *Daubert*, 509 U.S. at 593–94). Also, the record is devoid of any evidence showing that her EEB theory has general acceptance in the scientific community. *Daubert*, 509 U.S. at 594. On these facts, Sanofi hasn't demonstrated that Dr. Scott Morton's EEB analysis is sufficiently reliable for the court to accept it. The court thus excludes Dr. Scott Morton's EEB calculations for this reason.

Second, Mylan argues the court should exclude Dr. Scott Morton's EEB analysis because it directly conflicts with the undisputed facts in the case. Dr. Scott Morton's Expert Report provides two examples of how Mylan's exclusionary rebate offers "played out" with two PBMs.

Doc. 1680-4 at 102-03 (Scott Morton Expert Report ¶ 165). Using her EEB formula, Dr. Scott Morton calculates that Sanofi would have had to offer Express Scripts Holding Company ("ESI") a 94% rebate to counter Mylan's 30% discount. Id. at 102-03 (Scott Morton Expert Report ¶ 165-66); see also id. at 103 (Scott Morton Expert Report ¶ 166 ("[I]n order to make it in ESI's interest to not exclude Auvi-Q, Sanofi would have had to offer a discount of at least 94%—almost the entire value of the product—and a discount that is more than three times as high as that offered by Mylan.")). And, she calculates that Sanofi would have had to offer Aetna "a discount of 63% to counter Mylan's discount of 20% to Aetna—or a discount more than three times as high as that offered by Mylan." Id. at 104 (Scott Morton Expert Report ¶ 168).

Sanofi recognizes that the record here doesn't support Dr. Scott Morton's EEB calculation for Aetna. Instead, the evidence shows that Sanofi paid Aetna just half of what Dr. Scott Morton's Expert Report predicts for the EEB. See Doc. 1681-11 (2015 Aetna Rebate Agreement with Sanofi showing agreement to a 30% rebate). Also, the record shows that Sanofi achieved coverage with ESI in 2015, with rebates lower than what Dr. Scott Morton predicts with her EEB calculations. Doc. 1866-10 at 7–8, 24 (Sanofi slide deck showing rebates of 60% and 20%). Dr. Scott Morton explains the discrepancies by testifying that "[a] plan might decide that it was interested in serving its customers by giving them interesting, innovative, helpful treatments on the formulary and not just taking the monopolist's money to exclude the entrant . . . But I'm talking about Mylan creating a financial burden for the PBM that would cause them to want to exclude Auvi-Q." Doc. 1796-4 at 16 (Scott Morton Dep. 206:3–17). That may be true,

but it's speculative. Also, her calculations conflict with other evidence. None of Sanofi's projections include rebates at the level predicted by Dr. Scott Morton's EEB calculations. Instead, Sanofi's own projections include estimated rebates that allowed it to "breakeven," and these percentages are less than half of what Dr. Scott Morton calculates as the EEB that Sanofi had to offer ESI. *See* Doc. 1681-24 at 19–20 (Sanofi slide deck projecting either a 43% or 35% "breakeven" rebate).

Also, Mylan criticizes Dr. Scott Morton's EEB theory because, as applied, it generates "false positive" results. Doc. 1866-1 at 17 n.7. Dr. Scott Morton's article opines that "generally, liability for discounting practices accompanies effective entrant burdens above 10 percent." Morton & Abrahamson, *supra*, at 825. But, her article analyzed 13 cases and identified three cases where EEB exceeded 10% but courts did not find liability. *Id.* at 827. The article explains that the three cases "involved analytically difficult, non-standard settings" where "courts allowed rebate schemes that produced significant EEBs." *Id.* Sanofi stresses that Dr. Scott Morton's EEB theory is not outcome determinative. But still, with this small sample size of 13 cases, Dr. Scott Morton's EEB theory produces a false positive rate of more than 20%.

Our Circuit has explained that "a district court 'is accorded great latitude in determining how to make *Daubert* reliability findings." *Pioneer Ctrs. Holding Co. Emp. Stock Ownership Plan & Tr. v. Alerus Fin., N.A.*, 858 F.3d 1324, 1342 (10th Cir. 2017) (quoting *United States v. Velarde*, 214 F.3d 1204, 1209 (10th Cir. 2000)). "When expert opinion 'is not supported by sufficient facts to validate it in the eyes of the law, or when indisputable record facts contradict or otherwise render the opinion unreasonable, it cannot support a jury's verdict' and will be excluded." *Id.* (quoting *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993)). Here, Dr. Scott Morton's EEB opinion is contradicted by "indisputable record

facts." *Id.* And so, the court excludes her EEB calculations for this second and independent reason.

# 3. Is Dr. Scott Morton's calculation of entrenched share supported by the record?

Next, Mylan asks the court to exclude Dr. Scott Morton's opinion about Mylan's "entrenched share" of the EAI market. *See* Doc. 1680-4 at 96–97 (Scott Morton Expert Report ¶¶ 151–54). Dr. Scott Morton testified that the definition of entrenched share is the "noncontestable share" of the market or "that part of demand that the entrant cannot satisfy immediately." Doc. 1680-5 at 9 (Scott Morton Dep. 76:7–12). To calculate Mylan's entrenched share, Dr. Scott Morton looked at "evidence from various sources . . . in the 2013-2015 timeframe, while Sanofi was trying to expand its competitive presence." Doc. 1680-4 at 96 (Scott Morton Expert Report ¶ 151). And, she concluded that the evidence "indicates . . . Mylan had an entrenched share in the range of 50-70% of the EAI market." *Id*.

Mylan argues this opinion is unreliable because it's not based on a quantitative analysis, but, instead, on record evidence that, Mylan contends, doesn't support her conclusion. Dr. Scott Morton's Expert Report identifies four pieces of evidence that, she believes, support her entrenched share opinion. *Id.* at 55–56, 96–97 (Scott Morton Expert Report ¶ 82, 152–53). Mylan argues that none of this evidence supports her opinion that EpiPen had an entrenched share of 50–70% of the EAI market when Auvi-Q also was on the market. Thus, Mylan asks the court to exclude Dr. Scott Morton's entrenched share opinion because it's not based on "sufficient facts or data" as Fed. R. Evid. 702(b) requires. The court disagrees. Each of Mylan's challenges to the evidence goes to the weight of Dr. Scott Morton's opinion, but doesn't nullify its admissibility. Thus, the court refuses to exclude her entrenched share opinion.

First, Dr. Scott Morton relied on an email sent by Mylan's Bruce Foster that "concluded that EpiPen had a 40–70% range of entrenched share based on the impact of EpiPen previously having been blocked with a step edit on Medicaid formularies." Doc. 1680-4 at 96 (Scott Morton Expert Report ¶ 152). Mylan argues that this email doesn't provide a reliable basis for Dr. Scott Morton's entrenched share opinion because it refers to Medicaid plans, not commercial plans. But, as Dr. Scott Morton's Expert Report explains, "Medicaid serves low income patients that will generally be more price sensitive than the overall commercially insured population." Id. Thus, Dr. Scott Morton opines that this email supports her 50–70% entrenched share opinion because "the entrenched share for commercial payers should be higher than it is for Medicaid customers." Id. Also, she explained, "Mr. Foster's range was based on Mylan's experience before it engaged in the above-discussed conduct aimed at further entrenching its market share."

Id. "As a result, the entrenched EpiPen share after this conduct took place must be higher than 40%." Id.

Also, Mylan argues that the email doesn't support Dr. Scott Morton's conclusion because it refers to plans that preferred Adrenaclick (a rival EAI) and not Auvi-Q. But, Dr. Scott Morton opines that "Adrenaclick is more similar to EpiPen as a result of its comparable size, features, and instructions," which "suggests that the non-contestable EpiPen share in the Adrenaclick experience . . . would be *lower* than in a situation where the EpiPen was blocked with a step edit in favor of the Auvi-Q device with its much different shape, features, and instructions for usage."

Doc. 1680-6 at 44–45 (Scott Morton Expert Reply Report ¶ 90). So, Dr. Scott Morton opines, this evidence supports her higher 50–70% entrenched share opinion for other entrants offering products that are different from the EpiPen. Mylan disputes this distinction, arguing that the evidence doesn't support it. The court disagrees. Dr. Scott Morton adequately has explained

how the record evidence provides a reliable basis for her to form her entrenched share opinion.

And, she has explained why she found Mr. Foster's email a reliable data point to use when forming her opinion. Mylan's criticisms of her reliance on that data is a proper subject for cross-examination. But her reliance on this email doesn't warrant the court excluding her entrenched share opinion.

Second, Dr. Scott Morton relied on data from Express Scripts Holding Company ("ESI") showing that EpiPen maintained a market share of more than 60%, even though it was excluded on this formulary. Doc. 1680-4 at 97 (Scott Morton Expert Report ¶ 153). Mylan argues that this data isn't a reliable indicator of EpiPen market share because it is aggregate data that includes EpiPen market share on ESI plans where it wasn't restricted. Mylan argues that isolating the data just to ESI formularies where EpiPen was excluded shows that EpiPen's market share dropped to zero. But, Dr. Scott Morton testified that she relied on the ESI data because it provided an "average." Doc. 1796-4 at 3 (Scott Morton Dep. 84:15–85:4). She recognized that "there's variation across plans" which "is to be expected" and "normal." Id. And, that data shows "on average . . . that EpiPen continues to get above a 60 percent share. Despite the fact that there's variation across plans within the ESI plan." Id. (Scott Morton Dep. 85:5–16).

Dr. Scott Morton also explains that the fact that some plans "contracted around the exclusion so as to maintain EpiPen coverage" and "get around the exclusion of EpiPen is an expression of noncontestable demand." Doc. 1680-6 at 41 (Scott Morton Expert Reply Report ¶¶ 79–80). Mylan asserts that its expert disagrees with the conclusion that a plan would contract around an exclusion for a single drug. But that's not a reason to exclude Dr. Scott Morton's opinion. See In re Urethane Antitrust Litig., 2012 WL 6681783, at \*8 (rejecting arguments that

expert relied on the wrong data to form an opinion and that other evidence contradicted the data relied on because "such complaints are better made in cross-examination of [the expert], and do not show that [the expert's] method was unreliable in this case"); see also RMD, LLC v. Nitto Ams., Inc., No. 09-2056-JAR-DJW, 2012 WL 5398345, at \*10 (D. Kan. Nov. 5, 2012) (refusing to exclude opinion of plaintiff's expert simply because defendants' rebuttal experts disputed the factual basis for the opinion finding that kind of challenge "go[es] to the weight and not the admissibility of [the expert's] opinion, and [defendants] are free to cross-examine him on this point"). Dr. Scott Morton adequately explains why she found the ESI data reliable and why she used it to form her entrenched share opinion. So, the court declines to exclude her entrenched share opinion on this basis.

Third, Dr. Scott Morton's entrenched share opinion is based on her analysis of two CVS formularies where EpiPen was excluded. Doc. 1680-4 at 97 (Scott Morton Expert Report ¶ 153). She found that on those formularies "EpiPen share was even higher—averaging 66% across the two formularies over the period during which EpiPen was excluded." Id. Mylan argues that Dr. Scott Morton's analysis of the CVS data is wrong. Its only support for that argument is its own expert's analysis of the CVS data. But Dr. Scott Morton has responded to the expert's criticism by asserting that he "selectively looked at only [one formulary] while completely disregarding data from the [second formulary]" which "not only . . . ignore[d] a good portion of available data, but . . . also ignore[d] data that undermine his conclusion." Doc. 1680-6 at 42 (Scott Morton Expert Reply Report ¶ 83). Dr. Scott Morton says her analysis "[i]n contrast" involved "review[ing] the available data across all CVS formularies that attempted to exclude EpiPen."

Id. As she explains, she found it "important to look at the average EpiPen shares across both CVS formularies." Id. And, she criticizes Mylan's expert for failing "to examine the average

EpiPen share across both formularies" and, instead, "just selectively cherry-pick[ing] the subset of data that is most supportive of one's claim." *Id.* at 42–43 (Scott Morton Expert Reply Report ¶ 84). For the same reasons already discussed, these competing views of the CVS data are fodder for cross-examination. But they aren't the kind of fodder needed to exclude Dr. Scott Morton's entrenched share opinion.

Finally, Dr. Scott Morton's entrenched share opinion relies on a comment made by a member of a Florida Medicaid formulary committee at a 2014 meeting. Doc. 1680-4 at 55–56 (Scott Morton Expert Report ¶ 82). The committee member said that the plan could not exclude EpiPen because of its large market share. Id. But, Mylan argues, that same plan ended up excluding EpiPen just one year later. Dr. Scott Morton responds that the Medicaid population is more price sensitive than the commercially-insured population. Doc. 1680-6 at 45 (Scott Morton Expert Reply Report ¶ 91). So, she opines, entrenched share is even lower in this population. Id. Thus, she believes it is reasonable to rely on this evidence to support her 50–70% entrenched share opinion. Again, any criticisms of how Dr. Scott Morton analyzed the evidence go to the weight of her opinion but not its admissibility. Thus, the court refuses to exclude Dr. Scott Morton's opinion for this reason.

After reviewing the evidence that Dr. Scott Morton relied on to form her entrenched share opinion, the court finds that she has provided a reliable basis for considering each piece of evidence to reach her conclusion that Mylan had an entrenched share of 50–70% of the EAI market. Mylan's objections to her reliance on any of the record evidence go to the weight of her opinion, not it's admissibility. The court refuses to exclude Dr. Scott Morton's entrenched share opinion.

# 4. Does Dr. Scott Morton improperly opine about state of mind?

Last, Mylan argues that Dr. Scott Morton improperly asserts opinions about (1) Mylan's anticompetitive intent, (2) Mylan's evaluation of Auvi-Q, and (3) Sanofi's reasons for returning its rights to Auvi-Q. Mylan contends that these opinions involve improper factual narratives and make state-of-mind conclusions that usurp the jury's role as fact finder. *See, e.g., Pioneer Ctrs. Holding Co. Emp. Stock Ownership Plan & Tr. v. Alerus Fin., N.A.*, 858 F.3d 1324, 1342 (10th Cir. 2017) (affirming district court's exclusion of expert testimony that "would require the experts to read the mind of [a party], predict how [the party] would have weighed factors it deemed relevant, and find that [the party] would not only reach the conclusion that it must consent but also do so" because "[s]uch prediction . . . is beyond the scope of any expert" (citations omitted)); *Ornelas v. Lovewell*, No. 11-2261-JAR-KMH, 2013 WL 3271016, at \*6 (D. Kan. June 27, 2013) (explaining that "an expert witness's testimony must assist the jury to be deemed admissible" under Fed. R. Evid. 702(a) "however, an expert witness's testimony may not usurp the jury's fact-finding function"). Thus, Mylan argues the court should exclude these opinions.

Sanofi responds that Dr. Scott Morton isn't improperly offering opinions about the parties' states of mind. Instead, Sanofi asserts, Dr. Scott Morton's opinions are proper because she has identified record evidence that, she contends, is *consistent with* the alleged conduct. Sanofi correctly argues that such expert testimony is admissible. *See In re Urethane Antitrust Litig.*, 2012 WL 6681783, at \*3 (recognizing that the expert "may not give any opinion concerning the credibility of witnesses or whether a particular event actually occurred" but allowing expert opinion "that certain conduct by the alleged conspirators *is consistent* with the existence of an agreement to fix prices" because the expert's "opinion is essentially that

particular events, assuming they occurred, are *consistent with* a conspiracy" (emphasis added)); see also In re Processed Egg Prods. Antitrust Litig., 81 F. Supp. 3d 412, 424 (E.D. Pa. 2015) ("An economic expert may permissibly testify . . . whether certain conduct is consistent with collusion or an entity or individual's self-interest . . . .").

Here, Dr. Scott Morton's Expert Report explains why, she believes, the record evidence is consistent with anticompetitive behavior on Mylan's part. First, Dr. Scott Morton opines that Mylan recognized Auvi-Q's entry into the EAI market posed an "impending threat." Doc. 1680-4 at 63 (Scott Morton Expert Report ¶ 91). To support this conclusion, Dr. Scott Morton cites testimony by several Mylan witnesses and many internal Mylan and Pfizer documents. Id. at 62–70 (Scott Morton Expert Report ¶¶ 90–103). According to Dr. Scott Morton, this evidence includes efforts by Mylan to license or acquire Auvi-Q and to develop a smaller EpiPen. Id. at 64–67 (Scott Morton Expert Report ¶¶ 93–96). After these efforts proved "[u]nsuccessful," Dr. Scott Morton opines that "Mylan pivoted and instead developed a plan to block Auvi-Q from the market." Id. at 67 (Scott Morton Expert Report ¶ 97). Dr. Scott Morton opines that part of Mylan's plan included structuring its PBM contracts specifically to exclude Auvi-Q because it wanted to prevent Auvi-Q from "gaining a foothold in the market." Doc. 1680-4 at 78 (Scott Morton Expert Report ¶ 122). Again, Dr. Scott Morton supports these opinions with record evidence—i.e., deposition testimony and internal Mylan documents—that, she contends, are consistent with Mylan engaging in anticompetitive behavior. Id. at 67–70, 78–82 (Scott Morton Expert Report  $\P$  97–103, 122–25). As discussed, this type of expert opinion is proper under the governing case law.

Also, Dr. Scott Morton opines that Sanofi returned its rights to Auvi-Q to kaléo as "a direct result of its expectation that Mylan would continue its exclusionary conduct." *Id.* at 126

(Scott Morton Expert Report ¶ 212). To support that conclusion, Dr. Scott Morton cites deposition testimony that, she asserts, shows Sanofi had the ability to relaunch Auvi-Q and would have done so but-for Mylan's anticompetitive conduct. *Id.* at 127–28 (Scott Morton Expert Report ¶ 213–15); see also Doc. 1684-6 at 74–81 (Scott Morton Expert Reply Report ¶ 161–72). Mylan responds by citing other record evidence that, it contends, shows that Mylan's conduct was not the reason Sanofi returned the rights to Auvi-Q. Doc. 1866-1 at 20. But, Mylan's competing view of the evidence doesn't require the court to exclude Dr. Scott Morton's opinion. Instead, this is a proper subject for cross-examination. See, e.g., Gomez v. Martin Marietta Corp., 50 F.3d 1511, 1519 (10th Cir. 1995) (affirming trial court's admission of expert testimony because the opposing party never "establish[ed] that the challenged opinions had no basis in fact" and, instead, "the asserted weaknesses of [the expert's] assumptions . . . go to the weight the jury should have given her opinions" but "did not render her testimony too speculative as a matter of law"); In re Urethane Antitrust Litig., 2012 WL 6681783, at \*3 (denying motion to exclude expert opinion and explaining "[t]he extent to which [the expert] considered the entirety of the evidence in the case is a matter for cross-examination" but didn't "render[] fatally unreliable his opinion that certain events are consistent with collusion").

The cases that Mylan cites don't require a different conclusion. For example, in *Pioneer Centres*, the Tenth Circuit affirmed the trial court's exclusion of expert testimony about causation that "amount[ed] to nothing more than speculation." <u>858 F.3d at 1342</u> (citation and internal quotation marks omitted). In contrast, here, Dr. Scott Morton's Expert Reports cite the record evidence that, she contends, supports her opinions. The court concludes Dr. Scott Morton has provided a reliable basis for her opinions. Consequently, the court rejects Mylan's

argument that the court should exclude the three identified opinions as improper narrative or state-of-mind opinions.

#### 5. Conclusion

For the above reasons, the court grants in part and denies in part Mylan's Motion to Exclude Opinion Testimony of Fiona M. Scott Morton, Ph.D. (<u>Doc. 1682</u>). The court grants Mylan's request to exclude Dr. Scott Morton EEB's calculations. The court denies the motion in all other respects.

## B. Motion to Exclude Opinions of Dr. Mary Ann Michelis

Mylan next asks the court to exclude certain opinions offered by Dr. Mary Ann Michelis. Sanofi has retained Dr. Michelis as an expert witness to offer testimony that (1) describes the disease of anaphylaxis; (2) explains the treatment options for anaphylaxis; and (3) discusses the factors considered when prescribing treatment, including the roles of patient choice, coverage, cost, communications from pharmaceutical companies, and efficacy and safety. Doc. 1678-4 at 3 (Michelis Feb. 2, 2019 Expert Report ¶ 1). Sanofi also asked Dr. Michelis to review and respond to portions of Mylan's expert, Gary Zieziula's, Expert Report. In response to Mr. Zieziula's opinions, Dr. Michelis offers opinions about: (1) the effect of pharmaceutical sales representatives on prescribers and medical staff; (2) whether certain marketing statements about the Auvi-Q device would have been confusing to doctors; and (3) what the medical literature has shown about patients carrying their EAI device as directed. Doc. 1678-6 at 3 (Michelis Mar. 25, 2019 Expert Report ¶ 1). Also, Dr. Michelis provides a Rebuttal Report that offers opinions about (1) the differences between Auvi-Q and EpiPen; (2) appropriate medical substitutes for EAI devices; and (3) safety considerations about the availability of EAI devices and recalls of such devices. Doc. 1678-5 at 3 (Michelis Rebuttal Report ¶ 1).

Mylan doesn't challenge Dr. Michelis's qualifications to offer these opinions. Nevertheless, the court has reviewed her qualifications to confirm that she "is qualified by knowledge, skill, experience, training, or education' to render an opinion." *United States v.* Nacchio, 555 F.3d 1234, 1241 (10th Cir. 2009) (quoting Fed. R. Evid. 702). Dr. Michelis is the Chief of Allergy and Immunology for the Division of Internal Medicine and Pediatrics at Hackensack University Medical Center in New Jersey. Doc. 1678-4 at 3 (Michelis Feb. 2, 2019) Expert Report ¶ 2). She earned a medical degree from the University of Pittsburgh School of Medicine, completed an Allergy and Immunology fellowship at Weill-Cornell Hospital, and completed a post-doctorate fellowship at Rockefeller University in New York. Id. In 1981, Hackensack University Medical Center recruited Dr. Michelis to create a Flow Cytometry Immunology laboratory, a laboratory that uses specialized tools to analyze the physical and chemical characteristics of cells when diagnosing immunological disorders and allergies. *Id.* Ever since then, Dr. Michelis has been affiliated with Hackensack University Medical Center. Id. Dr. Michelis is certified in Allergy and Immunology by the American Board of Allergy and Immunology and certified in Diagnostic Laboratory Immunology and Internal Medicine by the American Board of Internal Medicine. Id.

Dr. Michelis currently sees about 60 to 70 patients each week in her allergy practice. *Id.* (Michelis Feb. 2, 2019 Expert Report ¶ 3). Over her career, Dr. Michelis has treated thousands of patients. *Id.* And, she has taught many patients (both adults and children) and caregivers how to use EAI devices. *Id.* In addition to her patient practice, Dr. Michelis teaches residents about anaphylaxis to prepare for the American Board of Internal Medicine. *Id.* (Michelis Feb. 2, 2019 Expert Report ¶ 4). Also, she is an active member of the American Academy of Allergy, Asthma

& Immunology ("AAAAI"). *Id.* She has served on AAAAI national committees and helped to organize seminars for national meetings. *Id.* 

Based on her education, training, and experience, Dr. Michelis appears qualified to offer her proffered expert opinions. But, even if she is qualified to render her opinions, Mylan argues that the court should exclude some of her opinions because they are unreliable and not proper expert testimony. Specifically, Mylan asks the court to exclude Dr. Michelis's expert testimony on three topics: (1) the factors considered when prescribing anaphylaxis treatment, including patient choice, safety and efficacy, and insurance coverage; (2) the role of the pharmaceutical sales force and its influence on physicians' prescribing habits; and (3) EpiPen shortages. The court addresses the three topics, separately, below.

## 1. Factors Considered When Prescribing Treatment

Dr. Michelis opines about certain factors she considers when prescribing anaphylaxis treatment, including patient choice, safety and efficacy, and insurance coverage. *See*, *e.g.*, <u>Doc. 1678-4 at 15</u>–20 (Michelis Feb. 2, 2019 Expert Report ¶¶ 37–46). Mylan argues that Sanofi cannot offer Dr. Michelis's opinions to demonstrate the prescribing practices that are commonly used or accepted in the anaphylaxis field. Mylan asserts that Dr. Michelis bases her opinions just on her personal views—not reliable information about things other physicians consider when prescribing anaphylaxis treatment. Thus, Mylan asserts, Dr. Michelis's opinions on this topic are not proper expert testimony about how physicians—in general—prescribe EAI devices.

Sanofi responds that Dr. Michelis's opinions properly are grounded in her review of prominent medical journals, her medical training, and her 40 years of clinical experience. But none of the medical literature that Sanofi cites discusses how physicians prescribe anaphylaxis treatment. Sanofi cites one article referenced in Dr. Michelis's March 25, 2019 Expert Report

that describes various steps physicians follow when treating patients and prescribing mediation.

Doc. 1678-6 at 4–5 (Michelis Mar. 25, 2019 Expert Report ¶ 10) (citing Madelyn Pollock, M.D., et al., Appropriate Prescribing of Medications: An Eight Step Approach, 75(2) Am. Fam.

Physician 231, 231–36 (2007)). But, according to Dr. Michelis's description of the article, it never discusses how physicians prescribe anaphylaxis treatment for their patients, much less the factors that physicians consider when making this decision. Instead, she describes the article as providing general steps that physicians often take when treating patients for a number of medical issues.

Also, Dr. Michelis never describes how her training and experience supports her opinions about how doctors—in general—prescribe anaphylaxis treatment. To the contrary, she testified that she doesn't know how long physicians meet with new patients during an appointment or whether other physicians show patients multiple EAI devices to give them a choice about their treatment. Doc. 1678-7 at 29–30, 34–35 (Michelis Dep. 58:23–59:17, 63:9–64:8).

The court recognizes "most courts have prohibited experts from testifying 'about what all doctors generally consider in making prescription decisions' or about 'what doctors generally think,' unless the testimony is based on something more reliable than simply the expert's own experience as a doctor." *Bartlett v. Mut. Pharm. Co.*, 742 F. Supp. 2d 182, 195 (D.N.H. 2010) (quoting *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, No. MDL 1203, 2000 WL 876900, at \*11–12 (E.D. Pa. June 20, 2000)). For example, Mylan cites *Elorac, Inc. v. Sanofi-Aventis Canada, Inc.*, where the court prohibited an expert from opining about the "number of different factors that influence what sort of treatment a physician prescribes, including efficacy, cost, and insurance coverage" because the expert's opinion was "based on anecdotal evidence consisting of [the expert's] own observations as a member of the

medical community in Canada" and not supported by any "scientific analysis" such as a "systematic review of medical records or other data that might have provided a scientifically reliable basis for an opinion on physicians' general prescribing practices." No. 14 C 1859, 2017 WL 3592775, at \*21–22 (N.D. Ill. Aug. 21, 2017); see also In re Diet Drugs, 2000 WL 876900, at \*11 (finding that, although two physicians were "fully qualified within their specialties," their "qualifications do not qualify them to opine as experts about what all doctors generally consider in making prescription decisions").

Similarly, here, Dr. Michelis's opinions about the factors taken into account when prescribing anaphylaxis treatment are based on her own experience as a physician. But she cites no scientific analysis that permits her to opine reliably about the prescribing decisions of physicians in general. So, to the extent Dr. Michelis opines about prescribing practices of other physicians in the anaphylaxis field, the court excludes that opinion.

However, the court allows Dr. Michelis to opine about her own prescribing practices—

i.e., the factors she considers when prescribing anaphylaxis treatment. Mylan argues that she can't do even that because her testimony won't assist the jury. Mylan contends that the prescribing habits of a single physician have little probative value, and if the court permits Dr. Michelis to testify on this topic as an expert, such testimony will unduly prejudice Mylan because, as the Supreme Court has observed, "[e]xpert evidence can be both powerful and quite misleading because of the difficulty in evaluating it." Daubert, 509 U.S. at 595 (citation and internal quotation marks omitted). The court disagrees with Mylan's narrow view. Dr. Michelis's personal prescribing habits—as a practicing allergist with 40 years of experience—are probative to the question of the factors a physician may consider when prescribing anaphylaxis treatment. See Pfizer Inc. v. Teva Pharm. USA, Inc., 461 F. Supp. 2d 271, 278

(D.N.J. 2006) (prohibiting an expert from testifying about "what all doctors generally consider when making prescription decisions" but allowing the expert to testify about "the general factors that physicians may consider when making prescription decisions"). And, the court finds the value of this opinion is not outweighed by the danger of unfair prejudice. Instead, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof" are the appropriate means to diminish any prejudice from this testimony. Daubert, 509 U.S. at 596; see also Smith v. Bankers Life & Cas. Co., No. 3:05-cv-00130, 2008 WL 2845081, at \*8 (S.D. Iowa Mar. 3, 2008) (denying motion to exclude expert testimony as prejudicial because "[a]ny remaining prejudice can be resolved by 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof . . . the traditional and appropriate means of attacking shaky but admissible evidence" (quoting Daubert, 509 U.S. at 596)); In re Orthopedic Bone Screw Prods. Liab. Litig., No. 1014, 1997 WL 230818, at \*10–11 (E.D. Pa. May 5, 1997) (recognizing that a court should consider the "usefulness of cross-examination, competing expert testimony, and judicial control" when deciding whether expert opinion is unduly prejudicial, and concluding that "a properly instructed jury is competent to afford [an expert opinion] its appropriate weight" and thus "there [was] no danger of unfair prejudice, confusion of the issues, or misleading the jury" in admitting the opinion (citation and internal quotation marks omitted)).

The court also rejects Mylan's arguments that Dr. Michelis's opinions aren't supported by reliable data or information. As discussed, Dr. Michelis opines that the factors she considers when prescribing EAI devices include patient preference and choice, efficacy and safety, and insurance coverage. Doc. 1678-4 at 15–20 (Michelis Feb. 2, 2019 Expert Report ¶¶ 37–46). For the first factor—patient choice—Dr. Michelis opines that when she offers patients a choice

of EAI devices, many of her patients prefer Auvi-Q. *Id.* at 16 (Michelis Feb. 2, 2019 Expert Report ¶ 39). She cites record evidence that supports her opinion about patient preference based on Auvi-Q's size, shape, and portability. *Id.* at 16–17 (Michelis Feb. 2, 2019 Expert Report ¶¶ 39–40 nn.43–44). Mylan argues that this opinion isn't reliable because Dr. Michelis isn't able to say with certainty the percentage of her patients who chose Auvi-Q over the EpiPen. *See* Doc. 1678-7 at 45 (Michelis Dep. 74:15–21). That is no reason to exclude her opinion. Mylan's attacks on Dr. Michelis's ability to quantify the exact number of her patients who prefer Auvi-Q go to the weight of her opinion, not its admissibility. Dr. Michelis's opinion about patient preference is based on her 40 years of experience practicing as an allergist, and it is supported by the record evidence cited in her Report.<sup>7</sup> Her opinion is sufficiently reliable for a factfinder to hear it.

Dr. Michelis also opines that patient "[c]hoice increases the likelihood that [her] patients will carry their EAI device consistently and have it readily accessible in the event of an anaphylactic reaction." Doc. 1678-4 at 15 (Michelis Feb. 2, 2019 Expert Report ¶ 37). Mylan again argues that this opinion is not reliable because Dr. Michelis wasn't able to quantify what percentage of her patients carried their EAI devices with them to office appointments. See Doc. 1678-7 at 41–43 (Michelis Dep. 70:9–72:23). The court again refuses to exclude Dr. Michelis's opinion because she wasn't able to provide an exact percentage to support her opinion. Dr.

Mylan also argues that Sanofi can't use its expert simply to summarize and interpret the record evidence. See, e.g., In re Viagra Prods. Liab. Litig., 658 F. Supp. 2d 950, 967 (D. Minn. 2009) (excluding expert opinion because it was a "narrative" "summarizing the regulatory history of" a pharmaceutical drug which the "jury [was] equally capable of completing"). The court disagrees that this is what Dr. Michelis's opinions do here. Instead, Dr. Michelis has formed her opinions based on her experience as a practicing allergist. And, she supports those opinions by citing record evidence that is consistent with her opinions. The court finds nothing improper with this approach. See In re Mirena IUD Prods. Liab. Litig., 169 F. Supp. 3d 396, 478 (S.D.N.Y. 2016) (holding that expert couldn't provide narrative testimony that simply "repeats facts" but allowing expert "to us[e] documents and background to opine" about her various conclusions).

Michelis's Expert Report explains that anaphylaxis occurs unexpectedly so "EAI devices must be kept readily available for at-risk patients." Doc. 1678-4 at 10–11 (Michelis Feb. 2, 2019 Expert Report ¶ 22). She cites a study showing that failing to carry an EAI device is a problem among patients. *Id.* And, she opines, in her experience as a practicing allergist her patients are more likely to carry their device if they have a choice when selecting an EAI device. *Id.* at 15–16 (Michelis Expert Report ¶ 37). Mylan's criticisms of this opinion are fodder for cross-examination. But, the court declines to exclude her opinion on this basis.

For the second factor—efficacy and safety—Dr. Michelis opines that "Auvi-Q [is] a better choice for some patients" because it has a retractable needle. Doc. 1678-4 at 18–19 (Michelis Feb. 2, 2019 Expert Report ¶ 43). Dr. Michelis supports this opinion by citing a study conducted by the *Annals of Emergency Medicine* that documented skin lacerations sustained by anaphylaxis patients, particularly children, from using an EpiPen. *Id.* at 17–18 (Michelis Feb. 2, 2019 Expert Report ¶ 42). Mylan argues that Dr. Michelis concedes that "there is no data comparing the safety of" Auvi-Q and EpiPen. Doc. 1678-5 at 5 (Michelis Rebuttal Report ¶ 2). But this admission doesn't render her opinion unreliable. Dr. Michelis has explained, based on her experience as a practicing allergist, that she considers efficacy and safety before prescribing an EAI device to her patients. And, she supports her opinion about how she considers the efficacy and safety specifically of Auvi-Q and EpiPen when prescribing EAI devices by citing evidence that is consistent with her conclusions. The court thus finds her opinion reliable.

Finally, for the last factor—insurance coverage—Dr. Michelis opines that she considers a patient's out-of-pocket cost when prescribing an EAI device. <u>Doc. 1678-4 at 19</u> (Michelis Feb. 2, 2019 Expert Report ¶ 44). She explains that, during 2013–2015, many insurers didn't cover Auvi-Q, making it more expensive or inaccessible to her patients. *Id.* at 20 (Michelis Feb. 2,

2019 Expert Report ¶ 46). That is why she "wrote more prescriptions for EpiPen than Auvi-Q during that period" even though Auvi-Q had a "convenient size and helpful audio instructions which appealed to many of [her] patients." *Id.* Mylan argues that this opinion isn't reliable because its own expert opines that he didn't have any issues with Auvi-Q insurance coverage so it didn't influence his prescribing decisions. The court refuses to exclude Dr. Michelis's opinion simply because Mylan's expert disagrees. The conflicting testimony is something that the trier of fact must weigh and consider. *See In re Universal Serv. Fund Tel. Billing Practices Litig.*, No. 02-MD-1468-JWL, 2008 WL 4382141, at \*8–9 (D. Kan. Sept. 26, 2008) (explaining that a "dispute among the experts concerning whether other events caused over-recoveries . . . must be left for the jury"). But it doesn't render unreliable Dr. Michelis's opinion about factoring insurance coverage into her prescribing decisions.

For all these reasons, the court refuses to exclude Dr. Michelis's opinions about her own prescribing practices and the factors she considers when prescribing anaphylaxis treatment, including patient choice, safety and efficacy, and insurance coverage. But, as discussed, the court prohibits Dr. Michelis from opining about the factors that physicians—in general—consider when prescribing anaphylaxis treatment.

#### 2. Pharmaceutical Sales Force's Role in Prescriptions

Next, Mylan argues that Dr. Michelis's opinions about the pharmaceutical sales force are inadmissible. Dr. Michelis's Expert Report describes her interactions with Mylan and Sanofi sales representatives who visited her in the 2013–2015 period to discuss either the EpiPen or Auvi-Q. Doc. 1678-4 at 20 (Michelis Feb. 2, 2019 Expert Report ¶ 47). She opines that "[m]eetings with pharmaceutical sales representatives and the flyers they leave behind can have a meaningful impact on prescribing behavior" and that "price messaging from pharmaceutical

companies can play a considerable role in encouraging doctors to prescribe one EAI device over the other." *Id.* at 21 (Michelis Feb. 2, 2019 Expert Report ¶ 48).

Mylan again argues that Dr. Michelis's opinion is unreliable to the extent she opines about the influence of pharmaceutical sales representatives on physicians generally. Mylan asserts that her opinion is based just on her own experience as a practicing allergist, but she cites no reliable methodology for reaching a conclusion about the prescribing practices of all physicians. Indeed, Dr. Michelis testified that she has "no idea what goes on with all physicians" when they receive information from a pharmaceutical sales representative. Doc. 1678-7 at 60–61 (Michelis Dep. 108:20–109:9); see also id. at 69 (Michelis Dep. 130:13–25) (testifying that she is "not aware what goes on in other [physicians'] offices" with information shared by pharmaceutical sales representatives). Also, she testified that she has "no idea" what Sanofi sales representatives told other physicians about EAI devices, and so, she has "no idea" whether statements made by Sanofi sales representatives had any "impact" on other physicians. Id. at 63–64 (Michelis Dep. 111:19–112:6).

Sanofi argues that Dr. Michelis's testimony is reliable based on her experience as a practicing allergist and from teaching and supervising other doctors' prescribing habits. Sanofi cites *Forest Laboratories, Inc. v. Ivax Pharmaceuticals, Inc.*, where the court allowed a clinical psychiatrist to provide expert testimony about the effects of pharmaceutical marketing on physicians' prescribing habits. 237 F.R.D. 106, 111–12 (D. Del. 2006). The court held that the proffered expert was qualified to provide the opinion based on his "experience in writing prescriptions himself, *as well as supervising others who write prescriptions*[.]" *Id.* at 112 (emphasis added). But, the record here doesn't show as much. It doesn't reflect that Dr. Michelis has the same supervising experience that would qualify her to opine about other

physicians' prescribing practices. Dr. Michelis testified that she teaches residents about allergy and immunology and that other physicians refer her patients. Doc. 1794-4 at 4 (Michelis Dep. 124:5–125:25). But, she conceded that she doesn't know what information physicians "access" when making prescribing decisions. *Id.* (Michelis Dep. 125:20–25). Because the court finds no reliable basis for Dr. Michelis to opine about how pharmaceutical sales representatives affect the prescribing habits of physicians in general, the court precludes her opinion on this topic. See, e.g., Elorac, 2017 WL 3592775, at \*22 (excluding expert testimony about promotional effects for a pharmaceutical product because it was based "on nothing more than [the expert's] own observations as a target of [the pharmaceutical sales people]"); In re Baycol Prods. Litig., 532 F. Supp. 2d 1029, 1069 (D. Minn. 2007) (prohibiting physician from testifying about what other physicians knew about a product based on the information received from a pharmaceutical company); Pfizer, 461 F. Supp. 2d at 278 (excluding expert opinion about the "the extent to which marketing drove [a drug's] prescriptions" because the expert relied on his "personal knowledge and experience . . . [to] support [the] opinion" and that didn't "form[] a sufficient basis for his broad conclusions concerning the impact of sales and marketing efforts on [the drug's] prescriptions").

Also, Mylan argues that Dr. Michelis's opinions about her own experiences with pharmaceutical sales representatives is inadmissible. Mylan asserts that her testimony is nothing more than late-disclosed fact testimony and not proper expert testimony. Mylan cites *Elorac*, where the court precluded the expert from offering an opinion about a pharmaceutical company's promotional effects that was based on his "own observations as a target of [pharmaceutical] salespeople." 2017 WL 3592775, at \*22. The court held that the expert's opinion was just "fact

testimony in the midst of expert testimony." *Id.* And, it excluded the opinion, finding that it "could confuse and mislead the jury and cause prejudice to [the opposing party]." *Id.* 

The court reaches a different conclusion here. Dr. Michelis's Expert Report describes the messaging she received from pharmaceutical companies about EAI devices. Doc. 1678-4 at 20-21 (Michelis Feb. 2, 2019 Expert Report ¶¶ 47–48). And, she explains how that factor—along with several others—may influence her prescribing decisions as a practicing allergist. *Id.* at 15— 21 (Michelis Feb. 2, 2019 Expert Report ¶¶ 37–49). So, the court finds that Dr. Michelis's testimony isn't just fact testimony—like the proffered expert was offering in *Elorac*. Instead, it's testimony about one of the several factors she considers when prescribing anaphylaxis treatment. And, it supports her opinion about how she considers and applies those factors when prescribing treatment to patients. As discussed above, her testimony has probative value that is not outweighed by the risk of undue prejudice. The court is confident that "[v]igorous crossexamination, presentation of contrary evidence, and careful instruction on the burden of proof" can mitigate any potential confusion or prejudice from her testimony about pharmaceutical marketing. Daubert, 509 U.S. at 596. The court thus declines to exclude this portion of her opinion. Instead, Dr. Michelis may opine about how pharmaceutical sales representatives may influence her own prescribing decisions when treating anaphylaxis patients.

# 3. EpiPen Shortages

Finally, Mylan argues that Dr. Michelis's opinion about EpiPen shortages is inadmissible. In her Rebuttal Report, Dr. Michelis responds to Mylan's expert's opinion that patients are not harmed if Auvi-Q isn't available. Doc. 1678-5 at 7 (Michelis Rebuttal Report ¶ 15). Dr. Michelis criticizes this opinion because it "ignores the fact that EpiPen is not always available."

Id. As, she describes EpiPen shortages that occurred in 2018. Id. at 7–9 (Michelis Rebuttal

Report ¶¶ 16–19). Mylan argues that her opinion isn't relevant, but even if it is, her testimony is prejudicial, misleading, and late-disclosed fact testimony. The court disagrees.

Dr. Michelis properly cites evidence of EpiPen shortages to support her opinion that patients were harmed by not having access to Auvi-Q on the EAI market. This is not improper fact testimony, but instead, Dr. Michelis properly "us[es] documents and background" about EpiPen recalls and shortages to support her expert opinion. In re Mirena IUD Prods. Liab. Litig., 169 F. Supp. 3d at 478. Specifically, she relies on evidence of the EpiPen recalls and shortages to support her opinion that "[h]aving more [EAIs] available to combat a shortage, therefore, is critically important for patients, who should carry their EAI devices at all times." Doc. 1678-5 at 9 (Michelis Rebuttal Report  $\P$  18). This type of expert testimony is permissible. See In re Mirena IUD Prods. Liab. Litig., 169 F. Supp. 3d at 478 (holding that expert couldn't provide narrative testimony that simply "repeats facts" but allowing expert "to us[e] documents and background to opine" about her conclusions); see also Scott v. Chipotle Mexican Grill, Inc., 315 F.R.D. 33, 47 (S.D.N.Y. 2016) (rejecting argument that expert opinion was inadmissible because it "simply summariz[ed] or quot[ed] deposition and declarant testimony" and concluding that the opinion was "helpful" because it "use[d] record evidence as a foundation for his expert opinion" and "relie[d] on these documents to attack the probative value of plaintiffs' experts' opinion"); In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig., No. 2:12-MD-02327, 2014 WL 186872, at \*16 (S.D.W. Va. Jan. 15, 2014) (rejecting argument that expert was offering an improper "historical narrative of the evidence" and finding instead that the expert's citations to the evidence "provide[d] the factual basis for [his] opinions and [was] therefore helpful for the jury to understand [his] opinions").

Also, the court finds that the probative value of Dr. Michelis's opinion isn't outweighed by risk of undue prejudice. "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof" remain "the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596. Those tools are capable of mitigating any prejudice derived from testimony about EpiPen shortages. So, the court refuses to exclude Dr. Michelis's opinion about EpiPen shortages.

#### 4. Conclusion

As discussed, the court excludes Dr. Michelis's opinions to the extent she offers opinions about the factors that physicians—in general—consider when prescribing anaphylaxis treatment. Also, the court excludes Dr. Michelis's opinions to the extent she opines about influence that pharmaceutical sales representatives have on how physicians—in general—prescribe anaphylaxis treatment.

But, the court permits Dr. Michelis to testify about her own prescribing practices and the factors she considers when prescribing an EAI device, including how pharmaceutical sales representatives influence her prescribing behavior. And, the court refuses to exclude Dr. Michelis's opinions about EpiPen shortages.

The court thus grants Mylan's Motion to Exclude Opinion Testimony of Mary Ann Michelis, M.D. (<u>Doc. 1683</u>) in part and denies it in part.

#### C. Motion to Exclude Opinions of Eduardo Schur

Mylan asks the court to exclude the opinions of Eduardo Schur. Sanofi has retained Mr. Schur to provide rebuttal expert opinion about the pharmaceutical industry in response to the expert opinions offered by Mylan's expert, Gary Zieziula. Mr. Schur has about 30 years' experience working in the pharmaceutical industry. Doc. 1676-4 at 4, 23–25 (Schur Expert

Rebuttal Report ¶ 3, App. 1). Mr. Schur has worked for three pharmaceutical companies that are separate divisions of Johnson & Johnson: He served as a Product Director and District Manager for Janssen Pharmaceutica, a New Products Director for McNeil Consumer Products, and a Group Product Director for Ortho McNeil Pharmaceutical. *Id.* In these positions, Mr. Schur either led the launches or managed the execution of launching several pharmaceutical products. *Id.* After his work at Johnson & Johnson, Mr. Schur joined Bristol Meyers Squibb as Vice President of Marketing. *Id.* There, Mr. Schur led the launch of Plavix (clopidogrel bisulfate) in acute coronary syndromes—which has proved one of the most successful pharmaceutical products in the United States. *Id.* While working in the pharmaceutical industry, Mr. Schur has developed and managed marketing plans for pharmaceutical products, supervised sales representatives, developed customer relationships (including ones with managed care organizations and hospitals), developed long-term strategy plans and forecasts, and participated in licensing and acquisition activities. *Id.* at 24–25 (Schur Expert Rebuttal Report App. 1).

Currently, Mr. Schur is a Managing Director with Navigant Consulting, Inc. *Id.* at 4 (Schur Expert Rebuttal Report ¶ 1). He serves as Global Practice Leader of Navigant's Life Sciences Consulting Practice where he provides consulting services to clients who include pharmaceutical companies and biotechnology organizations. *Id.* (Schur Expert Rebuttal Report ¶ 1–2). Mr. Schur assists these clients with strategy, regulatory, compliance, and market access issues. *Id.* (Schur Expert Rebuttal Report ¶ 1). Mr. Schur also is a faculty member at Rutgers University's Edward J. Bloustein School of Planning and Public Policy where he teaches courses on healthcare strategy and marketing as well as life sciences innovation and marketing. *Id.* (Schur Expert Rebuttal Report ¶ 2).

Mylan asks the court to exclude Mr. Schur's opinions on six topics. They include Mr. Schur's opinions about: (1) Mylan's rebating practices, (2) the Auvi-Q recall, (3) whether Sanofi's marketing practices complied with FDA standards, (4) whether Sanofi adequately monitored its sales representatives, (5) Auvi-Q's purported innovative features, and (6) Mylan and Sanofi's intentions and states of mind. Mylan contends that Mr. Schur either is not qualified to offer these opinions or his opinions are unreliable, and thus, not helpful to the trier of fact. The court addresses each of the six topics that Mylan challenges, in turn, below.

## 1. Mylan's Rebating Practices

Mr. Schur opines that "Sanofi's contracting and rebating strategy, like its overall marketing strategy, was reasonable and prudent, and consistent with industry practices" while "Mylan's plan to systematically block Auvi-Q from the U.S. EAI drug device market was not consistent with common industry practices." Doc. 1676-5 at 6 (Schur Second Expert Rebuttal Report ¶ 9). Mr. Schur describes Mylan's competitive strategy as "exclusionary" and not consistent with "common practice' in the [pharmaceutical] industry." *Id.* at 17 (Schur Second Expert Rebuttal Report ¶ 32). Also, Mr. Schur asserts that "based on [his] experience in the [pharmaceutical] industry" PBMs typically don't "pit competing pharmaceutical companies against one another to extract deep discounts and rebates from them." *Id.* at 16–17 (Schur Second Expert Rebuttal Report ¶ 31).

Mylan argues the court should exclude these opinions for two reasons. *First*, Mylan argues that Mr. Schur isn't qualified to offer them. Mylan asserts that Mr. Schur testified that he's not a "true expert[] in market access" and has no experience negotiating with PBMs. <u>Doc.</u> 1676-6 at 12–13, 17, 21 (Schur Dep. 32:23–33:12, 37:8–19, 41:2–14). Mylan contends that Mr. Schur merely relies on other experts from his consulting firm, as well as Sanofi's own research,

to form his opinions about PBM contracting and rebating. Thus, Mylan argues, Mr. Schur isn't qualified as an expert to offer these opinions because (a) he lacks expertise in this specific area, *i.e.*, PBM contracting, and (b) he's formed his opinions based on others' expertise.

Sanofi disagrees. It argues that Mr. Schur is qualified to offer these opinions based on his consulting experience with clients who regularly seek his guidance about market access and contracting issues. Indeed, Mr. Schur testified that he regularly consults with clients about market access and tier placement. Doc. 1676-6 at 12-13 (Schur Dep. 32:23-33:12); see id. at 17 (Schur Dep. 37:8–15) (testifying that he provides input to clients negotiating with PBMs or payors about a product's formulary placement). Also, he testified that he understands "the whole process" of contracting with PBMs "very well" and has "been exposed to it over and over." Id. at 12–13, 15 (Schur Dep. 32:23–33:12, 35:9–20). The court agrees that Mr. Schur's knowledge about and experience with PBM contracting makes him qualified to offer his opinions about rebating practices. Mylan's challenges to Mr. Schur's expertise in this realm go to the weight of his opinions, not their admissibility. See, e.g., Ralston v. Smith & Nephew Richards, Inc., 275 F.3d 965, 970 (10th Cir. 2001) ("[A]s long as an expert stays within the reasonable confines of his subject area, our case law establishes a lack of specialization does not affect the admissibility of [the expert] opinion, but only its weight." (citation and internal quotation marks omitted)); U.S. Fid. & Guar. Co. v. Sulco, Inc., 171 F.R.D. 305, 307 (D. Kan. 1997) (recognizing that "another witness might have provided greater expertise in the area of [insurance] claims handling," but nevertheless concluding that the expert was qualified to opine about how plaintiff handled insurance claims because the expert's "experience as an insurance industry professional [was] sufficient to permit his testimony").

Second, Mylan contends that Mr. Schur hasn't based his opinions on the relevant facts in the record. Mylan complains that Mr. Schur didn't review any of the PBMs' or payors' testimony. And, Mylan argues, Mr. Schur's opinions aren't reliable because he didn't review documents and testimony about Mylan and Sanofi's negotiations with any PBMs or payors, PBMs and payors' internal communications, or the rebate contracts at issue here. The court refuses to exclude Mr. Schur's opinions for this reason. As our court has recognized, "[t]he extent to which [an expert] considered the entirety of the evidence in the case is a matter for cross-examination." In re Urethane Antitrust Litig., MDL No. 1616, No. 04-1616-JWL, 2012 WL 6681783, at \*3 (D. Kan. Dec. 21, 2012), aff'd 768 F.3d 1245 (10th Cir. 2014) (concluding that an expert's "failure to examine the entire record" didn't "render[] fatally unreliable his opinion"); see also McGreevy v. Stroup, No. 1:CV-01-1461, 2003 WL 27374140, at \*5 (M.D. Pa. June 17, 2003) (explaining that "[w]hat [an expert] did and did not rely on in making his determinations goes to the weight that the jury should afford his testimony" (citing Stecyk v. Bell Helicopter Textron, Inc., 295 F.3d 408, 414 (3d Cir. 2002))). Here, Mr. Schur's Second Expert Rebuttal Report explains the evidence he considered to reach his conclusions. Doc. 1676-5 at 16–17 (Schur Second Expert Rebuttal Report ¶¶ 30–32). Mylan's complaints about the evidence Mr. Schur didn't consider when forming his opinions goes to their weight and value. But it doesn't preclude their admission. The court thus refuses to exclude Mr. Schur's opinions about Mylan's rebating practices.

#### 2. Auvi-Q Recall

Next, Mylan asserts that Mr. Schur is not qualified to opine about the Auvi-Q recall. Mr. Schur offers rebuttal opinions in response to opinions offered by one of Mylan's experts. Mr. Schur opines that Mylan's expert, Mr. Zieziula, "overplays the significance of a product recall"

and that "if Sanofi had decided to relaunch Auvi-Q, [it] would have been well positioned to do so relatively quickly." Doc. 1676-5 at 18, 20 (Schur Second Expert Rebuttal Report ¶ 33, 40). Mylan argues that Mr. Schur isn't qualified to offer these opinions because he lacks knowledge about and experience with total product recalls. Mylan criticizes Mr. Schur for not knowing the definition of a Class 1 recall when asked in his deposition and for relying on members of his team to define that term for him. Doc. 1676-6 at 83–85 (Schur Dep. 176:23–178:9). And, Mylan argues Mr. Schur isn't qualified to offer these opinions because he's never supervised a recall and only remembers working on one total recall as a consultant some five to ten years ago where he "helped develop a template of how to reintroduce a product in the marketplace." *Id.* at 82–83 (Schur Dep. 175:21–176:21).

But, Mr. Schur also testified about his first hand experience with recalls. *Id.* at 80–83 (Schur Dep. 173:15–176:21). Mr. Schur testified about training he received on recalls when he worked for a pharmaceutical company, and he described working as a consultant for a client who completely recalled a product from the market. *Id.*; *see also* Doc. 1676-5 at 18 (Schur Second Expert Rebuttal Report ¶ 33) ("In my career in the pharmaceutical industry, I have had first-hand experience with product recalls and I continue to work with clients on assessing best practices when facing product recalls and possible relaunch scenarios."). The court finds this experience qualifies Mr. Schur to offer his opinions about the Auvi-Q recall. Mylan may challenge the extent of Mr. Schur's experience with product recalls, but that subject is one Mylan can raise on cross-examination. *See Burton v. R.J. Reynolds Tobacco Co.*, 183 F. Supp. 2d 1308, 1312 (D. Kan. 2002) ("Any alleged gap in [an expert's] qualifications goes to the weight of his expert opinion and can be adequately addressed by cross-examination.").

Mylan also asks the court to exclude Mr. Schur's opinion that "Sanofi would have been able to relaunch Auvi-Q[]... more quickly than kaléo did." Doc. 1676-5 at 20 (Schur Second Expert Rebuttal Report ¶ 40). Mylan argues that the record doesn't support this conclusion. For support, Mylan cites internal Sanofi documents forecasting a relaunch date beyond that of kaléo's launch. But Sanofi cites other record evidence that, it contends, supports Mr. Schur's opinion. And, Sanofi argues, the trier of fact should decide whether it was reasonable for Mr. Schur to reach his conclusions based on that evidence. The court agrees. Mr. Schur has provided a reliable explanation about how he has reached his conclusion. Again, Mylan's arguments go to the weight of his opinions. See, e.g., McCoy v. Whirlpool Corp., 258 F. App'x 189, 196 (10th Cir. 2007) (reversing trial court's exclusion of expert testimony that failed to address competing expert's opinion about alternative causes of a fire because the fire's cause was "very much disputed, and it was the jury's province to decide this issue based on its assessment of the evidence and the credibility of [the experts'] conflicting testimony"); RMD, LLC v. Nitto Ams., Inc., No. 09-2056-JAR-DJW, 2012 WL 5398345, at \*10 (D. Kan. Nov. 5, 2012) (refusing to exclude plaintiff's expert opinion because expert hadn't taken into account other evidence when forming his opinion and concluding that defendants' arguments "go to the weight and not the admissibility of [the expert's] opinion, and [defendants] are free to cross-examine him on this point"). Mylan can challenge the factual basis for Mr. Schur's conclusions by cross-examining him about other evidence that, Mylan contends, contradicts his opinions. But Mylan's arguments don't render Mr. Schur's opinions about the Auvi-Q recall inadmissible.

The court thus denies Mylan's request to exclude Mr. Schur's opinions about the Auvi-Q recall.

## 3. Sanofi's Compliance with FDA Standards

Mylan next argues that that Mr. Schur isn't qualified to offer opinions whether Sanofi's marketing of Auvi-Q complied with FDA standards. As discussed, Sanofi retained Mr. Schur to rebut the opinions of Mylan's expert, Gary Zieziula. Mr. Zieziula opines that Sanofi made claims about patients' preference for Auvi-Q over the EpiPen that were misleading and "lack[ed] the substantiation required by [FDA] regulatory standards." Doc. 1676-4 at 7 (Schur Expert Rebuttal Report ¶ 11). Mr. Schur opines that Mr. Zieziula has reached the "wrong conclusion[s]" about Sanofi's marketing. *Id.* (Schur Expert Rebuttal Report ¶ 12). Mr. Schur concludes that Sanofi's patient preference claims were "in accordance with FDA's recommendations." *Id.* He opines that Sanofi engaged in a "rigorous process" with the FDA "for developing promotional claims" for Auvi-Q. *Id.* at 9 (Schur Expert Rebuttal Report ¶ 16). Also, Mr. Schur asserts that "Sanofi had rigorous internal processes and practices to ensure legal and regulatory compliance" and that "Sanofi's practices relating to promotional messaging [for] Auvi-Q were entirely consistent with commonly-accepted industry practices and were in no way overly aggressive, irresponsible, or improper." *Id.* at 10 (Schur Expert Rebuttal Report ¶ 17).

Mylan argues that Mr. Schur isn't qualified to offer these opinions because he neither has worked for the FDA nor had responsibility for regulatory compliance in pharmaceutical marketing. Instead, Mylan contends that Mr. Schur testified that he relied on other experts to form his opinions about FDA compliance. And, Mylan asserts, the court should exclude those opinions because Mr. Schur can't "merely parrot the opinions of other experts whose conclusions are not themselves in the record." *Beck's Office Furniture & Supplies, Inc. v. Haworth, Inc.*, Nos. 95-4018, 95-4029, 94 F.3d 655 (table), 1996 WL 466673, at \*7 (10th Cir. Aug. 16, 1996).

The court disagrees with Mylan's description of Mr. Schur's deposition testimony. Mr. Schur testified that he worked with members of his consulting firm's regulatory compliance team to prepare his Expert Report. Doc. 1676-6 at 5-9 (Schur Dep. 11:10-15:16). Mr. Schur testified that those team members helped him by "review[ing] the documents" including "every single interaction with the FDA," and they "tr[ied] to reconstruct the facts" necessary for Mr. Schur's analysis. *Id.* at 8–9 (Schur Dep. 14:10–15:16). Mr. Schur testified that these team members never explained to him "what a robust process with the FDA looks like" because he "could understand what that looks like." *Id.* (Schur Dep. 14:3–9). Also, they never explained to him "regulatory guidelines or processes that [he wasn't] otherwise familiar with." *Id.* (Schur Dep. 14:17–24). Mr. Schur testified that he relied on these team members' input but he was the one who came up with the "final conclusions." *Id.* at 6–7 (Schur Dep. 12:20–13:1). Also, Mr. Schur's Expert Report explains that he reached his opinions about FDA compliance based on his "review of this evidence and [his] experience in sales, sales management, and sales training." Doc. 1676-4 at 10 (Schur Expert Rebuttal Report ¶ 17); see also id. at 6 (Schur Expert Rebuttal Report ¶ 9).

As Sanofi asserts, as an expert witness, Mr. Schur "is permitted to use assistants in formulating his expert opinion . . . ." *Dura Auto. Sys. of Ind., Inc. v. CTS Corp.*, 285 F.3d 609, 612–13 (7th Cir. 2002) (citation omitted). Indeed, our court has refused to exclude expert opinion that was based on work performed by another person at the expert's direction.

Stephenson v. Honeywell Int'l, Inc., 703 F. Supp. 2d 1250, 1255–56 (D. Kan. 2010); see also *Titan Stone, Tile & Masonry, Inc. v. Hunt Constr. Grp., Inc.*, No. 05-3362 (GEB), 2007 WL 1659056, at \*3–4 (D.N.J. June 5, 2007) (denying motion to exclude opinions of an expert who relied "on information extracted" by another expert and finding that didn't make the expert "a

mere 'mouthpiece' for [the other expert's] opinion" when the other expert "merely extracted and presented raw data to [the testifying expert] in a format that was more user-friendly and manageable").

In *Stephenson*, Judge Lungstrum rejected the argument that the expert was "merely parroting the opinions of" another but instead found the expert had "formed his own opinions" after reviewing information provided by assistants. 703 F. Supp. 2d at 1255. The court noted that the opposing party was free to cross-examine the expert "about his supervision of those assistants and whether reliance on such assistants is standard practice in the field." *Id.* (citing *Dura*, 285 F.3d at 612–13). But, Judge Lungstrum found "no basis . . . to conclude that [the expert] improperly relied on any opinions formed by others that are outside of his own expertise." *Id.* at 1256.

The court reaches the same conclusion here. Mr. Schur is qualified to provide his opinions about FDA compliance based on his experience working in the pharmaceutical industry. He testified that his opinions on this topic are his own. And, he testified that he merely relied on team members to help him review documents and reconstruct the facts. Thus, the court concludes Mr. Schur isn't "merely parrot[ing] the opinions of other experts whose conclusions are not themselves in the record." *Beck's Office*, 1996 WL 466673, at \*7. Instead, Mr. Schur offers his own opinions on FDA compliance which he is qualified to do. The court thus refuses to exclude Mr. Schur's opinions about Sanofi's compliance with FDA standards.

## 4. Sanofi's Monitoring of Sales Force

Mylan next asks the court to exclude Mr. Schur's opinions that Sanofi adequately monitored its sales force. Mr. Schur offers expert opinion to rebut Mr. Zieziula's opinions that Sanofi management failed "to set the right tone at the top and put adequate measures in place to

ensure compliance with industry standard practices and all legal and regulatory requirements."

Doc. 1676-4 at 10 (Schur Expert Rebuttal Report ¶ 17). Mr. Schur disagrees with Mr. Zieziula's opinion, finding instead that "[b]ased on the materials [he has] reviewed and [his] experience in the industry, Sanofi had adequate oversight to enforce compliance with its Auvi-Q promotional messaging policies." *Id.* at 12 (Schur Expert Rebuttal Report ¶ 24). Mr. Schur concludes, "Sanofi took more than adequate investigative and corrective measures, including appropriate disciplinary actions, whenever necessary to enforce its company policies." *Id.* 

Mylan asserts that these opinions lack foundation and are speculative. For support, Mylan argues that Mr. Schur testified that he hadn't reviewed certain documents when forming his opinion. *See* Doc. 1676-6 at 93–94 (Schur Dep. 274:21–275:9) (conceding that Mr. Schur didn't "remember seeing that particular document"); *see also id.* at 98 (Schur Dep. 279:20–25) (testifying that "this is the first time [Mr. Schur was] seeing this" particular document). But, Mr. Schur also testified that he and his team "looked into all the materials" describing Sanofi's supervision of the sales force which led him to draw the conclusion asserted in his Expert Rebuttal Report. *Id.* at 93 (Schur Dep. 274:12–20); *see also* Doc. 1676-4 at 11–12 (Schur Expert Rebuttal Report ¶ 21–25) (describing the materials Mr. Schur reviewed about Sanofi's sales representative training, its enforcement of its policies, and remedial measures imposed).

To the extent Mylan challenges Mr. Schur's failure to review every document pertinent to this issue, that is a subject it can explore on cross-examination. *See In re Urethane Antitrust Litig.*, MDL No. 1616, No. 04-1616-JWL, 2012 WL 6681783, at \*3 (D. Kan. Dec. 21, 2012), aff'd 768 F.3d 1245 (10th Cir. 2014) (noting that "[t]he extent to which [an expert] considered the entirety of the evidence in the case is a matter for cross-examination" and concluding that an expert's "failure to examine the entire record" didn't "render[] fatally unreliable his opinion");

see also Stecyk v. Bell Helicopter Textron, Inc., 295 F.3d 408, 414 (3d Cir. 2002) (recognizing that "[a] party confronted with an adverse expert witness who has sufficient, though perhaps not overwhelming, facts and assumptions as the basis for his opinion can highlight those weaknesses through effective cross-examination" and explaining that once an expert meets "the foundational requirements for admissibility, the burden shift[s] to [the opposing party] to explore any deficiencies in the expert's sources"). But, Mylan's criticisms don't render Mr. Schur's opinions inadmissible. Instead, the court finds that Mr. Schur's background and experience in the pharmaceutical industry qualify him to testify on this topic. And, the court concludes that Mr. Schur's review of the evidence in the case provides a reliable basis for his opinions. Any challenge to the evidence Mr. Schur relied on to support his opinions goes to the weight, but not admissibility, of his opinions. The court thus refuses to exclude Mr. Schur's opinions about Sanofi's monitoring of its sales force.

## 5. Auvi-Q's Features

Mylan next argues that the court should exclude Mr. Schur's opinions about Auvi-Q's features because, Mylan contends, they will not assist the jury. Mr. Schur opines that "Auvi-Q was an innovative new [EAI] device that satisfied a significant unmet patient need in a market that, prior to Auvi-Q's launch, was uniquely characterized by a lack of innovation." Doc. 1676-5 at 6 (Schur Second Expert Rebuttal Report ¶ 2); see also id. at 7–9 (Schur Second Expert Rebuttal Report ¶ 12–15). Mylan asserts that Mr. Schur's opinions are not helpful to the jury because he was not able to identify any of Auvi-Q's innovative features at his deposition but instead referred to market research found in the factual record to support this opinion. See Doc. 1676-6 at 34–36 (Schur Dep. 90:14–92:23). The court disagrees with Mylan's argument for two reasons.

First, Mylan misconstrues Mr. Schur's deposition testimony. When asked what features he described as innovative, Mr. Schur testified that he'd have to go back to look at the consumer reports that he reviewed. *Id.* at 34–35 (Schur Dep. 90:24–91:10). But also, he was able to cite several features including the size of the device, its voice commands, and its shape. *Id.*; *see also id.* at 36 (Schur Dep. 92:2–23) (discussing how Auvi-Q's features addressed a "medical need in the marketplace" including "portability" and "ease of use"). Thus, Mr. Schur's testimony shows that he was able to identify features of Auvi-Q that he thinks are innovative.

Second, the court rejects Mylan's argument that Mr. Schur's testimony is not helpful to the trier of fact because it's "nothing more than a recitation of cherry-picked portions of the record that support Sanofi's theory of the case." Doc. 1676-2 at 13. Mr. Schur adequately identifies the evidence he reviewed to form his opinions—including market research conducted both by Sanofi and Mylan. Doc. 1676-5 at 7-9 (Schur Second Expert Rebuttal Report ¶¶ 12-15). Based on his experience in the pharmaceutical industry, Mr. Schur is qualified to review that evidence and provide his opinion about the need for innovation in the EAI market and how, in his opinion, Auvi-Q's features addressed that need. His reliance on the factual record to perform his analysis and reach his conclusions is not improper. See, e.g., Allen v. Am. Cap. Ltd., 287 F. Supp. 3d 763, 803–04 (D. Ariz. 2017) (recognizing an expert "may not provide narrative testimony pulled directly from the record without some analysis, opinion, or expertise" and holding that proffered expert opinion wasn't improper narrative because the experts had "utilize[d] their expertise . . . to interpret and explain the record, which will ultimately assist the jury in understanding these experts' opinions" (citation and internal quotation marks omitted)); *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 478 (S.D.N.Y. 2016) (holding that expert couldn't provide narrative testimony that "merely repeats facts" but allowing expert

opinion "using documents and background to opine" about her conclusions). And, the court finds that Mr. Schur's opinions will assist the trier of fact with understanding whether Auvi-Q offered features that were innovative to the EAI market.

The court thus refuses to exclude Mr. Schur's opinion about Auvi-Q's features.

## 6. Mylan and Sanofi's Intentions

Finally, Mylan argues that Mr. Schur improperly opines about Mylan and Sanofi's intent. For support, Mylan cites to three of Mr. Schur's opinions. First, Mr. Schur opines that his review of the evidence led him to conclude that "Mylan engaged in exclusionary conduct intended to block Auvi-Q from the market." Doc. 1676-5 at 17 (Schur Second Expert Rebuttal Report ¶ 32). Second, Mr. Schur opines that his "review of the materials demonstrate[s] that Sanofi intended to relaunch [Auvi-Q] following the recall." *Id.* at 18–19 (Schur Second Expert Rebuttal Report ¶ 35). Third, Mr. Schur opines that his review of the evidence caused him to conclude that Sanofi had no "intention to measure comparative messaging" or "incorporate results of competitive messaging" when marketing Auvi-Q. Doc. 1676-4 at 14 (Schur Expert Rebuttal Report ¶ 31(A)); *see also id.* at 15–16 (Schur Expert Rebuttal Report ¶ 32–34).

Mylan contends that these opinions are improper expert testimony about a party's state of mind. Thus, Mylan argues the court should exclude them. See Pioneer Ctrs. Holding Co. Emp. Stock Ownership Plan & Tr. v. Alerus Fin., N.A., 858 F.3d 1324, 1342 (10th Cir. 2017) (affirming district court's exclusion of expert testimony that "would require the experts to read the mind of [a party], predict how [the party] would have weighed factors it deemed relevant, and find that [the party] would not only reach the conclusion that it must consent but also do so" because "[s]uch prediction . . . is beyond the scope of any expert" (citations and internal quotation marks omitted)); see also In re Motor Fuel Temperature Sales Practices Litig., No. 07-

1840-KHV, 2012 WL 380159, at \*7 (D. Kan. Feb. 6, 2012) ("An expert witness may not speculate as to the intent or motives of parties or others" because "[t]he question of intent is a class jury question and not one for the experts" (citations omitted)).

The court disagrees that Mr. Schur offers improper expert testimony here about the parties' intentions. Instead, with each opinion, Mr. Schur has cited the evidence that, he contends, led him to reach his conclusions about Mylan and Sanofi's actions. As already discussed, our court has permitted an expert to offer opinions that the record evidence "is consistent with" a party engaging in certain conduct. See In re Urethane Antitrust Litig., MDL No. 1616, No. 04-1616-JWL, 2012 WL 6681783, at \*3 (D. Kan. Dec. 21, 2012) (recognizing that an expert may not "opine on the ultimate issue of whether a conspiracy existed" but allowing expert opinion "that certain conduct by the alleged conspirators is consistent with the existence of an agreement to fix prices" because the expert's "opinion is essentially that particular events, assuming they occurred, are consistent with a conspiracy" (emphasis added)); see also In re Processed Egg Prods. Antitrust Litig., 81 F. Supp. 3d 412, 424 (E.D. Pa. 2015) ("An economic expert may permissibly testify . . . whether certain conduct is consistent with collusion or an entity or individual's self-interest . . . ."). Also, other courts have recognized that an expert may testify about a party's intent "to the extent it is clearly indicated in public documents." See In re Mirena IUD Prods. Liab. Litig., 169 F. Supp. 3d at 479 (citation and internal quotation marks omitted); see also id. at 479–480 (granting motion to exclude opinion "on the motives, intent or state of mind of an entity that is not set forth in documents or grounded in specific, objectively knowable facts" (emphasis added)); In re Levaquin Prods. Liab. Litig., MDL No. 08-1943 (JRT), No. 08-5742 (JRT), <u>2011 WL 6888533</u>, at \*2 (D. Minn. Dec. 29, 2011) (finding expert testimony

about the FDA's intent was admissible so long as "the intent [was] clearly indicated in public documents").

Here, Mr. Schur supports his opinions about Mylan and Sanofi's conduct with specific references to the record evidence in his Expert Rebuttal Reports. *See*, e.g., Doc. 1676-4 at 14–16 (Schur Expert Rebuttal Report ¶¶ 31(A), 32–34); Doc. 1676-5 at 17–19 (Schur Second Expert Rebuttal Report ¶¶ 32, 35). Although the court agrees that the case law prohibits Mr. Schur from speculating about a party's motive or intent, the court allows him to provide the proffered testimony here because he opines that the record evidence is consistent with Mylan or Sanofi engaging in certain conduct. The court thus rejects Mylan's argument that the court should exclude Mr. Schur's opinions as improper opinions about intent or state-of-mind.

### 7. Conclusion

In sum, the court rejects each of Mylan's arguments supporting its request that the court exclude Mr. Schur's opinions. For reasons explained, the court denies Mylan's Motion to Exclude Opinion Testimony of Eduardo Schur (Doc. 1684).

## D. Motion to Exclude Opinions of Dr. Steven N. Wiggins

Last, Mylan asks the court to exclude the opinions of Dr. Steven N. Wiggins. Sanofi has retained Dr. Wiggins as a rebuttal damages expert for Mylan's Counterclaim asserting Lanham Act violations and unfair competition claims. Dr. Wiggins offers opinions to rebut the damages analysis offered by Mylan's expert, Dr. Thomas Varner. Doc. 1679-4 at 6 (Wiggins Expert Rebuttal Report ¶ 9).

Mylan argues that the court should exclude some of Dr. Wiggins's opinions because they aren't reliable and thus aren't helpful to the jury. Specifically, Mylan asks the court to exclude Dr. Wiggins's opinions that: (1) Sanofi's alleged misleading conduct had no measurable effect

on Auvi-Q's sales, (2) Auvi-Q is a "highly differentiated" product with desirable features, *id.* at 7 (Wiggins Expert Rebuttal Report ¶ 15), (3) EpiPen manufacturing problems affected Mylan's ability to supply EpiPen, and (4) patient choice drove Auvi-Q sales. The court addresses each of the four opinions, separately, below.

Mylan doesn't challenge Dr. Wiggins's qualifications to provide expert testimony on damages. Nevertheless, the court has reviewed Dr. Wiggins's background and experience and how they purportedly qualify him to offer his damages opinions. Dr. Wiggins earned a Ph.D. in Economics from MIT in 1979. *Id.* at 4 (Wiggins Expert Rebuttal Report ¶ 1). Since then, Dr. Wiggins has taught at Texas A&M, where he is a Professor of Economics. *Id.* Dr. Wiggins teaches Ph.D. and undergraduate level courses in Industrial Organization—which is a field of economics that involves competitive conditions in markets, antitrust, research and development, intellectual property, reputation and brand names, distribution, contracting, and the theory of the firm. *Id.* (Wiggins Expert Rebuttal Report ¶¶ 2–3). Dr. Wiggins has co-authored more than 35 scholarly articles addressing various economic issues published in leading scholarly journals in economics and law. Id. at 4–5 (Wiggins Expert Rebuttal Report ¶ 4). And, he has testified as an economic expert on issues involving Industrial Organization and antitrust, including matters involving the pharmaceutical industry. *Id.* at 5–6 (Wiggins Expert Rebuttal Report  $\P\P$  7–8). Based on his education and professional experience, Dr. Wiggins appears qualified to offer his expert opinions on damages.

The court now turns to address Mylan's arguments that the court should exclude some of Dr. Wiggins's opinions because, Mylan contends, they aren't reliable.

# 1. The Impact of Sanofi's Misleading Conduct on Auvi-Q Sales

As discussed, Dr. Wiggins offers expert opinions to rebut Dr. Varner's damages calculations for Mylan's lost profits and unjust enrichment damages. Doc. 1679-4 at 10–12 (Wiggins Expert Rebuttal Report ¶¶ 24–32). Dr. Wiggins identifies purported flaws in Dr. Varner's analysis. *Id.* And, Dr. Wiggins offers his own damages analysis, finding "no basis to conclude Mylan suffered any lost profits or that Sanofi was unjustly enriched." *Id.* at 25 (Wiggins Expert Rebuttal Report ¶ 81).

Dr. Wiggins reaches his conclusion using a "benchmark" analysis that compares Mylan and Sanofi's pre-launch forecasts for Auvi-Q with Auvi-Q's actual market shares. *Id.* at 14, 24— 25 (Wiggins Expert Rebuttal Report ¶¶ 40, 76–81). Dr. Wiggins opines that the Mylan and Sanofi pre-launch forecasts didn't consider the effect of Sanofi's alleged false and misleading statements because, before launch, Sanofi hadn't made any of the alleged statements. *Id.* at 13 (Wiggins Expert Rebuttal Report ¶ 37). So, Dr. Wiggins uses the "pre-launch sales forecasts . . . as the benchmark of sales that Auvi-Q® would have achieved but-for the alleged statements and practices." *Id.* at 14 (Wiggins Expert Rebuttal Report ¶ 40). Then, he compares the benchmark "to actual sales to assess the impact of the alleged conduct on Auvi-Q® sales." *Id.* This comparison shows that Auvi-Q's actual market share fell short of both Mylan and Sanofi's forecasts. *Id.* at 24 (Wiggins Expert Rebuttal Report ¶ 77 ("Comparison of Auvi-Q®'s actual sales to the benchmark... shows no evidence of incremental sales above the benchmark, and in fact overall sales fell significantly short of the benchmark.")). So, Dr. Wiggins concludes, this "comparison indicates that the alleged conduct had no impact on Auvi-Q® sales." *Id.*; see also id. at 25 (Wiggins Expert Rebuttal Report ¶ 81 ("The implication is that a comparison of sales with benchmark sales does not support a finding of any sales increase associated with the alleged practices identified by Mr. Zieziula.")); see also Doc. 1679-5 at 7 (Wiggins Dep. 11:4–14) (explaining that Dr. Wiggins concluded that any alleged false and misleading statements had "no measurable impact on [Auvi-Q] sales"). And, as a consequence, Dr. Wiggins opines that Mylan sustained no lost profit or unjust enrichment damages from any alleged misleading statements.

Doc. 1679-4 at 25 (Wiggins Expert Rebuttal Report ¶ 81).

Mylan argues that this opinion is unreliable because Dr. Wiggins improperly relies on other experts to identify and create the data on which he bases his opinion. Sanofi disagrees. It argues that "Dr. Wiggins was familiar with the data, and independently assessed and evaluated the data to determine that it was suitable for his analysis." Doc. 1799 at 11. But the record belies that assertion. Instead, Dr. Wiggins testified that he never conducted "an in-depth analysis of all of the forecasts." Doc. 1679-5 at 14 (Wiggins Dep. 21:1-23). He conceded that he chose the 2012 Sanofi prelaunch forecast for his analysis because he was "relying on [Dr. Scott Morton's conclusion" that it was reliable but he had not "independent[ly] arriv[ed] at that conclusion." *Id.*; see also id. at 14–16, 79–80 (Wiggins Dep. 21:24–23:14, 92:2–93:14). Dr. Wiggins testified that he didn't know who did the work to prepare the Sanofi forecast, didn't know the process by which it was prepared, and didn't know the inputs that went into the forecast. Id. at 76–77 (Wiggins Dep. 89:23–90:11). In short, Dr. Wiggins has no independent opinion whether the Sanofi forecast is reliable because he's done no independent analysis of it. Instead, he concedes he's "relying on the conclusions reached by Dr. Scott Morton." *Id.* at 77 (Wiggins Dep. 90:12–21).

Similarly, Dr. Wiggins testified that he didn't know the details about how the Mylan forecast was prepared, and he didn't know the inputs or assumptions that went into that forecast. *Id.* at 81–82 (Wiggins Dep. 94:25–95:6). Also, Dr. Wiggins testified that he considered how

Auvi-Q performed in two particular health plans where the effects of Mylan's alleged anticompetitive conduct weren't as great. *Id.* at 17–18 (Wiggins Dep. 24:23–25:10). But, again, Dr. Wiggins didn't perform any independent analysis about the data's reliability. *Id.* at 55 (Wiggins Dep 66:4–17). Instead, he testified that he "relied on [Dr.] Scott Morton, who identified those as health plans where there were minimal spillovers and formulary placement was comparable." *Id.* at 46 (Wiggins Dep. 57:2–11).

Unlike Dr. Scott Morton—who, as discussed above (see supra Part IV.A.1.a.i.), independently verified the reliability of forecasts that she used to form her opinions—Dr. Wiggins hasn't done any independent verification of the Mylan and Sanofi forecasts. Instead, he relies on Dr. Scott Morton's opinion that these forecasts are reliable. Sanofi cites no authority holding that an expert's reliance on another expert's opinion—without verifying that opinion—is proper expert testimony. To the contrary, Dr. Wiggins's failure to verify independently the reliability of the forecasts renders his analysis unreliable. See TK-7 Corp. v. Estate of Barbouti, 993 F.2d 722, 732 (10th Cir. 1993) (holding that expert's "assumption of [another expert's] sales figures cannot be considered 'reasonable reliance' for purposes of forming his own opinion of the amount of lost profits" when the testifying expert had no "familiarity with the methods or reasoning used by [the other expert] in arriving at his projections" and merely "assumed the validity of the projections made by [the other expert]"); see also ZF Meritor, LLC v. Eaton Corp., 696 F.3d 254, 292 (3d Cir. 2012) ("In some circumstances, an expert might be able to rely on the estimates of others . . . , but to do so, the expert must explain why he relied on such estimates and must demonstrate why he believed the estimates were reliable." (emphasis added)); Bruno v. Bozzuto's, Inc., 311 F.R.D. 124, 138 (M.D. Pa. 2015) ("[E]xperts who use data in their reports without independently verifying the accuracy or reliability of those figures fail to

satisfy this Circuit's reliability requirement."); *Leese v. Lockheed Martin Corp.*, <u>6 F. Supp. 3d</u> 546, 553 (D.N.J. 2014) ("[E]xperts may not parrot or act as a mouthpiece for other experts' opinions, without independent verification of those opinions.").

For this reason, the court excludes Dr. Wiggins's opinion that Sanofi's alleged misleading statements had no measurable effect on Auvi-Q's sales.<sup>8</sup>

## 2. Auvi-Q Features

Next, Mylan asks the court to exclude Dr. Wiggins's opinion that "Auvi-Q® was a highly differentiated product that represented significant innovation in the market for epinephrine auto-injectors." Doc. 1679-4 at 7 (Wiggins Expert Rebuttal Report ¶ 15). Dr. Wiggins offers this opinion to rebut Dr. Varner's damages analysis. *Id.* Dr. Wiggins contends that Dr. Varner's analysis erroneously attributes Auvi-Q sales to Sanofi's alleged misleading statements. *Id.* Dr. Wiggins asserts that Dr. Varner disregarded the fact that Auvi-Q offered innovative features. *Id.* And, Dr. Wiggins contends, Dr. Varner's analysis ignores Auvi-Q's "market potential, as well as all independent drivers of Auvi-Q® sales." *Id.* 

Mylan argues that Dr. Wiggins's opinion about Auvi-Q's features merely summarizes the record evidence. So, Mylan contends, this opinion is just improper factual narrative and speculation about the parties' states of mind. The court disagrees.

As discussed, an expert cannot "construct[] a factual narrative based on the record of evidence." *In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-MD-02327, 2014

Mylan asserts two other arguments why this opinion is unreliable. It contends Dr. Wiggins's opinion is unreliable because (1) he failed to consider other factors that may have caused Auvi-Q's market share to perform below the Mylan and Sanofi's forecasts, and (2) he unscientifically cherry-picked data to help him reach his conclusion. Because the court agrees with Mylan that Dr. Wiggins's opinion is unreliable because he improperly bases his opinion on Dr. Scott Morton's expert opinion about the data's reliability data and without performing his own verification of that data, the court need not address Mylan's other two arguments for excluding this opinion.

WL 186872, at \*16 (S.D.W. Va. Jan. 15, 2014) (citation and internal quotation marks omitted). But, courts permit expert testimony that relies on the factual record to "provide the factual basis for [an expert's] opinions" because that kind of description of the facts is "helpful for the jury to understand [the expert's opinion]." *Id.*; *see also Allen v. Am. Cap. Ltd.*, 287 F. Supp. 3d 763, 803–04 (D. Ariz. 2017) (explaining that while an expert "may not provide narrative testimony pulled directly from the record without some analysis, opinion, or expertise[,]" expert testimony is admissible when experts "utilize their expertise . . . to interpret and explain the record, which will ultimately assist the jury in understanding these experts' opinions" (citation and internal quotation marks omitted)); *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 478 (S.D.N.Y. 2016) (holding that expert couldn't provide narrative testimony that simply "repeats facts" but allowing expert "to us[e] documents and background to opine" about her conclusions).

Here, Dr. Wiggins's Expert Rebuttal Report explains how he relies on certain record evidence to form his opinion that Auvi-Q's innovative features drove Auvi-Q's sales numbers.

Doc. 1679-4 at 15–19, 20–23 (Wiggins Expert Rebuttal Report ¶¶ 44–56, 62–74). He also uses this analysis of the evidence to rebut Dr. Varner's opinion attributing Auvi-Q's sales to Sanofi's alleged misleading statements—not Auvi-Q's innovative features. *Id.* at 7, 11–12, 14 (Wiggins Expert Rebuttal Report ¶¶ 15, 28–31, 39). Indeed, Dr. Wiggins testified that his analysis "evaluat[ed] qualitative evidence." Doc. 1679-5 at 37–38 (Wiggins Dep. 48:24–49:18). He reviewed documents, and then "using [his] background and experience as an economist," he "evaluat[ed] why [certain] things are happening." *Id.* Based on this record, the court finds that Dr. Wiggins's opinion about Auvi-Q's features is reliable expert testimony, derived from the record evidence and supported by his analysis of that evidence. The court thus refuses to exclude this opinion.

## 3. EpiPen Manufacturing Problems

Next, Mylan asks the court to exclude Dr. Wiggins's opinion about EpiPen manufacturing capacity. As discussed, *see supra* Part III.B.2., Mylan's expert—Dr. Varner—opines that Meridian—Mylan's EpiPen supplier—could manufacture and supply Mylan with EpiPens equaling the number of Auvi-Q sold by Sanofi. Dr. Wiggins offers this expert opinion to rebut Dr. Varner's opinion on this topic. Doc. 1679-4 at 30–31 (Wiggins Expert Report Rebuttal ¶¶ 92–96). Dr. Wiggins opines that Dr. Varner's damages analysis "ignores well-documented issues with Meridian's manufacturing of EpiPen® during the time when Sanofi marketed Auvi-Q®." *Id.* at 30 (Wiggins Expert Rebuttal Report ¶ 93). Dr. Wiggins asserts that Dr. Varner's "calculat[ion] [of] Mylan's allegedly lost profits and ability to make additional sales" fails to consider whether these manufacturing issues "would have prevented Meridian from producing millions of additional units over and above existing EpiPen® manufacturing" or "could have, in fact, exacerbated Meridian's manufacturing issues, bringing about the EpiPen® shortage at an earlier time and/or creating an even larger EpiPen® recall or shortage than experienced." *Id.* at 31 (Wiggins Expert Rebuttal Report ¶ 96).

Again, Mylan argues that Dr. Wiggins's opinion on this topic is not helpful to the jury because, Mylan contends, Dr. Wiggins simply summarizes evidence and provides no independent analysis. Thus, Mylan asserts, the court should exclude this opinion because it's not proper expert testimony. For the same reasons discussed in the above-section, the court disagrees with Mylan's argument.

Dr. Wiggins properly describes the record evidence and explains how it supports his expert opinion rebutting Dr. Varner's opinion. *See id.* at 30–31 (Wiggins Expert Rebuttal Report ¶¶ 92–96) (citing and describing documents that form the basis for his opinion that Dr. Varner's

damages analysis ignores how EpiPen manufacturing issues could have prevented Mylan from selling millions of additional EpiPens). This type of expert opinion—one that relies on the record evidence to provide the factual basis for Dr. Wiggins's expert opinion—is proper and admissible. See, e.g., Allen, 287 F. Supp. 3d at 803–04 (explaining that expert testimony is admissible when experts "utilize their expertise . . . to interpret and explain the record, which will ultimately assist the jury in understanding these experts' opinions"); In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig., 2014 WL 186872, at \*16 (allowing expert to testify about factual "statements [that] provide the factual basis for [an expert's] opinions"). Dr. Wiggins's opinion also is proper rebuttal opinion. See Tanberg v. Sholtis, 401 F.3d 1151, 1166 (10th Cir. 2005) ("Rebuttal evidence is evidence which attempts to 'disprove or contradict' the evidence to which it is contrasted." (quoting Black's Law Dictionary 579 (7th ed. 1999))); see also Finizie v. Principi, 69 F. App'x 571, 574 (3d Cir. 2003) ("Rebuttal evidence is properly admissible when it will 'explain, repel, counteract or disprove the evidence of the adverse party." (quoting United States v. Chrzanowski, 502 F.2d 573, 576 (3d Cir. 1974))).

For these reasons, the court denies Mylan's motion to exclude Dr. Wiggins's opinion about EpiPen's manufacturing capabilities.

### 4. Patient Choice

Last, Mylan asks the court to exclude Dr. Wiggins's opinion explaining how patient choice played a role in generating Auvi-Q sales. Dr. Wiggins's Expert Rebuttal Report discusses two pieces of evidence that he relies on to support his opinion. Doc. 1679-4 at 22–23 (Wiggins Expert Rebuttal Report ¶¶ 70). First, he cites the Expert Report of Dr. Mary Ann Michelis. *Id.* Dr. Michelis's Expert Report describes how she finds it important to give patients a choice when prescribing an EAI device to treat anaphylaxis. *Id.* In her practice as an allergist, Dr. Michelis

says she shows her patients different EAI devices so that the patient can compare the devices and select the device that the patient prefers. 

Id. Second, Dr. Wiggins cites an internal Mylan document that "identif[ies] the practice [by doctors] of presenting both products to patients as common."

Id. (citing MYEP00140817). From this evidence, Dr. Wiggins opines that "alleged statements by Sanofi are highly unlikely to impact sales because patients are choosing for themselves based on their own handling of the products in a physician's office."

Id.

Mylan again argues that Dr. Wiggins's opinion just summarizes the record evidence, and thus, Mylan contends, his opinion isn't helpful to the jury. Again, the court disagrees. Here, Dr. Wiggins's Expert Rebuttal Report analyzes the record evidence and relies on it (a) to support his opinion that other factors—including patient choice—affected Auvi-Q sales, and (b) to rebut Dr. Varner's opinion that Sanofi's alleged misleading statements drove Auvi-Q sales. *Id.* Also, Dr. Wiggins testified that "economists study purchase behavior of goods." Doc. 1679-5 at 154–55 (Wiggins Dep. 199:13–200:5). And, as an economist qualified to provide expert testimony, Dr. Wiggins described the economics of consumer behavior: "When a product can be purchased and the consumer can sit there and evaluate its quality, then the reason that it is being purchased is not because of noise out there . . . it is because [of] the person's assessment of that product quality . . . ." *Id.* at 154–156 (Wiggins Dep. 199:13–201:18). Applying that theory to the evidence he reviewed, Dr. Wiggins explained how he formed his opinion that patient choice affected Auvi-Q sales. *Id.* at 151–158 (Wiggins Dep. 194:8–203:9). For reasons already explained in the previous two sections, this type of expert opinion is proper and admissible. The

Mylan notes that it has moved to exclude Dr. Michelis's opinions on this topic. As discussed, *see supra* Part IV.B.1., the court declines to exclude Dr. Michelis's opinions about her own prescribing practices and the factors she considers when prescribing anaphylaxis treatment, including patient choice. Thus, Dr. Wiggins properly may rely on her Expert Report to form his own opinions about the effect of patient choice on Auvi-Q sales.

court thus refuses to exclude Dr. Wiggins's opinion about the effects of patient choice on Auvi-Q sales.

#### 5. Conclusion

For reasons explained, the court excludes Dr. Wiggins's opinion that Sanofi's alleged misleading conduct had no measurable effect on Auvi-Q's sales. The court concludes that Sanofi hasn't shouldered its burden to demonstrate the reliability of this particular opinion. But the court denies Mylan's Motion to Exclude Opinions Testimony of Dr. Wiggins (Doc. 1685) in all other respects.

### V. Conclusion

For reasons explained, the court rules the parties' motions seeking to exclude expert opinions and testimony as set forth in the above Order.

IT IS THEREFORE ORDERED BY THE COURT THAT plaintiff/counterclaim defendant Sanofi-Aventis U.S. LLC's Motion to Exclude the Expert Reports and Testimony Offered by Gary Zieziula (Doc. 1666) is granted in part and denied in part.

IT IS FURTHER ORDERED THAT plaintiff/counterclaim defendant Sanofi-Aventis U.S. LLC's Motion to Exclude the Expert Reports and Testimony Offered by Thomas Varner (Doc. 1675) is denied.

IT IS FURTHER ORDERED THAT defendant Mylan Inc. and defendant/counterclaim-plaintiff Mylan Specialty L.P.'s Motion to Exclude Opinion Testimony of Fiona M. Scott Morton, Ph.D. (Doc. 1682) is granted in part and denied in part.

IT IS FURTHER ORDERED THAT defendant Mylan Inc. and defendant/counterclaim-plaintiff Mylan Specialty L.P.'s Motion to Exclude Opinion Testimony of Mary Ann Michelis, M.D. (<u>Doc. 1683</u>) is granted in part and denied in part.

IT IS FURTHER ORDERED THAT defendant Mylan Inc. and

defendant/counterclaim-plaintiff Mylan Specialty L.P.'s Motion to Exclude Opinion Testimony of Eduardo Schur (<u>Doc. 1684</u>) is denied.

IT IS FURTHER ORDERED THAT defendant Mylan Inc. and

defendant/counterclaim-plaintiff Mylan Specialty L.P.'s Motion to Exclude Opinion Testimony of Steven N. Wiggins, Ph.D. (<u>Doc. 1685</u>) is granted in part and denied in part.

IT IS SO ORDERED.

Dated this 17th day of December, 2020, at Kansas City, Kansas.

s/ Daniel D. CrabtreeDaniel D. CrabtreeUnited States District Judge