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 Consumer Class Cases)	

MEMORANDUM AND ORDER

This Order rules the seven motions seeking to exclude expert opinions filed in the Consumer Class track of this MDL. The consumer class plaintiffs have filed one of the seven motions. And, the Mylan and Pfizer defendants,[1] have filed the other six. As explained more fully below, the court rules the motions as follows:

[1] The named defendants in this case are: Mylan N.V., Mylan Specialty L.P., Mylan Pharmaceuticals Inc., and Heather Bresch (collectively, "Mylan") and Pfizer, Inc., King Pharmaceuticals, Inc. (n/k/a King Pharmaceuticals LLC), and Meridian Medical Technologies, Inc. (collectively "Pfizer"). Doc. 2169 at 1 (Pretrial Order).

This Order rules just the Mylan defendants' portions of the motions seeking to exclude plaintiffs' experts. The court defers ruling the Pfizer defendants' portions of the motions, and it will address their motions in a future Order. Thus, the court's references to "defendants" in this Order refer only to the Mylan defendants unless specifically noted that the term is meant to refer to other named defendants in this action.

Also, the court enters this Order as a publicly-available document on the court's docket. The court recognizes that the parties have moved for leave to file under seal portions of their briefing on these motions as well as many of the exhibits submitted either supporting or opposing the motions. But, the public enjoys a "common-law right of access" to judicial records. *Nixon v. Warner Commc'ns, Inc.*, 435 U.S 589, 599 (1978); *United States v. Bacon*, 950 F.3d 1286, 1292 (10th Cir. 2020). A litigant can rebut the "strong presumption in favor of public access" when "countervailing interests heavily outweigh the public interests in access to the judicial record." *Bacon*, 950 F.3d at 1293 (citations and internal quotation marks omitted). The court finds that none of the information in this Order qualifies for sealing under the governing legal standard for several reasons. *First*, the court's analysis relies on the factual information submitted by the parties to determine the litigants' rights; so, the public has a strong interest in accessing the information. *See Riker v. Fed. Bureau of Prisons*, 315 F. App'x 752, 755 (10th Cir. 2009) ("Especially 'where documents are used to determine litigants' substantive legal rights, a strong

- Plaintiffs' Motion to Strike in Part the Testimony of Dr. John H. Johnson, IV (Doc. 2132-1) is denied.
- The Mylan defendants' portion of the Motion to Exclude the Testimony and Report of Plaintiffs' Expert Witness Einer Elhauge (Doc. 2133) is denied.
- The Mylan defendants' portion of the Motion to Exclude the Testimony and Report of Plaintiffs' Expert Witness Professor Meredith Rosenthal (Doc. 2134) is denied.
- The Mylan defendants' portion of the Motion to Exclude the Testimony and Report of Plaintiffs' Expert Witness Dr. Carl Peck (Doc. 2135) is granted in part and denied in part.
- The Mylan defendants' portion of the Motion to Exclude the Testimony and Report of Plaintiffs' Expert Witness James Bruno (Doc. 2136) is granted.
- The Mylan defendants' portion of the Motion to Exclude Plaintiffs' Patent Litigation Expert (Doc. 2151) is denied.
- The Mylan defendants' portion of the Motion to Exclude Plaintiffs' Rebuttal Report Regarding the '827 Patent (Doc. 2156) is granted.

The court explains how it reaches these decisions, below.

I. Factual Background

The Consumer Class litigation track in this MDL involves claims brought by consumers and third-party payors of the EpiPen. They allege that the Mylan and Pfizer defendants, who

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presumption of access attaches.'" (quoting *Lugosch v. Pyramid Co. of Onondaga*, 435 F.3d 110, 121 (2d Cir. 2006))). *Second*, a good portion of the factual information already is publicly-available through other sources. *And third*, most of the factual information is quite dated. Thus, the court finds that the public's right to access the entire contents of this Order to understand the facts and the court's analysis of the parties' motions seeking to exclude these experts' opinions outweighs any privacy interest that the parties assert over the information.

supply and manufacture the EpiPen, violated certain state antitrust laws and the federal civil RICO statute. Doc. 2169 at 42, 44–45 (Pretrial Order ¶¶ 4.a., 4.d.). On February 27, 2020, the court certified the two following classes under Fed. R. Civ. P. 23(b)(3):

> **1. Nationwide RICO Damages Class ("RICO Class").** All persons and entities in the United States who paid or provided reimbursement for some or all of the purchase price of Branded or authorized generic EpiPens for the purpose of consumption, and not resale, by themselves, their family member(s), insureds, plan participants, employees, or beneficiaries, at any time between August 24, 2011, and [November 1, 2020].
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> **2. State Antitrust Damages Class ("State Antitrust Class")**. All persons and entities in the Antitrust States[2] who paid or provided reimbursement for some or all of the purchase price of Branded EpiPens at any time between January 28, 2013, and [November 1, 2020], for the purpose of consumption, and not resale, by themselves, their family member(s), insureds, plan participants, employees, or beneficiaries.

Doc. 2018-1 at 126; *see also* EpiPen Long Form Notice at 1, https://epipenclassaction.com/documents/EpiPen%20Long%20Form%20Notice%20-%20FINAL.pdf.

The EpiPen is an epinephrine auto-injector ("EAI") that delivers an intramuscular dose of epinephrine to treat severe allergic reactions known as anaphylaxis. Doc. 2169 at 3–4 (Pretrial Order ¶¶ 14–17, 20). Defendant Mylan Specialty L.P. has the exclusive right and license to market, distribute, and sell EpiPen products in the United States. *Id.* at 3 (Pretrial Order ¶ 13). Defendant Mylan Specialty L.P. currently sells EpiPens in the United States exclusively in packages of two devices ("the EpiPen 2-Pak"). *Id.* at 7 (Pretrial Order ¶ 56). Each EpiPen 2-Pak contains two EpiPen devices each containing a single dose of epinephrine. *Id.* at 4 (Pretrial

[2] The "Antitrust States" include: Alabama, California, Florida, Hawaii, Illinois, Kansas, Maine, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New York, North Carolina, Tennessee, and Utah. Doc. 2018-1 at 126 n.72; *see also* Doc. 2169 at 2 n.3 (Pretrial Order ¶ 1.d.).

Order ¶ 22). Defendant Pfizer, Inc., through its subsidiaries, manufactures the EpiPen and supplies it to Mylan for sale in the United States. *Id.* at 3 (Pretrial Order ¶¶ 6, 10–12).

Plaintiffs allege that, beginning in 2010, the Mylan and Pfizer defendants engaged in an unlawful scheme to raise prices on the EpiPen. *Id.* at 9 (Pretrial Order ¶ 3.a.1.). The alleged scheme included: "(1) withdrawing the single pack in the United States only (the 2-Pak hard switch) based on a false medical rationale and associated public campaign; (2) stifling generic competition through pay-for-delay settlements and other tactics and schemes; and (3) foreclosing branded competition from the Auvi-Q [(a competing EAI device)] using rebates and kickbacks." *Id.*

The Mylan defendants have filed a Motion for Summary Judgment against plaintiffs' state antitrust and federal RICO claims. Doc. 2141. Contemporaneously, the parties have filed motions seeking to exclude certain expert testimony offered either to support or oppose plaintiffs' claims on summary judgment. The court addresses those motions, below.

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)); *see also Petersen v. The Raymond Corp.*, 994 F.3d 1224, 1225 (10th Cir. 2021) (explaining a "district court serves as a gatekeeper, shutting the door on unreliable expert testimony" (citing *Kumho Tire*, 526 U.S. at 152)). 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)); *see also Peterson*, 2021 WL 1568812, at *1 (explaining that the Circuit affords "district courts 'considerable leeway' in deciding when the door [for admitting expert testimony] should be

closed" (quoting *Kumho Tire*, 526 U.S. at 152)). 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:
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> (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;
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> (b) the testimony is based on sufficient facts or data;
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> (c) the testimony is the product of reliable principles and methods; and
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> (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 proffered expert testimony's reliability 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 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. Plaintiffs' Motion to Strike in Part the Testimony of Dr. John H. Johnson, IV (Doc. 2131-1)

Plaintiffs ask the court to exclude part of Dr. John H. Johnson's testimony. Defendants have retained Dr. Johnson "to review and respond to the opinions, and specifically the damages estimates" offered by plaintiffs' experts, including Prof. Meredith Rosenthal and Prof. Einer

Elhauge. Doc. 2132-4 at 6 (Johnson Dec. 23, 2019 Expert Report ¶ 1). Plaintiffs argue that certain of Dr. Johnson's opinions aren't grounded in scientific methodology and are unreliable. So, plaintiffs ask the court to exclude these particular opinions.

In response, defendants assert that Dr. Johnson is qualified to offer his expert opinions. The court agrees. Dr. Johnson has a Ph.D. in economics, with a specialization in econometrics, from the Massachusetts Institute of Technology. Doc. 2132-4 at 122 (Johnson curriculum vitae); Doc. 1724 at 88 (Tr. of Mot. Hr'g Class Certification 88:19–25). He has authored "academic literature on the application of econometrics in class actions in that intersection of the field called law and economics." Doc. 1724 at 89 (Tr. of Mot. Hr'g Class Cert. 89:13–19); *see also* Doc. 2132-4 at 128–29 (listing books and articles that Dr. Johnson has authored). And, Dr. Johnson has testified as an expert "in a wide range of antitrust and class action litigation" including "40 class actions." Doc. 1724 at 89 (Tr. of Mot. Hr'g Class Certification 89:1–19); *see also* Doc. 2132-4 at 124–28 (listing expert testimony and reports provided between 2016 and 2019). Dr. Johnson's education, experience, and knowledge qualify him to opine about the measure of damages in this case.

But, plaintiffs argue, Dr. Johnson lacks expertise in the area of health economics. So, plaintiffs contend, this gap in his resume makes him unqualified to offer expert opinions in this particular case involving a pharmaceutical product. Defendants respond that plaintiffs' criticism ignores Dr. Johnson's demonstrated expertise in the pharmaceutical industry. *See, e.g.*, Doc. 1636-2 at 35–46 (Johnson Mar. 18, 2019 Expert Report ¶¶ 33–53) (providing background about the pharmaceutical industry, including how its supply chain operates and how negotiation and pricing within that supply chain affect the ultimate price that consumers pay for pharmaceuticals). Plaintiffs downplay this pharmaceutical expertise, arguing that Dr. Johnson

gained this knowledge only through his work as a paid litigation expert for class action defendants. Plaintiffs' criticisms about the depth and origin of Dr. Johnson's expertise in the specialized area of health economics go to the weight the finder of fact should assign his opinions. *See, e.g.*, *Wheeler v. John Deere Co.*, 935 F.2d 1090, 1100 (10th Cir. 1991) ("[A] lack of specialization does not affect the admissibility of the opinion, but only it's weight."); *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."); *United States v. Kelley*, 6 F. Supp. 2d 1168, 1183 (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)). But plaintiffs' arguments don't show that Dr. Johnson is unqualified to provide his proffered expert opinions in this case.

Having found Dr. Johnson sufficiently qualified as an expert, the court now turns to his four opinions that plaintiffs ask to exclude.

A. Dr. Johnson's Criticisms of Prof. Rosenthal's Assumed Generic Penetration Rate

First, plaintiffs argue that the court should exclude Dr. Johnson's criticisms about the assumed generic penetration rate that Prof. Rosenthal used in her generic delay damages model. Prof. Rosenthal's generic delay damages model assumes a 95% generic penetration rate—which is the estimated amount of market share a generic would have captured from the branded EpiPen after the generic entered the market. Doc. 2132-7 at 30 (Rosenthal Oct. 31, 2019 Expert Report ¶ 68). Prof. Rosenthal explains that she selected the 95% penetration rate because it came from a Mylan forecast—known as the "Mylan 1" standard generic capture curve. *Id.* Prof. Rosenthal further explains that Mylan used the Mylan 1 forecast in its decision-making in 2010 and 2011,

and Pfizer still was projecting a penetration rate consistent with the Mylan 1 forecast in 2015. *Id.* at 30–31 (¶¶ 69–70). Prof. Rosenthal's Expert Report also provides reasons why she believes the Mylan 1 forecast is economically reasonable, thus supporting her decision to use Mylan 1's 95% generic penetration rate in her generic delay damages analysis. *Id.* at 31 (¶ 71).

Dr. Johnson criticizes Prof. Rosenthal's use of the Mylan 1 forecast. Doc. 2132-4 at 43 (Johnson Dec. 23, 2019 Expert Report ¶ 58). He explains that the Mylan 1 forecast was one of three forecasts Mylan prepared—the other two were called Mylan 2 and Mylan 3. *Id.* Dr. Johnson asserts that Prof. Rosenthal erred by using the Mylan 1 forecast because it was the most aggressive of the three generic penetration forecasts. *Id.* And, he contends, "only the Mylan 2 and Mylan 3 forecasts were actually used by the company to assess the financial effects of generic entry." *Id.*

Plaintiffs assert that Dr. Johnson's opinion misstates the evidence. Instead, Dr. Johnson conceded in his deposition that the "only basis" for his opinion that Mylan used the Mylan 2 and Mylan 3 forecasts comes from just one document. Doc. 2132-5 at 22 (Johnson Dep. 102:3–9). Plaintiffs argue that Dr. Johnson doesn't apply any specialized skill or knowledge to interpret this one document. And, plaintiffs contend, Dr. Johnson hasn't conducted any independent scientific or economic analysis to determine whether Prof. Rosenthal's reliance on the Mylan 1 forecast was appropriate. So, plaintiffs contend, the court should exclude Dr. Johnson's opinion about the appropriate generic penetration rate because it's improper expert opinion.

Defendants respond that Dr. Johnson properly criticizes Prof. Rosenthal's use of a single and the most aggressive generic penetration forecast in her generic delay damages analysis. Dr. Johnson asserts that Prof. Rosenthal ignored the other, less aggressive forecasts found in the Mylan 2 and Mylan 3 forecasts, and by doing so, Prof. Rosenthal artificially and improperly

inflated her damages estimates. Doc. 2132-4 at 43, 47–48 (Johnson Dec. 23, 2019 Expert Report ¶¶ 58, 62, & Ex. 4). Dr. Johnson's two Expert Reports identify the other forecasts with lower generic penetration rates. *See id.*; *see also* Doc. 1636-2 at 134–38 (Johnson Mar. 28, 2019 Expert Report ¶¶ 167–71) (redacted version); Doc. 1503-4 at 134–38 (sealed version). And, he analyzes the "sensitivity of Prof. Rosenthal's damages estimates to her assumed generic substitution rate, using the Mylan 2 and Mylan 3 forecasts for generic substitution, as well as the actual generic substitution observed using the Mylan authorized generic product." Doc. 2132-4 at 47–48 (Johnson Dec. 23, 2019 Expert Report ¶ 62 & Ex. 4).

Defendants argue that Dr. Johnson isn't opining about which forecast Mylan used in its own analysis of generic penetration. Instead, he testified that his expert testimony "interpret[s] for the trier [of] fact the economics behind the [Mylan 1] forecast, what the strong assumptions are underlying Mylan 1, and why [he] disagree[s] with . . . Professor Rosenthal's assessment that she should look at Mylan 1 and only Mylan 1 in calculating damages." Doc. 2132-5 at 23 (Johnson Dep. 107:6–20). Defendants assert that Dr. Johnson applies his economics expertise to the data, which will help the jury understand how Prof. Rosenthal's damages estimates can fluctuate, depending on the generic penetration rate selected to perform the analysis. Also, Dr. Johnson explains why he believes it was improper for Prof. Rosenthal to rely on the literature as support for using the Mylan 1 forecast. Doc. 1636-2 at 132–33 (Johnson Mar. 28, 2019 Expert Report ¶¶ 164–65). Dr. Johnson asserts that Prof. Rosenthal's chosen literature isn't relevant to assessing generic penetration against EpiPen because the literature addresses generic substitution of oral tablets and not injectable products, like EpiPen. *Id.* Also, he alleges, the literature fails to account for competitive steps Mylan may have taken to support EpiPen's continued sales. *Id.* Also, Dr. Johnson analyzed the actual rate of generic substitution when Mylan introduced its

own authorized generic EpiPen ("the Mylan AG"). Doc. 2132-4 at 44–46 (Johnson Dec. 23, 2019 Expert Report ¶ 61 & Ex. 3). His analysis shows that the actual generic penetration rate for Mylan AG was lower than the Mylan 1 forecast used by Prof. Rosenthal. *Id.* Thus, he asserts this analysis provides further support for his opinion that Prof. Rosenthal erred by using the Mylan 1 forecast in her damages analysis. *Id.*

Plaintiffs argue that Dr. Johnson does nothing more than regurgitate information found in documents, thus he doesn't provide expert opinion. The court disagrees. Dr. Johnson not only identifies other generic penetration forecasts, but also he explains, using his economic expertise, why he believes Prof. Rosenthal erred by selecting the Mylan 1 forecast—instead of other generic penetration rates—to perform her generic delay damages analysis. This type of opinion is proper expert rebuttal opinion. *See In re Cessna 208 Series Aircraft Prods. Liab. Litig.*, No. 05-md-1721-KHV, 2009 WL 1649773, at *1 (D. Kan. June 9, 2009) (explaining that "a rebuttal expert who critiques another expert's theories or conclusions need not offer his own independent theories or conclusions (though of course his testimony may be more persuasive if he does so)" and "[s]uch evidence, which attacks the opposing expert's substantive testimony, is proper rebuttal"); *see also Pandora Jewelers 1995, Inc. v. Pandora Jewelry, LLC*, No. 09-61490-Civ., 2011 WL 2295269, at *5 (S.D. Fla. June 8, 2011) (explaining that a "rebuttal expert can testify [about] the flaws that she believed are inherent in another expert's report that implicitly assumes or ignores certain facts" and "[t]his is a well-accepted way to criticize damages estimates" (citation and internal quotation marks omitted)). *Cf. Frederick v. Swift Transp. Co., Inc.*, 591 F. Supp. 2d 1149, 1155 (D. Kan. 2008) (explaining that in a "battle of the experts" over which opinion is correct, the court won't "credit one expert's opinion over the other" but instead leaves the decision "to the trier of fact to determine how much weight to give to each expert's

opinions"). The court finds no reason to exclude Dr. Johnson's opinion criticizing Prof. Rosenthal's use of the Mylan 1 generic penetration rate.

Also, plaintiffs argue that the court should exclude Dr. Johnson's opinion criticizing Prof. Rosenthal's analysis because it uses the Mylan AG's price when estimating the "but-for" price while it ignores the Mylan AG's actual penetration rate in her damages calculations. *See* Doc. 2132-7 at 36–38 (Rosenthal Oct. 31, 2019 Expert Report ¶¶ 84–86) (explaining that, in her generic delay damages calculations, the "generic price discount yardsticks are based on the actual pricing trends when Mylan's authorized generic entered the market in December 2016"). Prof. Rosenthal explains why she chose not to use the Mylan AG penetration rate in her analysis. *Id.* at 29 (¶ 67). She found it "unsuitable" for several reasons, including that "it was not a competitor product" because "it was launched by Mylan" which was "quite different from the but-for scenario [she was] asked to assume, where Teva [(a rival pharmaceutical company)] would have launched along with an authorized generic—or alone." *Id.*; *see also* Doc. 2132-16 at 9 (Rosenthal Feb. 7, 2020 Rebuttal Expert Report ¶ 10) (explaining that her analysis assumes a "but-for world . . . where both the Mylan AG and an independent generic would have launched at the same time if it had not been for the challenged conduct" while "[i]n the actual world, both EpiPen and the Mylan AG were marketed by the same entity" creating a situation "devoid of the incentives for competing on price and gaining market share").

But Dr. Johnson criticizes Prof. Rosenthal's dismissal of the Mylan AG penetration rate for "several reasons." Doc. 2132-4 at 44–45 (Johnson Dec. 23, 2019 Expert Report ¶ 61). He opines that the Mylan AG penetration rate is a more reasonable rate to use because—even though Mylan launched this generic—it still was "a competing generic EAI product available at a lower price." *Id.* at 44 (¶ 61). And, "when Teva ultimately launched its generic EAI device in

November 2018, it did so at the exact same price as the Mylan authorized generic device." *Id.* at 44–45 (¶ 61). So, in Dr. Johnson's opinion, "[t]he fact that the authorized generic product was available from Mylan instead of a different manufacturer does not change the fact that, after it launched, consumers had an AB rated generic product available to them at a lower price." *Id.* at 45 (¶ 61).

Plaintiffs argue that the court should exclude Dr. Johnson's opinion because, as he testified, he never conducted any scientific analysis to determine whether competition between the Mylan AG and the branded EpiPen occurred in exactly the same way it would have occurred with an alternative, independent generic product. Doc. 2132-5 at 24 (Johnson Dep. 116:18–25). And, plaintiffs contend, he has no practical experience in health economics to assert his opinions about Prof. Rosenthal's choice of generic penetration rate. The court disagrees. As discussed above, Dr. Johnson is qualified as an economist to provide expert opinions in this case. And his experience with and knowledge about the pharmaceutical industry qualify him to render his opinions here. He has drawn from that experience to render his opinions that rebut Prof. Rosenthal's damages analysis, making his opinions sufficiently reliable and relevant. *See In re Cessna 208 Series Aircraft Prods. Liab. Litig.*, 2009 WL 1649773, at *1 (explaining that "expert opinions which assess or critique another expert's substantive testimony are relevant," and constitute "proper rebuttal"); *see also Marmo v. Tyson Fresh Meats, Inc.*, 457 F.3d 748, 759 (8th Cir. 2006) ("The function of rebuttal testimony is to explain, repel, counteract or disprove evidence of the adverse party." (citation and internal quotation marks omitted)). So, the court declines plaintiffs' invitation to exclude Dr. Johnson's opinions criticizing Prof. Rosenthal's use of the Mylan 1 generic penetration rate in her generic delay damages calculations.

B. Dr. Johnson's Opinion About the Ratio of Single-EpiPen Versus Two-EpiPen Prescriptions

Next, plaintiffs ask the court to exclude Dr. Johnson's opinion about the ratio of single-EpiPen prescriptions to EpiPen 2-Pak prescriptions. Dr. Johnson offers this opinion in response to Prof. Rosenthal's analysis of Mylan's withdrawal of the single EpiPen from the market. Prof. Rosenthal opines that "the annual average pens-per-prescription ratio [for EpiPen] was essentially constant from 2009 to the first half of 2011." Doc. 2132-16 at 13–14 (Rosenthal Feb. 7, 2020 Rebuttal Expert Report ¶ 21 & Fig. 1). But, Prof. Rosenthal's analysis shows that after August 2011, when Mylan withdrew the single EpiPen from the market, the ratio of pens-per-prescription increased. *See id.* Prof. Rosenthal then uses this analysis to estimate the "but-for" pens per prescription to calculate plaintiffs' EpiPen 2-Pak damages. *Id.* at 12–14 (¶¶ 17, 21).

Dr. Johnson rebuts Prof. Rosenthal's opinion, arguing her estimate of "but-for" pens for prescriptions is flawed. Doc. 2132-4 at 60 (Johnson Dec. 23, 2019 Expert Report ¶¶ 88–90). He contends that Prof. Rosenthal erred by "assuming that the average share of two-pack and single pack prescriptions would be unchanged in every year after the second quarter of 2011." *Id.* (¶ 90). And, he asserts, her assumption ignores the upward trend in the number of EpiPen 2-Paks prescribed between 2008 and 2011 as well as the downward trend in the number of single EpiPen prescriptions for the same time period. *Id.* (¶ 88). Dr. Johnson uses a graph to document this supposed upward and downward trend. *Id.* at 61 (Ex. 6). He contends that, by ignoring these trends, Prof. Rosenthal underestimated the "but-for" annual average of pens per prescription. *Id.* at 60 (¶ 89). And, in turn, he argues that Prof. Rosenthal's use of this "but for" average overstates the amount of plaintiffs' purported EpiPen 2-Pak damages. *Id.* (¶ 90).

Plaintiffs argue the court should exclude Dr. Johnson's opinion about the increasing trend in EpiPen 2-Pak prescriptions for two reasons: They say (1) it will mislead the jury, and (2) it's unreliable.

First, plaintiffs argue that Dr. Johnson's graph showing the purported upward trend of EpiPen 2-Pak prescriptions is misleading because Dr. Johnson's graph doesn't plot the actual data points across time. Instead, plaintiffs contend, Dr. Johnson uses the "trend line" function in Microsoft Excel that smooths out the data into a straight line, giving it an appearance of trending upward. Plaintiffs argue that the actual data points show that 2-Pak prescriptions stayed constant throughout 2008 and 2011, which is consistent with Prof. Rosenthal's analysis. *See* Doc. 2132-2 at 19 (Mem. of Law in Supp. of Class Pls.' Mot. to Strike) (providing a chart that shows actual data points).

Defendants respond that plaintiffs are "free to present an alternative depiction of the trend that Dr. Johnson observed" but his conclusion remains the same, *i.e.*, that the data shows an upward trend of EpiPen 2-Pak prescriptions. Doc. 2186-1 at 14–15. The court agrees with defendants. The court believes a jury is capable of understanding the data for EpiPen 2-Pak prescriptions and recognizing the differences between how Dr. Johnson and Prof. Rosenthal interpreted that data. Plaintiffs can cross-examine Dr. Johnson about his use of the "trend line" feature to interpret the data—as opposed to the actual data points—and the jury can decide whether his approach to analyzing that data affects his opinion's credibility. *See, e.g.*, *Corr v. Terex USA, LLC*, No. 08-1285-MLB, 2011 WL 976718, at *6 (D. Kan. Mar. 17, 2011) (rejecting defendant's argument that plaintiff's expert's "opinions will confuse or mislead the jury because he has not tested or designed an alternate" product because defendant "can, through cross examination of [the expert], explore these areas," and finding that "a jury will be able to

understand what [the expert] did in this case and make their own decision about whether his opinions are credible"). The court finds no reason to exclude his opinion as misleading.

Second, plaintiffs argue that Dr. Johnson's analysis of the data is unreliable because he's measuring the number of prescriptions, not the number of pens. Thus, plaintiffs contend, Dr. Johnson's analysis doesn't demonstrate adequately the effects of withdrawing the single EpiPen from the market and replacing it exclusively with the 2-Pak. Plaintiffs illustrate this point by arguing that, if Dr. Johnson continued his chart, the number of 2-Pak prescriptions would increase to 100% and the number of single prescriptions would fall to 0% because, after Mylan's switch to the 2-Pak, doctors weren't able to prescribe single EpiPens. Plaintiffs argue that Prof. Rosenthal's analysis of pens per prescription is more informative and better grounded in the facts and science. Thus, plaintiffs contend, the court should exclude Dr. Johnson's opinion on this topic.

Defendants disagree. Defendants argue that the point of Dr. Johnson's analysis is to analyze purchasing trends before the switch to the 2-Pak. Dr. Johnson asserts that his analysis of the purchasing trends for the EpiPen 2-Pak undermines Prof. Rosenthal's conclusion that EpiPen's annual average pens-per-prescription ratio would remain constant after 2011. Dr. Johnson's Expert Report provides a reliable basis for his opinion about Prof. Rosenthal's assumptions. *See* Doc. 2132-4 at 60 (Johnson Dec. 23, 2019 Expert Report ¶¶ 88–90). And, the court finds, plaintiffs' challenges to Dr. Johnson's opinion go to the weight the trier of fact should assign to his opinion—but not its admissibility. *See Aspen Highlands Skiing Corp. v. Aspen Skiing Co.*, 738 F.2d 1509, 1524 (10th Cir. 1984) (affirming admission of expert testimony where "there may have been considerable evidence contradicting the expert's assumptions" but also "his assumptions were not without support" and explaining that "the full

burden of exploration of the facts *and assumptions* underlying the testimony of an expert witness" falls "squarely on the shoulders of opposing counsel's cross-examination" (citation and internal quotation marks omitted)), *aff'd*, 472 U.S. 585 (1985); *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").

The court thus declines to exclude Dr. Johnson's opinion about the appropriate measure of the ratio between single-EpiPen prescriptions and EpiPen 2-Pak prescriptions.

C. Dr. Johnson's Opinion Comparing Individual Co-Payments to Prof. Rosenthal's Calculation of the Average "But-For" Co-Payment

Next, plaintiffs assert that the court should exclude as unreliable Dr. Johnson's opinion comparing real-world individual co-payments to Prof. Rosenthal's calculation of class members' average "but-for" co-payment. Prof. Rosenthal developed an aggregate model to determine generic delay damages that assumes an average "but-for" price that consumers would have paid for a generic EpiPen "but for" defendants' alleged scheme that delayed generic competition. Doc. 2186-4 at 5 (Rosenthal Feb. 8, 2019 Dep. 214:7–17). Dr. Johnson criticizes Prof. Rosenthal's calculation of the average "but for" price because, he says, it "ignore[s] the underlying variation in insured consumers' *actual* copayments for *branded* EpiPen devices." Doc. 2132-4 at 51 (Johnson Dec. 23, 2019 Expert Report ¶ 65) (emphasis added). Dr. Johnson identifies "a substantial share of transactions [that] had monthly copayments that were *less* than Prof. Rosenthal's but-for generic copayment." *Id.* (citing Doc. 1636-2 at 114–18 (Johnson Mar. 18, 2019 Expert Report ¶¶ 151–53)) (emphasis added). Dr. Johnson argues that these identified "class members would be uninjured[,]" and he criticizes Prof. Rosenthal for offering "no methodology to identify them and remove" these transactions from her damages analysis. *Id.*

Plaintiffs assert that the court should exclude Dr. Johnson's comparison of real-world co-payments to Prof. Rosenthal's calculated "but-for" average price because it is unreliable and will mislead the jury. Plaintiffs offer several arguments to support the request to exclude this opinion.

First, plaintiffs argue, Dr. Johnson has cherry-picked examples of actual co-payments for named plaintiffs that don't provide an accurate representation of what Prof. Rosenthal calculated—*i.e.*, the distribution of co-payments among consumers in both the actual and "but-for" worlds to calculate an average. But, defendants respond, Dr. Johnson used the same "IQVIA Xponent copayment data" that Prof. Rosenthal used in her analysis. Doc. 1636-2 at 115–18 (Johnson Mar. 18, 2019 Expert Report ¶ 152 & Ex. 26); Doc. 1503-4 at 115–18 (sealed version). According to Dr. Johnson's analysis, 54% of the branded co-payments in the entire data set are less than Prof. Rosenthal's calculated average "but-for" copayment. Doc. 1636-2 at 118, 120 (¶ 154 & Ex. 28); Doc. 1503-4 at 118, 120. Dr. Johnson highlights some of the named plaintiffs whose actual co-payments were less than Prof. Rosenthal's average "but-for" copayment. Doc. 1636-2 at 118 (¶ 153). Defendants argue this isn't "cherry-picking" data. Instead, defendants say, it's just providing an illustration of certain class plaintiffs whose actual co-payments fall into the 54% of co-payments that are less than Prof. Rosenthal's average "but-for" co-payment.

The court agrees with defendants. Dr. Johnson offers a different way to examine the data to support his argument that Prof. Rosenthal's analysis is flawed. Plaintiffs assert that Dr. Johnson's analysis of the data is nonsensical from a mathematical perspective. Plaintiffs explain why they think it's nonsense—*i.e.*, Prof. Rosenthal is calculating an average, not examining individual payments, like Dr. Johnson does. But, Dr. Johnson's Expert Report explains how and

why he has analyzed the data in this fashion, thus providing a reliable basis for his opinion. *See* Doc. 1636-2 at 114–18 (Johnson Mar. 18, 2019 Expert Report ¶¶ 151–53). The disagreement between Prof. Rosenthal and Dr. Johnson over the best way to analyze the data is an issue for the jury to decide when assigning weight to each opinion. But, the court can't exclude Dr. Johnson's opinion as unreliable simply because it differs from the way Prof. Rosenthal analyzed the data. *See, e.g.*, *In re Pool Prods. Distrib. Mkt. Antitrust Litig.*, MDL No. 2328, 2016 WL 2756437, at *9 (E.D. La. May 12, 2016) (refusing to exclude defendant's rebuttal expert's opinion that critiqued the opinions of and analyzed the data differently than plaintiffs' expert because the rebuttal expert provided a reliable basis for his methodology and the "mere fact that the parties' experts disagree on the best way to test the model is no basis for excluding one expert's approach" (citation and internal quotation marks omitted)); *Johnson v. Big Lots Stores, Inc.*, Nos. 04-3201, 05-6627, 2008 WL 1930681, at *11 (E.D. La. Apr. 29, 2008) (finding "no reliability issue" with rebuttal testimony offered by defendant's expert economist "to critique" plaintiffs' expert's "methodology and interpretation of the data" because defendant's rebuttal expert relied on the same data and merely "analyze[d] the survey data in different ways from" plaintiffs' expert).

Second, plaintiffs assert, Dr. Johnson ignores a well-established principle that consumers generally pay more for branded products than generic products. Prof. Rosenthal applies this principle to her analysis—*i.e.*, she notes that "the vast majority of consumers pay more for brand products than generic products"—and opines that "almost everyone in the class suffered an overcharge because any copayment they paid in the actual world would necessarily have been lower in the but-for world." Doc. 2132-16 at 18 (Rosenthal Feb. 7, 2020 Rebuttal Expert Report ¶ 32). Defendants respond that Dr. Johnson's analysis of the data undermines Prof. Rosenthal's

assumption about the costs of branded products versus generics. Moreover, defendants assert, Prof. Rosenthal testified that she wasn't asked to opine on individual issues, like this one. Doc. 2186-4 at 3 (Rosenthal Feb. 8, 2019 Dep. 98:8–13). Plaintiffs' arguments about the various principles that Dr. Johnson assumed or ignored in his analysis go to the weight of his opinions, but not their admissibility. *See, e.g.*, *In re Syngenta AG MIR 162 Corn Litig.*, No. 14-md-2591-JWL, 2016 WL 5371856, at *10 (D. Kan. Sept. 26, 2016) (holding that criticisms about reliability of plaintiffs' experts' opinions "go to the weight of those opinions and not . . . their admissibility" and concluding "the experts' methodologies [weren't] so unreliable as to preclude certification"). Dr. Johnson's alleged failure to assume that consumers pay more for branded products than generics doesn't render his opinion so unreliable that the court must exclude it from evidence. Instead, plaintiffs' criticisms about Dr. Johnson's underlying assumptions are "fodder for cross-examination at trial." *ZF Meritor LLC v. Eaton Corp.*, No. 06-623-SLR, 2013 WL 6729509, at *5 (D. Del. Dec. 20, 2013). The court thus declines to exclude Dr. Johnson's opinion on this basis.

Last, plaintiffs argue that Dr. Johnson's opinion will mislead the jury into believing that a great number of class members sustained no injury. The court disagrees. As discussed, Dr. Johnson provides a reliable basis for his opinion, and he explains adequately how he analyzed the data differently than Prof. Rosenthal. At the same time, Prof. Rosenthal has explained why she uses her average "but-for" co-payment to calculate damages and why she believes it is the appropriate metric for her analysis. The trier of fact is more than capable of understanding the two approaches and parsing the differences of the two methods for analyzing the data. It is for the jury to decide which methodology it finds more credible and assign the appropriate weight to each opinion based on that credibility determination.

For all these reasons, the court won't exclude Dr. Johnson's opinion comparing actual co-payments to Prof. Rosenthal's calculation of the average "but-for" co-payment.

D. Dr. Johnson's Opinion About Teva's "But-For" Generic Entry Date

Finally, plaintiffs ask the court to exclude Dr. Johnson's opinion about Teva's "but-for" generic entry date because, plaintiffs contend, it's unreliable and not based on any expert analysis. Dr. Johnson's opinion takes issue with the "but-for" generic entry date that Prof. Rosenthal uses in her damages analysis. Prof. Rosenthal's damages model relies on a "but-for" generic entry date that comes from another one of plaintiff's experts—Prof. Einer Elhauge. Doc. 2132-16 at 11–12 (Rosenthal Feb. 7, 2020 Rebuttal Expert Report ¶ 16). Prof. Elhauge estimates a "but-for" generic date of March, 14, 2014. *Id.* And, Prof. Rosenthal's damage model assumes Prof. Elhauge's "but-for" generic entry date to calculate plaintiffs' purported generic delay damages. *Id.*

Dr. Johnson's Expert Report criticizes Prof. Rosenthal's assumed "but-for" generic entry date because, he contends, it fails to account for the time it took Teva to secure FDA approval for its generic in the real world. Doc. 2132-4 at 36 (Johnson Dec. 23, 2019 Expert Report ¶ 49). Dr. Johnson notes that Teva "had every incentive to have planned its regulatory efforts to obtain final FDA approval by [June 22, 2015] at the latest" but yet "it still took Teva an additional 1,254 days (about 41 months) to launch its generic EAI *after* the June 2015 licensed entry date." *Id.* Dr. Johnson also recognizes that "Teva's request for approval was *rejected* by the FDA on February 23, 2016, more than eight months after the allowed entry date from the settlement, due to 'certain major deficiencies.'" *Id.* (quoting Teva Pharm. Indus. Ltd., Report of Foreign Private Issuer Pursuant to Rule 13a-16 or 15d-16 under the Securities Exchange Act of 1934 (Form 6-K) (Feb. 29, 2016)). So, Dr. Johnson believes, "[i]f it is reasonable to assume that, in the but-for

world, it would have taken Teva the same 1,254 days to obtain FDA approval from the time it was free to launch a generic product, any but-for allowed entry date estimated by Prof. Elhauge would have to be pushed out by 1,254 days to estimate the corresponding but-for generic entry date by Teva." *Id.*

Plaintiffs argue the court should exclude this opinion for two reasons.

First, they argue that Dr. Johnson's opinion isn't reliable because he's not an FDA expert qualified to opine about generic entry date. Defendants respond that Dr. Johnson isn't providing an opinion about FDA approval. Instead, he's providing an opinion as an economist that a proper damages model must input an appropriate "but-for" generic entry date that reasonably measures when an generic product *could have* entered the market. *See, e.g.*, *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 165 (3d Cir. 2017) ("It is not enough for [plaintiffs] to show that [generic company] wanted to launch its drug; they must also show that the launch would have been legal."); *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 270 (D. Mass. 2014) ("Analyzing this issue requires looking at two separate questions: absent the [generic delay] Settlement, did [the generic company] have the 'will' to enter the market before 2014, and was there a 'way' for it to enter had the agreement allowed for earlier entry, considering both manufacturing and FDA approval requirements?").

Like Prof. Rosenthal, Dr. Johnson relies on opinions from other experts to form his opinion about a reasonable "but-for" generic entry date. Doc. 2132-4 at 33, 34 (Johnson Dec. 23, 2019 Expert Report ¶¶ 41, 43) (referring to Dr. Weisman and Dr. Peck's opinions). Specifically, Dr. Johnson cites another expert's opinion that "Teva's generic EAI device was a challenging product to develop and that its lengthy approval timeline, resulting in FDA approval in August 2018, was reasonable given the complexity of the product." *Id.* at 33 (¶ 41); *see also*

id. at 34 (¶ 43) (noting expert's opinion "that Teva faced substantial regulatory issues and product development complications that prolonged the length of the FDA approval process until August 2018, and that the delay in FDA approval was not due to conduct by the Defendants"). Dr. Johnson then uses that opinion to assert that Prof. Rosenthal's damages model is flawed because it relies on Prof. Elhauge's "but-for" generic entry date and doesn't take into account the time it took Teva to secure FDA approval in the real world. *Id.* at 33–36 (¶¶ 41, 43–45 48–49). Dr. Johnson, as an economist qualified to provide expert testimony in this case, may opine about the purported flaws he finds in Prof.'s Rosenthal's damages analysis based on her assumed "but-for" generic entry date. Plaintiffs' attacks on Dr. Johnson's assumptions about FDA approval go to the weight of his opinion about an appropriate "but-for" generic entry date. But, they don't warrant excluding his opinion.

Second, plaintiffs assert that Dr. Johnson's opinion is unreliable because he didn't conduct any scientific analysis to determine whether Teva would have required the same 1,254 days to secure FDA approval in both the actual and "but-for" worlds. Plaintiffs argue that Dr. Johnson merely provides "a simple arithmetic calculation" by taking the number of days it took Teva to secure FDA approval in the actual world and adding it to Prof. Elhauge's "but-for" generic entry date without recognizing the differences between the actual and "but-for" worlds. Doc. 2132-2 at 24. Plaintiffs argue that Dr. Johnson's basic arithmetic isn't grounded in specialized knowledge or expertise. Thus, plaintiffs contend, it doesn't qualify as admissible expert opinion.

Defendants respond with arguments similar to the ones asserted in response to plaintiffs' first argument. Defendants contend that Dr. Johnson's opinion is grounded in his economic expertise. And, they argue, he uses that expertise to criticize Prof. Rosenthal's assumption of a

purportedly flawed "but-for" generic entry date in her damages model. Again, this type of expert opinion testimony is proper rebuttal testimony. *See U.S. Gypsum Co. v. Lafarge N. Am. Inc.*, 670 F. Supp. 2d 768, 776–77 (N.D. Ill. 2009) (permitting rebuttal expert "[t]o opine on what he views as intrinsic weaknesses in [opposing party's expert's] reports" where the expert didn't "undertake an independent investigation" but instead reviewed "the allegedly flawed reports" which was "enough" to allow admission of the opinion and where "the jury will benefit from having access to criticism from another expert in the field"); *see also Aviva Sports, Inc. v. Fingerhut Direct Mktg., Inc.*, 829 F. Supp. 2d 802, 835 (D. Minn. 2011) (explaining that it's "the proper role of rebuttal experts to critique plaintiffs' expert's methodologies and point out potential flaws in the plaintiff's experts' reports" and denying motion to exclude expert opinion where the "rebuttal experts sufficiently applied their expertise to the facts and methodologies used by each of [plaintiff's] experts in forming their conclusions" and the "experts' testimony will be helpful for the jury to weigh the evidence presented at trial").

Here, the court finds Dr. Johnson's opinion will assist the trier of fact's efforts to understand the evidence at issue, specifically how Prof. Rosenthal arrived at her generic delay damages calculations and why Dr. Johnson believes her analysis is flawed based on her assumed "but-for" generic entry date. Plaintiffs' criticisms about Dr. Johnson's assumptions and the methodologies he uses to reach his opinion go to his opinion's weight. But, they don't preclude the court from admitting the opinion. The court thus denies plaintiffs' request to exclude his opinion criticizing Prof. Rosenthal's use of Prof. Elhauge's estimated "but-for" generic entry date.

For reasons explained, the court rejects each of plaintiffs' arguments seeking to exclude Dr. Johnson's expert opinions. The court thus denies plaintiffs' Motion to Strike in Part the Testimony of Dr. John H. Johnson, IV.

IV. Defendants' Motion to Exclude the Testimony and Report of Plaintiffs' Expert Witness Einer Elhauge (Doc. 2133)

Now, the court turns to defendants' motions seeking to exclude expert opinions. First, defendants ask the court to exclude the opinions of Prof. Einer Elhauge. Plaintiffs have retained Prof. Elhauge to provide expert testimony about the nature of, bases for, and calculations of plaintiffs' damages. Defendants argue the court should exclude two of Prof. Elhauge's opinions as unreliable: (1) his reverse payment analysis, and (2) his rebate analysis.[3] The court addresses each opinion, in turn, below.

A. Prof. Elhauge's Reverse Payment Analysis

One of the factual theories plaintiffs assert in this case contends that defendants delayed generic competition by entering into an unlawful reverse payment settlement with rival pharmaceutical company, Teva. *See* Doc. 2169 at 15–17 (Pretrial Order ¶ 3.a.1.b.). The theory involves Mylan and Teva's settlement of two separate lawsuits. Pfizer, through its subsidiaries, had sued Teva alleging that Teva's generic EAI infringed Pfizer's EpiPen patents. *Id.* at 15. Shortly after Pfizer filed this infringement lawsuit, Teva sued Mylan for patent infringement based on Mylan's FDA application seeking approval to market a generic version of Teva's drug, Nuvigil. *Id.* Plaintiffs here allege that Mylan and Teva entered settlement agreements to resolve

[3] Defendants' motion never asserts that Prof. Elhauge isn't qualified "by knowledge, skill, experience, training, or education" to provide the proffered expert testimony. Fed. R. Evid. 702. At class certification, the court concluded that Prof. Elhauge had sufficient qualifications to render his expert opinions. Doc. 2017-1 at 48–50. His qualifications haven't subsided. And, so, for the same reasons articulated in the court's earlier Order, the court finds Prof. Elhauge sufficiently qualified to provide expert testimony in this case. *Id.*

both lawsuits, and under those settlements, Teva agreed to delay entry of its generic EAI in exchange for Mylan's agreement to delay entry of its generic Nuvigil product. *Id.* Plaintiffs allege that "[n]either settlement, viewed independently, was economically rational." *Id.* at 16. But, plaintiffs contend, "the tandem EpiPen and Nuvigil settlements . . . guaranteed" that both Mylan and Teva "would both profit by limiting competition in their respective monopoly marketplaces rather than compete." *Id.*

Plaintiffs offer Prof. Elhauge's expert opinion to support their generic delay theory. Prof. Elhauge opines that settlement of the EpiPen infringement suit—on a standalone basis—was profitable for Mylan but unprofitable for Teva. Meanwhile, he opines, the Nuvigil settlement—standing alone—was unprofitable for Mylan but profitable for Teva. Doc. 2138-2 at 54 (Elhauge Oct. 31, 2019 Expert Report ¶ 103); *see also* Doc. 2187-5 at 23–25, 30–31 (Elhauge Feb. 12, 2020 Reply Expert Report ¶¶ 31–34, 44). So, Prof. Elhauge asserts, "the Nuvigil settlement that induced Teva to agree to the EpiPen settlement constituted a reverse payment to Teva." Doc. 2138-2 at 54 (¶ 103).

Defendants argue that the court should exclude Prof. Elhauge's reverse payment analysis as unreliable for two reasons. *First*, defendants argue that the reverse payment analysis uses a methodology that isn't scientifically sound and it also constitutes an improper reply opinion. *Second*, defendants contend that Prof. Elhauge's reverse payment analysis is based on flawed assumptions that don't comport with the facts of this case. The court addresses these two arguments, separately, below.

1. The Reverse Payment Analysis's Methodology

After Prof. Elhauge asserted his reverse payment opinion in his initial Expert Report, defendants' expert—Jonathan Orszag—reviewed the analysis and identified various

computational errors in the backup materials Prof. Elhauge used to calculate his reverse payment analysis. Doc. 2187-5 at 25–26 (¶ 35). Prof. Elhauge's Reply Report acknowledges Mr. Orszag's criticisms, *id.* at 25, and Prof. Elhauge concedes that his backup materials contained the identified errors, *id.* So, Prof. Elhauge's Reply Report adopts Mr. Orszag's corrections. *Id.* at 25–26. But, Prof. Elhauge asserts, the corrections don't change his opinion that the Nuvigil settlement constituted a reverse payment settlement that delayed generic competition. *Id.* at 26.

Defendants argue that Prof. Elhauge's new calculation shows that Mylan was better off settling the Nuvigil litigation. *See* Doc. 2187-5 at 27–29 (¶ 40 & Revised Table 1) (showing a $17 million "gain" to Mylan in the Nuvigil settlement "from Actual Settlement Relative to Litigation"). Defendants contend that this revision dooms plaintiffs' generic delay theory. So, defendants argue, Prof. Elhauge's Reply Report changes his entire methodology for analyzing the settlements by comparing the Nuvigil settlement to a manufactured "but-for" settlement instead of comparing it to the costs of continued litigation as he did in his initial Expert Report. Also, defendants argue that the analysis offered by Prof. Elhauge's Reply Report isn't scientifically sound and constitutes improper reply opinion.

First, the court addresses whether Prof. Elhauge's Reply Report uses a flawed methodology for analyzing the EpiPen and Nuvigil settlements. Defendants argue that the court should exclude the Reply Report's analysis because it's not "the product of reliable principles and methods[.]" Fed. R. Evid. 702(c). In short, defendants argue that Prof. Elhauge's initial hypothesis—*i.e.*, that the Nuvigil settlement, standing alone, was unprofitable for Mylan but profitable for Teva—failed after testing, so Prof. Elhauge came up with a different hypothesis in his Reply Report that the data could support. Defendants assert that this kind of analysis is improper scientific opinion, and the court must exclude it. *See, e.g.*, *Estate of Mitchell v.*

Gencorp, Inc., 968 F. Supp. 592, 600 (D. Kan. 1997) (Rogers, J.) ("Coming to a firm conclusion first and then doing research to support it is the antithesis of" the scientific method and "is not proper[.]" (citation and internal quotation marks omitted)).

But, plaintiffs respond to defendants' arguments by asserting that Prof. Elhauge's Reply Report doesn't change any aspect of his methodology for analyzing whether the Nuvigil settlement constituted a reverse payment settlement. To the contrary, they argue that Prof. Elhauge uses "precisely the same model" from his initial Report and that his computational corrections only produced an 11-day change to the economically rational allowed entry date in a but-for EpiPen settlement. Doc. 2187-1 at 8–9 (emphasis omitted). *Compare* Doc. 2138-2 at 55 (¶ 106) ("I calculate that the allowed entry date . . . in the but-for settlement was March 3, 2014."), *with* Doc. 2187-5 at 9–10 (¶ 3) ("Correcting these computational errors changes the predicted allowed no-payment settlement entry date 11 days, from March 3, 2014 to March 14, 2014.").[4]

Also, plaintiffs assert that Prof. Elhauge's "first and primary basis" for concluding that the Nuvigil settlement was a reverse payment settlement was that the EpiPen settlement undercompensated Teva compared to continued litigation; so, he asserts, the Nuvigil settlement must have overcompensated Teva, even if it didn't produce a loss for Mylan. Doc. 2187-1 at 9 (citing Doc. 2138-2 at 43, 45–46, 51–52 (¶¶ 79, 85–86, 98)). And, plaintiffs cite other evidence that Prof. Elhauge relied on to reach his conclusion that the two settlements had an economic link, including: (1) the parties' agreement to enter the two settlement agreements on the very

[4] In other places, Prof. Elhauge's Reply Report lists the revised no-payment settlement entry date as "March 14, *2013*." *See, e.g.*, Doc. 2187-5 at 27 (¶ 38) (emphasis added). Plaintiffs explain that this 2013 reference is a typographical error. And, they emphasize, March 14, 2014 is the correct date, as evidenced by Prof. Elhauge's repeated explanation that his revised calculation is just "11 days" later than the date his initial Report calculated. *See* Doc. 2187-5 at 9–10, 27 (¶¶ 3, 38).

same day, (2) "documentary evidence indicating that the EpiPen and Nuvigil settlements were discussed together as [a] package[,]" and (3) Mylan's submission of "the two settlements together to the DOJ and FTC as 'potentially related' for the purposes of antitrust review." Doc. 2138-2 at 45–46 (¶¶ 84, 86).

Plaintiffs further contend that defendants have mischaracterized Prof. Elhauge's analysis comparing the actual settlement to a "but-for" settlement. Prof. Elhauge's Reply Report asserts that "Mr. Orszag is wrong that if the Nuvigil settlement left Mylan better off than continued Nuvigil litigation, that means that the Nuvigil settlement was beneficial to Mylan." Doc. 2187-5 at 27 (¶ 39). He opines: "Continued Nuvigil litigation is not the right but-for baseline against which to measure the net effects of the actual Nuvigil settlement because without that settlement Mylan would not have continued to litigate, but rather would have entered into a standalone no-payment Nuvigil settlement that would have left both parties better off than with continued litigation." *Id.* Prof. Elhauge then calculates the "but-for" standalone no-payment settlements, using the calculated bargaining power of Mylan and Teva respectively, as demonstrated in the actual settlements. *Id.* at 27–31 (¶¶ 39–44). Prof. Elhauge based his analysis on his opinion that Mylan had 47.3% of the bargaining power in the actual settlements. *Id.* at 27–28 (¶ 40). And, his calculation concluded that the actual Nuvigil settlement under-compensated Mylan compared to an arm's length transaction where Mylan would have rationally exercised its share of the bargaining power. *Id.* at 27–31 (¶¶ 39–44). Contrary to defendants' assertion, Prof. Elhauge didn't invent his "but-for" settlement analysis "out of whole cloth." Doc. 2137-1 at 12. Just the opposite, Prof. Elhauge's Reply Report provides his methodology for his conclusions about comparing the actual settlement to a "but-for" settlement. Doc. 2187-5 at 27–31 (¶¶ 39–44).

And, as Prof. Elhauge explains, this calculation provides further support for his initial hypothesis that the Nuvigil settlement is a reverse payment settlement. *Id.*

In sum, plaintiffs argue that Prof. Elhauge's Reply Report's revised calculation showing that the Nuvigil settlement produced a gain for Mylan doesn't doom his original hypothesis that the Nuvigil settlement constitutes a reverse payment settlement because Prof. Elhauge has supported his conclusion with other reliable data and evidence. Also, they contend, Prof. Elhauge's discussion of the "but-for" settlements doesn't present a new hypothesis in the Reply Report. Instead, Prof. Elhauge includes this analysis to provide further support for his original hypothesis and as rebuttal to Mr. Orszag's criticisms. The court agrees with plaintiffs.

Defendants' attacks on Prof. Elhauge's analysis go to the weight of his opinions but not their admissibility.[5] As Prof. Elhauge explains, nothing about his methodology changed in his Reply Report. Other courts have allowed Prof. Elhauge to use this same methodology to provide expert testimony in pay-for-delay cases. *See, e.g.*, *In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 174 (S.D.N.Y. 2018) (rejecting defendants' arguments that Prof. Elhauge's reverse payment opinions "are speculative, internally inconsistent, and contradicted by the evidence" because those challenges were "appropriate subjects for cross-examination"); *In re Androgel Antitrust Litig. (No. II)*, No. 1:09-MD-2084-TWT, 2018 WL 2984873, at *17 (N.D. Ga. June 14, 2018) (holding that any "criticism" defendants had for Prof. Elhauge's

[5] Prof. Elhauge further asserts that Mr. Orszag's criticism—that Prof. Elhauge's reverse payment analysis is flawed because it shows that the Nuvigil settlement produced a gain for Mylan—contradicts Mr. Orszag's own scholarship. Doc. 2187-5 at 26–27 (¶¶ 36–37, 39). Defendants say plaintiffs are wrong—that Mr. Orszag's scholarship applies to single patent settlements but not an agreement to transfer value across one patent settlement to another patent settlement, as Prof. Elhauge opines was the purpose of the EpiPen and Nuvigil settlements. These attacks also go to the opinion's weight, but not admissibility. Prof. Elhauge and Mr. Orszag's competing views about the scholarship and whether it applies to the settlements at issue here go to the credibility the trier of fact should assign each expert's opinion. But, it doesn't warrant excluding Prof. Elhauge's opinion.

"methodologies or conclusions are best handled through cross-examination and the production of contrary evidence"); *United Food & Com. Workers Loc. 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma USA*, 296 F. Supp. 3d 1142, 1186–88 (N.D. Cal. 2017) (denying motion to exclude Prof. Elhauge's reverse payment opinions after finding that "both the components of his model (estimating parties' bargaining strengths and expectations of patent strength) and the assumptions that go with it (the parties' own pre-settlement forecasts) are consistent with accepted economic theory and well-established principles"). Similar to the conclusions reached in the cited cases, the court here finds Prof. Elhauge's methodology reliable and scientifically sound. Defendants' criticisms of Prof. Elhauge's analysis—specifically, how it concludes that the Nuvigil settlement produced a gain for Mylan yet still finds that the Nuvigil settlement was a reverse payment settlement—are appropriate subjects for cross-examination. But, they don't convince the court that Prof. Elhauge's opinion is so unreliable that the court should exclude it from evidence.

The court also rejects defendants' arguments that Prof. Elhauge's analysis conflicts with *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013). *Actavis* held that "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects[.]" *Id.* at 158. And, it instructs courts to apply a rule of reason analysis to alleged unlawful reverse payments because, as the Supreme Court recognized, the anticompetitive effects of a reverse payment depend on "its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification" and "may also vary as among industries." *Id.* at 159. Defendants argue that Prof. Elhauge's analysis of whether a settlement overcompensated or undercompensated a generic entrant creates an impossible standard for a generic entrant to prove that it didn't enter an

unlawful reverse payment. According to defendants, Prof. Elhauge's analysis requires the generic entrant to prove that it negotiated the best possible settlement or otherwise face antitrust liability for a reverse payment settlement under *Actavis*. But, defendants argue, "*Actavis* does not stand for the proposition that parties must reach the most procompetitive settlements possible." *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 408–09 (3d Cir. 2015); *see also In re ACTOS Direct Purchaser Antitrust Litig.*, 414 F. Supp. 3d 635, 646 (S.D.N.Y. 2019) (rejecting argument that was "tantamount to asserting that the generics were required to agree to the most pro-competitive settlement under the circumstances" because that "is not the law: *Actavis* requires only that the parties to a patent litigation settlement refrain from unlawfully restricting competition, not that they maximize competition").

Plaintiffs disagree. They explain that *Actavis* requires a rule of reason analysis involving many factors—*i.e.*, a reverse payment's "size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." *Actavis*, 570 U.S at 159. They argue that Prof. Elhauge's analysis is consistent with *Actavis* because it considers the size of the Nuvigil settlement in relation to costs associated with continued litigation and the Nuvigil settlement's independence from other services—*i.e.*, the EpiPen settlement—for which it might represent payment. Also, they contend, Prof. Elhauge's analysis doesn't require a generic entrant to show that it negotiated the best settlement possible—*i.e.*, securing the earliest possible entry date—because that would require his model to assume the generic had 100% of the bargaining power. And, plaintiffs say, his model doesn't do that.

The court agrees with this description of Prof. Elhauge's reverse payment analysis. Defendants correctly argue that *Actavis* doesn't require a generic entrant to prove that it entered

the most pro-competitive settlement. But, Prof. Elhauge's analysis doesn't require a generic entrant to meet that standard. Instead, Prof. Elhauge's analysis considers the metrics of the Nuvigil and EpiPen settlements using the factors discussed in *Actavis*. And, his analysis opines whether the settlements overcompensated or undercompensated Mylan and Teva. The court finds his analysis consistent with *Actavis*. And, it thus finds no reason to exclude Prof. Elhauge's opinion on this basis.

Also, the court isn't persuaded by defendants' argument that Prof. Elhauge's opinion is unsound because it doesn't identify any record evidence showing that any other settlement in either the EpiPen or Nuvigil settlements even was possible. As plaintiffs correctly argue, *Actavis* places the burden of proof on a plaintiff to prove that a reverse payment produces anticompetitive effects violating the antitrust laws. *Actavis*, 570 U.S. at 159. But, defendants cite no case suggesting that a plaintiff can satisfy that burden by adducing direct evidence that the parties considered and rejected a no-payment settlement with an earlier generic entry date. And, as plaintiffs assert, other courts have recognized that the law doesn't require a plaintiff to come forward with such direct evidence to support a reverse payment claim. *See, e.g.*, *United Food & Com. Workers Loc. 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma USA*, 296 F. Supp. 3d 1142, 1190 (N.D. Cal. 2017) ("Because this case is set in a but-for world, it is not surprising that no evidence shows that defendants were contemplating anything other than the actual Settlement."); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-md-02503, 2018 WL 563144, at *21 (D. Mass. Jan. 25, 2018) (recognizing that "it is unreasonable to expect a paper trail signifying rational, lawful business choices" and "[r]equiring such evidence . . . would be an almost impossible standard to require of Plaintiffs, given that this is a but-for scenario"). As plaintiffs note, evidence that Teva and Mylan considered other

settlements certainly might corroborate Prof. Elhauge's analysis. But, the absence of such evidence doesn't render the model unreliable.

In sum, none of defendants' arguments convinces the court that it should exclude Prof. Elhauge's reverse payment analysis as unreliable. To the contrary, the court finds that Prof. Elhauge has provided a reliable methodology for his analysis. Defendants' attacks go to the credibility of his analysis but don't require the court to exclude his opinion.

Second, defendants argue that the court should exclude Prof. Elhauge's reverse payment analysis because, they contend, his Reply Report asserts an entirely new model. Thus, defendants argue, his opinion amounts to improper rebuttal opinion violating Fed. R. Civ. P. 26(a)(2)(D)(ii) because it's not evidence "intended solely to contradict or rebut evidence on the same subject matter identified by another party[.]" Fed. R. Civ. P. 26(a)(2)(D)(ii). The court disagrees.

As discussed above, Prof. Elhauge's Reply Report uses the same methodology as his initial Expert Report. The Reply Report includes an analysis where Prof. Elhauge compared the actual settlements to "but-for" standalone no-payment settlements that he calculated using the bargaining power percentages that Mylan and Teva respectively demonstrated in the actual settlements. As the court previously explained, it rejects defendants' argument that Prof. Elhauge's "but-for" standalone no-payment settlement analysis is an entirely new opinion asserted in the Reply Report. Instead, the court finds, Prof. Elhauge proffers that analysis to rebut Mr. Orszag's criticisms—specifically, his criticism that Prof. Elhauge's analysis doesn't show a reverse payment settlement when his calculations demonstrate that the Nuvigil settlement produced a gain for Mylan. Prof. Elhauge offers this analysis to explain why Mr. Orszag's criticism doesn't render Prof. Elhauge's original analysis unreliable. That is, according to Prof.

Elhauge, his analysis still shows that it wasn't rationale from an economic perspective for Mylan to enter the Nuvigil settlement, just as it wasn't rationale for Teva to enter the EpiPen settlement. This 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." (citation and internal quotation marks omitted)). So, the court won't exclude this opinion.[6]

For reasons explained, the court rejects defendants' arguments that Prof. Elhauge's reverse payment analysis uses an unreliable methodology or constitutes improper rebuttal opinion. The court thus declines to exclude Prof. Elhauge's reverse payment analysis.

2. The Reverse Payment Analysis's Assumptions

Next, defendants argue that Prof. Elhauge's reverse payment analysis relies on flawed assumptions that render his opinion unreliable, and thus, inadmissible. Defendants present three reasons supporting this argument.

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[6] Even if the court found Prof. Elhauge's Reply Report constituted improper rebuttal violating Fed. R. Civ. P. 26(a)(2)(D)(ii), the court still could admit the evidence if it finds the failure to disclose "was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). The Tenth Circuit has instructed district courts to consider four factors when excising their "broad discretion" to decide whether a Rule 26(a) violation is justified or harmless. *HCG Platinum, LLC v. Preferred Prod. Placement Corp.*, 873 F.3d 1191, 1200 (10th Cir. 2017) (citation and internal quotation marks omitted). They are: "'(1) the prejudice or surprise to the party against whom the testimony is offered; (2) the ability of the party to cure the prejudice; (3) the extent to which introducing such testimony would disrupt the trial; and (4) the moving party's bad faith or willfulness.'" *Id.* (quoting *Woodworker's Supply, Inc. v. Principal Mut. Life Ins. Co.*, 170 F.3d 985, 993 (10th Cir. 1999)).

Plaintiffs contend that even if they had failed to disclose Prof. Elhauge's analysis in a timely manner, any delay was harmless because defendants submitted 62 pages of additional expert declarations in response to the Reply Report. Thus, plaintiffs contend, defendants have had ample opportunity to review and respond to Prof. Elhauge's Reply Report. And, defendants have sustained no prejudice. Defendants' Reply never responds to this argument. Plaintiffs have the better of this argument, by far. Even if the court found that Prof. Elhauge's opinion isn't proper rebuttal and wasn't disclosed in a timely manner, the court wouldn't bar its admission under Fed. R. Civ. P. 37 because any untimely disclosure was harmless.

First, defendants argue that Prof. Elhauge's model comparing the actual settlements to "but for" settlements is unreliable because it uses a circular methodology and assumes the very conclusion that Prof. Elhauge seeks to prove—*i.e.*, he assumes that the Nuvigil and EpiPen settlements were linked and included a reverse payment, and then he uses each party's bargaining power in the actual settlements to calculate a "but-for" settlement that he concludes proves that the Nuvigil and EpiPen settlements contained a reverse payment. *See* Doc. 2187-5 at 27, 30–31 (Elhauge Feb. 12, 2020 Expert Reply Report ¶¶ 39, 44). Plaintiffs respond that Prof. Elhauge didn't just assume that the actual settlements were linked. Instead, as discussed above, Prof. Elhauge relied on documented and economic evidence to support his initial assumption—*i.e.*, economic analysis showing that the EpiPen settlement standing alone was unprofitable for Teva, the fact the settlements were signed the same day, documents show that the settlements were negotiated as a package, and Mylan's submission of the two settlements to the FTC as potentially related. *See* Doc. 2138-2 at 43, 45–46, 51–54 (Elhauge Oct. 31, 2019 Expert Report ¶¶ 79, 84–86, 98, 101, 103). And, as discussed above, Prof. Elhauge's Reply Report uses the "but-for" settlement analysis to rebut Mr. Orszag's opinion that Prof. Elhauge's revised calculations fail to show a reverse payment existed when he calculated that the Nuvigil settlement resulted in a gain to Mylan. To the extent defendants seek to challenge the assumptions Prof. Elhauge made in the Reply Report's rebuttal opinion, they can attack those assumptions on cross-examination. But, the court doesn't find that Prof. Elhauge's assumptions render his opinion unreliable.

Second, defendants assert that Prof. Elhauge incorrectly assumed that the parties would have the same bargaining strength in his hypothetical "but-for" settlements as they had in the actual settlements. Doc. 2187-5 at 27–30 (¶¶ 40, 41). Defendants say this is a flawed

assumption because with a linked settlement, both parties would have patents at issue, but with an independent settlement, only one party seeks to enforce a patent. So, defendants contend, it's illogical for Prof. Elhauge to assume that a party would have the same bargaining strength in a case where it was seeking to enforce a patent compared to a case where it had no patent rights.

As with defendants' first argument, these criticisms are fodder for cross-examination. Defendants' attacks against Prof. Elhauge's assumption that the parties' bargaining power in the actual settlement would translate to a "but-for" settlement go to the weight the trier of fact should assign his opinion when making a credibility determination. But, the court doesn't find that this assumption renders Prof. Elhauge's analysis so unreliable that the court must exclude his opinion.

Finally, defendants argue that Prof. Elhauge's analysis is flawed because it fails to account for all of the patents involved in the EpiPen settlement. Prof Elhauge's model assumes that only two EpiPen patents were at issue in the settlement. Doc. 2187-5 at 54–57 (¶¶ 87–92). But, defendants argue, that assumption ignores two additional EpiPen patents that came within the settlement's scope because the settlement gave Teva the license to sell "any and all" EpiPen patents now or in the future. Doc. 2138-9 at 16 (EpiPen Settlement Agreement Ex. A ¶ 8). Defendants argue that this flawed assumption renders Prof. Elhauge's opinion unreliable because he can't opine that the EpiPen settlement was economically irrational for Teva when he failed to consider the value that Teva derived from the two other patents included as part of the EpiPen settlement. But, Prof. Elhauge's Reply Report explains why, he believes, his analysis is sound even though it didn't consider the two additional EpiPen patents. Doc. 2187-5 at 54–57 (¶¶ 87–92). He cites Prof. Torrance's opinion that the two additional patents "added almost nothing that is patentably or technically new" when compared to the two patents that Prof. Elhauge's model

considers. *Id.* at 54 (¶ 87). So, Prof. Torrance opines, if the originally litigated patents were invalidated, then the two additional patents would face the same fate. *Id.*; *see also id.* at 55–56 (¶¶ 89–90). Moreover, Prof. Elhauge asserts that even if his failure to consider the two other patents "should change the patent strength estimate from the one that Prof. Torrance estimated," Prof. Elhauge believes his "sensitivity analysis already accounted for any such adjustment in perceived patent strength." *Id.* at 56 (¶ 91). Based on these assertions, Prof. Elhauge provides a rational basis for why he believes it was reasonable for his analysis to consider just the two EpiPen patents. Once again, defendants' attacks against his assumption go to the weight of his opinion, but don't preclude the court from admitting his reverse payment analysis.

In sum, the court rejects defendants' arguments that Prof. Elhauge's reverse payment analysis is inadmissible expert opinion. So, the court denies defendants' request to exclude from the evidence the reverse payment analysis.

B. Prof. Elhauge's Rebate Analysis

Another theory plaintiffs assert in this case claims that defendants "engaged in an anticompetitive scheme to delay—and ultimately block—[ ]entry of competing branded epinephrine auto-injectors." Doc. 2169 at 17 (Pretrial Order ¶ 3.a.1.c.). Plaintiffs allege that defendants "condition[ed] rebates paid to pharmacy benefit managers ('PBMs') on their agreement to block competing EAIs from formulary placement" as a way "to maintain their monopoly power by preventing their primary branded competitor, Auvi-Q, from gaining a foothold in the market." *Id.* at 17–18. Plaintiffs also allege that defendants' exclusionary rebating practices forced class members "to pay supra-competitive prices for EpiPens" and prevented class members from "obtain[ing] their preferred device." *Id.* at 18. Plaintiffs contend that defendants' exclusionary scheme "inflated EpiPen's price in at least two ways: (i) directly

increasing Mylan's profit-maximizing price by increasing the market share Mylan would attain at any given set of prices; and (ii) depriving Auvi-Q of economies of scale, which in turn further increases Auvi-Q's price and Mylan's price." *Id.*

Plaintiffs have retained Prof. Elhauge to provide expert opinion to support their exclusionary rebating theory. Prof. Elhauge offers expert analysis that, he contends, demonstrates "Mylan's exclusionary contracts with PBMs . . . harmed the entire class by foreclosing a large share of the market to Auvi-Q, which reduced Auvi-Q sales and competition with Mylan and thus reduced Mylan's incentives to lower its prices across the market." Doc. 2138-2 at 6 (Elhauge Oct. 31, 2019 Expert Report ¶ 3). He asserts that "Mylan leveraged its market power by offering rebates to PBMs conditioned on placing Auvi-Q in restrictive formulary positions, successfully reducing Auvi-Q's share amongst customers placed on those formularies." *Id.* Then, he estimates "the share and price impact . . . caused by this foreclosure[.]" *Id.* He concludes that the foreclosure produced overcharges that the class members paid, and he calculates those overcharges as the damages class members sustained by the Auvi-Q foreclosure. *Id.*

Defendants assert that Prof. Elhauge's rebate analysis is unreliable for three reasons. *Firs*t, defendants argue that the rebate analysis uses a foreclosure regression that's flawed. *Second*, defendants argue that Prof. Elhauge's analysis assumes foreclosure theories that aren't supported by the facts. *Last*, defendants contend, Prof. Elhauge uses a flawed model to translate his foreclosure regression into a price effect on EpiPen. The court addresses each of these three arguments, separately, below.

1. The Rebate Analysis's Foreclosure Regression

Prof. Elhauge uses a regression analysis that, he contends, demonstrates how the restrictions imposed on Auvi-Q's formulary placement reduced Auvi-Q's market share which, in turn, allowed Mylan to increase EpiPen prices and forced class members to pay overcharges for the EpiPen. Doc. 2138-2 at 87–92, 109–12 (Elhauge Oct. 31, 2019 Expert Report ¶¶ 164–70 & App. A). A regression analysis "is a statistical tool used to determine the relationship between an unknown variable (the 'dependent' variable) and one or more 'independent' variables that are thought to impact the dependent variable." *In re Urethane Antitrust Litig.*, 768 F.3d 1245, 1260 (10th Cir. 2014) (citing Saks, Michael J., et al., *Reference Manual on Scientific Evidence* 179, 181 (2d ed. 2000)); *see also* Daniel L. Rubinfeld, "Reference Guide on Multiple Regression," in *Reference Manual on Scientific Evidence* 303, 305 (3d ed. 2011), https://www.fjc.gov/sites/default/files/2015/SciMan3D01.pdf (hereinafter "Reference Guide on Multiple Regression") (explaining that regression analysis "involves a variable to be explained—called the dependent variable—and additional explanatory variables that are thought to produce or be associated with changes in the dependent variable").

"The fundamental goal of regression analysis is to convert an observation of correlation (*e.g.*, apartments in Manhattan cost more than those in Queens) into a statement of causation (apartments in Manhattan cost more than those in Queens *because* they are in Manhattan, not because they are larger or more luxuriously appointed)." *Reed Constr. Data Inc. v. McGraw-Hill Cos., Inc.*, 49 F. Supp. 3d 385, 397 (S.D.N.Y. 2014), *aff'd on other grounds*, 638 F. App'x 43 (2d Cir. 2016). But, "[c]ausality cannot be inferred by data analysis alone[.]" *See supra* Reference Guide on Multiple Regression, at 310. Instead, "one must infer that a causal

relationship exists on the basis of an underlying causal theory that explains the relationship between the two variables." *Id.*

Here, Prof. Elhauge performs a regression analysis that evaluates the effects of two independent variables—(1) Auvi-Q's formulary coverage, and (2) the average net price of Auvi-Q compared to EpiPen—on Auvi-Q's market share, the "dependent variable." Doc. 2138-2 at 88–90 (¶¶ 165–68). Prof. Elhauge asserts that he included the "price-ratio variable" in his regression because it "explicitly control[s] for the extent to which price differences rather than formulary restrictions affected Auvi-Q's share." *Id.* at 90 (¶ 168). But he "also considered an alternative regression specification" by "dropping the price variable." *Id.* And, after running both models, Prof. Elhauge concludes that each model demonstrates that the formulary restrictions reduced Auvi-Q's market share "regardless of whether one includes the price-ratio variable." *Id.*

Defendants assert three reasons why Prof. Elhauge's regression model is unreliable. They say: (1) it rests on flawed assumptions, (2) it is incapable of accurately measuring price, and (3) it generates false positives. The next three subsections address these arguments.

a. The Regression Analysis's Assumptions

First, defendants argue that Prof. Elhauge's regression analysis is unreliable because it rests on the flawed assumption that formulary placement is independent of Auvi-Q and EpiPen's prices. Defendants say this assumption is wrong and contrary to how the pharmaceutical industry works. They cite the Report of their own expert, who opines that PBMs use preferred formulary placement and restrictions to negotiate lower prices on drugs in the form of rebates. Doc. 2163-5 at 24–25 (Willig Dec. 23, 2019 Expert Report ¶¶ 55–57); *see also id.* at 85 (¶ 197) (explaining that "the effects of prices net of rebates and of formulary restrictions are one and the

same" and "the reality of the industry is that manufacturers are willing to pay higher rebates for favorable formulary placement due to PBMs' ability to use formulary placement to affect doctors' and patients' product choices and to move volume"). Thus, defendants contend, formulary restrictions are dependent on relative drug prices. And, they argue, Prof. Elhauge's regression model is wrong to attribute Auvi-Q's formulary restrictions as having an effect on its market share when that result likely is the product of Auvi-Q's higher price relative to EpiPen.

Plaintiffs respond that defendants' argument—not Prof. Elhauge's analysis—is what is based on a flawed assumption about the pharmaceutical industry. Plaintiffs assert that defendants' assumption that PBMs extract lower prices from drug manufacturers by negotiating formulary placement is premised on comparing the discounted price to the Wholesale Acquisition Cost ("WAC")—*i.e.*, the gross price. But, plaintiffs contend, this is the wrong comparison. They contend defendants' own expert found EpiPen's net price increased when Auvi-Q was subjected to formulary restrictions. Doc. 2163-5 at 94–95 (Willig Dec. 23, 2019 Expert Report ¶ 221 & Fig. 11). And, Prof. Elhauge opines that the rebate agreements actually "help Mylan anticompetitively increase *net prices*" because they require PBMs to impose the formulary restrictions "in exchange for a share of Mylan's resulting supracompetitive profits." Doc. 2187-5 at 214–215 (Elhauge Feb. 12, 2020 Reply Expert Report ¶ 362) (emphasis added). Prof. Elhauge explains that PBMs don't pass all rebates they receive from drug manufacturers to their customers, and as a result, PBMs also can profit from restrictions that help the manufacturer anticompetitively increase prices. *Id.*

Also, plaintiffs argue that Prof. Elhauge's analysis shows that Mylan's exclusionary restrictions—not the rebates—drove PBMs to restrict Auvi-Q from preferred formulary placement. He asserts: "the data shows that: (a) plans that were subject to Mylan agreements

that conditioned rebates on formulary restrictions were 10 times more likely to restrict Auvi-Q's formulary position; and (b) plans rarely restricted Auvi-Q's formulary position when they were not subject to Mylan's exclusionary agreements." Doc. 2187-5 at 11 (¶ 8). So, Prof. Elhauge concludes, his analysis "clearly shows that Mylan's conditioned rebates were the main driver of plans adopting formulary restrictions." *Id.* at 128 (¶ 218). Defendants respond, asserting that this conclusion doesn't make any sense. Instead, defendants contend, Prof. Elhauge's analysis simply demonstrates that PBMs were more likely to impose the formulary restrictions in exchange for higher rebates. And, defendants argue, this proves defendants' point that formulary position and prices aren't independent variables, but instead formulary positioning is dependent on drug price.

The parties' disagreement boils down to the accuracy of the assumptions that Prof. Elhauge makes about the pharmaceutical industry. Defendants say that Prof. Elhauge's analysis is flawed for failing to recognize that formulary placement drives price, and thus Prof. Elhauge is wrong to consider these two variables independently of one another. But Prof. Elhauge's initial Expert Report and Reply Report adequately explain the assumptions he makes and provides a reasonable rationale for them. Also, Prof. Elhauge provides a reasonable methodology for testing the independence between formulary placement and net price by controlling for the price variable in his model. Doc. 2138-2 at 89 (¶ 167). Defendants certainly can attack these assumptions by cross-examining Prof. Elhauge about his model and presenting their own evidence about the assumptions an expert should make about the pharmaceutical industry when conducting a rebate analysis. But, Prof. Elhauge's assumptions don't render his regression analysis so unreliable that the court should exclude it. The court denies this aspect of defendants' motion.

b. The Price Ratio Variable

Next, defendants argue the court should exclude Prof. Elhauge's regression analysis as unreliable because it uses a price ratio variable that doesn't measure price accurately. Defendants assert that the price ratio variable—*i.e.*, the variable that Prof. Elhauge's regression uses to control for price—is flawed because it measures prices at the *PBM level*, but the data he uses to measure Auvi-Q's market share is taken from the *health plan level*.[7] Doc. 2138-2 at 88–89 (Elhauge Oct. 31, 2019 Expert Report ¶ 166). Defendants explain that prices can vary greatly across health plans, even within the same PBM. So, defendants contend, Prof. Elhauge's use of PBM level pricing data renders his regression unreliable because it can't show whether any reduction in Auvi-Q's market share is the product of the alleged unlawful exclusivity restrictions or whether it's the result of Auvi-Q's higher prices relative to EpiPen for a particular health plan.

Defendants rely on their expert to explain why using price data at the PBM level renders Prof. Elhauge's model flawed. Defendants' expert asserts that Prof. Elhauge's use of the PBM level pricing data introduces a "measurement error in the price variable[,]" which produces a biased model. Doc. 2163-5 at 86 (Willig Dec. 23, 2019 Expert Report ¶ 200); *see also* Doc. 2138-8 at 10 (Willig Decl. ¶ 20) (explaining that Prof. Elhauge's use of "the same average PBM-level price for each of the hundreds of plans typically sponsored by a single PBM. . . . introduces significant measurement error in the price variable and obscures the correlation between price and Auvi-Q share for which Professor Elhauge claims to be controlling"). And, defendants'

[7] Defendants repeatedly cite to certain pages of Prof. Elhauge's Dec. 5, 2019 deposition transcript to support their argument that his price ratio variable doesn't properly measure price. *See* Doc. 2137-1 at 21 (citing SJ Ex. 137 (Dec. 5, 2019 Elhauge Dep. 228:21–229:24, 252:13–18)); *see also id.* at 23 n.10 (citing SJ Ex. 137 (Dec. 5, 2019 Elhauge Dep. 25:6–8)). But the summary judgment exhibit they cite doesn't contain those pages. *See* Doc. 2146-4 (Ex. 137) (omitting pages 25, 228–29, & 252). The court has reviewed other deposition transcripts for Prof. Elhauge contained in the record and can't find the cited pages in those exhibits either.

expert provides an example how Prof. Elhauge's model can fail to observe the variation in pricing and formulary position between two plans within one PBM because Prof. Elhauge uses a PBM-wide average of the plans' prices to analyze the data. Doc. 2163-5 at 86–87 (Willig Dec. 23, 2019 Expert Report ¶ 201); *see also* Doc. 2138-8 at 10 (Willig Decl. ¶ 20).

Prof. Elhauge responds to this criticism, explaining that no data exists that would allow him to calculate health plan level pricing. Doc. 2187-5 at 118 (Elhauge Feb. 12, 2020 Expert Reply Report ¶ 196). Nevertheless, Prof. Elhauge used the data available to calculate estimated health plan level prices. *Id.* at 118–19 (¶¶ 197–198). Then, he re-ran his foreclosure regression, and he concluded that "using estimated plan-level prices does not significantly change the results of the share impact regression" because "the regression still indicates that the formulary restrictions reduced Auvi-Q's share by a statistically significant and practically significant amount." *Id.* at 119–20 (¶¶ 199–200 & Table 105). So, Prof. Elhauge asserts, his conclusion—*i.e.*, using the plan level data in the regression doesn't change the results of his initial model—shows that his use of PBM level prices accurately controls for price.

Defendants argue that the Reply Report's health plan level price regression is not proper rebuttal opinion, but instead qualifies as new expert opinion that plaintiffs failed to disclose timely. Defendants say that Prof. Elhauge could have performed his regression in his initial Expert Report. But, he didn't. So, they argue, the court should exclude the Reply Report's new regression as untimely. The court disagrees. As plaintiffs correctly argue, Prof. Elhauge offered his plan level price regression in response to criticisms by defendants' experts about his initial Expert Report's regression model. Thus, his health plan level regression rebuts Mylan's experts' opinions on the same subject matter. Also, according to plaintiffs, Prof. Elhauge couldn't have performed the plan level regression earlier because it uses more comprehensive data that Prof.

Elhauge didn't have access to until defendants' expert produced it on December 2, 2019. *See* Doc. 2187-5 at 83, 105 (¶¶ 134, 169). So, the court finds, the plan level price regression is proper rebuttal testimony.

Also, defendants argue that Prof. Elhauge's plan level regression is unreliable because his estimated plan level prices conflict with undisputed evidence showing that rebates fluctuate over PBMs across time and different health plans received different levels of rebates, even when Auvi-Q wasn't restricted. But, Prof. Elhauge provided a reasonable basis for his estimation. Doc. 2187-5 at 118–20 (¶¶ 196–200 & Table 105). Defendants' attacks against his assumption go to the weight of Prof. Elhauge's opinion—specifically, his estimation of plan level prices. Defendants are free to challenge this opinion using "[v]igorous cross-examination" or through the "presentation of contrary evidence" because, as the Supreme Court has instructed, that's what remains "the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596; *see also BC Tech., Inc. v. Ensil Int'l Corp.*, 464 F. App'x 689, 704 (10th Cir. 2012) (recognizing that omissions in the data the expert used "made his testimony vulnerable" but still "had sufficient evidentiary support to pass the admissibility threshold" and opposing party has the opportunity to "exploit[ ] the vulnerability [of the expert opinion] by presenting evidence contrary to [the expert's] assumptions and through cross examination"). But, the court refuses to exclude Prof. Elhauge's regression analysis based on the price ratio variable that it uses.

c. False Positives

Finally, defendants argue that Prof. Elhauge's regression analysis is unreliable because it generates false positives. Defendants' expert criticizes Prof. Elhauge's regression model because, he contends, even when the regression is limited to plans where Mylan *didn't* offer

rebates conditioned on restrictive formulary placement, the regression still calculates an effect on Auvi-Q market share. Doc. 2138-5 at 2 (Suppl. to Dec. 23, 2019 Willig Expert Report ¶¶ 1–4). According to defendants' expert, he performed an analysis using Prof. Elhauge's regression and found no "statistical differe[nce]" between the effects of Mylan's rebate offers conditioned on restrictive formulary placements and Mylan's rebates offers that had no conditions. *Id.* (¶ 4). Thus, defendants argue, the court must exclude the regression analysis because it can't distinguish between lawful conduct and the allegedly unlawful conduct at issue in this lawsuit. *See In re Rail Freight Fuel Surcharge Antitrust Litig.-MDL No. 1869*, 725 F.3d 244, 254 (D.C. Cir. 2013) (deciding the weight the court should assign to an expert opinion on class certification when a damages model had a "propensity toward false positives" so it provided "no way of knowing" whether "the overcharges the damages model calculates for class members is any more accurate than the obviously false estimates it produces" for others); *see also In re LIBOR-Based Fin. Instruments Antitrust Litig.*, 299 F. Supp. 3d 430, 487 (S.D.N.Y. 2018) (excluding expert regression model on class certification because it couldn't demonstrate that the challenged conduct—as opposed to other conduct—produced the measured effect).

Prof. Elhauge responds to this criticism, denying that his regression generates false positives. Doc. 2187-5 at 127–28 (¶¶ 214–19). First, he asserts that it was "incredibly rare" for a plan to restrict Auvi-Q in the absence of a conditional rebate. *Id.* at 126 (¶ 213) (finding that only 3% of plans who were offered no conditional rebates restricted Auvi-Q's formulary position). Next, he adjusted his regression analysis to adopt defendants' expert's opinion of which plans to include in the analysis, and, he contends, his regression still finds substantial market foreclosure for Auvi-Q. *Id.* at 128 (¶ 219) ("Consequently, *none* of the overcharges that

I calculate below stem from formulary restrictions on Auvi-Q that were imposed by the plan-months that Prof. Willig claims were not offered rebates conditioned on restricting Auvi-Q.").

Defendants dispute Prof. Elhauge's claim that he adjusted his analysis in a way that shows his regression model is reliable. Instead, they argue, defendants' expert only identified examples of plans that did and didn't include formulary restrictions based on rebates. But he didn't do a comprehensive analysis of all health plans. And so, they say, Prof. Elhauge's revised analysis still can't show that the allegedly unlawful conduct (as opposed to lawful conduct) had an effect on Auvi-Q's market share.

Once again, these challenges may supply fodder cross-examination. But Prof. Elhauge has provided a reliable methodology for his regression analysis, and he sufficiently explains why he believes it doesn't generate false positives. The criticisms that defendants' expert makes about false positives go to the weight that the trier of fact should assign to Prof. Elhauge's regression analysis. But these challenges don't render his model so unreliable that the court must exclude it under Fed. R. Evid. 702.

2. The Rebate Analysis's Foreclosure Theories

Next, defendants argue that Prof. Elhauge's rebate analysis is flawed because it never identifies any theory explaining why Mylan's rebates prevented Auvi-Q from competing against EpiPen. As defendants correctly assert, a regression analysis must identify "an underlying causal theory that explains the relationship between the two variables," and it must "look for empirical evidence that there is a casual relationship." *See supra* Reference Guide on Multiple Regression, at 310. But, plaintiffs say, Prof. Elhauge's initial Expert Report satisfies this requirement.

Indeed, Prof. Elhauge's Expert Report asserts that Mylan's rebate offers conditioned on exclusivity allowed Mylan to "leverage its existing market share to exclude Auvi-Q." Doc.

2138-2 at 84 (Elhauge Oct. 31, 2019 Expert Report ¶ 157). Prof. Elhauge relies on internal Sanofi and Mylan documents to support this conclusion. *See id.* (citing Sanofi document recognizing that "Epi-Pen's high market share coupled with a high discount creates an obstacle that cannot be overcome via discounting" (internal quotation marks omitted)); *see also id.* at 85 (¶ 158) (citing Mylan document that noted "how hard it would be to switch away from EpiPen" and that "plans are primarily concerned with reducing overall net spend," which Prof. Elhauge opines "provides an advantage to the incumbent with the higher market share when engaging in a conditional rebating strategy, since the same rebate reduces overall net spend by a greater amount the higher the market share" (internal quotation marks and alteration omitted)). Then, Prof. Elhauge's Expert Report asserts the regression analysis "shows that these restrictive formulary conditions had the cumulative effect of anticompetitively inflating Mylan's share of the EAI market by a significant amount." *Id.* at 85 (¶ 158). The court agrees that Prof. Elhauge's initial Expert Report sets out an underlying casual theory that, he contends, supports his rebate analysis.

But also, defendants assert that Prof. Elhauge's Reply Report improperly asserts two new theories to support his regression analysis: (1) a "collective action" problem among PBMs, Doc. 2187-5 at 229–34 (¶¶ 390–96); and (2) Mylan's bundling of contestable and incontestable demand, Doc. 2187-5 at 234–55 (¶¶ 397–431). Defendants assert that neither theory finds support in the facts and both theories lack a reliable methodology.

a. Theory About a "Collective Action" Problem

Prof. Elhauge's Reply Report asserts that "the predominant method of exclusion was not Mylan's price, but rather the problems of self-interest, externalities, or *collective action* that drive PBMs and plans to accept these restrictions despite their anticompetitive harm." Doc.

2187-5 at 229 (¶ 390) (emphasis added). Defendants assert two reasons that the court should exclude Prof. Elhauge's "collective action" opinion: (1) they say it was not disclosed timely, and (2) it lacks factual and analytical support.

First, defendants contend that Prof. Elhauge never mentioned a "collective action" problem until he submitted his Reply Report. They say Prof. Elhauge earlier testified about a "collective action" problem—before he disclosed his initial Expert Report. Doc. 2140-1 at 4–5 (Elhauge Feb. 6, 2018 Dep. 233:20–234:15). Thus, defendants contend, Prof. Elhauge knew about this theory before disclosing his initial Expert Report. And so, they argue, he should have included the "collective action" opinion in his initial Expert Report. Because he didn't, defendants assert the "collective action" opinion is improper rebuttal opinion that the court should exclude. Plaintiffs respond that Prof. Elhauge's "collective action" opinion is proper rebuttal because it responds directly to defendants' expert's assertions that: (1) "PBMs have increased their use of formulary exclusions over time to 'drive higher rebates from manufacturers and lower prices for payors[;]'" Doc. 2187-5 at 205 (¶ 341) (quoting Doc. 2187-10 at 26 (Willig Dec. 23, 2019 Expert Report ¶ V.B.)); and (2) "'price is the "clearly predominant" means of exclusion[;]'" Doc. 2187-5 at 228 (¶ 386) (quoting Doc. 2187-10 at 39–40 (¶ 89)). Also, Prof. Elhauge asserts, the reason he never included his "collective action" opinion in his initial Expert Report is because, before he submitted his initial Report, "the total discussion related to collective action problems constituted 0% of the defense expert reports, 0% of [his] class reports, and 0.2% of [his] class deposition[,]" so he had no "reason to believe that explaining the well-known collective action problem would be a key issue in the litigation when [he] wrote [his] initial merits report." Doc. 2187-7 at 30 (Elhauge Aug. 16, 2020 Decl. ¶ 52) (internal quotation marks and alternations omitted).

Plaintiffs have the better of the arguments. Prof. Elhauge adequately has explained why he didn't include the "collective action" opinion in his initial Expert Report. And, the court finds, he properly asserts it as rebuttal opinion in response to defendants' expert's criticisms levied at his initial Expert Report. So, the court won't exclude the opinion as improper rebuttal.[8]

Second, defendants argue that the court should exclude Prof. Elhauge's "collective action" theory because it isn't supported by the facts or a reliable methodology. Defendants assert that Prof. Elhauge premises his "collective action" opinion on an assertion that PBMs' acceptance of rebate offers is collectively irrational because it inflates market-wide prices.[9] But, defendants contend, a collective action problem like that one can exist only if Auvi-Q's low sales prevent its manufacturer—Sanofi—from achieving economies of scale. Plaintiffs disagree that Prof. Elhauge opines that his "collective action" theory relies on depriving a rival of economies of scale. Instead, they argue, Prof. Elhauge opines that depriving a rival of economies of scale is just one way to inflate market prices, but it's not the only way. As plaintiffs correctly assert, Prof. Elhauge's initial Expert Report opined that foreclosure can inflate EpiPen prices market-wide by "directly increasing Mylan's profit-maximizing price by increasing the market share Mylan would attain at any given set of prices[.]" Doc. 2138-2 at 85 (¶ 159). And, plaintiffs contend, Prof. Elhauge confirmed the foreclosure did inflate EpiPen prices market-wide (even

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[8] Plaintiffs also contend that even if the opinion constitutes improper rebuttal, defendants have sustained no prejudice from the timing of the opinion's disclosure. They assert that defendants' experts have had five months since the disclosure to review Prof. Elhauge's Reply Report and submit three declarations spanning 60 pages that respond to Reply Report. The court agrees. And, this conclusion—that defendants have sustained no prejudice—nullifies any request to exclude based on improper rebuttal status, even if that argument had merit.

[9] Defendants again cite Prof. Elhauge's deposition transcript to support the request to exclude this opinion. But the court can't find these portions of the transcript in the record. *Compare* Doc. 2137-1 at 26–27 (citing SJ Ex. 137 (Dec. 5, 2019 Elhauge Dep. 220:11–221:4, 238:14–239:4)), *with* Doc. 2146-4 (Ex. 137) (omitting pages 220, 221, 238 & 239).

though he assumed Sanofi wasn't deprived of economies of scale) by using his overcharge model to confirm the price increases. *Id.* at 85–86 (¶ 160).

Yet again, the parties' disagreements about facts and methodology used to support Prof. Elhauge's "collective action" opinion don't warrant excluding the opinion. Instead, defendants' challenges to this opinion go to the weight a trier of fact should assign the opinion when deciding whether Prof. Elhauge's opinion is credible. But, they don't convince the court that Prof. Elhauge's opinion isn't reliable. So, the court won't exclude this opinion.

b. Incontestable Demand Theory

Prof. Elhauge's Reply Report also asserts an incontestable demand theory. Doc. 2187-5 at 242–45 (¶¶ 410–14). He explains that incontestable demand is "the share that EpiPen earns at plans that restrict the formulary coverage of neither the EpiPen nor Auvi-Q." *Id.* at 242 (¶ 410). And, he calculates that "the incontestable share of the market is high (at least 60%) under either [his or defendants' expert's] definition of the incontestable share." *Id.* Defendants argue that the court should exclude the opinion for two reasons: (1) it lacks a scientific methodology, and (2) Prof. Elhauge performed his calculations incorrectly.[10]

[10] Defendants again argue that this opinion is improper rebuttal because Prof. Elhauge testified about the theory before submitting his Reply Report. Again, defendants cite deposition transcript pages that the court can't find in the record. Doc. 2137-1 at 27. Plaintiffs respond that Prof. Elhauge's incontestable demand opinion is proper rebuttal because Prof. Elhauge offers it in direct response to defendants' expert's criticisms on the same subject matter. And, they argue, Prof. Elhauge wasn't able to perform his calculations any earlier because defendants' expert didn't produce the underlying data until a month after Prof. Elhauge filed his initial Expert Report. Based on this record, the court agrees with plaintiffs. Prof. Elhauge's incontestable demand opinion is proper rebuttal opinion. So, the court won't exclude it as untimely.

Defendants' Reply also argues that plaintiffs' Opposition asserts a new theory that the court should exclude. Doc. 2228-1 at 16. The theory defendants reference—PBMs' alleged "self-interest"—was a theory Prof. Elhauge offered in his Reply Report in response to defendants' experts criticisms. So, it's proper expert rebuttal opinion. And the court refuses to exclude this opinion as unreliable when defendants assert this argument for the first time in their Reply. *See Minshall v. McGraw Hill Broad. Co.*, 323 F.3d 1273, 1288 (10th Cir. 2003) (holding that an argument raised for the first time in a reply brief is waived (citation omitted)); *see also Nat'l R.R. Passenger Corp. v. Cimarron Crossing Feeders, LLC*, No.

First, defendants assert that Prof. Elhauge's definition of incontestable demand is flawed because it measures sales among plans that didn't restrict either EpiPen or Auvi-Q. So, defendants argue, his model fails to capture the volume of sales that can't be contested. But, Prof. Elhauge provided a reason why his definition more accurately measures incontestable demand compared to the way defendants' expert defines the term. Doc. 2187-5 at 242 (¶ 410). Plaintiffs also cite economic literature that supports Prof. Elhauge's incontestable demand definition. Doc. 2187-1 at 26 n.99. The court thus finds that Prof. Elhauge has provided a reliable basis for his incontestable demand definition.

Also, defendants argue that Prof. Elhauge's analysis fails to consider case-specific facts that make his model improper. But, plaintiffs respond that Prof. Elhauge's analysis relies on case-specific facts including: (1) how much contestable demand exists in the market, and (2) the difference in the rebate depending on whether the customer agrees to the formulary restrictions. So, contrary to defendants' assertions, Prof. Elhauge's incontestable demand analysis does take into account certain case-specific facts.

Based on the reliable basis that Prof. Elhauge's Reply Report provides for his incontestable demand opinion, the court finds that this opinion qualifies as admissible expert opinion. Defendants' attacks on how Prof. Elhauge measures incontestable demand and whether his model properly considers case-specific facts go to the weight of his opinion. But, those challenges don't require the court to exclude his opinion.

Second, plaintiffs argue that Prof. Elhauge's calculation using defendants' expert's definition of incontestable share is incorrect. Defendants' expert asserts that the calculation

16-1094-JTM-TJJ, 2018 WL 489100, at *1 (D. Kan. Jan. 19, 2018) ("[T]he Court will not consider arguments raised for the first time in a reply brief, particularly where the arguments could have been made in the first instance.").

purports to measure sales among plans that excluded EpiPen from their formularies, but a review of the underlying data shows that Prof. Elhauge included data for plans where EpiPen wasn't excluded. *See* Doc. 2138-8 at 26 (Willig Decl. ¶ 57). Plaintiffs disagree. They say that Prof. Elhauge calculated incontestable demand consistent with defendants' expert's definition of incontestable share from his initial Expert Report. But, in defendants' expert's later-submitted declaration, he criticizes Prof. Elhauge for including plan data where EpiPen was excluded but consumers nevertheless paid less than full cost for the EpiPen because of lower co-pays. *Id.* at 24 (¶ 53) (explaining that "the relevant measure of non-contestable demand is the share that EpiPen would earn when it is off formulary and consumers had to pay the full cost out of pocket" and recognizing that "Professor Elhauge adopts this definition, but a basic check of his analysis demonstrates that he has failed to isolate plans that meet this definition").

The disagreement about which data Prof. Elhauge should and shouldn't have included in his analysis of defendants' expert's definition of incontestable demand goes to the weight the finder of fact should assign to Prof. Elhauge's opinion. Defendants can challenge the credibility of his opinion by cross-examining or presenting their own expert's criticisms of the analysis. But, because Prof. Elhauge has provided a reliable explanation for how he calculated incontestable demand, the court finds no reason to exclude his opinion on this topic.

3. The Rebate Analysis's Estimation of EpiPen Price

Finally, defendants argue that the court should exclude Prof. Elhauge's rebate analysis because it can't provide a reliable estimate of EpiPen price. Prof. Elhauge opines that Mylan's use of exclusionary rebating practices produced foreclosure in the market which, in turn, "directly increased Mylan's profit-maximizing price." Doc. 2138-2 at 85 (Elhauge Oct. 31, 2019 Expert Report ¶ 160). Prof. Elhauge's Expert Reply Report responds to criticisms that

defendants' experts levied against his "foreclosure overcharge" analysis. Doc. 2187-5 at 129–66 (Elhauge Feb. 12, 2020 Reply Expert Report Part VIII & ¶¶ 221–286). In doing so, the Reply Report presents another model showing how Prof. Elhauge's analysis changes if he adjusts his calculations in a way addressing the critiques asserted by defendants' experts. *Id.* at 130 (¶ 223). Defendants assert that the Reply Report's analysis is unreliable because: (1) it relies on flawed data, and (2) it is inconsistent with economic principles.[11]

First, defendants argue that Prof. Elhauge uses flawed data to measure what he calls the "cross-price responsiveness of demand." Doc. 2187-5 at 155 (¶ 266). He explains this phenomenon occurs when "higher prices caus[e] patients to switch from EpiPen to Auvi-Q[.]" *Id.* And, his model purports to measure the "cross-price responsiveness of demand" in both the actual and "but-for" worlds. To measure the "cross-price responsiveness of demand" in the actual world, Prof. Elhauge uses his foreclosure regression, "which includes a relative price control variable that directly measures how much customers substitute between Auvi-Q and EpiPen in response to relative price changes." *Id.* (¶ 267). Defendants assert—for the same reasons previously discussed—that Prof. Elhauge's regression model is inherently unreliable. And so, they argue, the court must exclude his analysis of "cross-price responsiveness of demand" relying on the same regression model. But, the court has rejected each of defendants' arguments asserting that Prof. Elhauge's regression model is unreliable. So, in turn, the court declines to exclude his analysis of "cross-price responsiveness of demand" in the actual world simply because it relies on his regression analysis.

[11] Again, defendants also argue that this opinion constitutes improper rebuttal opinion because it appears for the first time in Prof. Elhauge's Reply Report. The court rejects this argument for the same reasons it has rejected it before. The Reply Report's analysis responds directly to defendants' experts' criticisms of the model provided in Prof. Elhauge's initial Expert Report. Because Prof. Elhauge offers the Reply Report's opinion in response to defendants' experts' criticism on the same subject matter, it is proper expert rebuttal opinion.

To measure the "cross-price responsiveness of demand" in the "but-for" world, Prof. Elhauge opines that "the best available estimate of the *but-for* cross-price responsiveness is the Analysis Group pricing study commissioned by Sanofi in 2012." *Id.* at 156 (¶ 268). And, based on that study, Prof. Elhauge opines that, "but-for" the conditional rebates that Mylan offered, "EpiPen would lose 1.9 percentage points of market share for every $1 increase in EpiPen's relative price[.]" *Id.* (¶ 269). Defendants argue that Prof. Elhauge was wrong to rely on the Analysis Group pricing study. Relying on their own expert's opinion, defendants argue that the Analysis Group pricing study was "a preference share study, intended to analyze participants' responses under the conditions of the specific study" but doesn't qualify as a representative sample of patients who one could use to generalize to the wider population. Doc. 2138-6 at 10–11 (Johnson July 14, 2020 Decl. ¶¶ 13–14). To reach his conclusion about the characteristics of the pricing study, defendants' expert relies on deposition testimony of former Analysis Group employee, Justin Works. *Id.* at 10–11 nn. 20–25. Plaintiffs argue that Mr. Works never testified about the pricing chart on which Prof. Elhauge's analysis relies. Doc. 2187-1 at 28 (citing Doc. 2187-17 at 3, 5 (Works Dep. 178:3–4, 195:2, 195:22–196:8)). Defendants respond that Mr. Works authored the pricing chart and testified that the documents referred to preference share, not market share. Doc. 2228-1 at 17. But the deposition testimony that defendants cite isn't included in the exhibit they reference for support. And, defendants otherwise haven't supplied the court with the cited testimony. *See id.* (citing page 188 of plaintiffs exhibit, *i.e.*, the Works deposition, but that page isn't included in the referenced exhibit, *see generally* Doc. 2187-17 (Works Dep.)). So, the court can't resolve this dispute about reliability of the pricing study based on the record presented with the motion.

And it wouldn't matter if defendants provided the material. The sufficiency of the data supplied by the pricing study goes to the weight, not admissibility, of Prof. Elhauge's opinion. *See, e.g.*, *Auto. Ins. Co. of Hartford v. Electrolux Home Prods., Inc.*, No. 10-CV-0011(CS), 2012 WL 6629238, at *2 (S.D.N.Y. Dec. 20, 2012) ("Potential sample bias is a subject for cross-examination, and goes to the weight, not the admissibility, of the expert testimony."); *Big Dog Motorcycles, L.L.C. v. Big Dog Holdings, Inc.*, 402 F. Supp. 2d 1312, 1334 (D. Kan. 2005) ("The court should exclude the survey when the sample of respondents clearly does not represent the universe it is intended to reflect, but issues concerning the sufficiency of the sample universe bear[ ] on the weight and not the admissibility of the survey." (citation omitted)); *Ohio ex rel. Montgomery v. Louis Trauth Dairy, Inc.*, 925 F. Supp. 1247, 1253 (S.D. Ohio 1996) ("Problems in selection of a sample bear on the weight of the testimony, not its admissibility." (citing *Berry v. City of Detroit*, 25 F.3d 1342, 1352–52 n.11 (6th Cir. 1994))). So, the court declines to exclude Prof. Elhauge's analysis of "cross-price responsiveness of demand" simply because it relies on the Analysis Group pricing study.

Second, defendants argue that Prof. Elhauge's analysis is unreliable because its measurement of "market responsiveness of demand" is flawed. Prof. Elhauge's Reply Report explains that "market responsiveness of demand" occurs when "higher prices caus[e] patients to drop out of the market altogether[.]" Doc. 2187-5 at 155 (¶ 266). Defendants assert that Prof. Elhauge's measurement of this component is unreliable because he uses price and marginal cost data for EpiPen products from 2012—when Auvi-Q wasn't even on the market yet. Defendants' expert says Prof. Elhauge's use of the 2012 data renders his analysis unscientific. Doc. 2138-6 at 12–13 (Johnson July 14, 2020 Decl. ¶ 18).

Also, defendants argue Prof. Elhauge's analysis is flawed because he uses an estimate that assumes "EpiPen was the only EAI in the market." Doc. 2187-5 at 134 (¶ 227). Defendants' expert asserts that this approach conflicts with Prof Elhauge's model which purports to measure the simultaneous effects of "market responsiveness of demand"—*i.e.*, consumers can either (1) substitute EpiPen with Auvi-Q, or (2) leave the market altogether. Doc. 2138-6 at 12 (¶ 16). But, defendants' expert says Prof. Elhauge's underlying data presents a conflict because, with no competition, the only effect of a price increase is that consumers will leave the market. So, defendants contend, Prof. Elhauge's analysis fails to apply economic principles and methods reliably to the facts of this case.

Plaintiffs respond that Prof. Elhauge's analysis properly measures the overall market responsiveness of demand based on a 100% monopolist's price and cost. Doc. 2138-2 at 95 (¶ 175). They say this methodology is proper because (1) one can infer a firm's own responsiveness of demand from its price and costs; and (2) a 100% monopolist's own responsiveness of demand equates to the market's overall responsiveness of demand. *Id.* Plaintiffs assert that the analysis doesn't change when introducing competition from Auvi-Q. Instead, they explain, Auvi-Q competition changes the cross-price responsiveness between EpiPen and Auvi-Q—showing how many customers will substitute Auvi-Q for EpiPen when EpiPen's relative prices increase by $1. *Id.* at 94 (¶ 173); Doc. 2187-7 at 39 (Elhauge Aug. 16, 2020 Decl. ¶¶ 72–73). Prof. Elhauge says that he correctly used this measurement of the EAI market's overall responsiveness of demand to calculate Auvi-Q's firm-specific market responsiveness of demand. Doc. 2187-5 at 148–50 (¶¶ 249–56). Thus, plaintiffs assert, his analysis is reliable and proper expert opinion.

Defendants reply that plaintiffs' justification for Prof. Elhauge's analysis is flawed because it confirms that the analysis fails to account for the differences between consumer demand for Auvi-Q versus EpiPen. But, the court finds, this criticism goes to the weight of Prof. Elhauge's "market responsiveness of demand" analysis. Prof. Elhauge has provided a reliable basis for how he performed his analysis. Also, he supplies a reasonable explanation why the data he used to perform the analysis makes his calculation reliable. Any challenges to his methodology go to the credibility determination made by the trier of fact. They provide no reason to exclude the opinion.

In sum, none of defendants' arguments persuade the court that Prof. Elhauge's expert opinions are so unreliable that the court must exclude them as inadmissible expert opinion violating Fed. R. Civ. P. 702. The court thus denies defendants' Motion to Exclude the Testimony and Report of Plaintiffs' Expert Witness Einer Elhauge.

V. Defendants' Motion to Exclude the Testimony and Report of Plaintiffs' Expert Witness Professor Meredith Rosenthal (Doc. 2134)

Next, defendants ask the court to exclude Prof. Meredith Rosenthal's expert opinion. Plaintiffs have retained Prof. Rosenthal to provide expert testimony about plaintiffs' damages. Defendants argue the court should exclude five aspects of Prof. Rosenthal's expert opinion. Defendants assert that these five portions of Prof. Rosenthal's testimony are inadmissible under Fed. R. Evid. 702 because they fail to rely on sufficient facts and data to support the opinion. Alternatively, defendants argue that the court should exclude certain parts of Prof. Rosenthal's testimony under Fed. R. Evid. 403 because the opinions pose a danger of misleading the jury that outweighs the probative value of the evidence.[12] The five aspects of Prof. Rosenthal's testimony

[12] Defendants' motion never asserts that Prof. Rosenthal isn't qualified to provide the expert testimony she offers. At class certification, the court found that Prof. Rosenthal's education, experience, and credentials qualify her to provide expert testimony. Doc. 2017-1 at 21–22 n.7. For the same reasons,

defendants seek to exclude are: (1) her "alternative RICO" damages theory; (2) her "loss of choice" opinion; (3) her 2-Pak event study; (4) her probability analysis; and (5) her 2-Pak and generic delay methodologies, to the extent the court permits all of plaintiffs' theories of RICO liability to proceed, because, defendants argue, precluding these opinions will avoid awarding duplicative damages. The court addresses each opinion, separately, below.

A. "Alternative RICO" Damages Methodology

Prof. Rosenthal presents an "alternative RICO" damages methodology that purports to measure "the cumulative effect of all of [d]efendants' misconduct[.]" Doc. 2164-4 at 48 (Rosenthal Oct. 31, 2019 Expert Report ¶ 114). Defendants argue that the court should exclude Prof. Rosenthal's "alternative RICO" damages model for two reasons: (1) Prof. Rosenthal fails to apply her theory reliably to the facts of the case, and (2) she fails to "tie each theory" of injury "to a calculation of damages[,]" so her model violates the requirements of *Comcast Corp. v. Behrend*, 569 U.S. 27, 35 (2013) (citation and internal quotation marks omitted).

As the court explains in its Order ruling defendants' summary judgment motion, the uncontroverted summary judgment facts fail to present a triable issue whether plaintiffs can prevail on their RICO claims. So, the court grants summary judgment as a matter of law against the RICO claims. For this reason, it need not address defendants' argument that the court should exclude Prof. Rosenthal's "alternative RICO" damages theory because that request now is moot. Thus, the court denies as moot this portion of defendants' motion seeking to exclude Prof. Rosenthal's expert opinions.[13]

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the court finds that Prof. Rosenthal remains qualified to provide the expert opinions offered at this stage of the case.

[13] The court recognizes that defendants' motion seeks to exclude other of Prof. Rosenthal's opinions that pertain to the RICO claims. The court addresses the admissibility of those other opinions because plaintiffs offer Prof. Rosenthal's analysis as summary judgment evidence supporting a triable issue on the

B. Loss of Choice Opinion

Next, defendants ask the court to exclude Prof. Rosenthal's "loss of choice" opinion. Prof. Rosenthal's Expert Report offers an opinion about "common impact." Doc. 2164-4 at 52 (Rosenthal Oct. 31, 2019 Expert Report ¶¶ 118–19). It opines that each class member sustained classwide injury from defendants' alleged misconduct. *Id.* (¶ 118). And, it opines that each of the allegations of misconduct "deprived class members of choice[.]" *Id.* (¶ 119). She describes this "loss of choice" as "[l]osing the choice to purchase a single pen, a generic EpiPen, or another brand[.]" *Id.*

Defendants assert that the court should exclude this opinion under Fed. R. Evid. 702 because the facts of the case contradict her opinion. Also, defendants argue the court should exclude the opinion under Fed. R. Evid. 403 because it poses a risk of misleading the jury and that risk outweighs the opinion's probative value.

First, defendants assert that Prof. Rosenthal's "loss of choice" opinion is irrelevant because the court hasn't certified a RICO class based on the theory that class members sustained damages from a "loss of choice." Also, defendants argue that Prof. Rosenthal never calculated any damages, nor performed any economic analysis, nor developed any reliable methodology to support her "loss of choice" opinion. So, defendants assert, the court should exclude the opinion because it's not relevant to the other damages theories that she proffers in her Expert Reports. Plaintiffs respond that Prof. Rosenthal's "loss of choice" opinion isn't a measure of damages. Instead, they explain, Prof. Rosenthal offers this opinion to show that defendants' alleged misconduct had a "'classwide' impact" because their actions deprived class members the opportunity to choose to purchase single EpiPens or a generic EAI device. Doc. 2183-1 at 20.

RICO claims. So, the court must decide whether it can consider Prof. Rosenthal's opinions in the corresponding Order ruling the summary judgment motion.

Also, defendants argue that the facts of the case don't support Prof. Rosenthal's opinion. For support, defendants cite evidence purporting to show that some plaintiffs preferred 2-Paks and branded devices, and thus, these class members never sustained a "loss of choice." Plaintiffs respond that this evidence is cherry-picked. And, they provide their own citations to evidence purporting to show that just because some class members once purchased 2-Paks or had brand loyalty to EpiPen doesn't mean that they weren't deprived of a "loss of choice." *See* Doc. 2183-4 at 20–21 (Rosenthal Feb. 7, 2020 Expert Rebuttal Report ¶ 39) (recognizing that defendants' expert cites "to the testimony of a named plaintiff, Ms. Sumner, where she states that she prefers to keep 2 pens on hand" but this plaintiff also "described how she sought out a single EpiPen and was told at the pharmacy that she could only purchase a 2-Pak"). Prof. Rosenthal explains that her cited evidence demonstrates "the point of 'option value'" and "supports [her] assertion that consumers derive value from having more options." *Id.*; *see also* Doc. 2164-4 at 52 (¶ 119) (describing the "concept of 'option value'—the value that non-users place on the availability of a good—has long been recognized by economists as an important economic phenomenon").

The parties' disagreements about Prof. Rosenthal's "loss of choice" opinion go to the weight of the testimony. And, they don't require the court to exclude it. Prof. Rosenthal has provided a reliable basis for her opinion. She explains that the opinion is not a damages theory. So, that's why she didn't calculate any damages corresponding to the purported loss of choice. Thus, defendants' criticisms on that point ring hollow. As already discussed, Prof. Rosenthal offers this opinion only to show that defendants' alleged misconduct had a classwide impact because it deprived class members of certain choices when purchasing EAI devices. She adequately explains how she derives her opinion, she identifies the facts from this case that, she contends, support her opinion, and she cites academic literature that she relies on as support for

her opinion. *See* Doc. 2183-4 at 20–22 (¶¶ 39–44). Defendants' expert disagrees with Prof. Rosenthal's reading of the academic literature and says it doesn't support her opinion. But, like defendants' other challenges, that argument goes to the weight of Prof. Rosenthal's opinion. Because Prof. Rosenthal has provided a reliable basis for her "loss of choice" opinion, the court declines to exclude this opinion under Fed. R. Evid. 702.

Second, defendants argue that the court should exclude the "loss of choice" opinion under Fed. R. Evid. 403 because it poses a danger of misleading the jury that "substantially" outweighs the probative value of the opinion. The court disagrees. Prof. Rosenthal provides an understandable explanation for her opinion, including the disclaimer that her "loss of choice" opinion isn't a damages opinion. Also, defendants can offset any risk that this opinion will mislead the jury by engaging in "vigorous cross-examination" and by requesting a "limiting instruction[.]" *See Montag ex rel. Montag v. Honda Motor Co., Ltd.*, 75 F.3d 1414, 1420 (10th Cir. 1996) (holding that district court did not abuse its discretion by admitting evidence that plaintiffs alleged was inadmissible as "inflammatory and misleading under Fed. R. Evid. 403" because "any prejudicial effect was countered by the district court's limiting instruction and by Plaintiffs' opportunity for vigorous cross-examination"); *see also Noland v. City of Albuquerque*, 779 F. Supp. 2d 1235, 1241–42 (D.N.M. 2011) (refusing to exclude evidence under Fed. R. Evid. 403 because "with the proper jury instructions, this evidence will not mislead or confuse the jury").

Thus, the court declines to exclude Prof. Rosenthal's "loss of choice" opinion under either Fed. R. Evid. 702 or 403.

C. 2-Pak Methodology

Defendants next ask the court to exclude Prof. Rosenthal's methodology for determining plaintiffs' purported 2-Pak damages. Prof. Rosenthal "calculates overcharges due to the single pack withdrawal" by comparing "the difference between the actual average price per prescription with [an estimated] but-for price per prescription." Doc. 2164-4 at 39–40 (Rosenthal Oct. 31, 2019 Expert Report ¶ 93). Prof. Rosenthal explains that she performs this analysis using an "event study."[14] Doc. 2183-4 at 12 (Rosenthal Feb. 7, 2020 Expert Rebuttal Report ¶ 17). To estimate the "but-for" price per prescription, Prof. Rosenthal began by calculating the average number of pens per prescription during the first and second quarters of 2011—*i.e.*, the two quarters immediately preceding Mylan's withdrawal of single EpiPens from the market. Doc. 2164-4 at 39–40 (¶ 93). She explains that she used data just from these two quarters because, she found, using "the average number of pens per prescription for the four quarters prior to 2011Q3" produced "a 1% change in the average" and thus "only a *de minimus* effect on damages." *Id.* at 40 n.100. Also, she explains that she used "the two quarters prior to the withdrawal of the single pack . . . in order to eliminate the influence of other time-specific factors or 'events[.]'" *Id.*

Defendants argue that the court should exclude Prof. Rosenthal's 2-Pak event study because, in their view, it is not based on sufficient facts and data and one cannot apply it reliably

[14] Defendants' motion asserts in a footnote that defendants maintain that Prof. Rosenthal's event study is fundamentally unreliable and not an event study at all. Doc. 2137-2 at 15 n.7. But their motion advances no arguments to support that assertion, other than citing their earlier motion seeking to exclude Prof. Rosenthal's event study as unreliable that they filed at the class certification stage and asserting that they "preserve their arguments on appeal." *Id.* (citing Doc. 1586-2 at 10–13). The court rejected defendants' argument that the court should exclude Prof. Rosenthal's event study as unreliable when it ruled defendants' motion at class certification. Doc. 2017-1 at 24–25. Defendants provide no reason for the court to revisit this issue on this motion, and because the court already has decided the certification issue, defendants don't need to reference and re-reference every argument they've ever made about certification issues.

to the facts of the case. Thus, defendants argue, the event study is inadmissible under Fed. R. Evid. 702. Also, defendants argue that the court should exclude the event study under Fed. R. Evid. 403 because it poses a significant risk of confusing the jury that outweighs any probative value of the evidence.

First, the court considers whether Prof. Rosenthal's 2-Pak event study is based on sufficient facts and data such that one reasonably can apply it to the facts of this case. Defendants assert that Prof. Rosenthal's event study fails to control for factors that could have influenced consumers' decisions whether to purchase single EpiPens or 2-Paks before and after the first and second quarter of 2011. Specifically, defendants assert that, after 2011, medical literature increasingly confirmed the need for patients to carry two EAI devices with them at all times in case they required a second dose of epinephrine during an anaphylactic reaction. Also, defendants argue that Prof. Rosenthal's analysis fails to account for the back-to-school season—which falls in the third quarter—when EpiPen sales increase in general and also specifically for 2-Paks. Defendants argue that Prof. Rosenthal's failure to account for these factors renders her analysis inadmissible under Fed. R. Evid. 702.

For support, defendants cite *Sunlight Saunas, Inc. v. Sundance Sauna, Inc.*, 427 F. Supp. 2d 1022 (D. Kan. 2006). Defendants assert that *Sunlight Saunas* excluded expert testimony that "did not take into account significant factors, aside from defendants' conduct, which could have explained the decline in the growth of plaintiff's sales[.]" *Id.* at 1030. But, the language defendants lift from Judge Vratil's opinion in *Sunlight* merely recites one of five arguments that the *Sunlight Saunas* defendants asserted to support their request to exclude the expert opinion. *See id.* It doesn't come from Judge Vratil's analysis of the admissibility question. Instead, Judge Vratil's analysis concluded that the expert's "entire damage calculation [was] based on his

underlying assumptions regarding plaintiff's forecast of sales" that he "did not independently analyze" and plaintiff provided "no coherent explanation how it arrived at the projections." *Id.* So, Judge Vratil found, the expert's explanation for his assumptions was "conclusory, evasive and anything but expert." *Id.* That's nothing like the facts here.

Instead, here, Prof. Rosenthal provides a reasonable basis for her event study's assumptions. She adequately explains why she relied on the data from the first two quarters of 2011 to calculate a "but for" number of pens per prescription which, in turn, she used to calculate the "but for" price per prescription. Doc. 2164-4 at 39–40 & n.100 (¶ 93). And, she provides a reasonable basis why, in her expert opinion, the prevalence of medical literature after 2011 about the importance of carrying two EAI devices at all times doesn't require her to change her assumptions. *See* Doc. 2183-4 at 13 (¶ 20) (citing opinion from another one of plaintiffs' experts that the medical guidance issued after the withdrawal of single EpiPens was "nothing new" and her opinion that "level of use already reflected that information by the time of the single pack withdrawal"). Also, she meets defendants' criticisms about her failure to consider third quarter data that would reflect "back to school" increased purchases by explaining that she previously had examined data from the entire year preceding the single EpiPen withdrawal but it had "only a *de minimus* effect on damages." *Id.* at 12 (¶ 18) (quoting Doc. 2164-4 at 40 n.100). Based on Prof. Rosenthal's explanations, she has provided a reasonable basis for her underlying assumptions and calculations that she made as part of her methodology to render her 2-Pak damages opinion. Defendants' attacks against those assumptions go to the weight of her opinion, but they don't permit the court to exclude it. Prof. Rosenthal has cited sufficient facts and data to support her opinion, and she has shown that her opinion is capable of applying reasonably to the facts of this case. So, the court won't exclude it under Fed. R. Evid. 702.

Second, the court rejects defendants' argument that the court should exclude the event study under Fed. R. Evid. 403 based on a danger that it will confuse the jury. Defendants argue that Prof. Rosenthal's damages opinion is premised on Mylan's withdrawal of single EpiPens. But, Mylan contends, plaintiffs don't allege that the withdrawal was one of the predicate acts supporting the RICO claim. So, defendants argue, plaintiffs can't use Prof. Rosenthal's 2-Pak methodology to show RICO causation. And, they contend, the court should preclude its admission because it only would confuse the jury. Plaintiffs don't refute that Prof. Rosenthal's opinion only relies on the withdrawal of the 2-Pak—not any statements or omissions on defendants' part—to calculate 2-Pak damages. But, the court finds, the risk that this opinion will mislead or confuse the jury is offset by defendants' ability to engage in "vigorous cross-examination" and the court's capacity to instruct the jury about the purpose of and the limits to Prof. Rosenthal's 2-Pak damages methodology. *See Montag ex rel. Montag v. Honda Motor Co., Ltd.*, 75 F.3d 1414, 1420 (10th Cir. 1996); *see also Noland v. City of Albuquerque*, 779 F. Supp. 2d 1235, 1241–42 (D.N.M. 2011). The court thus concludes any risk that Prof. Rosenthal's opinion will confuse the jury doesn't outweigh the probative value of her expert opinion. So, the court declines to exclude Prof. Rosenthal's 2-Pak methodology under Fed. R. Evid. 403.

D. Probability Analysis

Next, defendants assert that the court should exclude Prof. Rosenthal's probability analysis. Prof. Rosenthal offers an opinion that plaintiffs sustained "a common injury on a class-wide basis as a result of [d]efendants' alleged misconduct[.]" Doc. 2164-4 at 52 (Rosenthal Oct. 31, 2019 Expert Report ¶ 118); *see also id* 52–60 (¶¶ 118–36). As support for this opinion, Prof. Rosenthal analyzed the "probability that class members would be overcharged by just the 2-Pak and generic delay allegations" by "combin[ing] probabilities of being affected by both

mechanisms based on the extent to which the affected groups for each allegation are overlapping[.]" *Id*. at 57 (¶ 132). She concludes that the "resulting probability lies between zero and the lower of the individual probabilities of not being overcharged by either (or any) one of the mechanisms." *Id.* at 59–60 (¶ 135).

Defendants argue that the court should exclude the opinion under Fed. R. Evid. 702 because it's not based on sufficient facts and data and one can't apply it reasonably to the facts of the case. Also, defendants argue, the court should exclude Prof. Rosenthal's probability opinion under Fed. R. Evid. 403 because it poses a danger of misleading the jury. The court rejects both arguments.

First, defendants argue that the court should exclude Prof. Rosenthal's opinion because it is based on "a single, cherry-picked generic launch forecast that itself contained two equally possible (and less aggressive) alternatives" and didn't consider any competing literature suggesting that a lower generic erosion rate was likely. Doc. 2137-2 at 17. Also, defendants argue that Prof. Rosenthal's opinion unreasonably relies on a Mylan slide deck from May 2010 to estimate the probability of 2-Pak injury while ignoring other evidence showing that doctors preferred to prescribe and patients preferred to purchase 2-Paks. Thus, defendants assert, the court should exclude Prof. Rosenthal's opinion because it doesn't properly consider the facts of the case.

Defendants made this same argument when moving to exclude Prof. Rosenthal's probability opinion at the class certification stage. Doc. 2017-1 at 38–40. Now, they say that the court's previous consideration of their argument was "limited" and doesn't account for all of the facts that are available now that discovery is closed. Doc. 2228-2 at 11. But, they don't point to any evidence revealed in merits discovery that requires the court to alter its previous analysis.

As the court already explained, "[a]ll of defendants' criticisms about the assumptions Prof. Rosenthal uses to support her probability opinion go to the weight of her opinion testimony, but not its admissibility." Doc. 2017-1 at 39.

Here, Prof. Rosenthal provides a reasonable basis for her assumptions. She explains why she relied on certain data in her analysis and why, she contends, those assumptions are appropriate for this case's facts. *See* Doc. 2183-4 at 22–24 (¶¶ 45–47); *see also* Doc. 2164-4 at 30–31, 52–60 (¶¶ 68–71, 118–36). And her Reply Report provides appropriate rebuttal for the criticisms defendants' expert levies against her factual assumptions. Doc. 2183-4 at 10–11, 22–24 (¶¶ 14, 45–47). As the court found before, defendants' "challenges to those assumptions don't show that Prof. Rosenthal's probability opinion is so unreliable that the court must exclude it." Doc. 2017-1 at 39 (citing *In re Lidoderm Antitrust Litig.*, No. 14-md-02521-WHO, 2017 WL 679367, at *28 (N.D. Cal. Feb. 21, 2017) (denying motion to exclude expert opinion because it was based on "reasonable assumptions and evidence, and supported by reasoned principles as well as academic scholarship" and while "some of those assumptions [were] disputed," those disputes did not "make [the expert's] reliance on them improper")). Instead, the court finds, as it did before, that "defendants' challenges more properly are presented through the 'presentation of contrary evidence'" which is one of the "'the traditional and appropriate means of attacking shaky but admissible evidence.'" *Id.* at 40 (quoting *Daubert*, 509 U.S. at 596). So, the court rejects defendants' argument that Prof. Rosenthal's probability opinion isn't based on sufficient facts and data.

Second, the court refuses to exclude Prof. Rosenthal's probability opinion under Fed. R. Evid. 403. Defendants argue that Prof. Rosenthal's analysis "hides" the fact that between 62 and 68 percent of consumers sustained no injury under the 2-Pak theory because they would not have

purchased a single EpiPen in the "but-for" world. Doc. 2137-2 at 18 (citing Doc. 2166-17 at 15–16 (Rosenthal Feb. 21, 2020 Dep. at 197:24–198:2)). But, as Prof. Rosenthal's Expert Report makes clear, her probability opinion "*combine[s]* probabilities of being affected by both" the 2-Pak and generic delay allegations. Doc. 2164-4 at 57 (¶ 132) (emphasis added). A trier of fact is capable of understanding how Prof. Rosenthal's probability opinion measures more than one type of alleged misconduct. And, any risk that the probability opinion will mislead the jury is mitigated by defendants' ability to cross-examine Prof. Rosenthal vigorously about her opinion and the court's instructions to the jury. So, the court finds that the probability opinion doesn't pose a danger of misleading the jury such that the court should exclude it under Fed. R. Evid. 403.

In sum, the court rejects defendants' arguments for excluding Prof. Rosenthal's probability opinion.[15]

[15] Defendants argue in a footnote that Prof. Rosenthal's probability analysis also is unreliable under Fed. R. Evid. 702 based on a recent Eastern District of Pennsylvania opinion that "rejected a near-identical model submitted by Prof. Rosenthal in a generic delay case as a method of showing class-wide injury because it improperly 'mask[ed] uninjured class members.'" Doc. 2137-2 at 18 n.8 (quoting *In re Niaspan Antitrust Litig.*, 464 F. Supp. 3d 678, 713 (E.D Pa. 2020)). There, the court looked specifically to the averages that Prof. Rosenthal used to calculate classwide injury among a putative class of end-payor consumers of the drug Niaspan. *Id.* at 713–14. After scrutinizing her analysis, the court found that Prof. Rosenthal's "use of averages hides several groups of uninjured class members who cannot be easily identified." *Id.* at 714. And, in the end, the court refused to certify a class because it was "concerned that the class contains, at minimum, substantial numbers of uninjured consumer brand loyalists, coupon users, and flat co-payers." *Id.* at 720. The facts differ here. As plaintiffs argue, the court already has certified a class based on, among other things, plaintiffs' showing that Prof. Rosenthal's probability analysis provides a plausible method for proving that the class doesn't contain "great numbers of class members who didn't sustain harm." Doc. 2018-1 at 67; *see also id.* at 67–76. And, here, defendants haven't shown that Prof. Rosenthal's probability analysis relied on underlying data that hides several groups of unidentified class members that she can't identify. In short, defendants have failed to establish—at least so far—that this case is like *In re Niaspan*. So, the court doesn't find that *In re Niaspan* changes the court's analysis.

E. Excluding the 2-Pak and Generic Delay RICO Models if All of Plaintiffs' RICO Theories Proceed to the Jury

Last, defendants argue that, if the court allows plaintiffs' RICO claims to proceed to the jury, then the court should exclude Prof. Rosenthal's 2-Pak and generic delay RICO models because these models pose a risk that the jury will double count damages. As discussed, the court's contemporaneously-issued Order grants summary judgment against plaintiffs' RICO claims. Thus, defendants' final argument is moot.

After considering each of defendants' arguments for excluding Prof. Rosenthal's opinions, the court finds two of them are moot and the remaining three are unpersuasive. The court thus denies defendants' Motion to Exclude the Testimony and Report of Plaintiffs' Expert Witness Meredith Rosenthal.

VI. Defendants' Motion to Exclude the Testimony and Report of Plaintiffs' Expert Witness Dr. Carl Peck (Doc. 2135)

Defendants next argue that the court should exclude the testimony and opinions proffered by Dr. Carl Peck. Plaintiffs have retained Dr. Peck, a former Director of the FDA Center for Drug Evaluation and Research, to opine "whether the [FDA] caused delays in the review and approval of the Abbreviated New Drug Application ('ANDA') for the AB-rated epinephrine auto-injector product, sponsored by [Teva]." Doc. 2164-8 at 4 (Peck Oct. 31, 2019 Expert Report ¶ 1). He explains that Teva submitted its ANDA to the FDA on December 21, 2007, and the FDA "found it to be 'acceptable for filing' on November 21, 2008." *Id.* at 8 (¶ 16). Then, "9 years and 9 months" later, in August 2018, Teva received FDA approval for the product. *Id.* at 27 (Table 2).

Dr. Peck opines "based on [his] independent review and analysis of materials identified in [his expert] report, [his] expertise, and [his] knowledge of the FDA drug-approval process . . .

these delays were not due to the FDA's conduct or inaction." *Id.* at 8–9 (¶ 17). He finds "[o]n the contrary . . . the FDA treated [the ANDA] as a priority application and was responsive well within the metrics for review time of the application." *Id.* at 9 (¶ 18). Also, Dr. Peck asserts that Mylan filed "deficient Citizen Petitions in a transparent attempt to delay approval of the Teva EAI." *Id.* (¶ 19). And, he opines that "it is reasonable to expect that the FDA would have completed its review and approval of Teva's EAI application by 2014 . . . had Teva been responsive to the FDA's requests in prosecuting its application." *Id.* at 10 (¶ 21).

Defendants assert several arguments why the court should exclude his opinions. The court addresses them, below. But first, the court considers whether Dr. Peck is qualified to offer the proffered expert opinion.

Dr. Peck is "a board-certified physician in internal medicine and clinical pharmacology." *Id.* at 4 (¶ 4). He earned a B.A. and M.D. from the University of Kansas. *Id.* From 1967 to 1990, he served in the U.S. Army Medical Corps and Medical Research and Development Command. *Id.* at 5 (¶ 6). In his career with the Army, he rose to the rank of Colonel. *Id.* For seven of his years in the Army, he served as a clinical pharmacology consultant to the Army Surgeon General. *Id.* In 1990, Dr. Peck joined the U.S. Public Health Service as a Rear Admiral and was appointed Assistant Surgeon General of the United States. *Id.*

From 1987 to 1993, Dr. Peck served as Director of FDA's Center for Drug Evaluation and Research. *Id.* (¶ 7). In that position, he was responsible for "establishing and enforcing FDA standards[;] reviewing, approving, or rejecting proposed new medical products[;] assuring safety of all marketed drug products[;] and regulating advertising and promotional practices of drug manufacturers." *Id.* Also, he "reviewed, commented or rendered decisions on data relating

to more than 500" investigational new drug applications ("INDs"), new drug applications ("NDAs"), abbreviated new drug applications ("ANDAs"), and other applications. *Id.*

Dr. Peck has held several research and teaching positions in government and academic institutions. *Id.* at 4–6 (¶¶ 5, 8). His research has focused on the "study of scientific and regulatory methods for evaluating the effectiveness and safety of new drugs." *Id.* at 6 (¶ 8). During his career, Dr. Peck has published more than 150 original scientific papers, a book, and several book chapters. *Id.* at 6 (¶ 10). Also, for more than 40 years, Dr. Peck has served as an active peer reviewer for several scientific publications. *Id.* And, Dr. Peck has received many awards and honors for his work in his field. *Id.* at 6–7 (¶ 11).

Dr. Peck is the co-founder of NDA Partners LLC, a consulting company that provides scientific and regulatory advice to scientists and entrepreneurs in private industry as well as government agencies. *Id.* at 7–8 (¶ 14). His company helps clients understand and meet FDA requirements. *Id.* Also, it "supports various aspects of their [clients'] engagements with the FDA" during drug applications and approval processes. *Id.* Personally, Dr. Peck has consulted with clients on more than 200 FDA applications. *Id.*

Based on Dr. Peck's education, experience, and professional qualifications, the court finds that he is qualified under Fed. R. Evid. 702 to provide his proffered expert opinions in this case. *See In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 475–77, 481–82 (S.D.N.Y. 2016) (holding that physician was qualified to opine about "the FDA regime generally, [defendant's] conduct in complying with regulatory standards, and the adequacy of the [drug] label" and that such testimony "would be helpful to the jury"); *see also In re Diet Drugs*, No. MDL 1203, 2001 WL 454586, at *5, 19 (E.D. Pa. Feb. 1, 2001) (concluding that a doctor and former FDA employee was "clearly qualified to testify [about] what reasonable FDA officials

. . . would do with adverse event information").

Finding that Dr. Peck sufficiently is qualified to render his expert opinions, the court now turns to address defendants' arguments for excluding his opinions.

A. Is Dr. Peck's Opinion Irrelevant to Plaintiffs' Causation Theory, and Thus, Unhelpful to the Trier of Fact?

First, defendants assert that Dr. Peck's opinion whether the FDA caused any delays in Teva's approval of its generic EpiPen product has nothing to do with plaintiffs' causation theory—*i.e.*, that Mylan and Pfizer caused generic delay by entering an unlawful reverse payment settlement with Teva. So, defendants argue, Dr. Peck's opinion is irrelevant to any question the jury must decide, and thus, the theory isn't helpful to the trier of fact. For that reason, defendants contend that Dr. Peck's opinion is inadmissible under Fed. R. Evid. 702. *See Daubert*, 509 U.S. at 591 ("Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful" to the trier of fact in "'understand[ing] the evidence'" or "'determin[ing] a fact in issue'" (quoting Fed. R. Evid. 702)).

The court disagrees. Defendants argue on summary judgment that the FDA's independent actions (*i.e.*, not approving the Teva generic until 2018) prevented Teva from launching its product any earlier than that date. Doc. 2228-3 at 5. So, defendants contend, the FDA's actions "break the chain of causation" and preclude defendants from incurring liability on plaintiffs' generic delay theory. *Id.* But, plaintiffs counter this argument by relying on Dr. Peck's opinion. They argue that Dr. Peck's opinion is "highly relevant because it rebuts the notion that it was [the] FDA, not Defendants, who were at fault for the delay" in the approval of Teva's generic product. Doc. 2182-1 at 9.

Defendants further contend that Dr. Peck made two key admissions that, they assert, show that the FDA's actions prevented the Teva generic from securing FDA approval. They

argue that these admissions provide further support for their argument that Dr. Peck's testimony is irrelevant to the question whether *defendants'* conduct caused any generic delay. Also, defendants argue that Dr. Peck conceded that he never assessed Mylan and Pfizer's conduct, or whether the Teva patent settlement slowed down FDA approval, or why the FDA approval process for the Teva generic took as long as it did, other than to opine that the FDA responded to Teva's submissions in a timely fashion. These challenges to Dr. Peck's analysis don't render his opinion irrelevant. His opinion still goes to the question whether the FDA broke the causal chain between defendants' actions and any generic delay. Defendants' attacks on Dr. Peck's admissions and assumptions go to the weight of his opinion and whether it is capable of showing that the FDA didn't break the causal chain. But that's a question for the trier of fact, not the court. And, it doesn't warrant excluding his opinion as irrelevant.

B. Should the Court Exclude Dr. Peck's Remaining Opinions Under *Daubert* and Fed. R. Evid. 702?

Next, defendants argue that the court should exclude any other opinions rendered by Dr. Peck for two reasons. *First*, defendants contend that Dr. Peck was retained to provide just one opinion—*i.e.*, whether the FDA caused delays in the approval process for the Teva generic. Defendants argue the court should exclude any other opinions that Dr. Peck offers because they are beyond the scope of Dr. Peck's Expert Report. *Second*, defendants argue that the court should exclude Dr. Peck's other opinions because they are outside his area of expertise.

The court disagrees with the limits defendants have placed on the scope of Dr. Peck's opinions. Dr. Peck's Expert Report makes it clear that he is offering opinions not limited merely to whether the FDA caused delays in the review and approval of Teva's generic product. Doc. 2164-8 at 8–10 (Peck Oct. 31, 2019 Expert Report ¶¶ 17–21). As part of Dr. Peck's analysis of that question, he also concluded that "the FDA was properly responsive, responsible, and

communicated in a timely manner in its review of [Teva's] ANDA[,]" he found "a noticeable slowing of responsiveness to FDA requests and guidance on Teva's part beginning around 2011," he found that "Defendants filed deficient Citizens Petitions in a transparent attempt to delay approval of the Teva EAI[,]" and he concluded "it is reasonable to expect that the FDA would have completed its review and approval of Teva's EAI application by 2014 . . . if not earlier—had Teva been responsive to the FDA's requests in prosecuting its application." *Id.* at 8–10 (¶¶ 17, 19–21); *see also id.* at 18–26, 30–34, 35 (¶¶ 38–56, 63–71, 75).

To confine Dr. Peck's opinion only to whether the FDA caused delays in the approval of a Teva generic, defendants cite Dr. Peck's deposition testimony where he testified that plaintiffs retained him in this case to render an opinion on that topic and that there were no "other opinions that the class plaintiffs retained [him] to render besides that one[.]" Doc. 2142-3 at 12–13 (Peck Dep. 121:21–122:13). But, Dr. Peck also testified that his Expert Report "contain[s] a complete statement of all the opinions that [he is] offering in this case[.]" *Id.* at 12 (Peck Dep. 121:13–17). And, throughout Dr. Peck's deposition, counsel asked him about other opinions disclosed in his Expert Report and the bases for his conclusions, including his opinions about Teva's slowing of its responsiveness to the FDA's requests and Mylan's submissions of Citizen Petitions to the FDA. *See, e.g.*, *id.* at 16, 51–53 (Peck Dep. 126:13–24, 320:10–321:24, 325:1–19). Thus, the court rejects defendants' argument that the court should exclude him from giving any of the other opinions that Dr. Peck asserts in his Expert Report.

Also, the court disagrees that any of these opinions fall outside the scope of Dr. Peck's expertise. Dr. Peck is qualified by his education, training, research, scholarship, and professional experience to offer opinions about Teva's responsiveness to the FDA's approval process, Mylan's use of Citizen Petitions in that process, and the date when Teva could have secured

FDA approval had it responded to the FDA's requests in its prosecution of the application in a fashion he opines was more timely.

Defendants next argue that, even if the court declines to exclude Dr. Peck's other opinions, the court should exclude three of those opinions from the jury. Defendants assert these three opinions are inadmissible under Fed. R. Evid. 702 and *Daubert* because Dr. Peck lacks a reliable methodology for reaching his conclusions, and instead, bases his opinions only on speculation. The court considers the three opinions that defendants challenge, below.

1. Opinion that Teva "Dropped the Ball"

First, defendants challenge Dr. Peck's opinion that "Teva 'dropped the ball' in the 2011–2014 time frame by not pursuing the [generic drug] application aggressively or responding to the FDA[.]" Doc. 2164-8 at 25 (¶ 56(c)). Dr. Peck asserts that Teva's inaction during that time "lost [it] the opportunity for approval in a shorter time frame." *Id.* Defendants argue that Dr. Peck's opinion is speculative because, as he testified, he never analyzed what Teva was doing during that time. Defendants assert that Dr. Peck failed to consider key facts, including that Teva was having manufacturing problems with its product, which, defendants contend, caused the delays in Teva's pursuit of FDA approval. So, defendants argue, Dr. Peck's opinion that Teva had "dropped the ball" in the application process suffers from a fatal flaw in that it's based simply on guesswork about Teva's actions.

The court disagrees. While defendants are correct that "an expert, no matter how good his credentials, is not permitted to speculate[,]" *Goebel v. Denver and Rio Grande W. R.R. Co.*, 215 F.3d 1083, 1088 (10th Cir. 2000), Dr. Peck's opinion isn't speculating. As plaintiffs argue, he never provides any opinion *why* Teva wasn't pursuing its ANDA aggressively. He just opines that Teva was slow to respond to the FDA's requests during the application process. And, he

explains that Teva's delays prevented it from achieving FDA approval for its generic earlier than 2018. It doesn't matter to Dr. Peck's opinion *what* caused those delays, only that the delays occurred. So, he's not speculating about anything.

Also, to reach this conclusion, Dr. Peck explains that he reviewed the correspondence between the FDA and Teva throughout the approval process. Doc. 2164-8 at 18–26 (¶¶ 38–56, Fig. 2); *see also id.* at 66–74 (Exs. C & D). Dr. Peck provides a reliable basis for his opinion based on his review of that correspondence and in light of his background and experience working for and with the FDA in drug approval applications. The court thus finds defendants have not shown that Dr. Peck has applied an unreliable methodology to the facts of this case under Fed. R. Evid. 702. So, the court refuses to exclude this opinion.

2. Opinion that Teva Could Have Launched Generic By 2014

Next, defendants ask the court to exclude Dr. Peck's opinion that "the FDA would have completed its review and approval of Teva's EAI application by 2014 . . . if not earlier—had Teva been responsive to the FDA's requests in prosecuting its application." Doc. 2164-8 at 10 (¶ 21). Defendants argue that Dr. Peck has no basis for this opinion because he never analyzed the challenges, priorities, and actions of those involved in the approval process, including Teva, the FDA, and others. Defendants contend that Dr. Peck thus relied on incomplete and false information to reach his opinion that Teva could have achieved FDA approval by 2014. So, they argue, the court should exclude it.

More specifically, defendants make two arguments why this opinion is unreliable. *First*, defendants say that Dr. Peck ignored the FDA's rejection of Teva's human factors study in 2016, and its later acceptance of the study, which imposed a delay in the application process. *Second*, defendants argue that Dr. Peck failed to use a reliable methodology when he considered the times

that it took other products to secure FDA approval and used those other products as "benchmarks" in his analysis. The court addresses these arguments, next. As explained below, each of these criticisms go to the weight of Dr. Peck's opinion, but don't render his opinion inadmissible. Instead, the court finds that Dr. Peck has provided a reliable basis for his opinion. Dr. Peck explains that he reached his opinion after reviewing and analyzing the regulatory records between Teva and the FDA, Teva's own projections for when it anticipated securing FDA approval,[16] and the FDA approval times for other, similar drugs. *See* Doc. 2164-8 at 9–10, 18–26, 29 (¶¶ 20–21, 38–56, 60). Based on that information and his knowledge and experience about the FDA approval process, he concludes that Teva could have secured FDA approval no later than 2014 had it pursued its ANDA more aggressively. The court finds this opinion sufficiently reliable under Fed. R. Evid. 702. Defendants' challenges to this opinion don't change the court's conclusion.

a. The FDA's 2016 Rejection of the Human Factors Study

Defendants assert that Dr. Peck's failure to consider the FDA's rejection of Teva's human factors study in 2016 renders his opinion unreliable. Dr. Peck's Expert Report explains that, on May 17, 2011, the FDA told Teva that it needed to perform a human factors study comparing the Teva generic to the EpiPen. Doc. 2164-8 at 22–23 (¶ 48). Eight months later, Teva submitted the requested protocol for a human factors study to the FDA on January 20,

[16] Defendants argue that Dr. Peck "cherry-picked" these Teva internal projections and that the selected projections don't account for many design, formulation, regulatory, and manufacturing issues that Teva faced during the approval process. They also identify other projections that Dr. Peck didn't consider. Plaintiffs respond that Dr. Peck relied on internal projections that Teva made before it commenced settlement talks in the patent litigation. So, they argue, the projections Dr. Peck considered aren't tainted by Teva's post-settlement conduct. This dispute goes to the weight that a trier of fact should assign Dr. Peck's opinion based on his decision to rely on certain internal Teva projections, but not others. And, the court doesn't find that Dr. Peck has "cherry-picked" evidence here in a way that renders his opinion unreliable.

2012. *Id.* After receiving no response from the FDA about the submitted protocol, Teva went ahead and conducted its human factors study in 2013 and submitted the results to the FDA on August 29, 2013. *Id.* at 23 (¶ 49). Teva repeated the study on its re-designed device in 2014, and it submitted the study's report to the FDA in December 2014. Doc. 2146-20 at 7–9 (Peck Feb. 7, 2020 Rebuttal Report ¶¶ 14, 16). Then, in 2016, the FDA sent Teva a Complete Response Letter that identified several deficiencies in Teva's application, including concerns about the human factors study. *Id.* at 20–21 (¶ 44); *see also* Doc. 2147-3 at 2, 7 (Complete Response Letter). Teva never performed a new human factors study on its product. Doc. 2146-20 at 7–8 & n.12 (¶ 14). Yet, in August 2018, the FDA approved the human factors study that Teva had performed in 2014, and it approved its ANDA for its generic product. *See* Doc. 2147-4 at 3; *see also* Doc. 2147-5.

Defendants argue that Dr. Peck's opinion isn't reliable because he improperly ignored "informal" correspondence between Teva and the FDA showing that Teva repeatedly sought guidance from the FDA about a human factors study, but didn't receive answers to its questions. But, Dr. Peck adequately responds to this criticism, explaining that he didn't consider informal correspondence because "informal interactions such as phone calls are mainly for clarification or follow ups as to the status of the FDA's review or inquiries concerning the timing of further feedback from the FDA." Doc. 2146-20 at 14 (¶ 28). Instead, Dr. Peck identifies the "real work" when prosecuting an ANDA is "responding to deficiencies[,]" and that work by Teva, in his opinion, "was dormant." *Id.*

Also, defendants assert that Dr. Peck's opinion is unreliable because it ignores that Teva couldn't have secured FDA approval in 2014 because it didn't receive the FDA's rejection of its human factors study until 2016. But, Dr. Peck asserts that the human factors study requirement

wasn't "rate limiting to the review and approval of the application" because "there were additional deficiencies that Teva needed to address." Doc. 2164-8 at 23 (¶ 49); *see also* Doc. 2146-20 at 9 (¶ 16) ("While Teva submitted an application that had a sufficient [human factors study] in 2013 and 2014, the ANDA was ultimately not approved until 2018 because further review on other parts of the applications was required based on Teva's other submissions."). Based on Dr. Peck's assertions, defendants argue that it is inconsequential that the FDA initially rejected the human factors study in 2016 because, in 2018, it approved the same study after Teva had rectified the other deficiencies that the FDA had told it to address.

Defendants argue that the court should exclude Dr. Peck's opinion because he "completely ignored or discounted without explanation" key evidence in this case—*i.e.*, the FDA's rejection of the human factors study in 2016. *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 884 (10th Cir. 2005). But, on this record, the court can't find that Dr. Peck "completely ignored or discounted without explanation" the FDA's initial rejection of the human factors study. To the contrary, Dr. Peck provides a reasonable explanation for why he didn't consider informal correspondence with the FDA and why he doesn't find the human factors study requirement "rate limiting." Doc. 2164-8 at 23 (¶ 49); *see also* Doc. 2146-20 at 9 (¶ 16). In sum, defendants assert proper challenges to his methodology but they don't show that his analysis is so unreliable that the court must exclude it. The court finds defendants' attacks against Dr. Peck's opinion are better left to "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof" because those tools remain "the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596 (citation omitted). So, the court won't exclude Dr. Peck's opinion about Teva's ability to secure FDA approval by 2014.

b. Dr. Peck's "Benchmarks"

Defendants also assert that the court should exclude Dr. Peck's opinion that Teva could have achieved FDA approval by 2014 because he failed to apply a reliable methodology when identifying "benchmark" products to compare against Teva's generic EAI. Dr. Peck opines that the "FDA's review and approval times of other drugs reveals that the Teva [EAI] review and approval time period is an extreme outlier." Doc. 2164-8 at 26 (¶ 57). To reach that conclusion, Dr. Peck analyzed the review and approval process for: (1) all of the EAI products that the FDA has approved, (2) all auto-injector products approved by the FDA between 2011 and 2018, and (3) all other Teva injectable products approved by the FDA between 2008 and 2019. *Id.* at 26–29 (¶¶ 58–60, Tables 2, 3, & 4). But, defendants argue, Dr. Peck's analysis comparing other drugs' FDA approval times to Teva's FDA approval time is unreliable because he conducted no analysis of the facts and circumstances surrounding those other drugs to demonstrate reasonably that they are proper comparisons to Teva's generic EAI.

Defendants assert several challenges to Dr. Peck's selected "benchmarks." But each attack goes to the weight of Dr. Peck's opinion, and none of them require the court to exclude his opinion. The court summarizes defendants' various challenges to this opinion, below.

First, defendants identify a couple of purported calculation errors in Dr. Peck's Expert Report. Defendants argue that Dr. Peck erred by finding that it took Teva 60 months to secure approval for the drug sumatriptan. *See* Doc. 2164-8 at 28 (Table 3) (identifying the submission date as 2010 and the approval date as December 10, 2015). Defendants assert, instead, it actually took 9 years and 7 months for sumatriptan to achieve FDA approval. Doc. 2140-3 at 2 (referring to the submission date as "May 31, 2006"). But plaintiffs respond that defendants' calculation of approval time is wrong because it relies on a 2006 submission date by another company that the

FDA rejected because the device was sufficiently different from the innovator's device that it didn't warrant an ANDA. Doc. 2182-9 at 18 (Antares Pharma, Inc. Dec. 31, 2012 Form 10-K). Instead, plaintiffs argue, the appropriate submission date occurred in 2010, when a different company acquired the device and submitted a completely different application to the FDA. *Id.* So, plaintiffs argue, Dr. Peck correctly calculated the approval time for this device. This factual dispute about what date Dr. Peck should have considered when calculating approval time for sumatriptan goes to the weight of his testimony. The factual record provides a reasonable basis for Dr. Peck's selection of a 2010 submission date.[17] Defendants may attack his selection by cross-examining Dr. Peck on that topic and presenting contrary evidence, but Dr. Peck's selection doesn't provide a basis to exclude his opinion.

Also, defendants argue that Dr. Peck repeatedly miscalculated the time it took for Teva to secure approval of its generic EAI. Dr. Peck explains that he calculates the approval time by starting with the date "the FDA found [Teva's ANDA] 'acceptable for filing' on November 21, 2008" and ending with the date Teva received FDA approval in August 2018. Doc. 2164-8 at 8 (¶ 16); *see id.* at 27 (Table 2). He calculates that approval time as "9 years and 9 months." *Id.* at 27 (Table 2). Defendants fault Dr. Peck for referring to this time frame as "approximately 10 years[.]" *Id.* at 9 (¶ 20). But that's an accurate description of the approval time he calculated—*i.e.*, 9 years and 9 months is 97.5% of 10 years. Dr. Peck's rounding up (by 2.5%) isn't a basis to

[17] Defendants take issue with plaintiffs using Antares Pharma Inc.'s Form 10-K as support for the calculation date when Dr. Peck's Expert Report doesn't say that's what he used to calculate the submission date. But, his Expert Report identifies a 2010 submission date for Antares's sumatriptan, Doc. 2164-8 at 28 (Table 3)—the same year that, according to its Form 10-K, it redesigned the device and submitted the new device to the FDA. Also, the parties don't cite any part of the record where Dr. Peck was challenged about his identification of the 2010 approval date or given an opportunity to explain why he chose that date. The court doesn't find—as defendants argue—that the citation to the Form 10-K provides an *ad hoc* justification for Dr. Peck's opinion. Instead, it simply provides the date that Antares submitted the new device to the FDA—a date that is consistent with what Dr. Peck identifies as Antares's submission date for sumatriptan.

exclude his opinion from the factfinder. Defendants also point out a typo in Dr. Peck's Report where he referred to the approval time as "11 years and 9 months." *Id.* at 8 (¶ 16). But that same paragraph refers to the dates that he used to calculate approval time—*i.e.*, starting in November 2008 and ending in August 2018. *Id.* And elsewhere, the Report correctly calculates the approval time as 9 years and 9 months. *Id.* at 27 (Table 2). The court doesn't find that either Dr. Peck's approximation of the approval time or his typographical error renders his opinion so unreliable that the court should exclude it.

Next, defendants argue that Dr. Peck's comparison of approval times for other EAI products isn't a reliable comparison to the approval time for the Teva generic. *See id.* at 27 (Table 2) (comparing approval time for Teva generic to three EAIs—EpiPen, Twinject, and Auvi-Q). Defendants say that these other EAIs aren't apt comparisons because they involved NDAs while the Teva generic involved an ANDA. *Id.* But, Dr. Peck explained in his Rebuttal Report that this criticism is "misplaced" because NDA applicants "must submit all new data with their application while an ANDA need only duplicate already known requirements." Doc. 2146-20 at 14–15 (¶ 30). So, in his view, the requirements of an NDA are more onerous than those for an ANDA. And, from that conclusion, one would expect longer approval times for NDAs than ANDAs. But, for his three comparisons—which involved NDAs—Dr. Peck calculates shorter approval times than compared to Teva's ANDA. Dr. Peck provides a reliable basis for his opinion that the approval times for these three EAIs serve as reasonable comparisons to Teva's ANDA approval time for its generic. Any discrepancies in the type of application submitted to the FDA and whether those differences should affect Dr. Peck's conclusions are fodder for cross-examination. But the court doesn't find these comparisons unreliable such that the court must exclude Dr. Peck's expert opinion.

Next, defendants criticize Dr. Peck for failing to consider whether any of the comparison drug products received complete response letters, had to redesign their products, or received FDA deficiency letters. Defendants argue that without considering these types of facts, one can't discern whether they are proper comparisons to the Teva generic's FDA approval process. But, Dr. Peck disagrees. He explains that the other EAIs listed in Table 2 "would have needed to address similar stability, sterility, and manufacturing complexities as Teva" but still "achieved approvals in less than half the time as Teva did." Doc. 2146-20 at 14 (¶ 30). Also, defendants assert that it was improper for Dr. Peck to ignore factual details about the approval process for these EAIs; yet, he considered certain facts surrounding Antares's sumatriptan's application. Specifically, as discussed above, he ignored the drug application's original submission date and calculated its approval time starting with Antares's resubmission date because it involved a different company submitting an application for a redesigned product. Once again, all these underlying assumptions Dr. Peck made when calculating FDA approval times for other drug products and comparing his calculations to the time it took Teva to achieve FDA approval for its generic go to the weight and credibility of his opinion. Dr. Peck provides a reliable basis for why he chose certain drugs as comparison products. Any flaws in his selection or factual differences that render his comparisons inappropriate are proper subjects for cross-examination. *See Werth v. Makita Elec. Works, Ltd.*, 950 F.2d 643, 654 (10th Cir. 1991) (explaining that "doubts . . . concerning the sufficiency of the factual basis to support [the expert's] opinion go to its *weight*, and not to its admissibility"); *see also Hose v. Chi. Nw. Transp. Co.*, 70 F.3d 968, 970 (8th Cir. 1995) ("As a general rule, the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual

basis for the opinion in cross-examination." (citation and internal quotation marks omitted)). Defendants' criticisms provide no basis to exclude his opinion.

Next, defendants argue that Dr. Peck's analysis is unsound because he doesn't analyze failed or pending ANDAs for other EAIs. But, Dr. Peck testified that he doesn't think failed applications are "relevant" to his analysis when he's calculating approval times for FDA-approved EAI devices. Doc. 2142-3 at 20 (Peck Dep. 148:10–22). Also, he noted it's likely that no public record exists for failed applications, so he couldn't consider that data in any event. *Id.* As plaintiffs argue, the purpose of Dr. Peck's analysis was to measure the time it took other drug products to secure FDA approval. So, any data about failed approval attempts wouldn't assist the analysis. Defendants are free to challenge Dr. Peck's opinion on this ground by cross-examining him about his decisions to consider only certain data when analyzing FDA approval times for other drugs. But this attack doesn't warrant excluding Dr. Peck's opinion.

Next, defendants criticize Dr. Peck for his inability to answer, during his deposition, whether the auto-injectors listed in his Table 3 (Doc. 2164-8 at 28) involved ANDAs or NDAs. Table 3 lists nine auto-injector products that the FDA approved between 2010 and 2018. *Id.* Dr. Peck's Expert Report provides the "source documents" that he reviewed when gathering the information contained in Table 3. *Id.* at 28 n.58; *see also id.* at 66–72 (Ex. C). But, when asked in his deposition whether the drugs in Table 3 involved ANDAs or NDAs, Dr. Peck answered that he "can't tell you right this minute." Doc. 2142-3 at 25 (Peck Dep. 158:5–9). Dr. Peck's inability to remember off the top of his head in a deposition setting whether the approval process for these other auto-injectors involved ANDAs or NDAs is no reason to exclude his opinion. *See Medina v. United Christian Evangelistic Ass'n*, No. 08-22111-CIV, 2009 WL 4030454, at *4 (S.D. Fla. Nov. 20, 2009) (finding that an expert's "inability to remember" certain details about

his analysis didn't require the court to exclude his opinion because the "fact that [the expert] could not recall, from memory" certain details about his analysis didn't "undermine the reliability" of his analysis). The court rejects this argument as a basis for excluding Dr. Peck's opinion.

Next, defendants argue that Dr. Peck's opinion is unreliable because he testified that he didn't know whether the other drugs listed in Table 3 faced development or reformulation challenges during the approval process. But, Dr. Peck also testified that, based on his experience, "[a]ll drug companies have issues during drug development" and "[a]ll companies receive deficiency letters[,]" but the "ones that are successful in short development time overcome them." Doc. 2142-3 at 28 (Peck Dep. 165:14–20). Again, Dr. Peck provides a reasonable basis for his opinion based on his relevant experience with and knowledge about the FDA approval applications. And, once again, defendants assert a challenge to this opinion that they can attack through cross-examination or by presenting contrary evidence. But, the court need not exclude the opinion on this basis.

Finally, defendants assert that the court should exclude Dr. Peck's opinion because, in Table 4, he considered the review and approval times for other Teva injectable products from 2008 to 2019. But, those products, defendants contend, aren't similar to the Teva generic. And thus, they argue, these products don't qualify as appropriate comparisons. This criticism also comes from Dr. Peck's deposition testimony. When counsel asked Dr. Peck whether the drugs listed in Table 4 have "devices associated with" them or whether "they are just vials of medication[,]" Dr. Peck responded that he didn't "know the answer to that right now." Doc. 2142-3 at 30 (Peck Dep. 167:12–16). For reasons already discussed, the court won't exclude Dr. Peck's opinion because he couldn't remember specifics about his analysis at a deposition. And,

to the extent these products differ from the Teva generic EAI, defendants can raise those challenges to Dr. Peck's opinion through cross-examination or by presenting contrary evidence to argue that the finder of fact shouldn't assign significant weight to his analysis because the other drugs he analyzed aren't proper comparisons to the Teva generic. But again, defendants' arguments provide no reason for the court to exclude his opinion.

In sum, the court concludes that Dr. Peck provides a reliable methodology for his analysis of the FDA approval times for "benchmark" products that is based on his extensive knowledge about and experience with the FDA approval process. So, the court finds this opinion qualifies as admissible expert testimony under Fed. R. Evid. 702 and *Daubert.*

3. Opinion About Mylan's Citizen Petition

Last, defendants assert the court should exclude Dr. Peck's opinion that defendants "filed deficient Citizens Petitions in a transparent attempt to delay approval of the Teva EAI." Doc. 2164-8 at 9 (¶ 19). Defendants assert that this opinion rests on factual inaccuracies and is based on pure speculation. They attack two separate parts of this opinion. Specifically, defendants say Dr. Peck has no basis to opine that (1) defendants filed "deficient" or improper Citizen Petitions, or that (2) the Citizen Petitions delayed Teva's FDA approval. The court addresses the two sub-arguments, separately, below.

a. Opinion that the Citizen Petitions Lacked Merit

Defendants argue that Dr. Peck conducted a cursory review of Mylan's Citizen Petitions that fails to meet Fed. R. Evid. 702's requirements. Defendants assert that Dr. Peck's Expert Report contains just one paragraph where he discusses the Citizen Petitions. But, that's just not right. Dr. Peck's analysis of the Citizen Petitions spans several pages of his Expert Report. Doc.

2164-8 at 30–34 (¶¶ 63–72). And, he provides additional support for his analysis in his Rebuttal Report. Doc. 2146-20 at 18–22 (¶¶ 37–46).

Dr. Peck's Expert Report opines that the "major flaw in the Mylan [Citizen Petitions] is that they are based on egregiously faulty trials" that were "so facially faulty that the FDA totally rejected the [Citizen Petitions] for the reason that the trials could not pass FDA standards." Doc. 2164-8 at 32–33 (¶ 68). Defendants assert that Dr. Peck has no basis for this opinion. They explain that the FDA denied Mylan's Citizen Petitions "'without comment'" but never mention that the denial was based on any faulty trials. *See* Doc. 2137-3 at 24 (quoting Doc. 2147-2 at 2 (explaining to Mylan that its "Petition is denied without comment on whether [the FDA] will take the actions you request")). But, plaintiffs respond, Dr. Peck testified that he concluded, based on his "qualifications as a former center director and [his] understanding of how FDA works and how it responds to the citizen petitions[,]" that the FDA's denial letter was "unusually brief, meaning [the FDA] just really didn't want to have much to do with this because it was so flawed." Doc. 2142-3 at 62–64 (Peck Dep. 337:12–338:3, 338:19–339:2). Defendants assert that Dr. Peck hasn't proffered a reliable methodology for reaching the opinion. But, as plaintiffs correctly argue, an expert may form his expert opinions relying on his education, background, and experience. *See* Fed. R. Evid. 702 advisory committee's note to 2000 amendments ("Rule 702 expressly contemplates that an expert may be qualified on the basis of experience. . . . 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." (citations omitted)); *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). Here, the court finds that Dr. Peck adequately provides a reliable methodology—based on his experience working with and for the FDA—for his conclusion that the FDA found Mylan's Citizen Petitions flawed based on its letter denying Mylan's Citizen Petitions "without comment."[18]

Next, defendants argue that Dr. Peck's analysis of the Citizen Petitions is flawed because his Rebuttal Report asserts that the FDA's denial letter suggests that "none of Mylan's arguments merited consideration." Doc. 2146-20 at 20 (¶ 43). But, at the same time, he asserts that Mylan "reiterated the same issues" that the FDA already had identified, and thus, the FDA "already knew this information" submitted by Mylan. *Id.* at 20–21 (¶ 44). Defendants argue Dr. Peck can't opine, on one hand, that the Citizen Petitions are meritless, and then assert, on the other hand, that Mylan submitted the same complaints that the FDA had identified as valid concerns about the Teva product. But, plaintiffs respond, Dr. Peck's assertions here show that the Mylan Citizen Petitions were superfluous because they didn't "raise novel concerns," but instead "simply reiterated the same issues identified by the FDA in its responses to the King and Dey [Citizen Petitions] in 2009 and 2010, respectively." *Id.* Thus, Dr. Peck opines, "[b]ecause the

[18] Defendants quibble about the absence of a citation to the FDA's denial letter in Dr. Peck's Expert Reports and fault plaintiffs for failing to argue that Dr. Peck even reviewed the FDA's denial letter in reaching his conclusions. Even if Dr. Peck didn't cite the letter in his Expert Reports with a Bates-number identification, he expressly discusses the letter and acknowledges that the FDA "denied the [Citizen Petition] without comment." Doc. 2164-8 at 33 (¶ 69); Doc. 2146-20 at 20 (¶ 43). So, Dr. Peck makes clear, he reviewed and understood the substance of the FDA's denial letter when he was forming his conclusions about Mylan's Citizen Petitions.

FDA already knew this information, Mylan's [Citizen Petitions] could not have had any effect on" the FDA's response to Teva's application. *Id.* Defendants disagree. They argue that the Mylan Citizen Petitions didn't just reiterate the same concerns that King and Dey had registered about the Teva product in the abstract. Instead, they contend, Mylan provided specific concerns about the specific product.

Defendants merely provide their disagreement with the way Dr. Peck has interpreted the content of the competing Citizen Petitions and the FDA's communications. But their attacks don't convince the court that it should exclude his opinion. Dr. Peck has provided an adequate basis for his conclusions about the contents of Mylan's Citizen Petitions and the FDA's response. Doc. 2164-8 at 30–34 (¶¶ 63–72); Doc. 2146-20 at 20–21 (¶¶ 43–44). Defendants can attack those conclusions on cross-examination or by presenting evidence contradicting his conclusions. But, the court won't exclude his opinion on this basis.

Last, defendants argue that Dr. Peck's opinion that the FDA rejected Mylan's Citizen Petitions based on "egregiously faulty trials" is inadmissible because Dr. Peck didn't perform an adequate analysis of Mylan's underlying study. Doc. 2164-8 at 32 (¶ 68). First, defendants again criticize Dr. Peck for failing to remember specific details about the study in his deposition. But, for reasons already discussed, the court won't exclude an opinion based on the expert's inability to recall certain details while testifying at a deposition. Second, defendants argue that Dr. Peck's criticism of Mylan's study incorrectly assumes—with no basis—that it used a "non-comparable proxy device" that had a different volume, liquid color, and needle gauge. Doc. 2164-8 at 32–33 n.70 (¶ 68). But, for support, defendants cite a document explaining that the study was "conducted using a prototype device based on a photograph of the proposed generic [EAI] released by Antares, the manufacturer of the device, and examination of the Otrexup™

product." Doc. 2147-1 at 5. Plaintiffs say this document confirms Dr. Peck's opinion that the Teva product differed from the prototype used in Mylan's study—*i.e.*, the Antares methotrexate auto-injector. The court agrees Dr. Peck provides a reliable basis for this portion of his opinion.[19] Doc. 2164-8 at 32–33 (¶ 68).

Also, Dr. Peck cites the review of the National Center for Health Research ("NCHR") of Mylan's study that identified problems with the study, including that "it lacked a control group, did not study the actual generic but a prototype instead, used a small number of participants, failed to provide them with proper instructions for use, and told participants to watch a video rather than actually use the Teva device." Doc. 2164-8 at 33 n.69 (¶ 68) (citing http://www.center4research.org/team-company-behind-epipen-fought-keep-cheaper-generic-off-market/).[20] Based on the information cited and described in Dr. Peck's Expert Report, he provides a sufficient reason why he reaches his conclusion that the study Mylan submitted to the FDA with its Citizen Petitions was based on faulty trials.

[19] Dr. Peck's Expert Report refers to the "Antares methotrexate autoinjector" as the "non-comparable proxy device." Doc. 2164-8 at 33 (¶ 68). The parties never explain explicitly whether that's the same thing as the "Otrexup™ product." But, according to the Otrexup™ website, that product is "a single-dose auto-injector containing a prescription medicine, methotrexate" that is sold by Antares Pharma, Inc. *See* Otrexup (Methotrexate) Injection for Subcutaneous Use, https://www.otrexup.com/ (last visited Apr. 6, 2021); *see also O'Toole v. Northrop Grumman Corp*., 499 F.3d 1218, 1224–25 (10th Cir. 2007) (holding that, under Fed. R. Evid. 201, "[i]t is not uncommon for courts to take judicial notice of factual information found on the world wide web"). Based on this information, the court considers Dr. Peck's references to the "Antares methotrexate autoinjectors" as ones referring to the Otrexup™ product.

[20] Defendants also assert that Dr. Peck fails to support his opinion about Mylan's study with a proper expert analysis because language from his Expert Report simply parrots portions of plaintiffs' Complaint. But, plaintiffs explain, both Dr. Peck's Expert Report and the Complaint relied on the NCHR's conclusions about Mylan's study. Indeed, Dr. Peck's Expert Report cites information gathered from the NCHR's website about its study as reported in the media. The court doesn't find that the similarities between how the Complaint describes the flaws of Mylan's study and how Dr. Peck describes them render his opinion inadmissible.

For all these reasons, the court rejects defendants' arguments that Dr. Peck fails to supply a reliable basis to support his opinion that Mylan submitted deficient Citizen Petitions with the FDA. So, the court won't exclude Dr. Peck's opinion on this basis.

b. Opinion that the Citizen Petitions Delayed Approval

Defendants next assert that Dr. Peck's opinion that Mylan's Citizen Petitions caused the FDA to delay its approval of Teva's generic is speculative, and thus, inadmissible.

First, defendants argue that the court should exclude Dr. Peck's opinion because he explicitly testified during his deposition that he was not offering an opinion whether Mylan's Citizen Petitions delayed FDA approval. *See* Doc. 2142-3 at 66 (Peck Dep. 346:18–24) ("Q. And you are not opining in this case that this citizen petition delayed this product's approval, are you? . . . That's not your opinion here? A. No, it's not."). Plaintiffs respond, arguing Dr. Peck misspoke during this portion of his deposition. And, plaintiffs argue, his Expert Report clearly identifies his opinions in this case. The court agrees.

Dr. Peck's Expert Report plainly recites that he's offering an opinion that Mylan filed its Citizen Petitions as an *attempt* to delay approval, and *likely did* cause a delay in FDA approval. *See* Doc. 2164-8 at 9 (¶ 19) (opining that "Defendants filed deficient Citizen Petitions in a transparent attempt *to delay approval* of the Teva EAI" (emphasis added)); *see also id.* at 34 (¶¶ 71–72) (describing Mylan's actions as "inappropriate and unprecedented" and "intended to prevent the FDA from approving the generic . . . and likely diverted . . . attention and time . . . to address the Mylan threats" and also explaining that Mylan's actions resulted in "burdening the agency, if not also delaying approval"). His deposition testimony never abandoned these opinions.

As Dr. Peck clarified in his Rebuttal Report, "both [his] opening report and other parts of [his] deposition testimony were clear that the Citizen Petition was a transparent attempt by defendants to delay approval." Doc. 2146-20 at 18 n.52 (¶ 38). Also, he concedes that he's "not rendering opinion about what happened after 2014" because he doesn't "have specific information about delays at the FDA caused by [Mylan's] Citizen Petition[.]" *Id.* So, he's not offering an opinion that the Citizen Petitions at issue here did—in fact—cause delay. But, as explained in his Rebuttal Report and "based on [his] experience, it is clear that this course of conduct *was designed to, and likely did, cause delays*." *Id.* (emphasis added).

The court finds no reason to exclude Dr. Peck's opinion based on just a few lines of deposition testimony that doesn't abandon any opinions that his Expert Report asserts. *See, e.g.*, *Assoc. of Christian Schs. Int'l v. Stearns*, 679 F. Supp. 2d 1083, 1093 (C.D. Cal. 2008) (finding that an argument "premised on a few lines of [an expert's] deposition does not hold" where "[u]pon inspection," the "deposition testimony is completely consistent with his expert report"). So, the court rejects defendants' first argument asserting that the court should exclude Dr. Peck's opinion about the Citizen Petitions.

Second, defendants assert that Dr. Peck conducted no analysis to reach his conclusion that Mylan's Citizen Petitions likely caused delays. Thus, they argue, the court should exclude the opinion as speculative. The court disagrees. Dr. Peck makes clear that he isn't opining that the Citizen Petitions *certainly* caused delay in the FDA's approval of the Teva generic. As discussed, his opinion is more nuanced. Instead, he opines that Mylan filed its Citizen Petitions as part of "a transparent *attempt* to delay approval of the Teva EAI," Doc. 2164-8 at 9 (¶ 19) (emphasis added), and that Mylan's "conduct *was designed to, and likely did, cause delays*[,]" Doc. 2146-20 at 18 n.52 (¶ 38) (emphasis added). To support that opinion, Dr. Peck relies on his

analysis of the Citizen Petitions, which he concludes "lacked merit." Doc. 2146-20 at 18 (¶ 37). Then, he explains, since the Citizen Petitions had no merit, their only "purpose . . . was to consume the FDA's finite resources and request the imposition of stricter standards than were necessary to establish Teva's EAI as an approvable generic equivalent." *Id.*; *see also* Doc. 2164-8 at 34 (¶ 71) (opining that Mylan's actions "occupied a great deal of time at the FDA, and likely diverted some OGD reviewer's attention and time during this time period to address the Mylan threats"). Dr. Peck further explains that even after the FDA denied Mylan's Citizen Petitions "'without comment,' Mylan's attorney repeatedly called and emailed the FDA from June until December 2015, threatening to pursue 'immediate legal action.'" Doc. 2146-20 at 18 (¶ 37). Dr. Peck has conducted a sufficient review of the evidence, and he has explained why it provides a reliable basis for his conclusion that Mylan filed its Citizen Petitions in "a transparent attempt" to delay approval. Doc. 2164-8 at 9 (¶ 19). And also, Dr. Peck provides a sufficient justification for his opinion that, based on his experience working for the FDA, Mylan's Citizen Petitions likely did delay approval.[21] So, the court won't exclude Dr. Peck's opinion about Mylan's filing of Citizen Petitions.

[21] The parties both cite the FDA's Reports to Congress for fiscal years 2015 and 2018, arguing that they either confirm or refute that the Mylan Citizen Petitions actually caused a delay in the FDA's approval of the Teva generic. The FDA's 2018 Report states that "[n]o approvals for ANDAs . . . were delayed because of a [Citizen Petition] in this reporting period." Report to Congress: 11th Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2018, at 1 (Feb. 11, 2020), *available at* https://www.fda.gov/media/135628/download. Defendants interpret this statement to mean that no FDA approvals in 2018 (which would include the Teva generic's approval) were delayed because of the filing of a Citizen Petition. But, plaintiffs argue, this sentence refers only to Citizen Petitions *filed* in 2018. Thus, plaintiffs argue, the Report doesn't pertain to the Mylan Citizen Petitions because Mylan filed them in 2015. So, both parties also look to the 2015 FDA Report. It states that the "approval of one ANDA was delayed because of two" Citizen Petitions. Report to Congress: Eighth Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2015, at 1 (July 29, 2016), *available at* https://www.fda.gov/media/99871/download. The parties dispute whether this sentence applies to the Mylan Citizen Petitions because while Mylan filed two Citizen Petitions against one ANDA (as the sentence references), the FDA treated the Citizen Petitions in a single response so it may have considered Mylan's submissions as a single filing. Neither of these

C. Should the Court Exclude Dr. Peck's References to Settlement Discussions Under Fed. R. Evid. 403?

Finally, defendants argue the court should exclude Dr. Peck's references to Teva settlement discussions under Fed. R. Evid. 403 because, they contend, it will mislead the jury and prejudice defendants. Defendants criticize Dr. Peck's Expert Report because it refers to Teva's settlement discussions in the context of the company's FDA approval process. But, Dr. Peck made it clear. He is providing no opinion whether the Teva settlement discussions *caused* delay in the FDA approval process. Defendants argue that Dr. Peck's references to the settlement discussions thus pose a danger of misleading the jury to think that he is opining that those settlement discussions *caused* delay in the FDA approval process when, instead, he only is offering opinions whether the FDA's actions caused delays in the FDA approval process.

Plaintiffs never respond directly to this argument. Instead, they contend that defendants are trying to use Dr. Peck's record of public service against him by arguing that his credentials as a former government official have the potential to mislead the jury. But, plaintiffs don't address whether Dr. Peck's references to the Teva settlement discussions pose a danger of misleading the jury.

Based on defendants' arguments and plaintiffs' failure to rebut them, the court agrees with defendants. Dr. Peck's references to the settlement discussions pose a danger of misleading the jury. So, the court excludes under Fed. R. Evid. 403 any portions of his opinions that refer to Teva settlement discussions in the context of Teva's process seeking to secure FDA approval of its generic EAI. Dr. Peck makes it clear that he is not offering opinions about *why* Teva slowed

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Reports conclusively discusses whether the Mylan Citizen Petitions actually delayed the FDA's approval of the Teva generic. So, the court finds, neither provides evidence contradicting Dr. Peck's opinion that Mylan's actions attempted to, and likely did, delay FDA approval. Thus, the court finds no reason to exclude Dr. Peck's opinion based on these FDA Reports.

its responsiveness during the FDA application process. Doc. 2142-3 at 7–8 (Peck Dep. 113:1–114:19). He testified that "it's basically mysterious why that happened." *Id.* at 7 (Peck Dep. 113:4–17). And, he concedes, for him to offer testimony about the cause for Teva slowing down its responsiveness would amount to "conjecture" because he doesn't "know specifically" the reason for Teva's actions. *Id.* at 8 (Peck Dep. 114:1–6). Also, Dr. Peck conceded that he never "conduct[ed] an analysis of whether there was a cause-and-effect relationship between Teva commencing settlement discussions with defendants and the noticeable slowing of responsiveness to the FDA requests[,]" and he has no "opinion one way or another about whether there was a cause-and-effect relationship between those two things[.]" *Id.* at 15–16 (Peck Dep. 125:19–126:12). Yet, his Expert Report repeatedly refers to the Teva settlement discussions and juxtaposes the timing of those settlement discussions with Teva's actions (or inaction) in the FDA approval process. The court agrees with defendants. These references to settlement discussions present a peril that the jury will misunderstand Dr. Peck's expert opinion as offering an opinion whether the Teva settlement discussions caused a delay in the FDA approval process. So, the court precludes Dr. Peck from testifying about the Teva settlement discussions in the context of his opinions about the FDA approval process.[22]

In sum, the court rejects all but one of defendants' arguments seeking to exclude Dr. Peck's expert opinions. As just discussed, the court won't permit Dr. Peck to testify about the Teva settlement discussions. But, it declines to exclude any other portions of Dr. Peck's expert

[22] With this ruling, the court only precludes *Dr. Peck* from referring to the timing of the Teva settlement discussions. This ruling doesn't bar plaintiffs from offering other admissible evidence about the timing of Teva settlement discussions. Also, it doesn't preclude argument that the evidence establishing the timing of the Teva settlement discussions corresponds with the times when Dr. Peck opines that Teva was non-responsive or slow to respond to the FDA's requests, if plaintiffs are able to support that argument with other admissible evidence.

opinions. The court thus grants in part defendants' Motion to Exclude the Testimony and Report of Plaintiffs' Expert Witness Dr. Carl Peck, and it also denies the motion in part.

VII. Defendants' Motion to Exclude the Testimony and Report of Plaintiffs' Expert Witness James Bruno (Doc. 2136)

Next, defendants ask the court to exclude James Bruno's testimony and Expert Report. Plaintiffs have retained James Bruno to provide rebuttal expert testimony in response to opinions offered by defendant's expert, Dr. Steven M. Weisman. Doc. 2164-5 at 5 (Bruno Feb. 7, 2020 Rebuttal Expert Report ¶ 1). Dr. Weisman offers an opinion that the Teva generic EAI "was an incredibly challenging product to develop, that Teva faced multiple developmental complications, and that the approval timeline of Teva's generic EAI was reflective of consistent and reasonable commercial efforts." *Id.* at 7–8 (¶ 16) (citation and internal quotation marks omitted). Dr. Weisman asserts "that Teva treated its generic EAI device as a priority project and made reasonable commercial efforts to bring it to market throughout the entire time period of its development." *Id.*

Plaintiffs retained Mr. Bruno to review Dr. Weisman's Expert Report and provide opinions about the manufacturing and commercial development of Teva's generic EAI that are beyond the scope of Dr. Carl Peck's Expert Report. *Id.* As part of his engagement, Mr. Bruno reviewed the factual record cited and relied on by Dr. Weisman, as well as other documents Dr. Weisman didn't review, including Teva's meeting minutes for the project. *Id.* at 8 (¶ 18). Generally, Mr. Bruno opines that "Teva neither treated its generic EAI device as a priority nor made reasonable commercial efforts to develop the product to bring it to market in the United States." *Id.* (¶ 20). He asserts that "the manufacturing issues experienced by Teva were by no means unique or complicated" and "could have been resolved far more quickly had Teva followed standard practices." *Id.* (¶ 21). He opines that Teva, instead, "took its proverbial 'foot

off the gas'" after it settled the patent infringement litigation with Mylan and Pfizer, but then "recommence[d] normal commercial efforts as the potential June 2015 entry date approached." *Id.* at 9 (¶ 22).

Defendants argue the court should exclude Mr. Bruno's opinions for several reasons. But the court needs to address only one of them. Defendants assert Mr. Bruno isn't qualified to render expert opinion about Teva's manufacturing of its generic EAI because he lacks the requisite knowledge or experience—specifically on manufacturing issues—to opine on this topic. The court agrees with them, and explains why, below.

A. Is Mr. Bruno Qualified to Render an Opinion about Manufacturing?

Defendants argue that the court should exclude Mr. Bruno's expert testimony because he lacks the required "knowledge, skill, experience, training, or education" to offer an expert opinion about Teva's manufacturing of its generic EAI. Fed. R. Evid. 702. But, plaintiffs respond, Mr. Bruno's extensive experience in the pharmaceutical industry renders him qualified to offer his proffered opinions in this case.

Mr. Bruno has more than 47 years' experience working in the pharmaceutical industry. Doc. 2164-5 at 32–33 (App. A) (listing professional experience from 1973 to the present). Mr. Bruno has a Bachelor of Science in Chemistry, a Master of Science in Chemistry, and a Master of Business Administration. *Id.* at 32. Working at six different companies, Mr. Bruno gained experience in developing and manufacturing pharmaceutical products. *Id.* at 32–33. Also, Mr. Bruno has worked on various submissions to the FDA, including NDAs and ADNAs, for both simple and complex pharmaceuticals. *Id.* at 6 (¶ 9). And, he has "interacted with the FDA on behalf of clients and [has] acted as the FDA agent for several foreign manufacturing companies." *Id.* During his career, Mr. Bruno has "worked on various dosage types, including solid oral

dosages (tablets and capsules), solutions, injectables (including prefilled syringes), liquids, creams, and lotions." *Id.* Also, he has "worked on several emergency use products such as Pralidoxime, which . . . is supplied in a prefilled syringe[,]" and he has "experience with the development of Epinephrine products." *Id.*

In 2002, Mr. Bruno founded Chemical and Pharmaceutical Solutions, Inc. ("CAP Solutions"), a pharmaceutical consulting company, where he currently serves as the Managing Director. *Id.* at 5 (¶ 2). In his position, he is "primarily responsible for offering executive-level consulting to pharmaceutical companies and contract manufacturers on matters of manufacturing, supply, and development of pharmaceutical products." *Id.*

Mr. Bruno has served as the President of the Drug, Chemical & Associated Technologies Association. *Id.* at 6 (¶ 12). He still is actively involved in this professional organization, as well as with the Society of Chemical Manufacturers & Affiliates and the American Chemical Society and BioNJ. *Id.* Also, Mr. Bruno has worked with chemical manufacturing trade publications, serving as a member of the Editorial Committee of *PharmaChem* and a reviewer for *Organic Process Research & Development*. *Id.* (¶ 13). Mr. Bruno has published many articles in trade publications on pharmaceutical manufacturing and has provided training on pharmaceutical manufacturing. *Id.*

Also, Mr. Bruno has served as an expert witness in antitrust and patent infringement cases involving pharmaceutical products. *Id.* at 7 (¶ 14). And, he has served as an expert for the Federal Trade Commission to offer opinions about manufacturing and contracts of both dosage and Active Pharmaceutical Ingredient ("API"), including for *In re Androgel Antitrust Litigation*, 1:09-md-2084 (N.D. Ga.). *Id.* at 6 (¶ 10).

Plaintiffs argue that Mr. Bruno's experience in the pharmaceutical manufacturing industry qualifies him sufficiently to provide expert testimony in this case—specifically, on the topic whether Teva made reasonable commercial efforts to develop its generic EAI product to bring it to market in the United States. Defendants disagree. Defendants rely on Mr. Bruno's deposition testimony to argue that he lacks the relevant expertise to opine about Teva's manufacturing efforts. Specifically, they argue that Mr. Bruno is not an engineer or mechanic, and he has no experience working on mechanical issues involving auto-injectors that could qualify him to render the expert opinions he offers in the case. *See* Doc. 2142-4 at 7–11 (Bruno Dep. 34:3–38:8) (testifying that he is not an engineer or mechanic and that he's worked on the development of drug formulation (*i.e.*, the chemical ingredients) intended for delivery in an auto-injector but he's never worked with a client "to correct mechanical issues involving an auto-injector"). The court agrees with defendants.

Without question, Mr. Bruno has significant experience working in the pharmaceutical industry. But his deposition testimony makes clear that he lacks the requisite knowledge or experience to render opinions about *the mechanics* of the Teva generic EAI, or Teva's ability and efforts to correct *mechanical issues* with its product when it was trying to secure FDA approval.

Most troubling, Mr. Bruno testified that he's never even handled the Teva generic EAI, and he can't explain how it works. *Id.* at 4 (Bruno Dep. 12:18–22) ("I can give you an idea of how auto-injectors work in general, but not specifically the Teva pen."). Also, Mr. Bruno incorrectly testified that the Teva generic, as well as EpiPen products, use a plunger for injection instead of what they actually do—*i.e.*, they auto-inject epinephrine when pressed into the patient's thigh. *Id.* at 3–5 (Bruno Dep. 11:14–21, 12:2–7, 12:23–13:8).

Defendants argue that Mr. Bruno's lack of knowledge about the specific product at issue—*i.e.*, the Teva generic EAI—make him unqualified to provide expert testimony. Without knowledge about the Teva generic EAI, defendants assert, Mr. Bruno is in no position to offer an opinion whether Teva experienced manufacturing issues that "were by no means unique or complicated" or "could have been resolved far more quickly had Teva followed standard practices." Doc. 2164-5 at 8 (¶ 21). Defendants are correct. Although an expert's "personal knowledge and experience" may qualify him to provide reliable expert testimony on a particular topic, *Kumho Tire*, 526 U.S. at 150, that kind of testimony satisfies the reliability standard when it is "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) (emphasis added and citations and internal quotation marks omitted). And, "[w]hen 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)).

That's precisely the situation here. As Mr. Bruno testified, he has no experience working as an engineer, a mechanic, or with clients to correct mechanical issues involving auto-injectors. Also, he has no experience specifically with the Teva generic EAI. He can't explain how it works, and he incorrectly testified that it uses a plunger for injection. Thus, he lacks the requisite personal knowledge and experience to offer an opinion about the mechanical issues that Teva faced with its generic EAI. And, despite Mr. Bruno's many years' experience working in the pharmaceutical industry generally, that experience doesn't include expertise with manufacturing or mechanical issues. Instead, the record shows that Mr. Bruno's pharmaceutical experience is

most grounded in chemistry—*i.e.*, he holds chemistry degrees and he has done extensive work developing the chemical components in pharmaceutical products. But, as he testified, he lacks experience working on engineering and mechanical issues with auto-injectors.

Without the requisite knowledge and experience to offer opinions about manufacturing issues, Mr. Bruno isn't qualified to opine whether Teva made reasonable commercial efforts to develop its generic EAI and to correct mechanical issues in a timely fashion so that it could bring its product to market. *See City of Hobbs v. Hartford Fire Ins. Co.*, 162 F.3d 576, 586–87 (10th Cir. 1998) (affirming exclusion of testimony by expert with about 30 years' experience in insurance claims adjustment and claims handling because the expert lacked specialized knowledge about New Mexico bad faith cases and lacked experience with third party claims and noting, "[t]hough a proffered expert possesses knowledge [in] a general field, the expert who lacks *specific knowledg*e does not necessarily assist the jury" (emphasis added)); *see also Ho v. Michelin N. Am., Inc.*, 520 F. App'x 658, 665 (10th Cir. 2013) (affirming exclusion of expert testimony because the proponent of the opinion "failed to explain how [the expert's] general experience in the tire industry qualified him to opine on [tire] design issues" and explaining that "[e]xperience is not necessarily a password to admissibility" because an expert also must "connect the dots" and explain how "that experience supports [the expert] opinion").

This problem is even more evident when one reads Mr. Bruno's testimony about the specific manufacturing issues that Teva experienced. For example, Mr. Bruno opines that Teva's modification of its device to prevent the issue it was having with accidently firing was "not a particularly complicated one to address[.]" Doc. 2164-5 at 24 (¶ 76). But, when asked about this opinion in his deposition, Mr. Bruno was unable to explain what steps Teva needed to take to fix this problem. Doc. 2142-4 at 111, 114 (303:8–19, 306:21–25). Instead, he testified that Teva

was a "sophisticated company" and there were other auto-injectors on the market that Teva could use as an example. *Id.* at 111 (303:8–19). But, with this response, Mr. Bruno provides no substance to support his opinion that, as he asserts, the firing issue was not a "complicated" mechanical issue for Teva to rectify with its generic EAI. Mr. Bruno can't reliably opine that a problem's fix was "not complicated" when he doesn't even know what the problem was. Instead, his conclusionary assertion that Teva could fix the problem simply because it was a sophisticated company sounds in conclusory speculation.

As another example, Mr. Bruno opines that Teva's issue with the stoppers in its generic EAI "was a minor compatibility issue that a company like Teva had the experience to easily resolve." Doc. 2164-5 at 24 (¶ 75). Mr. Bruno testified about his understanding of the problem based on his review of defendants' expert's Report, but he never reviewed any documents to determine what the precise issue was with the stoppers in the Teva generic EAI. Doc. 2226-4 at 13–14 (Bruno Dep. 297:18–298:15). And, as discussed, Mr. Bruno testified that he wasn't able to describe how the Teva product works—specifically—but instead only could testify generally about how EAIs work. Doc. 2142-4 at 4 (Bruno Dep. 12:18–22). But, nevertheless, Mr. Bruno asserts that the issue with the stopper was a "normal event[ ]" and one of the "very common issues" that a manufacturer faces in development of an auto-injector. Doc. 2226-4 at 14 (Bruno Dep. 298:1–15). The court doesn't understand how Mr. Bruno is qualified to render this opinion about a mechanical issue specific to the Teva generic EAI when he hasn't handled the product and he wasn't able to explain specifically—or even accurately—how it works. So, for all the reasons discussed, the court concludes that Mr. Bruno isn't qualified to render expert opinion about Teva's manufacturing issues with its generic EAI. The court thus grants defendants' Motion to Exclude the Testimony and Report of Plaintiffs' Expert Witness James Bruno.

VIII. Defendants' Motion to Exclude Plaintiffs' Patent Litigation Expert (Doc. 2151)

Defendants' next motion asks the court to exclude the affirmative merits opinions offered by plaintiffs' patent litigation expert. Plaintiffs have retained Prof. Andrew Torrance to opine about the parties' likelihood of success in the patent lawsuits involving EpiPen and Nuvigil.[23] Defendants assert two arguments why the court should exclude Prof. Torrance's opinions. They say: (1) Prof. Torrance's conclusions are based on an unreliable methodology, are misleading, and unhelpful to the trier of fact, and (2) Prof. Torrance implies that he performed scientific, validity, and infringement analyses that actually he never performed. The court discusses both of defendants' two arguments, below. But first, it addresses Prof. Torrance's qualifications to provide expert testimony in this case.

At class certification, defendants moved to exclude Prof. Torrance's expert opinions from the court's consideration of the class certification motion. The court denied that motion.[24] Doc.

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[23] Prof. Torrance offers two merits Expert Reports: (1) an affirmative merits Expert Report addressing the likelihood of success in the EpiPen and Nuvigil patent litigation, and (2) an Expert Report offering rebuttal opinions to the affirmative merits Expert Report offered by defendants' expert, Charles E. Clemens, about the '827 Patent. The motion discussed in this section of the Order (Part VIII.) addresses just the first Expert Report—*i.e.*, Prof. Torrance's affirmative merits opinions about the likelihood of success in the EpiPen and Nuvigil patent litigation. The motion discussed in the next section of the Order (Part IX.) addresses Prof. Torrance's rebuttal opinions offered in response to Mr. Clemens's expert opinions about the '827 Patent.

[24] Defendants repeatedly assert that the court must apply "a more stringent application" of the *Daubert* standard at the merits stage than it did at class certification. Doc. 2153-1 at 9; *see also id.* at 10 ("We are now past the class certification stage. A full-blown *Daubert* analysis is therefore warranted."); Doc. 2223-1 at 5 (asserting that the court admitted Prof. Torrance's opinion "under the more lenient standard applied at [the class certification] stage"). The court disagrees that it applied a "more lenient" *Daubert* standard at class certification. The court's Order discussed the two approaches that courts have taken when assessing challenges to expert testimony on class certification. Doc. 2017-1 at 3. It noted that the Tenth Circuit has not yet decided what standard a court should apply in that context. *Id.* And, it explained that the Third Circuit has declined to examine whether any differences exist between the two approaches because they both require applying a "'*Daubert* inquiry to expert testimony offered to prove satisfaction of Rule 23's requirements.'" *Id.* at 4 (quoting *In re Blood Reagents Antitrust Litig.*, 783 F.3d 183, 187, 188 n.8 (3d Cir. 2015)). The court followed the Third Circuit's approach and declined "to decide whether the two approaches differ in a material fashion." *Id.* at 4. Instead, the court applied "the *Daubert* standard" to the opinions the parties had proffered as support for or in opposition to the Rule 23

2017-1 at 69–81. When deciding that motion, the court concluded that "Prof. Torrance's experience and education qualify him to opine about Teva's likelihood of success in the Teva patent litigation." *Id.* at 70 n.24.[25] With the current motion, defendants never argue that Prof. Torrance isn't qualified to offer his expert opinions. And, plaintiffs provide ample support for finding Prof. Torrance qualified to render the expert opinions he offers at the merits stage of this litigation.

Prof. Torrance is a tenured professor and the Paul E. Wilson Distinguished Professor at the University of Kansas School of Law ("KU Law"). Doc. 2153-2 at 7–8 (Torrance Oct. 31, 2019 Expert Report ¶ 9). He earned a Bachelor of Science in biology from Queen's University, an A.M. and Ph.D. in biology from Harvard University, and a J.D. from Harvard Law School. *Id.* Since 2005, Prof. Torrance has taught courses at KU Law in patent law, intellectual property law, food and drug law, biolaw, biodiversity law, and legal analytics. *Id.* Since 2012, Prof. Torrance has served as a visiting scholar at the Massachusetts Institute of Technology ("MIT") Sloan School of Management. *Id.* And, he previously served as a Visiting Professor at Harvard University. *Id.*

Prof. Torrance has received many awards for his scholarship and teaching at KU Law. *Id.* at 8 (¶ 10). He has "published more than 50 articles or book chapters on patent law,

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class certification requirements. *Id.*; *see also id.* at 5–7 (reciting the standards governing expert testimony under *Daubert* and Fed. R. Evid. 702); *id.* at 70–71, 76–78, 80–81 (applying *Daubert* to Prof. Torrance's expert opinions). Thus, when considering defendants' previous challenges to Prof. Torrance's opinions, the court applied the *Daubert* standard to those opinions. It didn't stray from that standard by applying a more lenient test for admitting expert opinion testimony.

[25] Plaintiffs assert that the court previously found Prof. Torrance "'well-qualified' to opine on how a reasonable, competent, and experienced patent attorney would view the likely outcome, costs, and duration of prior patent infringement disputes had they not settled." Doc. 2185-1 at 8 (quoting Doc. 2017-1 at 70 n.24). This description takes some liberties with the actual language of the court's Order. The "well-qualified" reference is not from the court's conclusion about Dr. Torrance but, instead, from a description of plaintiffs' argument about him. Doc. 2017-1 at 70 n.24. What the court actually held when discussing Prof. Torrance's qualifications to provide expert testimony is quoted in the text above.

intellectual property law, food and drug regulation, biotechnology law, medical device innovation and regulation, legal analytics, and innovation[.]" *Id.* (¶ 11). And, he has made "more than 200 presentations to scholars and governmental and corporate audiences[.]" *Id.* Prof. Torrance has concentrated his scholarship on "patent strength, as reflected in patent validity, enforceability, and infringement." *Id.*

Since 2002, Prof. Torrance has been a registered patent attorney. *Id.* at 9 (¶ 13). He has practiced patent law at the law firms of Morrison & Foerster LLP and Fish & Richardson PC. *Id.* at 8–9 (¶ 12). He was in-house patent counsel for Inverness Medical Innovations, a medical device company. *Id.* And, he served as Intellectual Property Counsel for Uhlig LLC, a software-based publishing company, where he led intellectual property strategy. *Id.*

On August 26, 2019, Prof. Torrance was appointed as the head of intellectual property at the Broad Institute of MIT and Harvard. *Id.* In his position as Senior Director, Intellectual Property, he is the chief intellectual property counsel for the Broad Institute—which is "one of the foremost biomedical research institutions in the world (for example, ranking first according to Mapping Scientific Excellence)." *Id.* (citation omitted). His responsibilities at the Broad Institute include "all aspects of intellectual property, from filing and prosecuting patent applications, patent licensing, and assessment of patent strength, quality, invalidity, enforceability, and infringement, to patent litigation and establishment of new companies focused on patent rights to particular new technologies." *Id.* at 9–10 (¶ 14). At the Broad Institute, he supervises a team of patent attorneys and professional patent support staff; he works with transactional attorneys, business development professionals, patent financial specialists, and scientists; and he advises senior management on patent strategy. *Id.*

In Spring 2019, the Law and Economics Center ("LEC") at George Mason School of Law invited Prof. Torrance to start teaching "Legal Analytics" to classes of judges. *Id.* at 10 (¶ 15). He taught his first class in October 2019 in Santa Fe, New Mexico, giving 14 hours of lectures to a class of 40 to 60 judges (state and federal, trial and appeals) for more than four days. *Id.* The LEC has asked him to teach this class regularly, several times a year, to future classes of judges. *Id.* Also, the LEC invited Prof. Torrance to teach a class to the American College of Business Judges on "Legal Analytics and Expert Witnesses." *Id.* He taught his first class in October 2019 to about 60 state court judges gathered in Pittsburgh, Pennsylvania, and the LEC has asked him to teach the course regularly in the future. *Id.* Prof. Torrance also has a contract with Wolter Kluwer Aspen Press to write a textbook on "Legal Analytics." *Id.*

Based on this summary of Prof. Torrance's education, knowledge, and professional experience, the court finds that he is qualified to render his opinions about the likelihood of patent litigation success that he offers in this lawsuit. The court now turns to address defendants' arguments for excluding Prof. Torrance's opinions on reliability grounds.

A. Are Prof. Torrance's Conclusions Based on an Unreliable Methodology, Misleading, and Unhelpful to the Trier of Fact?

Defendants make four arguments to support their assertion that Prof. Torrance's opinions lack a reliable methodology, are misleading, and unhelpful to the trier of fact. The court addresses the four arguments, below.

1. Reliability of Prof. Torrance's "Holistic" Analysis

First, defendants argue that the court should exclude Prof. Torrance's opinions about the likelihood of success in the EpiPen and Nuvigil patent litigation because it is based on an unreliable "holistic" analysis that isn't capable of testing. For the EpiPen/Teva litigation, Prof. Torrance opines that "a reasonable, competent, and experienced patent attorney would estimate a

probability of about 85% ± 10% that Teva would not have been found liable for patent infringement of any valid patent claim in any final adjudication by the Federal Circuit." Doc. 2153-2 at 69 (Torrance Oct. 31, 2019 Expert Report ¶ 135). And, for the Nuvigil/Cephalon litigation, he opines that "a reasonable, competent, and experienced patent attorney would estimate a probability of about 80% ± 10% that Mylan would not have been found liable for patent infringement of at least one valid patent claim of the '570 patent (or the '516 patent, for that matter) in any final adjudication by the Federal Circuit." *Id.* at 101 (¶ 207).

Prof. Torrance testified that he performed a "holistic analysis" to reach his conclusions about the percentage likelihood of patent litigation success. Doc. 2153-3 at 13 (Torrance Dep. 105:12–106:10). He explained "the way that [he] came to this number was to feed in all of the information and all of the analysis" from his Expert Report. *Id.* He didn't assign a "particular percentage" to a "particular decision" but instead described his conclusions as "the end product of all of the analysis in the Merits Report." *Id.*

Defendants argue that the court should exclude Prof. Torrance's "holistic" analysis as unreliable because it isn't susceptible to testing to determine whether it is reliable. Defendants assert that when a court decides "whether a theory or technique is scientific knowledge that will assist the trier of fact[,]" it should ask "a key question . . . whether it can be (and has been) tested." *Daubert*, 509 U.S. at 593; *see also id.* ("Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified[.]" (citation and internal quotation marks omitted)). But here, defendants argue, Prof. Torrance's "holistic" methodology can't be tested or falsified. So, they contend, the court should exclude his opinions about the likelihood of patent litigation success.

As support for this argument, defendants fault Prof. Torrance's analysis for not using any mathematics or formula to reach the percentages he provides for the likelihood of success in patent litigation. Doc. 2153-3 at 37 (Torrance Dep. 302:20–303:3) (testifying that he didn't "put any mathematics in the report having to do with the 85 percent" but instead he bases the percentage on his "understanding of everything that [he has] reviewed, [his] experience, [and] the connections between things"); *see also id.* (Torrance Dep. 303:22–25) (conceding that his Expert Report "didn't lay out some sort of a formula" to calculate the percentage of likelihood of success). Also, defendants criticize his methodology because he didn't assign any certain percentages to underlying issues or decision points that he used to factor into his final conclusion for the percentage of likelihood of litigation success. *See id.* at 17 (Torrance Dep. 123:15–124:12) (testifying that "ascribing a particular number to [Teva's non-infringement defense] was not something that [he] was asked to do nor was it part of the method that [he] used"); *see also id.* at 20–21 (Torrance Dep. 140:19–141:23) (explaining "all of the factors that go into [his] calculus" but that he "can't give . . . a particular percentage on one isolated factor").

Plaintiffs respond that Prof. Torrance isn't required to set forth a mathematical formula to test his methodology for it to satisfy the *Daubert* standard. Instead, plaintiffs argue, Prof. Torrance sufficiently has described his methodology in both his Expert Report and his deposition testimony. In both, he cited the facts and documents that he relied on to form his conclusions and explained how he used that information to determine the likelihood of success in patent litigation based on his knowledge and experience as a patent lawyer, legal scholar, and law professor. *See* Doc. 2153-2 at 7, 28–34 (¶¶ 8, 48–65) (describing his analytic approach, listing the materials he reviewed to form his opinions, and providing the factors that he considers as the ones that affect patent litigation outcome, duration, and cost); *see also id.* at 34–75 (¶¶ 67–146)

(providing his analysis of the Teva litigation); *id.* at 75–81 (¶¶ 147–166) (providing his analysis of the Intellijject litigation); *id.* at 82–103 (¶¶ 169–214) (providing his analysis of the Cephalon litigation); Doc. 2153-3 at 11–12 (Torrance Dep. 99:15–103:9) (testifying about the material he reviewed and how he reached his conclusions after reviewing that material); *id.* at 20–21 (Torrance Dep. 140:19–141:23) (explaining his approach for reaching his opinions based on reviewing the documents and drawing on his experience); *id.* at 37–38 (Torrance Dep. 304:25–305:5) (explaining that he calculated the percentage of litigation success by "look[ing] at all of the materials," "draw[ing] on my experience," and "com[ing] up with a reasonable range").

While it is a closer call than others, the court agrees with plaintiffs. Here, Prof. Torrance has provided a reliable basis for his methodology. He explains that he reached his conclusions after reviewing the facts and evidence relevant to the patent litigation and then applying his expertise and knowledge about patent law to those facts. As this court noted in its *Daubert* Order at class certification, other courts have approved similar methodologies by patent experts rendering opinions about the likelihood of success in patent litigation. *See* Doc. 2017-1 at 70 (collecting cases); *see also In re Namenda Indirect Purchaser Antitrust Litig.*, No. 1:15-cv-6549 (CM) (RWL), 2021 WL 2403727, at *10 (S.D.N.Y. June 11, 2021) (holding on summary judgment in indirect purchaser class action that patent litigation expert had "provided a methodology, one that [the court] consider[s] to be perfectly sound" because it is "exactly what lawyers do when counseling clients on such matters—not firmly grounded in statistical probabilities, but far from *ipse dixit*"); *In re Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d 274, 306 n.10 (D.R.I. 2019) (denying motion to exclude expert opinion on the likelihood of patent litigation success because, among other reasons, the court is "satisfied that [the expert] connects his experience to his opinions"); *In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp.

3d 152, 187–88 (S.D.N.Y. 2018) (holding on summary judgment and class certification in a direct purchaser action that opinions of a "patent attorney with extensive experience in the area of patent law" about "the likelihood [of success] in [a patent] lawsuit" because the expert "unquestionably has the expertise to evaluate the things he assessed—from expert reports to patent file folders—and to draw conclusions about who is more likely to win a patent lawsuit"); *In re Androgel Antitrust Litig. (No. 11)*, No. 1:09-MD-2084-TWT, 2018 WL 2984873, at *5–6 (N.D. Ga. June 14, 2018) (denying motion to exclude expert opinion about "how a reasonable and competent patent attorney would have advised litigants" about "the likelihood of success in the litigation" because the expert relied on his experience to "examine[ ] the merits of the underlying patent litigation" and determine the litigant's chance of success which showed the expert "clearly [had] a methodology, even if the Defendants believe it to be a weak one"); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-md-02503, 2018 WL 563144, at *16 (D. Mass. Jan. 25, 2018) (refusing to exclude opinion of patent law expert who opined about the likelihood of success in patent litigation "based upon his own expertise and experience in the field of patent law"); *United Food & Com. Workers Loc. 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma USA*, 296 F. Supp. 3d 1142, 1186–87 (N.D. Cal. 2017) (denying motion to exclude expert testimony about likely outcome of patent litigation when the expert had reached his conclusions by "applying his scientific background and knowledge to his review of the trial record"); *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 765–67 (E.D. Pa. 2015), *aff'd on other grounds*, 868 F.3d 132 (3d Cir. 2017) (denying motion to exclude expert's opinion about the chances of prevailing in underlying patent litigation because the expert—a patent law professor—was "a qualified expert offering appropriate expert testimony" and had reached his conclusions after "review of the briefs, pleadings, ANDA, and underlying

patent at issue in the . . . litigation"). The court understands defendants' arguments. It is concerning that Dr. Torrance arrived at a specific percentage range while, at the same time, there's no subsidiary calculations that permit the factfinder to retrace the steps leading to that range. *See In re Intuniv Antitrust Litig.*, No. 1:16-cv-12396-ADB, 2020 WL 5995326,*12 (D. Mass. Oct. 9, 2020) (joining the courts "that have permitted lawyers to testify as experts on the likelihood of success on the merits in a case underlying a reverse-payment litigation" but limiting that testimony to expert's "professional opinion that [a litigant] would not have prevailed in the underlying litigation" and prohibiting expert from testifying about "any specific percentage of likelihood" because he had "provided no concrete methodology for how he reached this figure"). But the vast majority of cases have permitted similar expert opinions using a similar methodology, so the court finds that Prof. Torrance has provided a sufficiently reliable methodology for how he reached his opinions about the likelihood of litigation success based on his review of the relevant materials and his application of his patent law expertise to the facts contained within that material.[26]

Also, the court finds no reason to exclude Prof. Torrance's opinions because he has not provided a way to test them. Nothing in the *Daubert* standard *mandates* that every expert must demonstrate a methodology that can be tested. Instead, *Daubert*'s language about testing merely is permissive. *See Daubert*, 509 U.S. at 593 (noting that "[m]any factors will bear on the [reliability] inquiry" but refusing "to set out a definitive checklist or test" and instead listing "general observations" that courts may consider when deciding whether to admit expert

[26] The parties don't cite and the court hasn't located in its own research any Tenth Circuit authority addressing whether an expert may testify about the likelihood of success in litigation using a methodology that involves reviewing the relevant materials and applying the expert's experience and knowledge about patent law to those materials. The court predicts that, if presented with the issue, the Tenth Circuit would follow the majority of district court cases that have permitted this type of expert testimony.

testimony); *see also Kumho Tire*, 526 U.S. at 149–50 (explaining that a trial judge "*may* consider" whether a theory "can be (and has been) tested" because "[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony" and refusing to "rule out, nor rule in, for all cases and for all time the applicability of the factors mentioned in *Daubert*" because "[t]oo much depends upon the particular circumstances of the particular case at issue" and, in some cases, "the relevant reliability concerns may focus upon personal knowledge or experience" (citations an internal quotation marks omitted)).

Prof. Torrance sufficiently satisfies that standard here by providing a reliable basis for the methodology that he used to reach his expert conclusions that involved reviewing the underlying patent litigation records and then applying his patent law experience and knowledge to those underlying facts.[27] So, the court won't exclude Prof. Torrance's opinions based on defendants' argument that he hasn't provided a mathematical formula that is capable of testing or falsifying the methodology that he used to render his opinions.

[27] In reaching this conclusion, the court rejects defendants' selective citation to Prof. Torrance's deposition testimony where he testified about the percentage estimates that he was "comfortable" and "uncomfortable with" when forming his conclusions. Doc. 2153-3 at 12 (Torrance Dep. 102:3–103:9). Defendants argue that this testimony shows that Prof. Torrance bases his opinions only on his comfort level and gut feelings which isn't a reliable methodology for rendering expert testimony. But, in the larger context of this deposition testimony, Prof. Torrance explained his methodology—*i.e.*, how he considered the validity of the claims in the underlying patent litigation "under a variety of different patent law theories," how he reviewed the materials from the underlying patent litigation, how he analyzed "the patents themselves in detail," and how after "consider[ing] all of those factors," he reached his "best estimate" of Teva's litigation success and "considered what a reasonable bounding would be of" his estimate "given all of the information and the uncertainties of human behavior" and concluded that "a plus or minus 10 percent would be an appropriate range to bound it." *Id.* at 11–12 (Torrance Dep. 99:15–103:9). Like the expert discussed in the *Androgel* case, Prof. Torrance here "clearly [had] a methodology, even if the Defendants believe it to be a weak one." *In re Androgel Antitrust Litig. (No. 11)*, 2018 WL 2984873, at *6. And, as he testified, it's based on a methodology that isn't just a gut feeling or comfort level, as defendants describe it.

2. Prof. Torrance's Analysis of Likelihood of Success in the Teva Litigation

Next, defendants argue that the court should exclude Prof. Torrance's estimates about the likelihood of success in the Teva litigation. Defendants assert that this opinion is unreliable because Prof. Torrance's Expert Report provides estimates that differ from the percentages he provided at class certification, but he fails to explain why his numbers have changed using the methodology that he followed when rendering his opinion.

Prof. Torrance's Expert Report in support of class certification opined that "a reasonable, competent, and experienced patent attorney would estimate a probability of above 70% that Teva would not have been found liable for patent infringement of any valid patent claim in any final adjudication by the Court of Appeals for the Federal Circuit ('CAFC')" in the Teva patent litigation. Doc. 2153-5 at 4–5 (Torrance Dec. 7, 2018 Expert Report ¶ 3.a.). Also, he opined that "a reasonable, competent, and experienced patent attorney would estimate a probability of above 80% that Intelliject would not have been found liable for patent infringement of any valid patent claim in any final adjudication by the CAFC" in the Intelliject litigation. *Id.* at 5 (¶ 4.a.). But, in his Merits Expert Report, he changed his estimates, opining that Teva had about an "85% ± 10%" chance of success in its patent lawsuit and that Intelliject had about a "90% ± 10%" chance of success in its litigation. Doc. 2153-2 at 69, 79 (Torrance Oct. 31, 2019 Expert Report ¶¶ 135, 159).

Defendants assert Prof. Torrance can't say why he increased his estimate for the likelihood of success in the Teva litigation. They contend that no new documents or evidence came to light between Prof. Torrance's Expert Report on class certification and his Merits Expert Report. And, they argue, Prof. Torrance testified that he couldn't recall reviewing any documents for his Merits Expert Report that weren't available to him earlier when he formed his

opinions at class certification. Doc. 2153-3 at 32–33 (Torrance Dep. 260:12–261:9) (testifying that "[u]nder time pressure right now, within the next couple of seconds [he] can't think of one [document] that [he] did not have available to [him] before that [he] did have available to [him] later"). Defendants assert that the only reason Prof. Torrance provides for the change in his estimates is a purported evolution in his thinking. *Id.* at 37 (Torrance Dep. 304:1–17) ("And as my thinking evolved working on the Merits Report, I was able to be confident that I could narrow that range to 20 percent."). But, with this answer, defendants argue, Prof. Torrance fails to show that he used any reliable methodology when forming his conclusions about Teva's likelihood of litigation success.

Plaintiffs respond that defendants' argument is based on cherry-picked excerpts from Prof. Torrance's deposition testimony. Plaintiffs assert that the deposition testimony, when read in its full context, shows that Prof. Torrance provided a proper explanation why his opinions evolved between class certification and his Merits Expert Report. Indeed, they say, he testified that he reviewed additional materials between the time he offered his opinions on class certification and when he rendered the opinions in his Merits Expert Report. *Id.* at 13–14 (Torrance Dep. 108:22–111:22) (describing the additional material that he reviewed and noting that his appendix to his Merits Expert Report contains a longer list of materials that he considered for his opinions in that Report than the list of materials appended to his Expert Report on class certification);[28] *see also id.* at 15 (Torrance Dep. 116:1–21) (testifying that there "were

[28] Prof. Torrance's testimony is an accurate description of the appendices attached to his two Expert Reports. The appendix attached to his Merits Expert Report includes significantly more material than what he listed in his appendix attached to his Expert Report on class certification. *Compare* Doc. 2185-3 at 105–28 (Torrance Oct. 31, 2019 Expert Report App. A) (listing in 24 pages the material considered to form the conclusions in his Merits Expert Report including academic literature; statutes, rules, and regulations; cases; litigation materials; patents and prosecution histories; press and press releases; other materials; websites; and Bates-stamped documents), *with* Doc. 1500-4 at 40–47 (Torrance Dec. 7, 2018 Expert Report in Support of Class Certification Ex. A) (listing in 8 pages the materials he considered to

many new documents that became available to [him] between the time" he authored his Expert Report on class certification and when he issued his Merits Expert Report). And, Prof. Torrance explained that those additional materials caused his "view" to "evolve[ ] over time" because "every time a newly discovered document comes along" it made him "re-evaluate the old information as well." *Id.* at 14 (Torrance Dep. 109:14–111:22); *see also id.* at 31–32 (Torrance Dep. 256:22–257:20) (explaining that "the more new information [he] look[ed] at, the more this sparks connections with things that [he has] thought about before and allows [him] to hone what [he] thought about before" and "with the Merits Report" he "had a fuller view of what was out there"). Prof. Torrance further explained how that additional material caused him to revise his percentage estimates of litigation success because the numbers provided in his Expert Report on class certification were his "best estimate at the time with the information that [he] had" but his view changed with his Merits Expert Report because he was "taking into account all of the information" that he had reviewed up to the time he issued his Merits Expert Report. *Id.* at 30 (Torrance Dep. 249:25–250:12); *see also id.* at 37 (Torrance Dep. 301:21–302:7) (testifying that "in general [his] certainty" increased so he "narrowed the range").

Defendants attack this testimony, again arguing that it lacks any reliable methodology to explain how Prof. Torrance formed his opinions. The court disagrees. Prof. Torrance has explained how he reached his opinions in his Merits Expert Report after a review of significantly more material than he considered at class certification. And, he has explained that he applied his expertise in patent law to the facts contained in that material to opine about Teva's chances of success in its patent litigation. The court finds that Prof. Torrance provides a sufficiently reliable

form his opinions on class certification). Tellingly, the Expert Reports that defendants have attached as exhibits to their motion to exclude Prof. Torrance's opinions omit the appendices from his two Expert Reports. *See* Docs. 2153-2 (Torrance Oct. 31, 2019 Expert Report) & 2153-5 (Torrance Dec. 7, 2018 Expert Report in Support of Class Certification).

methodology for his Teva litigation opinion. Defendants' challenges to Prof. Torrance's opinion based on the changes he made between his Expert Report on class certification and his Merits Expert Report go to the weight of his expert testimony. Defendants can raise these criticisms through their cross-examination of Prof. Torrance. But, the court won't exclude his opinion based on the fact Prof. Torrance revised his estimates of litigation success between the time he issued his Expert Report on class certification and when he authored his Merits Expert Report.

Also, defendants suggest that Prof. Torrance changed his opinion about the Teva litigation because plaintiffs learned at class certification that Prof. Elhauge's generic delay model showed no generic delay when using Prof. Torrance's 70% estimated probability of litigation success. Plaintiffs respond that this argument is speculation. As Prof. Torrance testified, he never has reviewed Prof. Elhauge's Expert Report, he never has spoken to Prof. Elhauge, and he wasn't aware that Prof. Elhauge's opinion on class certification relied on Prof. Torrance's estimated percentage of Teva litigation success. Doc. 2153-3 at 15 (Torrance Dep. 114:4–21). And, when asked directly whether he changed his opinion in his Merits Expert Report based on Prof. Elhauge's opinion, Prof. Torrance answered no. *Id.* (Torrance Dep. 114:22–115:4). Defendants' Reply appears to abandon this argument. It does so for good reason. Plaintiffs have shown that defendants' assertions about a purported connection between Prof. Torrance's revised estimate of Teva litigation success and Prof. Elhauge's opinions lack any evidentiary foundation. The court thus rejects this argument as a reason for excluding Prof. Torrance's opinion about the chances of success in the Teva litigation.

Last, defendants assert that Prof. Torrance inexplicably changed his opinions about the probability that the Teva generic EAI infringed any claims of the '432 patent. Prof. Torrance's Expert Report on class certification opined that "a reasonable, competent, and experienced patent

attorney . . . would likely conclude that Teva's generic auto-injector had a relatively large probability of infringing at least one claim of the '432 patent." Doc. 2153-5 at 31 (Torrance Dec. 7, 2018 Expert Report ¶ 76). But, in his Merits Expert Report, Prof. Torrance opines that "a reasonable, competent, and experienced patent attorney" likely would conclude that it was unlikely that the Teva generic EAI "would have been found to infringe any claim of the '432 patent." Doc. 2153-2 at 72 (Torrance Oct. 31, 2019 Expert Report ¶ 141); *see also id.* at 51, 54–55 (¶¶ 100, 103–04) (analyzing certain claims of the '432 Patent and concluding that it was unlikely that a court would have found that the Teva generic EAI infringed certain claims of the '432 Patent). Prof. Torrance addressed this difference both in his deposition testimony and his Rebuttal Report. He testified that his opinion at class certification used the word "relatively" as "compared to the Intellijject[,]" meaning that he was opining that Teva's chances of infringement were "relatively large compared to the Intellijject" and "the Intellijject has a lower probability of infringing than the Teva device." Doc. 2185-4 at 10 (Torrance Dep. 133:10–136:3). His Rebuttal Report further expands on this clarification. Doc. 2185-5 at 23–24, 33 (Torrance Feb. 7, 2020 Rebuttal Expert Report ¶¶ 27, 43). Based on this clarification, Prof. Torrance has provided a reliable explanation for why, he contends, his earlier opinion at class certification doesn't conflict with the opinion he offers at the merits stage of the litigation. Defendants' disagreements about this explanation go the credibility of Prof. Torrance's opinion, and they are fodder for cross-examination. But, based on this record, the court won't exclude Prof. Torrance's opinion about the likelihood of success in the Teva litigation.

3. The Facts Supporting Prof. Torrance's Opinion about the Cephalon Litigation

Next, defendants assert that Prof. Torrance's analysis about the likelihood of success in the Cephalon litigation is unreliable because he failed to consider important facts and events

from that litigation. The Cephalon litigation was a lawsuit that Cephalon filed in the United States District Court for the District of Delaware on December 11, 2009. Doc. 2153-2 at 86 (Torrance Oct. 31, 2019 Expert Report ¶ 185). Cephalon brought the lawsuit against Mylan and several other defendants, alleging that defendants had infringed their patent for the drug, Nuvigil. *Id.* In December 2010, the Judicial Panel on Multi-District Litigation transferred Cephalon's case against Mylan, along with seven other actions, to Judge Gregory M. Sleet in the District of Delaware. *Id.* at 86–87 (¶ 186). On April 26, 2012, Cephalon and Mylan settled their claims while the litigation still was pending. *Id.* at 88 (¶ 190). But, the Cephalon lawsuit continued against the other, remaining defendants, who defended the case through a bench trial before Judge Sleet. *See generally In re Armodafinil Pat. Litig.*, 939 F. Supp. 2d 456 (D. Del. 2013). After that bench trial concluded, Judge Sleet issued an Order holding that the asserted claims of the Cephalon patent were not invalid and enjoining defendants from manufacturing and selling their competing drug products before the patent's expiration. *Id.* at 503.

Defendants argue that Prof. Torrance's opinion about the Cephalon litigation is unreliable because he never considered Judge Sleet's opinion when reaching his conclusions. Even worse, defendants argue, Prof. Torrance reaches a conclusion that is the opposite of what Judge Sleet held in his Order, ruling that the patent was not invalid. But, plaintiffs explain, Prof. Torrance makes clear that his opinion about the likelihood of success for Mylan in the Cephalon litigation is "at the time of the actual settlement." Doc. 2153-2 at 5 (¶ 4.a.). And, Prof. Torrance explains in his Rebuttal Report that he didn't consider Judge Sleet's Order when forming his opinion "for good reason." Doc. 2185-5 at 39 (Torrance Feb. 7, 2020 Rebuttal Expert Report ¶ 58). That's because his "opinion takes into account only information known or available to the parties *on the settlement date*." *Id.* Since the settlement date occurred before the bench trial and Judge Sleet's

Order, "these sources of information were not available as of the settlement date." *Id.* So, that's why Prof. Torrance "did not rely on this information for [his] opinions." *Id.* And, although Prof. Torrance testified that he reviewed the oral argument in the appeal of the Cephalon litigation filed in the Federal Circuit, he also testified that he "did not take that into account nor did [he] take Judge Sleet's opinion into account because he analyzed from . . . the point in time of settlement." Doc. 2153-3 at 25 (Torrance Dep. 203:2–14); *see also* Doc. 2185-5 at 23 (¶ 26) (explaining that he "did review the post-settlement litigation record of the *Cephalon* litigation, including the Federal Circuit oral arguments" but he "also did not rely on any of this post-settlement information to come to conclusions for [his] Merits Report").[29]

Also, defendants criticize Prof. Torrance's opinion about the Cephalon litigation because, they contend, he reviewed only one expert report and failed to consider other, competing expert opinions about the validity of the Cephalon patent. But that's not an accurate description. Indeed, Prof. Torrance testified that he only was able to review one expert report "in full[.]" Doc. 2153-3 at 33 (Torrance Dep. 262:22–263:13). But also, he testified that he asked for other expert reports, and some of the ones he received were "heavily redacted." *Id.* Still, he "made [his] best efforts to determine what the various experts had said on particular issues." *Id.*; Doc. 2185-5 at 41 (¶ 59) ("In the case of the expert testimony in the *Cephalon* litigation . . . [Prof. Torrance] was able to locate sufficient pre-settlement information on expert opinions in that case to come to [his] opinion[.]"). He did that by "reconstruct[ing]" the experts' reports by "dig[ging] through the materials" and "find[ing] other documents that referenced them." Doc. 2153-3 at 33

[29] Also, contrary to defendants' assertions that Prof. Torrance never reviewed Judge Sleet's reversal rate, he testified that he looked up the statistics available on Lex Machina showing Judge Sleet's reversal rate. Doc. 2185-4 at 14 (Torrance Dep. 165:6–166:18). But also, he testified that the reversal rates from 2009 that defendants' counsel cited during the deposition wouldn't "necessarily be known to somebody at the time of settlement" and "it would be difficult to say that . . . a competent, experienced, and reasonable patent attorney at the time of settlement would have had access to that information." *Id.*

(Torrance Dep. 263:14–264:14). Based on that review, Prof. Torrance believes he has "a pretty good view of what happened in the expert reports and certainly enough to inform [his] opinions." *Id.* And, as his Expert Report shows, Prof. Torrance considered various opinions rendered by other experts in the Cephalon litigation to reach his conclusions about the likelihood of success. Doc. 2153-2 at 91–98 (¶¶ 196, 198–201); *see also id.* at 92–93 n.301 (¶ 198) (explaining that Prof. Torrance reviewed the rebuttal report of an expert that took into account various other "expert reports prepared on behalf of both plaintiffs and defendants").

As discussed above, Prof. Torrance provides a reliable basis for his methodology. He explains why he didn't consider certain post-settlement material, including Judge Sleet's Order, relevant to his analysis. Also, he explains that he considered other expert opinions to the extent he was able to access them or reconstruct them from the record. Defendants' challenges to the reliability of Prof. Torrance's opinion based on the information he considered when forming his opinion goes to the opinion's weight 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"). So, the court refuses to exclude Prof. Torrance's expert opinion about the Cephalon litigation based on defendants' argument that he ignored certain material when forming his conclusions. Importantly, Prof. Torrance didn't overlook the material. He knew it was available for his consideration. But, he has explained reliably why he didn't consider the material. So, the court refuses to exclude Prof. Torrance's opinion on this basis.

4. The Facts Supporting Prof. Torrance's Opinions about the Teva Litigation

Last, defendants argue that Prof. Torrance relied on incorrect or irrelevant facts and failed to consider material facts in his analysis about the likelihood of success in the Teva litigation.[30] Defendants contend that, by considering certain facts and failing to consider other facts, Prof. Torrance has proffered an unreliable opinion on this topic. Specifically, defendants criticize Prof. Torrance's opinion in three ways.

First, defendants assert that Prof. Torrance's opinion is unreliable because it analyzes the validity of the '012 Patent, but the Pfizer subsidiary plaintiffs dropped that patent from the case before trial in the Teva litigation. Indeed, Prof. Torrance's Expert Report thoroughly analyzes the '012 Patent. Doc. 2153-2 at 34–39 (Torrance Oct. 31, 2019 Expert Report ¶¶ 67–78). He concludes that a reasonable, competent, and experienced patent attorney would find that "the patent claims of the '012 patent are likely invalid." *Id.* at 39 (¶ 78); *see also id.* at 72 (¶ 141). Also, he recognizes that the Pfizer subsidiary plaintiff "ultimately withdrew" its claim based on the '012 Patent. *Id.* at 39 (¶ 78). And he finds that unsurprising because "continued reliance on the '012 patent claims would very likely have resulted in their being held invalid for nonobviousness." *Id.*

Prof. Torrance's Rebuttal Report explains why he considered the validity of the '012 Patent even though plaintiffs withdrew their infringement claim based on this patent. He "fundamentally disagree[s]" with defendants' argument that a reasonable, competent, and experienced patent attorney would not have considered the infringement or validity of the '012 Patent when evaluating the likelihood of success in the Teva litigation. Doc. 2185-5 at 20–22

[30] As previously discussed, the Teva litigation refers to a lawsuit filed by Pfizer, through its subsidiaries, against Teva alleging that Teva's generic EpiPen infringed the EpiPen patent. Doc. 2169 at 3, 5 (Pretrial Order ¶¶ 6, 10, 31).

(Torrance Feb. 7, 2020 Rebuttal Expert Report ¶ 23). Instead, he explains, patents "in the same patent family can be, and often are, relevant to the interpretation of their co-familial patents." *Id.* So, he considered both the '012 and '432 patents because they "are members of the same patent family." *Id.* He notes that these two patents "share identical specifications." *Id.* Also, the two patents' prosecution histories "would have been relevant to the construction of claim elements in the '432 patent." *Id.* And, he observes that one of the Pfizer subsidiary plaintiffs made decisions in the past "about how to proceed with its infringement suits against Teva and Intelliject—both of which did, at one time, involve the '012 patent[.]" *Id.* Prof. Torrance opines that those earlier decisions "would be relevant to assessments of [the Pfizer subsidiary plaintiff's] decisions about how to proceed with its infringement suits against Teva and Intelliject, as of the dates of settlement in these litigations." *Id.*

After explaining all this, Prof. Torrance asserts that "[i]gnoring the '012 patent, which is a member of the same patent family of the '432 patent, its claims, and the prosecution history of its claims would violate proper claim construction procedures." *Id.* He opines that a "patent attorney who ignored such information would not be engaging in reasonable or competent practice." *Id.* Defendants' expert disagrees with this conclusion. But, on this *Daubert* motion, the court need not decide which expert is correct. *See Frederick v. Swift Transp. Co., Inc.*, 591 F. Supp. 2d 1149, 1155 (D. Kan. 2008) (Belot, J.) (explaining that in a "battle of the experts" over which opinion is correct, the court won't "credit one expert's opinion over the other" but instead leaves the decision "to the trier of fact to determine how much weight to give to each expert's opinions" (citation and internal quotation marks omitted)). Instead, the court's task here is to decide whether Prof. Torrance has provided a reliable methodology for reaching his conclusions. Prof. Torrance satisfies that requirement here. He has provided a reliable

explanation for why he considered the '012 Patent in his analysis. And, the court won't exclude his opinion for that reason.

Second, defendants argue that Prof. Torrance unreliably considered a 2011 and 2019 deposition transcript when he formed his opinion about Teva's likelihood of success at the time of the litigation's settlement in 2012. With the 2011 deposition transcript, defendants contend it was wrong for Prof. Torrance to consider this material. *See* Doc. 2153-2 at 60–61 (¶¶ 114–117) (discussing the August 2011 deposition of John G. Wilmot in the Teva litigation). Defendants assert that this deposition testimony wasn't part of the patent litigation record because none of the parties introduced it into evidence at the trial, and thus, neither the district court nor Federal Circuit would have considered it in an analysis of the case's merits. But, plaintiffs respond, this deposition transcript was part of the Teva discovery record, and it would have been available for the parties to evaluate when reaching the decision to settle the case in 2012. So, they argue, it is entirely proper for Prof. Torrance to consider this deposition testimony when evaluating the likelihood of success when the parties settled the Teva litigation in 2012.

With the 2019 deposition transcript, Prof. Torrance testified that he read the transcript and that it "helped [him] find some information" but he was clear that he didn't rely on that deposition transcript to form his opinions. Doc. 2153-3 at 34 (Torrance Dep. 282:19–283:9); *see also* Doc. 2185-5 at 22–23 (¶ 25) (explaining that he "did read the 2019 Wilmot deposition" but he "did not rely on the 2019 Wilmot deposition to come to conclusions for [his] Merits Report" and instead, his review of that deposition "helped put into context information that would have been available to 'a reasonable, competent, and experienced patent attorney' at the time of settlement, but that, due to the passage of time, is now more challenging to put into context").

Again, defendants' arguments here go to the weight the trier of fact should assign to his opinion. Although defendants disagree with Prof. Torrance's references to the 2011 and 2019 deposition transcripts, Prof. Torrance has provided a reasonable explanation why he reviewed the transcripts and how they fit into his analysis. Defendants are free to raise these challenges on cross-examination. But, defendants haven't shown that Prof. Torrance's methodology here is so unreliable that the court must exclude his expert testimony.

Third, defendants contend that Prof. Torrance unreliably discounts the Teva litigation record in favor of defenses and arguments that the parties never raised at trial. Defendants assert that Prof. Torrance relies on an inequitable conduct or unenforceability defense. Doc. 2153-1 at 21 (citing Doc. 2153-2 at 21–23, 28, 37 (¶¶ 38, 40, 49, 72)). But, as plaintiffs correctly respond, none of these paragraphs in Prof. Torrance's Expert Report discuss or even mention an inequitable conduct or unenforceability defense. Instead, plaintiffs assert, Prof. Torrance's Expert Report only considers the invalidity and non-infringement defenses asserted in the Teva litigation and factors those defenses into his likelihood of success analysis. Doc. 2153-2 at 39, 42–43, 51, 54–55, 58–59, 60–62 (¶¶ 78, 86–87, 100, 103–04, 109, 113, 117–18). Defendants' Reply comes back with a different citation to paragraphs in Prof. Torrance's Expert Report that, they contend, analyze an inequitable conduct or unenforceability defense. Doc. 2223-1 at 13 (citing Doc. 2153-2 at 35–36 (¶¶ 69–70)). But, these paragraphs merely discuss the actions taken by a Pfizer subsidiary in its patent prosecution. Prof. Torrance criticizes the actions as "careless" or "at worst" based on "a desire to postpone consideration by the examiner of potentially damaging prior art." Doc. 2153-2 at 36 (¶ 70). But he never asserts that these actions form the basis for an inequitable conduct or unenforceability defense. *Id.* And, his Expert Report never analyzes these defenses in the context of his opinion about the likelihood of success

in the Teva litigation. So, the court rejects defendants' argument that Prof. Torrance has relied on defenses and arguments that the parties never raised at trial because the contents of his Expert Report don't support that argument.

For the reasons discussed, Prof. Torrance has provided a reliable basis for considering certain facts and ignoring other facts that he found irrelevant to his analysis about the likelihood of success in the Teva litigation. Thus, the court finds, defendants' argument here provides no reason for the court to exclude Prof. Torrance's opinion on this topic.

B. Does Prof. Torrance Improperly Imply That He Performed Scientific, Validity, and Infringement Analyses When He Never Performed Such Analyses?

Next, defendants argue that Prof. Torrance's opinions are unreliable because he references analyses that, defendants contend, he never performed. Defendants make two arguments in this part of their motion seeking to exclude Prof. Torrance's opinions.

First, defendants argue that Prof. Torrance's use of percentage values and confidence intervals in his opinions about the likelihood of litigation success improperly invokes statistical terminology and concepts. Defendants say Prof. Torrance misappropriates these terms because he never performed any mathematical or statistical analysis when forming his opinions. So, defendants contend, Prof. Torrance's opinions pose a danger of misleading or confusing the jury because the terminology he uses may cause the jury to assume his analysis involves some kind of mathematical exactness when it actually does not. As a consequence, defendants assert that the court should exclude Prof. Torrance's opinions under Fed. R. Evid. 403.

A court may exclude relevant evidence under Rule 403 "if its probative value is substantially outweighed by a danger of . . . confusing the issues [or] misleading the jury . . . ." Fed. R. Evid. 403. Using Rule 403 to exclude otherwise admissible evidence is an

"extraordinary remedy" that "should be used sparingly." *Eisenhour v. County*, 897 F.3d 1272, 1277 (10th Cir. 2018) (citations and internal quotation marks omitted). The Tenth Circuit has instructed courts to "give the evidence its maximum reasonable probative force and its minimum reasonable prejudicial value" when "performing the [Rule] 403 balancing[.]" *Id.* (citation and internal quotation marks omitted).

Plaintiffs argue that the court shouldn't apply Rule 403's extraordinary remedy to Prof. Torrance's opinions. Plaintiffs assert that Prof. Torrance has provided reliable opinions about the likelihood of litigation success that, as previously discussed, he rendered after reviewing relevant materials from the underlying patent lawsuits and applying his knowledge and expertise about patent law to those facts to opine about the likely outcomes in the litigation. As the court already has explained, other courts have allowed patent law experts to provide similar opinions about the likelihood of success in patent litigation using methodologies that are similar to what Prof. Torrance used to reach his conclusions. *See In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 187–88 (S.D.N.Y. 2018) (allowing expert opinion where the expert had "the expertise to evaluate the things he assessed—from expert reports to patent file folders—and to draw conclusions about who is more likely to win a patent lawsuit"); *see also In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-md-02503, 2018 WL 563144, at *16 (D. Mass. Jan. 25, 2018) (permitting expert to testify "based upon his own expertise and experience in the field of patent law" about "likelihood of success in patent litigation"); *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 765–67 (E.D. Pa. 2015), *aff'd on other grounds*, 868 F.3d 132 (3d Cir. 2017) (finding that a patent law professor was "a qualified expert offering appropriate expert testimony" where he reviewed relevant materials from the underlying litigation and applied his expertise to opine about the likelihood of litigation success).

Defendants argue that these cases differ because the experts there didn't use a "holistic" analysis to evaluate likelihood of success as, they assert, Prof. Torrance uses to render his opinions. The court disagrees for reasons already discussed in Part VII.A.1., above. Although none of the experts in those cases referred to the analysis as a "holistic" one, the experts used methodologies similar to what Prof. Torrance uses here—*i.e.*, reviewing the relevant litigation materials and applying knowledge and expertise about patent law to those materials to opine about the likelihood of success. *See In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d at 187–88 (allowing opinion where expert used his "expertise" in patent law to "evaluate" patent litigation materials "from expert reports to patent file folders" and then "draw conclusions about who is more likely to win a patent lawsuit"); *see also In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2018 WL 563144, at *16 (permitting expert opinion that relied on a review of the technical experts' conclusions and then applied "his own expertise and experience in the field of patent law" to offer an opinion about "likelihood of success in patent litigation"); *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d at 765–67 (allowing expert opinion by patent law professor who reached his conclusions about the likelihood of litigation success after "review of the briefs, pleadings, ANDA, and underlying patent at issue in the . . . litigation"). For the same reasons that other courts have found sound the methodologies patent experts have used to opine about the likelihood of litigation success, the court finds Prof. Torrance's methodology reliable here.

And, although Prof. Torrance uses no mathematical formula or statistical analysis to render his opinions, the court can't find that the terminology he uses is so misleading or confusing that it "substantially" outweighs the probative value of his opinions. As plaintiffs correctly argue, defendants can address any concerns about Prof. Torrance's terminology

through cross-examination and by introducing into evidence their own experts' opinions. *See In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2018 WL 563144, at *16 (denying motion to exclude expert opinion about "likelihood of success in patent litigation" and noting that "[t]o the extent Defendants seek to challenge [the expert's] conclusions [about] the likely outcome of the patent challenges, they may do so with their own expert testimony—as they have proposed to do"); *see also In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d at 188 (denying motion to exclude expert opinion and recognizing that defendants can challenge the opinion by cross-examining the expert about his "evaluation of technical material" and by "offering the testimony of its own expert"). So, the court finds, Prof. Torrance's use of certain terminology doesn't render his opinions so misleading or confusing that the court must exclude them under Fed. R. Evid. 403.

Second, defendants argue that the court should exclude Prof. Torrance's opinions because his Expert Report fails to explain how he construed the patent claims or how he analyzed the prior art to reach his conclusions about the likelihood of patent litigation success. Plaintiffs respond with a litany of specific citations to Prof. Torrance's Expert Report where, they argue, he construed the patent claims and analyzed prior art to formulate his opinions. The court agrees with plaintiffs. Paragraphs 91 through 117 of Prof. Torrance's Expert Report contain his analysis of the elements of Claims 19, 20, and 21 of the '432 Patent. Doc. 2153-2 at 46–61 (Torrance Oct. 31, 2019 Expert Report ¶¶ 91–117). Prof. Torrance discusses in detail certain patent claim elements, including "drive the needle," "first locked retraced position," "kickback," and "transfer of the residual force to the needle cover." *Id.* at 49–59 (¶¶ 96–103, 105–109). With each of these patent claim elements, Prof. Torrance analyzes the construction of these elements in the context of the claims themselves and the patent's specification, and in some

cases, he considers the prosecution history (or lack thereof) and extrinsic evidence such as dictionary definitions and trial testimony. *See id.* And, in paragraph 118, Prof. Torrance discusses the prior art and how that prior art is relevant to the patent's invalidity by anticipation or obviousness. *Id.* at 62 (¶ 118). These portions of the Expert Report show that Prof. Torrance offers a reliable explanation how he construed the patent claims and how he analyzed the prior art as part of his analysis of determining the likelihood of litigation success. To the extent defendants challenge how Prof. Torrance performed that analysis, those arguments go to the weight of his testimony, not its admissibility. *Kumho Tire*, 526 U.S. at 153 (explaining that expert opinion is admissible when it falls within "the range where experts might reasonably differ, and where the jury must decide among the conflicting views of different experts, even though the evidence is 'shaky'" (quoting *Daubert*, 509 U.S. at 596)). And, defendants properly may raise those challenges through cross-examination or by presenting evidence contradicting Prof. Torrance's conclusions. *Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.") But, defendants' attacks here don't warrant excluding Prof. Torrance's opinions.[31]

[31] This section of defendants' brief makes a passing argument in a footnote that the court should exclude Prof. Torrance's opinions because he "asserts certain invalidity and infringement opinions, despite not being qualified as a person of ordinary skill in the art ('POSITA') of the patents at issue, and without relying on the testimony of any POSITA expert to support his conclusions." Doc. 2153-1 at 25 n.54. Plaintiffs' Response doesn't respond to this argument, and defendants' Reply never mentions it. Our Circuit instructs that "[a]rguments made in a perfunctory manner, such as in a footnote, are waived." *United States v. Hardman*, 297 F.3d 1116, 1131 (10th Cir. 2002); *see also Therrien v. Target Corp.*, 617 F.3d 1242, 1253 (10th Cir. 2010) ("Many courts have . . . held that an argument made only in a footnote of an appellate brief is waived." (citation and internal quotation marks omitted)); *United States v. Zabokrtsky*, No. 5:19-cr-40089-HLT-1, 2020 WL 1082583, at *3 n.4 (D. Kan. Mar. 6, 2020) ("Arguments raised in a footnote are not properly before the Court."); *Fish v. Kobach*, No. 16-2105-JAR, 2016 WL 6125029, at *3 (D. Kan. Oct. 20, 2016) (holding argument was "waived" because "plaintiffs raised this argument 'in a perfunctory manner' and in a footnote" (quoting *Hardman*, 297 F.3d at 1131)). Because defendants raise in a perfunctory manner their argument that Prof. Torrance's opinions are inadmissible because he fails to rely on a POSITA expert—*i.e.*, by asserting the argument in a footnote in their opening

For all the reasons discussed, the court rejects each of the arguments presented by defendants' Motion to Exclude Plaintiffs' Patent Litigation Expert. So, the court denies defendants' request to exclude the merits expert opinions of Prof. Torrance.

IX. Defendants' Motion to Exclude Plaintiffs' Rebuttal Report Regarding the '827 Patent (Doc. 2156)

Last, defendants move the court to exclude the rebuttal report that plaintiffs' expert offers about the '827 Patent. Plaintiffs have retained Prof. Andrew Torrance to provide a separate set

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brief and never mentioning it in their Reply—the court could decline to address it here. Nevertheless, the court explains that this argument, even when considered in full, doesn't require the court to exclude Prof. Torrance's opinions about the likelihood of litigation success.

In the following section, *infra* Part IX., the court addresses the POSITA argument more fully because the parties actually have briefed the issue as it pertains to the question whether Prof. Torrance may offer opinions rebutting Charles E. Clemens's opinions whether the Teva generic likely infringed the '827 Patent. As discussed below, the court finds Prof. Torrance isn't qualified to offer those opinions because he's not a POSITA. But this ruling doesn't require the court to exclude Prof. Torrance's opinions on the likelihood of patent litigation success. Here, Prof. Torrance offers his opinions as a qualified expert—a patent lawyer and professor—about the litigants' chances of success in underlying patent litigation. Defendants cite no case law, and the court has found none in its own research, that require a POSITA to render that type of expert opinion involving the chances of litigation success. In fact, other courts have reached the opposite conclusion when addressing this same challenge targeted at lawyers offering opinions about patent litigation success. *See, e.g.*, *In re Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d 274, 306 (D.R.I. 2019) (rejecting argument that expert "improperly opines about materiality, the significance of prior art references, and technical patent issues; opinions that may only come from a person of ordinary skill in the art" when expert offered opinions "directed to how a patent attorney in the field would have evaluated the prosecution of the '394 patent and what advice and opinions a patent attorney would have given to his or her client regarding that prosecution and the related litigation" and recognizing that while only a POSITA "may opine on . . . technical patent law issues" the expert at issue "clearly [did] not do so" but instead offered opinions about how a patent attorney in the field would have evaluated the patent (citation and internal quotation marks omitted)); *In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 187 (S.D.N.Y. 2018) (denying motion to exclude expert testimony based on an argument that a lawyer was not a chemist, and thus, not a POSITA qualified to opine about patent infringement and validity because the expert was not opining that the patent is invalid or that a generic competitor didn't infringe the patent but instead offered "a reasonable patent attorney's assessment of the likelihood that [the generic competitor] would win its patent case—exactly the sort of assessment he would have offered his client during the nearly two decades when he served as" in-house patent counsel (citation and internal quotation marks omitted)). For the same reasons discussed in the cited cases, the court declines to exclude Prof. Torrance's likelihood of patent litigation success opinions based on the argument that he's not a POSITA. Instead, his opinions on this topic properly opine about how a patent lawyer would evaluate the chances of litigation success and don't touch on technical patent issues for which he's not qualified to offer opinions.

of opinions from the ones offered in his Merits Expert Report. Prof. Torrance offers an Expert Rebuttal Report to the Expert Report of Charles E. Clemens, who defendants have retained to opine whether the Teva generic EAI likely infringed the '827 Patent.

As already discussed, the Teva litigation was a lawsuit filed by Pfizer, through its subsidiaries, against Teva alleging that Teva's generic EAI infringed the EpiPen's patents. Doc. 2169 at 3, 5 (Pretrial Order ¶¶ 6, 10, 31). In that lawsuit, the Pfizer subsidiaries argued that the Teva generic infringed two patents—the '012 Patent and the '432 Patent. *Id.* at 5 (Pretrial Order ¶¶ 31–32). After the Teva litigation concluded, the United States Patent and Trademark Office issued the '827 Patent to a Pfizer subsidiary. In defendants' Motion for Summary Judgment, they assert that the '827 Patent posed "a substantial risk of infringement" by the Teva generic EAI such that it affected Teva's ability to launch its generic EAI before June 2015 (the licensed entry date under the settlement agreement in the Teva litigation). Doc. 2142-1 at 79.

To support this theory of infringement at the summary judgment stage, defendants rely on Mr. Clemens's expert opinion. *See id.* (citing Doc. 2164-7 (Clemens Dec. 23, 2019 Expert Report)). Mr. Clemens is an engineer who founded a consulting business specializing in the design and development of medical devices. Doc. 2156-2 at 4 (Clemens Dec. 23, 2019 Expert Report ¶ 1). He opines "there is a substantial likelihood that Teva's EAI device infringes at least the following claims of the '827 Patent: independent Claims 1 and 22; and dependent Claims 5, 11, 18, 21, and 23." *Id.* at 6 (¶ 13). Also, he "conclude[s] that there is a substantial likelihood that Teva's EAI device, even after the December 2014 ANDA amendment, still infringes at least one independent claim of the '827 Patent (Claim 22)." *Id.* (¶ 14).

Plaintiffs offer Prof. Torrance's Rebuttal Report to rebut Mr. Clemens's infringement analysis of the '827 Patent. Specifically, Prof. Torrance opines that Mr. Clemens's infringement

analysis is "faulty in a number of regards, including for not applying patent law correctly, for applying the incorrect standard of claim construction during his interpretation of the claims of the '827 patent, and for focusing largely on the time period after the *Teva* settlement." Doc. 2158-2 at 5 (Torrance Feb. 21, 2020 Rebuttal Report to Clemens Expert Report ¶ 4). And, he asserts "no reasonable, competent, and experienced patent attorney would carry out the infringement analysis [Mr. Clemens] did, nor conclude that there would be infringement of any valid and enforceable patent claim." *Id.*

Defendants argue the court should exclude Prof. Torrance's rebuttal opinions because he's not qualified to offer expert testimony whether the Teva generic EAI infringes the '827 Patent. And, defendants further contend, even if Prof. Torrance is qualified to render the expert opinions here, his opinions are inadmissible because they are unreliable and irrelevant. Because the court agrees with defendants' first argument, it need not address the second. The court explains, below, why it concludes that Prof. Torrance isn't qualified to offer rebuttal expert opinions in response to Mr. Clemens's infringement analysis of the '827 Patent.

A. Is Prof. Torrance Qualified to Offer His Rebuttal Opinions?

Defendants assert that Prof. Torrance isn't qualified to provide his rebuttal opinions that analyze whether the Teva generic EAI infringes the '827 Patent because he's not a person of ordinary skill in the art ("POSITA"). Defendants argue that "the issues of infringement or validity" are "analyzed in great part from the perspective of a" POSITA. *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1361 (Fed. Cir. 2008). But when an expert lacks "any suggestion of relevant technical expertise," the expert cannot offer testimony of infringement or validity issues because those issues "are exclusively determined from the perspective of ordinary skill in the art." *Id.*

Defendants argue that Prof. Torrance doesn't qualify as a POSITA here because he lacks the specialized engineering expertise to opine whether the Teva generic EAI infringes the '827 Patent. Indeed, Prof. Torrance testified that he's not a mechanical engineer. Doc. 2156-5 at 23–24 (Torrance Dep. 156:24–157:5). He doesn't have any degrees or certifications in engineering. Doc. 2158-2 at 43–44 (Ex. A (Prof. Torrance Curriculum Vitae)). And, he conceded that he's not an expert in the particular field of "mechanical engineering with respect to autoinjectors." Doc. 2156-5 at 16 (Torrance Dep. 70:15–21); *see also id.* at 36 (Torrance Dep. 213:1–6) (testifying that he "would not offer [himself] as an expert in mechanical engineering").

Also, Prof. Torrance testified that he doesn't fit the definition of POSITA that the parties to the Teva litigation agreed qualified an expert to opine about the '432 Patent—which, like the '827 Patent, claims an auto-injector device. *Id.* at 14 (Torrance Dep. 64:12–23); *see also id.* at 36 (Torrance Dep. 215:7–13) (testifying that Prof. Torrance wasn't "offering an opinion that [he is] a POSITA under either of [the] definitions" of POSITA in the Teva litigation but instead he was "hired as a patent law expert"). The parties to the Teva litigation agreed that an expert, to qualify as a POSITA capable of offering expert opinions about the '432 Patent, must have a degree in engineering or a related field and at least five years of experience in the engineering field. Doc. 2156-3 at 4 (Trial Tr. 234:16–235:14); Doc. 2164-4 at 10 (Trial Tr. 488:2–18). As already discussed, Prof. Torrance doesn't have those qualifications.

Plaintiffs don't put forth much of a response to this argument. Instead, plaintiffs emphasize that the court found Prof. Torrance qualified to render his opinions about the likelihood of litigation success at class certification. So, they argue, the court should find him qualified here to offer opinions that rebut Mr. Clemens's infringement analysis. This argument likens apples to oranges. At class certification, the court found Prof. Torrance qualified to render

expert opinions about the likelihood of litigation success in patent litigation. That ruling has nothing to do with the question whether Prof. Torrance is qualified to render rebuttal opinions to Mr. Clemens's infringement analysis of the '827 Patent at the merits stage of the case.

Also, plaintiffs don't address any of the case authority that defendants have cited. And they don't respond with any citations of their own where courts have permitted a lawyer—who is not a POSITA—to opine whether a patent is invalid or whether a device infringes a specific patent. Instead, plaintiffs concede that Prof. Torrance isn't a mechanical engineer. Doc. 2188-1 at 11. But, they argue this doesn't disqualify Prof. Torrance as an expert. To the contrary, plaintiffs contend that Prof. Torrance is qualified to render his rebuttal opinions about infringement because he's a lawyer and law professor with expertise in patent law. But, a patent lawyer may qualify to opine as a technical expert on issues of patent infringement or validity only if the expert has "such a qualification [that] derive[s] from a lawyer's technical qualifications in the pertinent art." *Sundance*, 550 F.3d at 1363. And, if an expert "lack[s] the relevant technical expertise[,]" the expert testimony "fails the standard of admissibility under Fed. R. Evid. 702." *Id.*; *see also id.* ("[W]here an issue calls for consideration of evidence from the perspective of one of ordinary skill in the art, it is contradictory to Rule 702 to allow a witness to testify on the issue who is not qualified as a technical expert in that art.").

Here, plaintiffs concede Prof. Torrance lacks the technical qualifications that would qualify him as a POSITA because he isn't a mechanical engineer and doesn't have relevant engineering experience. And, because he's not a POSITA, Prof. Torrance isn't qualified to opine whether Teva's generic EAI infringes the '827 Patent. So, the court excludes Prof. Torrance's opinions about the '827 Patent because he's not qualified to opine on this topic. *See Sundance*, 550 F.3d at 1364–65 (holding it was an "abuse of discretion" for a district court to permit a

patent attorney who was "a person not skilled in the pertinent art" to offer expert testimony because "[a]llowing a patent law expert without any technical expertise to testify on the issues of infringement and validity amounts to nothing more than advocacy from the witness stand"); *see also Union Carbide Corp. v. Am. Can Co.*, 724 F.2d 1567, 1572 (Fed. Cir. 1984) (concluding that a former patent lawyer who had "no expertise as to the scope of the field of endeavor of the inventions of the patents in suit or as to what other fields are analogous art" rendered an invalidity opinion that "expressed no more than an unsupported conclusory opinion" (citation and internal quotation marks omitted)).

Also, Prof. Torrance's rebuttal opinions here—whether a patent attorney would carry out the infringement analysis like Mr. Clemens did or whether a patent attorney would conclude that there was infringement of any valid and enforceable patent claim—aren't proper rebuttal to Mr. Clemens's opinions. Mr. Clemens offers opinions about the likelihood that the Teva generic EAI infringes the claims of the '827 Patent based on his review of the device and comparing it to the '827 Patent. Doc. 2156-2 at 6 (¶¶ 12–14). But, he doesn't offer any opinions about patent law or whether the Teva generic EAI device is liable under the law for infringing the '827 Patent. Indeed, plaintiffs' Response to the motion to exclude recognizes that Mr. Clemens's opinions offer "'a technical analysis of whether a device infringes patent claims[.]'" Doc. 2188-1 at 6 (quoting Doc. 2188-3 at 7 (Clemens Dep. 61:25–62:12)). And, Mr. Clemens's opinions don't consider whether "there [was] infringement" of the patent. *Id.* (quoting Doc. 2188-3 at 7 (Clemens Dep. 62:14–24)); *see also* Doc. 2188-3 at 7 (Clemens Dep. 62:14–24) (recognizing that "if there [was] infringement, that may have subsequent legal consequences, but that really has no relevance to the analysis of whether a device is infringing a particular claim in a patent"). So, Prof. Torrance's opinions don't rebut the opinions that Mr. Clemens offers—*i.e.*, a technical

analysis of the device compared to the patent claims. Thus, they aren't proper rebuttal opinions. *See* Fed. R. Civ. P. 26(a)(2)(D)(ii) (explaining that rebuttal expert opinions are "intended solely to contradict or rebut evidence *on the same subject matter* identified by another party" (emphasis added)). And, even if it was, Prof. Torrance isn't qualified to render those opinions because, as just discussed, he's not a POSITA.

The court also recognizes that Prof. Torrance's rebuttal opinions differ significantly from the opinions he offers in his Merits Expert Report. His Merits Expert Report opines about the chances of litigation success from the perspective of a reasonable, competent, and experienced patent attorney *at the time the parties settled the litigation*. His rebuttal opinion analyzes a patent issued *after* the Teva litigation ended and that never was the subject of litigation. Thus, unlike the opinions discussed in the section where the court found Prof. Torrance qualified to opine about the chances of patent litigation success, Prof. Torrance's analysis of the patent from the perspective of a patent lawyer isn't relevant to rebutting Mr. Clemens's opinion whether the Teva generic EAI infringed the '827 Patent because Mr. Clemens's opinion has nothing to do with analyzing litigation or the law that applies to patented devices.

For all these reasons, the court agrees with defendants. Prof. Torrance isn't qualified to render the opinions he offers as rebuttal to Mr. Clemens's infringement analysis of the '827 Patent because Prof. Torrance isn't a POSITA. The court thus grants defendants' motion to exclude Prof. Torrance's rebuttal opinions. And, it excludes Prof. Torrance from offering any opinions about the '827 Patent as rebuttal to Mr. Clemens's opinions.

X. Conclusion

As this Order has explained, the court rules each of the parties' motions seeking to exclude as follows:

IT IS THEREFORE ORDERED BY THE COURT THAT plaintiffs' Motion to Strike in Part the Testimony of Dr. John H. Johnson, IV (Doc. 2132-1) is denied.

IT IS FURTHER ORDERED THAT the Mylan defendants' portion of the Motion to Exclude the Testimony and Report of Plaintiffs' Expert Witness Einer Elhauge (Doc. 2133) is denied.

IT IS FURTHER ORDERED THAT the Mylan defendants' portion of the Motion to Exclude the Testimony and Report of Plaintiffs' Expert Witness Professor Meredith Rosenthal (Doc. 2134) is denied.

IT IS FURTHER ORDERED THAT the Mylan defendants' portion of the Motion to Exclude the Testimony and Report of Plaintiffs' Expert Witness Dr. Carl Peck (Doc. 2135) is granted in part and denied in part.

IT IS FURTHER ORDERED THAT the Mylan defendants' portion of the Motion to Exclude the Testimony and Report of Plaintiffs' Expert Witness James Bruno (Doc. 2136) is granted.

IT IS FURTHER ORDERED THAT the Mylan defendants' portion of the Motion to Exclude Plaintiffs' Patent Litigation Expert (Doc. 2151) is denied.

IT IS FURTHER ORDERED THAT the Mylan defendants' portion of the Motion to Exclude Plaintiffs' Rebuttal Report Regarding the '827 Patent (Doc. 2156) is granted.

IT IS SO ORDERED.

Dated this 23rd day of June, 2021, at Kansas City, Kansas.

s/ Daniel D. Crabtree
Daniel D. Crabtree
United States District Judge