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 case involves a certified class action brought by consumers and third-party payors of the EpiPen. They allege that the Mylan and Pfizer defendants, who manufacture and sell 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.).

This matter comes before the court on the summary judgment motion filed by the Mylan defendants (Doc. 2141).[1] The Mylan defendants seek summary judgment against plaintiffs' remaining claims: (1) state antitrust conspiracy and monopolization claims asserted under certain state laws;[2] and (2) RICO claims asserted under 18 U.S.C. § 1962(c) & (d). Doc. 2169 at 42, 44–45 (Pretrial Order ¶¶ 4.a., 4.d.).

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[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 summary judgment motion filed by the Mylan defendants (Doc. 2141). 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.

[2] Plaintiffs assert their state antitrust claims under the laws of the following states: Alabama, California, Florida, Hawaii, Illinois, Kansas, Maine, Michigan, Minnesota, Mississippi,

The court has considered the parties' thorough and well-presented arguments. And, the court now is prepared to decide the motion for summary judgment.[3]

I. Undisputed Facts

The following facts are either uncontroverted, or, where genuinely controverted, are viewed in the light most favorable to the consumer class plaintiffs, the non-moving party opposing summary judgment. *Scott v. Harris*, 550 U.S. 372, 378–80 (2007).

Nebraska, Nevada, New Hampshire, New York, North Carolina, Tennessee, and Utah. Doc. 2169 at 2 n.3, 44–45 (Pretrial Order ¶¶ 1.d., 4.d.).

[3] Defendants' summary judgment motion asks "that a hearing be set for oral argument" on the motion "if the Court believes that would be helpful." Doc. 2141 at 2. Our court's local rule provides: "The court may set any motion for oral argument or hearing at the request of a party or on its own initiative." D. Kan. Rule 7.2. The court carefully has reviewed the parties' written submissions. And, the parties' papers have explained their positions quite effectively. The court finds that oral argument will not assist its work. Also, it concludes that ordering oral argument here would contradict Fed. R. Civ. P. 1. So, the court denies defendants' request to set the matter for oral argument.

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 summary judgment briefs as well as many of the exhibits submitted either supporting or opposing the summary judgment motion. 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 summary judgment 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 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 this information is quite stale—ranging in date from 2007 to 2017. The court finds that the public's right to access the entire contents of this Order to understand the summary judgment facts and the court's analysis of plaintiffs' antitrust claims and RICO claims outweighs any privacy interest that the parties assert over the information.

The Use of EAI Drug Devices to Treat Anaphylaxis

Anaphylaxis is a serious allergic reaction that can be life-threatening if not promptly and properly treated. Doc. 2165-1 at 2 (Defs.' Ex. 3).[4] Epinephrine is the only appropriate first-line treatment for anaphylaxis. Doc. 2142-5 at 8–9 (Defs.' Ex. 5). An epinephrine auto-injector ("EAI") is a device used to self-deliver a controlled dose of epinephrine. *Id.* at 9. EAIs have been available in the U.S. since the 1980s, when the EpiPen EAI first was approved by the FDA and marketed to consumers. Doc. 2169 at 4 (Pretrial Order ¶ 2.a.19.). But still, by 2007, fewer than one million of the 43 million patients who are at risk for anaphylaxis had access to an EAI. *Reviewing the Rising Price of EpiPens: Hearing Before the Comm. on Oversight and Gov't Reform H.R.*, 114th Cong. 17 (2016) (statements of Heather Bresch, CEO of Mylan), https://docs.house.gov/meetings/GO/GO00/20160921/105373/HHRG-114-GO00-Transcript-20160921.pdf (hereinafter, "Bresch Statements").[5]

Mylan Acquires the Rights To Market and Sell the EpiPen

In 2007, Mylan Pharmaceuticals, Inc. acquired Dey Pharma L.P. ("Dey"), which later was renamed Mylan Specialty. Doc. 2169 at 3 (Pretrial Order ¶¶ 2.a.7–8.). Dey had "the exclusive right and license to market, distribute and sell" EpiPen Auto-Injector in the United

[4] Plaintiffs don't controvert this statement of fact, but they argue that this exhibit is inadmissible hearsay for which no exception applies. Doc. 2190-1 at 20, 77; *see also* Doc. 2226-3 at 2 (discussing "SMF ¶ 1"). Defendants respond that the exhibit—a scholarly medical article—is admissible under the residual hearsay exception of Fed. R. Evid. 807. Doc. 2226-1 at 21. Even if defendants' cited exhibit doesn't qualify for admission under Rule 807, the parties have stipulated to the following factual statement that contains information almost identical to the fact supported by defendants' summary judgment exhibit: "Anaphylaxis is a life-threatening allergic reaction that can occur rapidly after exposure to an allergen." Doc. 2169 at 3 (Pretrial Order ¶ 2.a.14.).

[5] Plaintiffs have submitted the hearing's transcript as part of the summary judgment record. Doc. 2207-17 (Pls.' Ex. 349).

States under a Supply Agreement with Meridian Medical Technologies, Inc. ("Meridian"),[6] which manufactures EpiPen products. Doc. 2142-6 at 4, 6, 35 (Defs.' Ex. 7). So, since 2007, Mylan Specialty has marketed and sold EpiPen devices, which Meridian supplies under the Supply Agreement. Doc. 2169 at 3 (Pretrial Order ¶¶ 2.a.7., 2.a.11., 2.a.12.); *see also* Docs. 2142-6, 2142-7, 2142-8 (Defs.' Exs. 7, 8, & 9).

The 2010 Supply Agreement established a "Joint Commercial Committee" ("JCC") designed to streamline "distribution of EpiPen products." Doc. 2142-7 at 29 (Defs.' Ex. 8). The Agreement obligated Meridian to supply Mylan with the quantities of EpiPen products Mylan requested, for which Mylan compensated Meridian on a per-unit basis. *Id.* at 10, 17, & 42–44. Also, it requires Meridian to "prosecute and maintain any patents or patent applications" for EpiPen products. *Id.* at 27. Meridian held the "New Drug Application" ("NDA") for EpiPen and was thus responsible for filing advertising and promotional materials with the FDA until July 2013, when Pfizer transferred the NDA to Mylan. *See generally* Doc. 2142-10 (Defs.' Ex. 11).

As Mylan developed its branding strategy for EpiPen, it recognized that anaphylaxis was "[h]ighly prevalent but under-recognized and undertreated," that "[o]ne out of 25 people is at risk for anaphylaxis," that "1,500 people die from anaphylaxis each year," and that "5 out of 6 people at risk for anaphylaxis have not been prescribed an epinephrine injector[.]" Doc. 2142-11 at 7–8 (Defs.' Ex. 12).[7]

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[6] Meridian now is a subsidiary of Pfizer, Inc. Doc. 2169 at 3 (Pretrial Order ¶ 10). Pfizer acquired King Pharmaceuticals LLC ("King") and Meridian in 2011. *Id.* And now, Meridian and King are indirect wholly-owned subsidiaries of Pfizer, Inc. *Id.* (Pretrial Order ¶¶ 2.a.6., 2.a.10.). This Order refers to Pfizer, Meridian, and King collectively as "Pfizer" unless otherwise noted.

[7] Plaintiffs assert that this exhibit constitutes inadmissible hearsay to which no exception applies. Doc. 2190-1 at 77. Defendants respond that this document is admissible under the business records exception to hearsay under Fed. R. Evid. 803(6). Doc. 2226-1 at 21. Defendants have the better argument because this exhibit—an internal Mylan document—appears to qualify as a business record under the hearsay exception of Fed. R. Evid. 803(6).

Mylan developed a marketing strategy designed to expand anaphylaxis awareness by focusing on schools. Doc. 2142-12 at 77 (Defs.' Ex. 13).[8] When Mylan acquired Dey, some state laws barred schools from keeping EAIs not prescribed to a particular child and prohibited school personnel from administering an EAI to a child who did not have a prescription, even in an emergency. *Id.* Mylan cites two examples where these prohibitions produced tragic and preventable consequences. *See* Noreen S. Ahmed-Ullah, *Epinephrine Bill Sparked By Death of CPS Student Passes Legislature*, Chi. Trib., May 18, 2011, https://bit.ly/2ZU3gSv (describing the death of a seventh-grader who had an anaphylactic episode after eating food served at a classroom party and didn't have access to epinephrine); *see also* Emma Brown, *Virginia First-grader Ammaria Johnson Dies After Allergic Reaction*, Wash. Post, Jan. 5, 2012, https://wapo.st/2Ze2roH (reporting the death of a first-grader who had an allergic reaction at

[8] Like the exhibit discussed in the preceding footnote, plaintiffs assert that defendants' Exhibit 13 is inadmissible hearsay. Doc. 2190-1 at 77. Indeed, plaintiffs assert that more than 150 of defendants' exhibits are inadmissible hearsay. *See id.* Defendants respond that Exhibit 13—along with hundreds of others of their summary judgment exhibits—are admissible under the business records exception to the hearsay rule under Fed. R. Evid. 803(6). Doc. 2226-1 at 21; *see also* Doc. 2227-1 at 11–12 (Cuthbertson Decl.). Each of these exhibits that defendants cite as admissible under Fed. R. Evid. 803(6) are internal Mylan records. For the same reasons discussed above, *supra* note 7, the court finds that Exhibit 13—as well as the other, challenged exhibits that are internal Mylan business records—are admissible under Fed. R. Evid. 803(6)'s business records exception to the hearsay rule.

Also, the court finds plaintiffs' blanket hearsay objections to Mylan documents disingenuous. Plaintiffs themselves rely on many Mylan-produced business records to support their asserted summary judgment facts. For example, plaintiffs assert a hearsay objection to defendants' Exhibit 100. *See* Doc. 2190-1 at 77 (objecting to defendants' Exhibit 100 (Doc. 2167-2)). And, with their blanket hearsay objection, plaintiffs assert: "At the very least, *the Court should not consider any of the exhibits and other documents specifically identified in this paragraph* because Defendants failed to meet their burden of showing the documents' admissibility at trial." *Id.* (emphasis added). Incredibly, while plaintiffs ask the court to ignore defendants' Exhibit 100 (and hundreds of other documents defendants submitted as summary judgment exhibits), plaintiffs also cite the very same document to support one of their summary judgment facts. *See* Doc. 2190-1 at 69 (Statement of Additional Material Fact ¶ 147) (citing Pls.' Ex. 322 (Doc. 2207-14 at 2–15)). This is not the only example. The court identifies more in footnotes below. Plaintiffs provide no explanation for why they contend the court should consider their proffered exhibits as admissible evidence under the Federal Rules of Evidence but simultaneously preclude defendants from offering the very same evidence on summary judgment. The court is unimpressed with plaintiffs' tactic. The only thing it has accomplished is complicating the court's work.

school and didn't have access to epinephrine).[9] So, Mylan worked to pass legislation in every state allowing schools to maintain epinephrine not prescribed to a particular student and permitting school personnel to administer epinephrine to anyone experiencing an anaphylactic emergency. Doc. 2142-12 at 77 (Defs.' Ex. 13). Forty-eight states adopted this legislation, and in 2013, President Obama signed the School Access to Emergency Epinephrine Act, which encouraged schools to keep epinephrine (whether an EpiPen or some other EAI) on-hand.[10] Plaintiff's expert, allergist Dr. Jay Portnoy, agreed that this legislation providing access to epinephrine in schools is a "good thing." Doc. 2165-4 at 18 (Defs.' Ex. 14) (Portnoy Dep. 139:7–12). Also, several named plaintiffs in this lawsuit agree this legislation was a "good idea." *See, e.g.*, Doc. 2165-5 at 7 (Defs.' Ex. 15) (Bowersock Dep. 107:8–23); Doc. 2165-6 at 3–4 (Defs.' Ex. 17) (Wemple Dep. 237:25–238:6); Doc. 2165-7 at 8–9 (Defs.' Ex. 18) (Beaulieu Dep. 102:14–103:14).

In August 2012, Mylan launched the EpiPen4Schools® Program, which made free EpiPen devices available—"with no strings attached"—to K–12 schools across the United States. Doc. 2143-3 at 10–11 (Defs.' Ex. 21) (Bresch Dep. 129:6–130:24); *see also* Doc. 2142-5 at 25–26 (Defs.' Ex. 5). By 2017, Mylan had donated more than one million EAIs through this

[9] Defendants cite these news reports, but don't attach them as exhibits to their summary judgment motion. Plaintiffs complain that these two news reports—along with some 56 other documents that defendants have cited to support their summary judgment facts—aren't attached as exhibits to their summary judgment motion. Doc. 2190-1 at 76–77. And, plaintiffs argue that the unattached exhibits are inadmissible hearsay for which no exception applies. *Id.* To the extent plaintiffs challenge defendants' citation to these news articles because they aren't attached as summary judgment exhibits, *see id.* at 76–77, the court rejects that challenge because plaintiffs also don't controvert the summary judgment facts cited in this statement of fact, *see id.* at 20. Also, the court rejects plaintiffs' hearsay challenge because defendants don't offer these news articles to prove the truth of the matters asserted. Instead, they offer them to show the information—true or not—that Mylan considered when deciding how to sell and market the EpiPen. Thus, these exhibits don't qualify as hearsay under Fed. R. Evid. 801(c). *See infra* n.12.

[10] The citation defendants provide for this statement of fact is no longer available online, but plaintiffs don't controvert this fact. So, the court accepts it for this summary judgment motion.

program. Doc. 2142-5 at 25 (Defs.' Ex. 5). Patients have used these donated devices more than 2,000 times to treat anaphylaxis in schools, accounting for up to 60% of the EAIs used in the participating schools. *Id.* Mylan's costs associated with this program totaled $71 million in the first four years alone. Doc. 2143-4 at 2 (Defs.' Ex. 22).

Mylan implemented another marketing strategy in October 2009, when it launched the "Next Generation Auto-injector ('NGA')." *Dey Launches and Unveils Next-Generation, Needle-Protected EpiPen(R) (Epinephrine) Auto-Injector with Enhanced Patient-Friendly Features*, Mylan (Oct. 26, 2009), https://bit.ly/38HRzCD.[11] The NGA had several new features—including built-in needle protection—which made it the first EAI with no exposed needle before and after use. *See id.*; *see also* Doc. 2143-5 at 2 (Defs.' Ex. 23). Other new features included an ergonomically designed barrel to prevent the device from rolling out of reach during an emergency, a flip-top case for single-handed removal, and bright orange colors and arrows to help identify quickly the needle end of the device and to make the product more usable for people who are color-blind. Doc. 2143-5 at 2–3 (Defs.' Ex. 23); Doc. 2143-6 at 2–3 (Defs.' Ex. 25); Doc. 2143-8 at 4, 7 (Defs.' Ex. 27).

EpiPen Pricing

Mylan reported in a securities filing that during 2008—the first full year after it acquired Dey—the net product profitability of EpiPen was $1 per device, and in 2009 that number increased to $2. Mylan N.V., Current Report (Form 8-K), Ex. 99.1 (Sept. 26, 2016), https://www.sec.gov/Archives/edgar/data/1623613/000119312516719397/d265624dex991.htm.

[11] This fact is tied to another public record—a press release—that defendants didn't attach as a summary judgment exhibit. To the extent plaintiffs object to this citation, the court rejects that objection. This press release is publicly available online, and likely qualifies as a Mylan business record that is admissible under Fed. R. Evid. 803(6)'s exception to the hearsay rule.

A Mylan executive testified that the EpiPen franchise was "very undervalued" when Mylan acquired its rights. Doc. 2143-11 at 5 (Defs.' Ex. 30) (Graybill Dep. 71:10–12). And, Joshua Parks, defendants' pricing expert, opines that as late as 2009, EpiPen products likely were "not . . . sufficiently profitable to justify [their] continued promotion at a major drug company." Doc. 2143-12 at 32 (Defs.' Ex. 31) (Parks Expert Report ¶ 72).

Between 2009 to 2016, Mylan Specialty periodically increased the EpiPen's Wholesale Acquisition Costs ("WAC"). Doc. 2143-14 at 5 (Defs.' Ex. 33) (Graham Dep. 67:5–10); Doc. 2143-12 at 16–28 (Defs.' Ex. 31) (Parks Expert Report ¶¶ 33–63). The WAC is a list price that manufacturers charge wholesalers. Doc. 2143-12 at 15–16 (Defs.' Ex. 31) (Parks Expert Report ¶ 32). The WAC is not the price that consumers or health plans pay for pharmaceutical products. *Id.* Mylan Specialty's largest WAC increase for EpiPen products (on a percentage basis) occurred in October 2009, when Mylan Specialty launched the Next Generation Auto-injector. *Id.* at 16 (Parks Expert Report ¶ 34). EpiPen's WAC increased by 20.1%. *Id.*; *see also* Doc. 2143-13 at 2 (Defs.' Ex. 32). Mylan Specialty's President testified that Mylan—not Pfizer—made EpiPen pricing decisions unilaterally. Doc. 2142-9 at 10 (Defs.' Ex. 10) (Graham Dep. 103:12–17).

Mylan CEO Heather Bresch's Congressional Testimony

In September 2016, Mylan CEO Heather Bresch testified before the House Committee on Oversight and Government reform. Bresch Statements, 114th Cong. at 17–22. Ms. Bresch testified about Mylan's efforts to improve access to EAIs. *Id.* at 17–18. She explained:

> Before Mylan acquired the company that owned EpiPen in 2007, fewer than 1 million of the 43 million people at risk had access to an epinephrine auto-injector. At the same time, it was estimated that anaphylaxis was causing 1,500 deaths annually. We've read stories of children dying at school because they did not have access to an epinephrine auto-injector or due to a lack of education about the need. We saw this as an unacceptable and largely preventable health problem.

> We've worked diligently and invested to enhance EpiPen and make it more available. In fact, we have invested more than $1 billion in these efforts over the last few years and have succeeded on many fronts. We put an improved EpiPen device on the market in 2009. We now reach 80 percent more patients. And today, approximately 85 percent of EpiPen patients pay less than $100 for two and a majority less than $50.

Id. at 17–18.

Ms. Bresch also testified about the EpiPen4Schools® program and explained how Mylan had used this program to donate free EpiPens "with no strings attached." *Id.* at 18. And, Ms. Bresch testified that the $608 WAC per two-pack was not the actual "pricing of EpiPens" or what Mylan profited from each EpiPen sale. *Id.* at 18, 21. She explained that Mylan's actual profit per EpiPen device is "approximately $50 per pen." *Id.* at 21. Also, Ms. Bresch testified, "[o]ver the last decade, Mylan's medicines have reduced the U.S. healthcare costs by approximately 180 billion." *Id.* at 17.

As a supplement to Ms. Bresch's testimony, Mylan provided Congress a profitability analysis for EpiPen that applied a 37.5% tax rate. Doc. 2208-20 at 2 (Pls.' Ex. 353). Mylan's securities filings show that Mylan had a negative effective tax rate in the U.S. in 2015 and 2016. Doc. 2207-19 at 142 (Pls.' Ex. 352). Following the congressional hearing, 17 members of the United States Senate noted that Ms. Bresch's testimony about EpiPen profits was based on "calculations [that] included an *undisclosed* 37.5% tax rate—which reduced [Mylan's] reported profits by 60%." Doc. 2205-7 at 2 (Pls.' Ex. 354). Using the 37.5% tax rate to calculate Mylan's profits reduced its annual profits by $264 million. Doc. 2207-22 at 3 (Pls.' Ex. 356).

Of the "one billion dollars" that Ms. Bresch testified Mylan had invested to enhance the EpiPen and make it more available, $879 million was spent on marketing and selling the EpiPen. Doc. 2194-17 at 9, 16 (Pls.' Ex. 118). And, a letter signed by 17 Senators noted that "Mylan's My EpiPen Savings Card and Patient Assistance Program do not help the vast majority of

EpiPen users." Doc. 2205-7 at 3 (Pls.' Ex. 354). The 17 Senators also criticized Ms. Bresch for her "lack of information and lack of clarity" in her September 12, 2016 response to the Senators' letter addressing EpiPen price increases, as well as her "insistence that [she was] not aware of the basic facts about sale of [Mylan's] own drug[.]" *Id.* at 2.

Before Ms. Bresch gave her testimony to Congress, Mylan had issued a press release on August 24, 2016. Doc. 2206-2 (Pls.' Ex. 3). The press release quoted Ms. Bresch as stating: "Patients deserve . . . price transparency[.]" *Id.* at 2. And, Ms. Bresch suggested Mylan was "addressing" this "problem" with its "actions" that day. *Id.* The press release also asserted that 80% of patients paid "nothing out of pocket" for EpiPen products. *Id.*

Ms. Bresch's compensation from Mylan includes a "long-term incentive" that compensates her based on the company's performance using "several metrics" including "earnings." Doc. 2194-9 at 3 (Pls.' Ex. 109) (Bresch Dep. 43:13–45:7).

The Medical Guidance about Repeat Doses of Epinephrine

In December 2010, the National Institute of Allergy and Infectious Diseases ("NIAID")—a division of the National Institutes of Health ("NIH"), who conducts and supports research relating to infectious, immunologic, and allergic diseases—published "Guidelines for the Diagnosis and Management of Food Allergy in the US: Report of the NIAID-Sponsored Expert Panel" ("NIAID Guidelines"). Doc. 2165-10 at 6 (Defs.' Ex. 34).[12] Dr. Anthony Fauci—

[12] Plaintiffs assert that this exhibit is inadmissible hearsay for which no exception applies. Doc. 2190-1 at 20. Plaintiffs make this same objection to more than 40 of defendants' exhibits—many of which are scholarly medical articles. *Id.* Defendants respond that each exhibit is admissible under the residual hearsay exception of Fed. R. Evid. 807. Doc. 2226-1 at 21. Rule 807(a) provides an exception permitting the admission of hearsay evidence if "(1) the statement is supported by sufficient guarantees of trustworthiness . . . and (2) it is more probative on the point for which it is offered than any other evidence that the proponent can obtain through reasonable efforts." Fed. R. Evid. 807(a). The parties haven't provided the court enough information here to determine whether the scholarly medical articles at issue satisfy both requirements of Rule 807's residual exception. And, as our court has noted before, "scholarly articles, standing alone, contain inadmissible hearsay and have limited utility under the Federal Rules of

Evidence." *In re Universal Serv. Fund Tel. Billing Pracs. Litig.*, No. 02-MD-1468-JWL, 2008 WL 1884125, at *2 (D. Kan. Apr. 25, 2008).

Nevertheless, the court considers the scholarly articles because they aren't hearsay evidence in the context of this summary judgment motion. The Federal Rules of Evidence define hearsay as "a statement that: (1) the declarant does not make while testifying at the current trial or hearing; and (2) a party offers in evidence *to prove the truth of the matter asserted in the statement*." Fed. R. Evid. 801(c). But, statements that are offered for purposes other than proving the truth of the matter asserted don't count as hearsay. *See, e.g.*, *Faulkner v. Super Valu Stores, Inc.*, 3 F.3d 1419, 1434–35 (10th Cir. 1993) (holding that statements about job applicants' bad conduct wasn't hearsay because they weren't offered to prove the truth of the matter asserted but instead offered to establish the employer's state of mind when it decided not to hire applicants); *Allen v. Montgomery*, 728 F.2d 1409, 1412 (11th Cir. 1984) (recognizing that newspaper articles about jury sequestration during a criminal trial "were not objectionable as hearsay because they were not offered to prove the truth of the matter asserted—that the jury stayed with the sheriff" but instead were offered "to establish . . . pretrial publicity"); *Eaton v. Harsha*, 505 F. Supp. 2d 948, 952–53 nn. 4 & 6 (D. Kan. 2007) (Robinson, J.) (finding that statements made to a police chief by members of the public who had complained that two police officers had made offensive and racially insensitive comments were not hearsay because statements weren't offered to prove the truth of the matters asserted by the complaints—*i.e.*, that the police officers' comments were offensive and racially insensitive—but instead to show that the police chief had received complaints from community members). In short, a statement that is offered to show its effect on the listener isn't hearsay because it isn't offered to prove the truth of the matter asserted—*i.e.*, to prove the truth of the contents of the declarant's statement—but instead is offered to prove how the statement affected the person who heard the statement. *See United States v. Smalls*, 605 F.3d 765, 785 n.18 (10th Cir. 2010) (holding that statements weren't inadmissible hearsay when "they are not offered to prove the truth of the matter asserted, but rather are offered to establish their effect on [the listener] and provide context for his statement"); *see also Schindler v. Seiler*, 474 F.3d 1008, 1010 (7th Cir. 2007) (explaining that "a statement offered to show its effect on the person who heard the statement is not hearsay" (citing *United States v. Robinzine*, 80 F.3d 246, 252 (7th Cir. 1996)).

Here, defendants don't offer the scholarly articles to prove that their contents are true. Instead, defendants offer them as evidence of the relevant medical guidance about anaphylaxis and the proper treatment for that condition that Mylan asserts it considered when marketing and selling the EpiPen. To illustrate the principle, defendants don't offer the NIAID Guidelines to prove the truth of the Guidelines' contents about appropriate treatment of anaphylaxis or the number of epinephrine doses required to treat an anaphylactic reaction. Instead, defendants offer the NIAID Guidelines to show how they affected Mylan and its decision to discontinue selling single EpiPens and switch to selling EpiPens exclusively in a 2-Pak. So, because defendants don't offer the NIAID Guidelines to prove the truth of the matter asserted, the exhibit isn't hearsay. And, plaintiffs provide no other reason to exclude it from the summary judgment evidence.

Moreover, the court observes that plaintiffs object to many of defendants' exhibits as inadmissible hearsay, but then they turn around and rely on those same documents to support their statements of additional material facts. *Compare* Doc. 2190-1 at 77 (objecting to defendants' Exhibits 34, 36, 38–48 as inadmissible hearsay) *with id.* at 39 (relying on defendants' Exhibits 34, 36, 46, 47, & 48 to support plaintiffs' Statement of Additional Material Fact ¶ 12). Plaintiffs' blanket hearsay objections—which the court has attempted to address thoroughly in this order—have increased the court's work substantially. And, plaintiffs' practice of objecting to exhibits that they also rely on as summary judgment evidence appears to contravene Rule 1's directive to the parties to "employ[ ]" the Federal

Director of NIAID—explained that "[t]he Guidelines were developed over a 2-year period through the combined efforts of an Expert Panel and Coordinating Committee representing 34 professional organizations, federal agencies, and patient advocacy groups." *Id.* at 5. Each member of the Expert Panel was vetted by the NIAID for financial conflicts of interest and approved by the Coordinating Committee. *Id.* at 7.

The NIAID Guidelines assert that "repeated dosing" of epinephrine "may be required" to treat anaphylaxis. *Id.* at 41. The Guidelines describe that "[r]eports of patients receiving epinephrine for food-induced or nonfood-induced anaphylaxis note that as high as 10% to 20% of individuals who receive epinephrine will require more than 1 dose before recovery of symptoms." *Id.* And, the NIAID Guidelines explain, "it is impossible to predict the severity of any subsequent reactions with accuracy." *Id.* at 43. So, the NIAID Guidelines recommend that "[a]ll patients experiencing anaphylaxis should be provided directly with an epinephrine auto injector or, if this is not possible, with a prescription (recommended prescription is for 2 doses of epinephrine), and advised to fill it immediately." *Id.*; *see also id.* at 40 (recommending as therapy for patient at discharge an EAI "prescription (2 doses) and instructions").

But also, the NIAID Guidelines "did not specifically address whether, let alone recommend that, all patients should carry two doses of epinephrine at all times." Doc. 2206-3 at 11 (Pls.' Ex. 5) (Portnoy Expert Report ¶ 24). The NIAID Guidelines "are specific to food allergy and were intended for use by health care professionals." *Id.* (citation, internal quotation marks, and ellipses omitted); *see also* Doc. 2165-10 at 9 (Defs.' Ex. 34) ("The Guidelines are intended to assist health care professionals in making appropriate decisions about patient care in the United States."). Internally, Mylan recognized that the "NIAID guidelines are food

Rules of Civil Procedure—including Rule 56—"to secure the just, speedy, and inexpensive determination of every action and proceeding." Fed. R. Civ. P. 1.

specific[,]" but noted World Allergy Organization "guidelines are being published soon" that "will have a similar message" and will be "better to leverage[.]" Doc. 2193-15 at 11 (Pls.' Ex. 96).

Then, in February 2011, the World Allergy Organization ("WAO") published another set of anaphylaxis guidelines. Doc. 2165-11 at 2 (Defs.' Ex. 36). The WAO Guidelines state that "up to 23% of adults" will need "more than one epinephrine injection" for anaphylaxis and that "more than 2 doses are occasionally required." *Id.* at 23, 26. So, the WAO Guidelines suggest that medical providers "consider prescribing more than one epinephrine auto-injector." *Id.* at 26.

Plaintiffs' expert testified that it's "very hard to predict" whether "somebody with a food allergy" will need more than one dose of epinephrine. Doc. 2165-4 at 8 (Defs.' Ex. 14) (Portnoy Dep. 70:7–16). Medical researchers have identified various factors that may put patients at greater risk of needing more than one dose, but they have not identified any particular type of patient for whom a single dose is necessarily sufficient. *See, e.g.*, Doc. 2165-12 at 2 (Defs.' Ex. 38); Doc. 2165-13 at 2 (Defs.' Ex. 39); Doc. 2165-14 at 2 (Defs.' Ex. 40); Doc. 2165-15 at 2, 5–9 (Defs.' Ex. 41). But, both plaintiffs and defendants' experts opine that "a majority of patients will not need a second dose." Doc. 2190-7 at 3 (Pls.' Ex. 7) (Blaiss Dep. 27:12–16) (agreeing with Dr. Portnoy's conclusion that a majority of patients won't need a second dose).

Some patients whose initial experience with anaphylaxis is mild later may experience life-threatening anaphylaxis. Doc. 2165-10 at 19 (Defs.' Ex. 34). For example, one study of children "diagnosed with clinical hypersensitivity to peanut prior to the age of 4 years" found that of "patients who had an initial reaction that was not life-threatening and had a subsequent reaction, 44% (19 of 43) had potentially life-threatening reactions during at least 1 of these subsequent reactions." *Id.* Also, some patients may require more than one dose of epinephrine

for a variety of reasons: some might require a repeat dose to treat a severe allergic reaction, Doc. 2165-10 at 41 (Defs.' Ex. 34); others might experience a biphasic reaction which is the "complete clinical resolution of initial symptoms followed by onset of late-phase symptoms," Doc. 2165-17 at 2 (Defs.' Ex. 43);[13] some might have received an improperly administered first dose, Doc. 2165-18 at 2–7 (Defs.' Ex. 44); Doc. 2165-4 at 14–15 (Defs.' Ex. 14) (Portnoy Dep. 83:25–84:12); other patients with high body mass sometimes require more than one standard dose of epinephrine, Doc. 2143-16 at 21 (Defs.' Ex. 37) (Blaiss Expert Report ¶ 7.1); and some patients with certain mast cell diseases are at greater risk of severe anaphylaxis, which may require two doses to treat, Doc. 2165-19 at 6 (Defs.' Ex. 45).

Some medical guidance has recommended that patients at risk for anaphylaxis should carry two EAIs. *See* Doc. 2165-20 at 9 (Defs.' Ex. 46) ("Therefore, patients need to be prepared for possible recurrent anaphylaxis and should be given 2 auto-injectable epinephrine devices to carry with them at all times."); *see also* Doc. 2165-21 at 9 (Defs.' Ex. 47) ("Because anaphylactic episodes might require more than 1 dose of epinephrine, all patients should carry 2" EAIs.). But, none of the guidance mandates carrying two EAIs as "a medical necessity for patients at risk for anaphylaxis." Doc. 2190-7 at 4 (Pls.' Ex. 7) (Blaiss Dep. 40:13–25).

In 2017, the American Academy of Pediatrics ("AAP") published a Clinical Report stating that "[t]wo epinephrine autoinjectors should be available at all times, because a second administration may be needed if there is not a quick or adequate response to the first dose of epinephrine." Doc. 2165-22 at 5 (Defs.' Ex. 48). The Report also contains a disclaimer that the

[13] The "reported incidence of biphasic anaphylactic reactions varies from 1% to 20%" but typically are "mild, tend to be self-limited, and have not required additional epinephrine." Doc. 2164-17 at 2, 7 (Defs.' Ex. 43).

"guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care." *Id.* at 2.

The EpiPen 2-Pak

Starting in 2001, Dey (and later Mylan) sold EpiPen devices in two-packs and single-packs. Doc. 2143-3 at 12 (Defs.' Ex. 21) (Bresch Dep. 204:6–15). Some patients purchased EpiPens in two-packs or multiple single-packs per year (during the period when single-packs still were available). Doc. 2143-17 at 58 (Defs.' Ex. 49) (Johnson Report ¶ 84). Defendants' expert opines that consumers, before Mylan discontinued the EpiPen single-pack, "were opting to purchase, and doctors were prescribing, an increasing proportion of EpiPen two-pack products at a time." *Id.*

On November 24, 2010, Bruce Foster, a Senior Director at Mylan, emailed Ron Graybill, a Mylan Vice President, with a proposal to eliminate single-pack EpiPen sales. Doc. 2190-14 at 2 (Pls.' Ex. 15). The proposal provided two reasons for the elimination: (1) it would "double the revenue" per prescription, and (2) Mylan had a "[s]trong potential generic defense[.]" *Id.* at 5. It never mentioned medical guidance or patient safety as rationale for the strategy. *Id.* Mr. Graybill responded that the proposal was a "[g]reat idea" and recognized the potential to "double" sales. Doc. 2193-13 at 2 (Pls.' Ex. 94).

On January 6, 2011, a Mylan Project Manager emailed Bruce Foster about his "(genius) idea of removing the EpiPen single pack off the market" and working with him to manage the project in the coming year. Doc. 2193-14 at 2 (Pls.' Ex. 95). While Mr. Foster initially presented the idea of eliminating the EpiPen single-pack from the market, he didn't have authority to make that decision within Mylan. Doc. 2143-21 at 7 (Defs.' Ex. 53) (Foster Dep. 410:9–18); Doc. 2143-14 at 10 (Defs.' Ex. 33) (Graham Dep. 191:8–19). But, later that

month—in January 2011—Mylan put together a working group consisting of regulatory, medical, legal, and business personnel to consider "removing the single-pack EpiPen off the market[.]" Doc. 2143-19 at 5–6 (Defs.' Ex. 51). Mylan referred to the working group as "Project X2" or "Project Times Two." *Id.* at 4; *see also* Doc. 2143-21 at 3 (Defs.' Ex. 53) (Foster Dep. 28:19–20). No Pfizer employees were members of the Project X2 working group. Doc. 2165-23 at 4 (Kashtan Dep. 51:10–12).

On January 12, 2011, Mylan Manager Ivona Kopanja scheduled a Project X2 meeting. Doc. 2193-16 at (Pls.' Ex. 97). She explained the "purpose of the meeting is to evaluate EpiPen's opportunity around eliminating the single pack." *Id.* A presentation for the January 25, 2011 meeting noted the "compelling financial upside" for eliminating single EpiPen sales. Doc. 2190-12 at 6 (Pls.' Ex. 13). The presentation reported that the move to eliminate single EpiPens from the market could "[i]ncrease revenue by $81 million and gross profit by $41 million annually." *Id.* at 11. Also, the presentation noted that EpiPen was "still flying under the radar," such that the "[c]ombination of aggressive price increases plus sizing-up" that "may upset some payers" could be "smooth[ed] over" by "enhanced rebating" to "maintain preferred formulary position[.]" *Id.* at 16.

In a March 2011 email, Ms. Kopanja asked Project X2 Team member and Medical Director Ray Wolf: "I know that you were working on creating a 'medical' rationale for Project X2?" Doc. 2194-2 at 2 (Pls.' Ex. 102). In response, Mr. Wolf referenced the NIAID Guidelines, provided citations to medical literature, and noted that up "to 20% of patients have been reported to require a second dose of epinephrine, either due to ongoing symptoms or a biphasic reaction." Doc. 2226-7 at 2 (Defs.' Ex. 378).

In an April 2011 email, Mylan COO W. Lloyd Sanders reported internal concerns that removing single EpiPens from the market was "inconsistent with the guidelines." Doc. 2194-3 at 2 (Pls.' Ex. 103). But, after Mylan CEO Heather Bresch "learned that the co-pay that 'most' patients pay is the same for a single as it is for a two-pack, she became VERY motivated to pull the singles[.]" *Id.*

In minutes from later meetings of the Project X2 Team, Mylan cited the medical guidance advising that patients at risk for anaphylaxis carry two EAIs at all times as the "medical rationale" for discontinuing single-pack EpiPen sales. Doc. 2143-22 at 2 (Defs.' Ex. 55); Doc. 2143-23 at 5 (Defs.' Ex. 56). But, as Pfizer pointed out, the medical guidelines didn't include language about carrying two EAIs "at all times." Doc. 2190-11 at 2 (Pls.' Ex. 12). In 2010, about 75% of retail EpiPen devices were sold as two-packs, while an additional 11% of retail devices were sold as two or more single-packs together. Doc. 2143-24 at 5 (Defs.' Ex. 57). At the time, retail pens comprised 87% of all EpiPen sales. *Id.* But, in the non-retail market, single-pack sales made up 80% of sales. *Id.*

When making its decision to discontinue selling EpiPen single-packs, Mylan considered feedback from various stakeholders, including healthcare providers, pharmacists, and consumers; wholesalers, retail chains, and payors; and key opinion leaders in the medical field. Doc. 2143-24 at 10–17 (Defs.' Ex. 57); Doc. 2143-25 at 12, 14 (Defs.' Ex. 58). Also, Mylan considered the potential financial effect on its business if it eliminated single EpiPen sales. Doc. 2143-23 at 9–17 (Defs.' Ex. 56). As noted, the initial proposal for eliminating single EpiPens recognized that such action would "double the revenue" per prescription and that Mylan had a "[s]trong potential generic defense[.]" Doc. 2190-14 at 5 (Pls.' Ex. 15). And, Mylan projected that eliminating the

single-pack would increase its net revenue by $43.9M and Pfizer's net revenue by $15.9M in 2011 alone. Doc. 2190-10 at 26 (Pls.' Ex. 11).

The working group also considered the financial effect for customers. Doc. 2143-24 at 6 (Defs.' Ex. 57). It found that about 76% of consumers would receive two devices—instead of just one—for a single average co-pay of $25. *Id.* But, about 16% of customers with co-insurance would pay $32 instead of $16. *Id.* And, customers paying cash would have their costs increase from $85 to $170 per EpiPen purchase. *Id.* The working group also proposed developing a coupon program to mitigate increased prices faced by some customers. Doc. 2143-25 at 20 (Defs.' Ex. 58).

In May 2011, the working group recommended selling EpiPen devices exclusively in packages of two—which Mylan later named the 2-Pak. *See* Doc. 2143-22 at 2–3 (Defs.' Ex. 55); *see also* Doc. 2169 at 7 (Pretrial Order ¶ 2.a.54.) (referring to the product as the "2-Pak"). The Project X2 Team's meeting minutes note as an "[a]dded medical rationale" that as "many as 10–20% of individuals who receive epinephrine will require more than 1 dose before resolution of symptoms." *Id.* at 2. The minutes also reflect that the Team made the decision to "deplete 1 pak inventory in market" instead of "re-packag[ing]" the inventory. *Id.* And, the minutes note the following as a "message point[ ]" explaining the reason why the 2-Pak conversion took effect only in the U.S. is that there are "[n]o international guidelines[.]" *Id.*

Several Mylan witnesses testified that the decision to sell EpiPen devices exclusively in the 2-Pak was driven by medical guidance. *See* Doc. 2143-3 at 14–15 (Defs.' Ex. 21) (Bresch Dep. 211:14–212:3) (Mylan's CEO testifying that that decision was "based on guidelines that people should have two doses immediately available if you went into anaphylactic shock"); *see also* Doc. 2143-14 at 7–8 (Defs.' Ex. 33) (Graham Dep. 160:19–161:2) (Mylan's corporate

representative testifying that the decision "aligned with the guidelines of the world's smartest people in the area of treating allergies"). But, internally, Mylan recognized that the "WAO guidelines do not directly suggest 2 doses[.]" Doc. 2194-4 at 5 (Defs.' Ex. 104). And, on May 21, 2011, Mylan COO W. Lloyd Sanders emailed Heather Bresch stating that the WAO Guidelines "do not explicitly call for 2 epinephrine auto-injectors[.]" Doc. 2194-5 at 3 (Defs.' Ex. 105). Also, Ivona Kopanja noted it was "odd" to cite the WAO Guidelines as medical rationale and it "begs the question of why [Mylan is] not doing this ex-US." Doc. 2194-6 at 3 (Defs.' Ex. 106). Mylan recognized that "[a]nytime [it] reference[s] the NIAID food allergy guidelines as the reason" for the 2-Pak conversion, it "can only speak in terms of food-induced anaphylaxis." Doc. 2194-10 at 2 (Defs.' Ex. 110); *see also* Doc. 2194-12 at 2 (Defs.' Ex. 112) (Mylan public relations manager noting that "NIAID guidelines . . . only addresses food allergies" and recommending citing to the WAO Guidelines as medical rationale). According to Mylan's records, about 40% of people at risk for anaphylaxis have a food allergy. Doc. 2194-11 at 3 (Defs.' Ex. 111) (identifying "28M 'at risk' for anaphylaxis" with 11M due to food allergies).

In a June 2011 email, a Mylan public relations manager posed a list of Project X2 "Q&A," which included the question: "Is this change being driven in part to increase sales?" Doc. 2195-6 at 4 (Pls.' Ex. 126). The manager noted: "We don't need to reveal the true answer to these questions[.]" *Id.* Another proposed question was: "What should a patient do if they have an odd number of pens and cannot replenish to an even amount because they can't purchase a single EpiPen?" Doc. 2190-13 at 5 (Pls.' Ex. 14). Mylan chose to "delete the question" from the final version of the "Q&A." *Id*; *see also* Doc. 2195-8 (Pls.' Ex. 128). Mylan also removed questions about the percentages of prescriptions and purchases of EpiPen single packs and 2-

Paks. *Compare* 2190-13 at 7 (Pls.' Ex. 14) (questions 30 & 31), *with* Doc. 2195-8 (Pls. Ex. 128). Also, in 2011, Bruce Foster emailed Lloyd Sanders suggesting that Mylan "package" the 2-Pak conversion as part of a "bigger program" so that "it goes over better[.]" Doc. 2195-14 at 2 (Pls.' Ex. 134).

In a June 21, 2011 email, Mylan Vice President Ron Graybill reported that Heather Bresch "wanted to implement" Project X2's initiative of removing single EpiPens from the market "ASAP." Doc. 2193-18 at 2 (Pls.' Ex. 99). Then, in July 2011, Mylan informed Pfizer of its decision to stop selling EpiPen single-packs, explaining that the decision "aligns [with] NIAID guidelines [which] recommend that patients at risk for anaphylaxis have immediate access to two doses of epinephrine at all times." Doc. 2143-25 at 5 (Defs.' Ex. 58). Mylan told Pfizer that EpiPen's revenue is "'below the radar' for most managed care organizations" but if "managed care organizations do raise concerns," Mylan had reserved "1.5% of all revenue . . . as rebates[.]" *Id.* at 16. Mylan prepared a presentation about Project X2 to provide at the July 14, 2011 JCC meeting. Doc. 2195-5 at 3 (Pls.' Ex. 125). But, the meeting minutes for that date reflect that the "2 Pack Conversion was the only topic that the JCC was not able to review." Doc. 2143-29 at 18 (Defs.' Ex. 62).

Meridian's General Manager testified that the decision to withdraw the single-pack was "Mylan's alone" and that Pfizer did not have any right to reject Mylan's decision. Doc. 2143-31 at 9–10 (Defs.' Ex. 64) (Handel Dep. 376:20–377:19). But, in some Pfizer communications about the proposal to eliminate EpiPen single-packs, a Pfizer executive stated that they did not "have agreement to [discontinue] the single-injector[;]" "such decisions need to be vetted" through the "JCC[;]" and "Pfizer/Meridian cannot approve this piece until the manufacturing issues are resolved and there is commercial alignment around this change." Doc. 2190-16 at 2, 4

(Pls.' Ex. 17). Early on in Project X2, Mylan understood that it "need[ed] to bring Meridian in the loop soon" about the proposal to eliminate single EpiPens because the project involved "a significant manufacturing/packing component." Doc. 2195-1 at 3 (Pls.' Ex. 121). And, in May 2011, Mylan approached Meridian with the "2 Pack Conversion" proposal noting that Mylan "believes EpiPen is a $1B brand." Doc. 2195-2 at 3 (Defs.' Ex. 122). In July 2011, Lloyd Sanders reported to Heather Bresch that Pfizer was "completely on board" with the 2-Pak conversion and "will rapidly push through [the] talking points." Doc. 2195-4 at 2 (Pls.' Ex. 124). Heather Bresch testified that Mylan didn't "persuade[ ] Pfizer on anything" and instead Pfizer was Mylan's "partner in the product." Doc. 2194-9 at 5 (Pls.' Ex. 109) (Bresch Dep. 227:9–228:19).

Pfizer "charged Mylan for EpiPen units" and "earned a 2% royalty on Mylan's profits." Doc. 2194-1 at 5 (Pls.' Ex. 101) (Handle Dep. 391:22–392:9). Pfizer recognized that its "revenue growth is largely driven by volume" and that the "majority of [its] growth comes from increases in the number of units sold to Mylan." Doc. 2194-14 at 8–9 (Pls.' Ex 115) (Muma Dep. 73:12–75:23, 80:1–13). And, Pfizer forecasted that the switch to the 2-Pak "could add approximately 15 percent to the current EpiPen annual sales figure (approximately $280 million)[.]" *Id.* at 12–13 (Muma Dep. 98:18–101:24).

In August 2011, Mylan stopped selling EpiPen single-packs in the United States and began selling EpiPen devices exclusively in packages of two. Doc. 2169 at 7 (Pretrial Order ¶¶ 2.a.54., 2.a.56.). After that switch, patients no longer could purchase a single EpiPen. Doc. 2193-19 at 4–5 (Graham Dep. 92:16–93:1). Patients only could purchase EpiPens in a 2-Pak. *Id.*; *see also id.* at 4–7 (Graham Dep. 171:8–23).

Mylan prepared communications to send to wholesalers, payors, pharmacists, and others about its conversion to the EpiPen 2-Pak. Doc. 2195-9 (Pls.' Ex. 129); Doc. 2195-10 (Pls.' Ex. 130); Doc. 2196-11 (Pls.' Ex. 131). An internal Mylan communication noted, "in advance of the public announcement on Aug. 24, [Mylan] proactively communicated to health care professionals, customers, wholesalers, pharmacists, payers and advocacy groups to inform them of" the 2-Pak switch, along with "the rationale for this change." Doc. 2195-11 at 2 (Pls.' Ex. 131). Mylan made the communications by "letters, emails and conference calls." *Id.* Also, Mylan concluded it didn't "need to call/write FDA" about the 2-Pak conversion. Doc. 2195-13 at 2 (Pls.' Ex. 133). A Mylan Vice President noted "it's not necessary and will raise more questions than we have answers." *Id.* at 9.

On August 15, 2011, Mylan's Director of Sales Training emailed a presentation titled "Project X2 Training" to Ron Graybill who then sent it to other Mylan employees. Doc. 2195-10 at 2 (Pls.' Ex. 130). The presentation cited the NIAID and WAO Guidelines as "rationale" for Mylan's switch to the 2-Pak. *Id.* at 10. It instructed the sales team to "be sure to speak to the medical rationale" and then mention the 2-Pak switch "at the end of the call" because "[i]t is critical to position this news in a secondary position." *Id.* at 12.

Mylan sells EpiPens in single packs in every country in the world except the United States and France. Doc. 2194-15 at 10 (Pls.' Ex. 116). When defendants solicited Pfizer Canada to introduce the 2-Pak in Canada, its "key opinion leaders" "push[ed] back" and reported they did "not plan to force patients to a 2 Pak." Doc. 2194-19 at 2 (Defs.' Ex. 120); Doc. 2194-14 at 6 (Defs.' Ex. 115) (Muma Dep. 63:15–65:3). In Canada, where "Pfizer Canada Inc. is the exclusive distributor of EpiPen devices[,]" it "markets and sells EpiPen devices in single-unit packages because it has determined that marketing or selling EpiPen devices in other package

configurations would not be commercially viable in the Canadian market." Doc. 2194-16 at 18 (Defs.' Ex. 117).

Mylan's 2-Pak Press Release

On August 24, 2011, Mylan issued a press release titled "Dey Pharma to Offer EpiPen 2-Pak® and EpiPen Jr 2-Pak® Exclusively." Doc. 2169 at 7 (Pretrial Order ¶ 2.a.55.); *see also* Doc. 2206-16 (Pls.' Ex. 135). The press release referenced, quoted from, and cited to the NIAID and WAO Guidelines. Doc. 2206-16 at 2–5 (Pls.' Ex. 135). Also, it quoted Mylan's then-President Heather Bresch and Dr. Phillip Lieberman, Clinical Professor of Medicine and Pediatrics at the University of Tennessee College of Medicine and a member of the NIAID expert panel. *Id.* at 2–3. The press release stated, "The decision to exclusively offer the EpiPen 2-Pak, which contains two single EpiPen Auto-Injectors, aligns with [the NIAID] guidelines, as well as with the [WAO] anaphylaxis guidelines which recommend that physicians consider prescribing more than one epinephrine auto-injector." *Id.* at 2. The press release did not state that either set of Guidelines imposed any requirements for EpiPen packaging.

Dr. Lieberman testified that "in [his] mind" "there's no option" but to prescribe two doses of epinephrine, "based upon what [he] would consider what is ethical as a physician." Doc. 2165-24 at 3–4 (Defs.' Ex. 66) (Lieberman Dep. 47:10–48:6). He consistently has prescribed two-packs for his patients since the 1970s. *Id.* at 4 (Lieberman Dep. 48:8–15). And, he told Mylan that it was a "'good idea'" to sell EpiPen devices exclusively in packages of two. Doc. 2144-1 at 2 (Defs' Ex. 67).[14] But, Dr. Lieberman also testified that he never advised Mylan to start selling the EpiPen exclusively in the 2-Pak, that he agrees with the FDA that "[w]hether a

[14] Plaintiffs object that this exhibit contains inadmissible hearsay. Doc. 2190-1 at 77. Defendants respond that it qualifies as a business record under Fed. R. Evid. 803(6)'s exception to the hearsay rule. Doc. 2226-1 at 21. They also argue that it doesn't qualify as hearsay because defendants don't offer the exhibit to prove the truth of the matter asserted. *Id.* The court agrees with defendants on

patient requires one or two doses is at the discretion of the prescriber and the patient or caregiver," and his decision "in [his] personal practice" to prescribe all patients two doses is "a philosophical decision, and it's debatable." Doc. 2190-9 at 3–5 (Pls.' Ex. 10) (Lieberman Dep. 45:6–9, 66:20–67:2, 101:7–19) (internal quotation marks omitted). Some physicians testified that they use their judgment to determine whether to prescribe EpiPen (or competing) devices based on a variety of factors, including the patient's medical history and the physician's product preferences. Doc. 2165-4 at 91 (Defs.' Ex. 14) (Portnoy Dep. 91:1–16); Doc. 2165-24 at 6 (Defs.' Ex. 66) (Liberman Dep. 79:14–25) (explaining reasons why he would prescribe Auvi-Q instead of EpiPen).

In the weeks leading up to the August 24 2-Pak press release, Mylan and Pfizer executives, including Heather Bresch, sent emails with edits to the language of the 2-Pak press release. *See, e.g.*, Doc. 2190-11 (Pls.' Ex. 12); Doc. 2195-17 (Pls.' Ex. 139). Ms. Bresch, Pfizer, and then Mylan CEO Robert Coury approved the 2-Pak press release. Doc. 2195-15 at 2 (Pls.' Ex. 137); Doc. 2195-16 at 2 (Pls.' Ex. 138). On August 24, 2011, Mylan emailed the 2-Pak press release to more than 100 Mylan employees. Doc. 2206-17 (Pls.' Ex. 136).

None of the named plaintiffs testified that he or she saw the August 2011 press release before becoming involved in this litigation. *See* Doc. 2142-1 at 34 & n.110 (Defs.' Mem.) (citing named plaintiffs' deposition testimony).[15] And, no named plaintiff testified that he or she relied on any statements by defendants when purchasing EpiPen devices. *Id.*

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the latter point. Defendants don't offer this exhibit to prove that it was a "good idea" to sell EpiPens exclusively in a 2-Pak. Instead, they offer it to show what Dr. Lieberman—as a member of the NIAID expert panel—told Mylan about its decision to discontinue selling single EpiPens.

[15] One plaintiff, Donna Dvorak, when asked whether she had seen the press release, testified, "I think I have[,]" but she wasn't "sure when [she] first saw" it, and she testified that she didn't "think that [the press release] would have influenced" her decision to purchase an EpiPen. Doc. 2144-3 at 9 (Defs.' Ex. 73) (Dvorak Dep. 340:2–22).

Many of the named plaintiffs purchased 2-Paks or multiple single-packs before 2011. Doc. 2144-16 at 2–8 (Defs.' Ex. 102 (citing Defs.' Ex. 102-A)).[16] At least 11 named plaintiffs purchased multiple devices in a single transaction while the single-pack was available. *Id.* Also, several named plaintiffs testified that they prefer to have more than one EpiPen device at any given time. *Id.* For example, named plaintiff Stacee Svites testified, "I have to have two packs. I mean, I have to carry two. I've known it all along." Doc. 2144-9 at 4 (Defs.' Ex. 90) (Svites Dep. 148:4–8). Also, plaintiff Angie Nordstrum testified that she wanted to purchase two EAI devices "because that's what I was advised as medically necessary." Doc. 2166-1 at 5 (Defs.' Ex. 70) (Nordstrum Dep. 132:17–20). And, plaintiff Lorraine Wight testified: "We were told by our doctors that we needed to have a minimum of two." Doc. 2144-1 at 6–7 (Defs.' Ex. 92) (Wight Dep. 141:17–142:7). Plaintiffs' expert, Meredith Rosenthal, testified that 62–68% of patients were not "forced" to buy EpiPen 2-Paks. Doc. 2166-17 at 15–16 (Defs.' Ex. 96) (Rosenthal Dep. 197:12–198:2).

Effects of the 2-Pak Switch

On August 24, 2011, Harry Jordan, Mylan's Director of National Accounts, emailed Bruce Foster and Ron Graybill, giving Mr. Foster "some major kudos for coming up with" the 2-Pak conversion idea and "Ron for seeing it through." Doc. 2195-18 at 3 (Pls.' Ex. 140). Mr.

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[16] Plaintiffs assert defendants' Exhibit 102 is inadmissible hearsay. Doc. 2190-1 at 77. Defendants respond that: (1) the exhibit's contents aren't hearsay under Fed. R. Evid. 801(c)(2)'s definition of hearsay; and (2) the contents qualify as an admission by a party opponent under Fed. R. Evid. 801(d)(2). Doc. 2226-1 at 21. Exhibit 102 is a summary of each plaintiff's EAI purchasing history and deposition testimony about purchasing EAIs with citations to the supporting evidence which is attached to Exhibit 102 as Exhibits 102-A–102-Z. *See* Doc. 2144-16 at 14–177. Exhibit 102 accurately cites the supporting exhibits, which plaintiffs don't challenge as inadmissible on summary judgment. So, the court considers the evidence summarized in Exhibit 102 because the supporting exhibits accurately support the evidence presented in summary fashion. And, under Fed. R. Evid. 1006, a summary is admissible "to prove the content of voluminous writings . . . that cannot be conveniently examined in court."

Graybill then emailed Mr. Jordan asking where was his "idea to bring $50 million per year to the bottom line?" *Id.* at 2. Mr. Graybill responded: "Why don't we just have an EpiPen 6 pack. . . . We can charge $450. Heck with 50 million. How about 150 million to the bottom line." *Id.* In January 2012, Mylan named Bruce Foster as the "President's Circle Winner for 2011." Doc. 2196-4 at 2 (Pls.' Ex. 146). Ron Graybill noted that Mr. Foster had "proposed and helped implement the idea to remove the EpiPen single pack from the market" which "resulted in an increase in sales of over $20 million in 2011, should increase sales in 2012 by over $50 million and will continue to have a similar positive impact in 2013 and beyond." *Id.*

In October 2011, Lloyd Sanders emailed Heather Bresch to propose raising the EpiPen price. Doc. 2196-2 at 2 (Pls.' Ex. 144). He reported that Mylan had implemented the 2-Pak switch without "ANY issues" and "no backlash" by payors. *Id.* He forecasted that the price increase would produce "$5.5M–$6.0M and it all drops to the bottom line." *Id.*

The switch to the 2-Pak "resulted in an increase in sales of over $20 million" for Mylan in 2011. Doc. 2196-4 at 2 (Pls.' Ex. 146). Between 2010 (when EpiPen single packs still were available) and 2012 (after the switch to the 2-Pak), Mylan's net sales increased from $278.6 million to $623.3 million and Pfizer's EpiPen revenue increased from $142 million to $225 million. Doc. 2196-6 at 4–5 (Pls.' Ex. 148). Pfizer attributed the majority "of growth" to "increases in number of units sold to Mylan." *Id.* at 3.

In February 2017, Mylan received a letter from the FDA confirming that Mylan still was authorized to sell single EpiPen devices, recognizing that Mylan currently was selling the EpiPen only in a 2-Pak, and noting that the "number of patients reported to require more than one dose of epinephrine for treatment of anaphylaxis is generally quoted as approximately 12–36%."

Doc. 2144-14 at 2 (Defs.' Ex. 98).[17] The letter also recognized that, by selling EpiPen exclusively as a 2-Pak, "patients are unable to obtain a single dose even if their health care practitioner determines a single dose is appropriate or the patient needs to replace one used dose." *Id.* The letter noted that "the approved labeling does not recommend that patients be prescribed two doses" and "[w]hether a patient requires one or two doses is at the discretion of the prescriber and the patient or caregiver." *Id.* at 2–3. And, the FDA told Mylan that offering the EpiPen in both single packs and the 2-Pak would "provide patients and caregivers greater options and in turn access to care when only a single dose is necessary." *Id.* at 3.

Plaintiffs' expert asserts that "patients should have the ability to purchase only one" EpiPen because "it is not always medically necessary for every patient who uses EAIs to

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[17] Plaintiffs object that this exhibit is inadmissible hearsay to which no exception applies. Doc. 2190-1 at 77. Defendants respond that this letter from the FDA is a public record that qualifies for admission under Fed. R. Evid. 803(8)'s exception to the hearsay rule. Doc. 2226-1 at 21. Rule 803(8)'s public records exception to the hearsay rule defines a public record as:

> A record or statement of a public office if: (A) it sets out: (i) the office's activities; (ii) a matter observed while under a legal duty to report, but not including, in a criminal case, a matter observed by law enforcement personnel; or (iii) in a civil case or against the government in a criminal case, factual findings from a legally authorized investigation; and (B) the opponent does not show that the source of the information or other circumstances indicate a lack of trustworthiness.

Fed. R. Evid. 803(8). The advisory committee's notes explain that the "[j]ustification for the exception is the assumption that a public official will perform his duty properly and the unlikelihood that he will remember details independently of the record." Fed. R. Evid. 803 advisory committee's note to Paragraph (8). And, cases "illustrating the admissibility of records of the office's or agency's own activities are numerous." *Id.* The court agrees that defendants' Exhibit 98 falls within the public records exception to the hearsay rule because it is a record of a public office—the FDA—setting out its activities and plaintiffs have marshaled no circumstances "indicat[ing] a lack of trustworthiness" with the document. Fed. R. Evid. 803(8).

Also, once again, plaintiffs object to an exhibit that they then turn around and cite as an exhibit supporting their own asserted summary judgment facts. *See* Doc. 2190-1 at 42 (Statement of Additional Material Fact ¶ 24 (citing Pls.' Ex. 22)). Plaintiffs' Exhibit 22 is the very same document as defendants' Exhibit 98—all the way down to the Bates numbering. Again, plaintiffs' cat-and-mouse tactics—asserting blanket evidentiary objections to defendants' summary judgment exhibits while relying themselves on the same exhibits—is unimpressive advocacy.

purchase or carry two doses[.]" Doc. 2206-3 at 17 (Pls.' Ex. 5) (Portnoy Expert Report ¶ 45). And, he opines, "the unavailability of a one-pack interferes with patient choice and with the provider's ability to exercise and implement medical judgment." *Id.*

The packaging of every EpiPen device contains the following FDA-approved instructions about the second dose: "With severe persistent anaphylaxis, repeat injections with an additional EpiPen or EpiPen Jr may be necessary." *Label: EPIPEN- epinephrine injection EPIPEN JR- epinephrine injection*, U.S. Nat'l Library of Medicine, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7560c201-9246-487c-a13b-6295db04274a (Updated Dec. 29, 2020).

Patent Litigation with Teva

EAIs may not be sold in the United States absent FDA approval. Doc. 2169 at 4 (Pretrial Order ¶ 2.a.18.). To secure FDA approval, a new generic drug product must submit an Abbreviated New Drug Application ("ANDA") proposing that the FDA approve the new product for sale and marketing in the United States. *New Drug Application*, FDA (last updated June 10, 2019), https://www.fda.gov/drugs/types-applications/new-drug-application-nda. In the context of an ANDA, the FDA sometimes uses the phrases "Reference Listed Drug" ("RLD") and "innovator drug" to refer to the branded product to which the FDA will compare the proposed generic. *Drugs@FDA Glossary*, FDA, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=glossary.page (last visited May 3, 2020).

Since 1984, the Hatch-Waxman Amendments (the "Hatch-Waxman Act") have provided a framework for the FDA to evaluate ANDA applications while also allowing generic manufacturers to challenge patents associated with RLDs. *Patent Certifications and Suitability*

Petitions, FDA (last updated Apr. 22, 2021), https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/patent-certifications-and-suitability-petitions. Under the Hatch-Waxman Act, all ANDA applicants, and certain NDA applicants, must make certifications for patents associated with their RLD counterparts, including a "Paragraph IV certification," which is a certification by the applicant that, "in the opinion of the applicant," the relevant patent is "invalid or will not be infringed by" the new proposed generic product. 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *id.* § 355(b)(2)(A)(iv). Any applicant filing a Paragraph IV certification must notify the holder of the relevant patent and the holder of the approved drug application who claims that patent. 21 U.S.C. § 355(j)(2)(B)(iii)(II); *id.* § 355(b)(3)(C). Once a patent holder receives a Paragraph IV certification, it may file an infringement suit within 45 days, triggering an automatic 30-month stay of FDA approval of the ANDA. 21 U.S.C. § 355(j)(5)(B)(iii); *id.* § 355(c)(3)(C).

In 2007, Teva filed ANDA 90-0589 to develop a generic EAI. Doc. 2144-15 at 2 (Defs.' Ex. 101).[18] Teva submitted additional information to the FDA in May, June, and November 2008. Doc. 2201-3 at 2 (Pls.' Ex. 252). And, the FDA found Teva's application "acceptable for filing" on November 21, 2008. *Id.* Plaintiffs' expert, Dr. Carl Peck, who is a former Director of the FDA's Center for Drug Evaluation and Research, asserts that the "FDA could have sent Teva a 'refuse to receive' letter in early 2008 since the ANDA was not 'substantially complete' and required additional information/data." Doc. 2191-7 at 20 (Pls.' Ex. 30) (Peck Expert Report ¶

[18] The court rejects plaintiffs' objection that defendants' Exhibit 101 is inadmissible hearsay to which no exception applies. Doc. 2190-1 at 77. As defendants have shown, documents produced by Teva qualify for admission as business records under Fed. R. Evid. 803(6)'s exception to the hearsay rule. Doc. 2226-1 at 21 & n.35; *see also* Doc. 2227-1 at 15–17 (Savage Decl. Concerning Teva Docs.). For the same reasons, the court rejects plaintiffs' objections to defendants' Exhibits 104, 106, 108, 114, 117–28, 131–33, 144–52, 159–60, & 163. All of these exhibits consist of Teva-produced business records that qualify for admission under Fed. R. Evid. 803(6)'s exception to the hearsay rule.

40). But, he asserts that "the FDA proactively worked directly with Teva to enable the Teva ANDA to be substantially complete for filing." *Id.*

With its ANDA, Teva's goal was to develop and secure approval for a generic product that the FDA would consider "A-rated" to the EpiPen EAI.[19] Doc. 2144-7 at 11 (Defs' Ex. 103) (Weisman Expert Report ¶ 35); *see also* Doc. 2144-18 at 2 (Defs.' Ex. 104) (Teva email explaining that without an "A-rating," Teva "would then be required to have a sales team dedicated to training and education of the use of our device/product").

On May 1, 2009, the FDA sent Teva a deficiency letter. Doc. 2203-7 at 2 (Pls.' Ex. 299). In response, Teva submitted amendments to its application on May 22, 2009 and June 12, 2009. *See id.* at 2–153; *see also* Doc. 2203-8 at 2 (Pls.' Ex. 300) (referring to "May 23 and June 12, 2009 amendments"). On June 4, 2009, the FDA sent Teva another deficiency letter. Doc. 2203-9 at 2 (Pls.' Ex. 301). Teva responded with an amendment to its ANDA, but not until October 11, 2010. *Id.* On July 6, 2009, the FDA sent another deficiency letter to Teva. Doc. 2203-10 at 2 (Pls.' Ex. 302). On September 8, 2009, Teva responded with another amendment to its ANDA. *Id.* Dr. Peck opines that this part of the FDA's review process "proceeded in a timely manner" and "the FDA's review times were generally consistent with its review times as reported by the Inspector General's 2008 report and also not far afield from the statutory mandate of 180 days." Doc. 2191-7 at 20 (Pls.' Ex. 30) (Peck Expert Report ¶¶ 40–41).

When Teva submitted its ANDA, Pfizer's subsidiary Meridian held a patent on the auto-injector component of the branded EpiPen product. Doc. 2167-3 (Defs.' Ex. 105) (the '012

[19] An A-rating (sometimes referred to as "AB" or "AP" in the context of injectable products) signifies that two products are "therapeutically equivalent" and can be substituted for one another at the pharmacy counter. *Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book Preface")*, FDA at ¶ 1.7 (last updated Jan. 21, 2021), https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface.

Patent).[20] To secure approval of its ANDA, Teva had to demonstrate that its device was "equivalent to" the EpiPen. Doc. 2167-2 at 6 (Defs.' Ex. 100); *see also id.* at 14. At the same time, however, Teva could not just copy the EpiPen without infringing on patents held by Pfizer's subsidiaries. Doc. 2144-19 at 9–10 (Defs.' Ex. 106). To avoid infringing these patents, Teva's proposed generic product for which it sought FDA approval included a different auto-injector than EpiPen. Doc. 2144-20 at 2 (Defs.' Ex. 108); Doc. 2145-1 at 20–26 (Defs' Ex. 109).

In July 2009, consistent with the Hatch-Waxman Act, Teva notified King and Meridian that it had filed ANDA 90-0589 to market a generic version of EpiPen Auto-Injector and had submitted a Paragraph IV certification. Complaint ¶ 17, *King Pharms., Inc. v. Teva Parenteral Meds., Inc.*, No. 1:09-cv-00652-GMS (D. Del. Aug. 28, 2009), ECF No. 1 at 4. Then, on August 28, 2009, King and Meridian sued Teva in the District of Delaware to enforce U.S. Patent No. 7,449,012B2 (the "'012 Patent"). *See generally id.* Mylan and Pfizer entered a Common Interest Agreement in connection with the EpiPen patent litigation against Teva. Doc. 2201-4 at 2 (Pls.' Ex. 253).

[20] Plaintiffs dispute that the '012 Patent was a valid patent. But, that dispute doesn't controvert the undisputed fact that Meridian held the '012 Patent when Teva filed its ANDA. *See United States v. You*, No. 2:19-CR-14, 2021 WL 1539579, at *3 (E.D. Tenn. Apr. 19, 2021) ("The fact that some patents might not be valid does not affect the fact that a patent filed with the United States Patent and Trademark Office remains part of the public record.").

Also, plaintiffs object that defendants' Ex. 105 is inadmissible hearsay to which no exception applies. Doc. 2190-1 at 77. The court disagrees. The '012 Patent itself likely doesn't qualify as hearsay because defendants don't offer the '012 Patent to prove any of its contents, but even if they did, the '012 Patent is a public record that qualifies for admission under Fed. R. Evid. 803(8). *See Hay & Forage Indus. v. New Holland N. Am., Inc.*, 25 F. Supp. 2d 1170, 1175 n.2 (D. Kan. 1998) (holding that patents were admissible evidence because "the documents offered are not hearsay" when they were offered "not to prove the truth of any of the matters which they assert, but rather to prove that various patents use" a particular term, but in "any event, even if the patents were hearsay, they would be subject to the public records exception to the hearsay rule" (citing Fed. R. Evid. 803(8))). *Cf. SB IP Holdings, LLC v. Vivint Smart Home, Inc.*, No. 4:20-cv-886, 2021 WL 1721715, at *1 (E.D. Tex. Apr. 30, 2021) ("Courts routinely take judicial notice of patents, prosecution history, and patent applications.").

In 2007, King Pharmaceuticals, Inc. submitted a citizen petition[21] (the "King Petition") to the FDA asking it to apply certain standards to ANDAs for proposed EAI products. Doc. 2167-1 at 2 (Defs.' Ex. 99) (describing King Petition in FDA response letter).[22] Specifically, it asked the FDA to "[d]ecline to approve" any ANDA "unless it has been demonstrated that the proposed auto-injector is . . . 'the same' as the auto-injected in the refence listed drug (RLD)[.]" *Id.*

The FDA responded to the King Petition on July 29, 2009. *Id.* The response recognized that an ANDA must "ensure that its performance characteristics and critical design attributes will result in a product that will perform the same as the RLD[,]" but "[t]his does not mean, however, that all design features of the autoinjector in the ANDA and its RLD must be exactly the same." *Id.* at 7. Also, the FDA's letter stated, for emergency use products like EAIs, "it is particularly important to ensure that patients in an emergency situation can use the product safely and effectively in accordance with instructions provided for the RLD without additional physician intervention or retraining[.]" *Id.* The FDA further explained that if it were to determine that the auto-injector constituent of a product proposed in an ANDA is not the "same as" the auto-injector constituent of the RLD, "FDA will refuse to approve the ANDA." *Id.* at 7–8. But, the FDA did note that some "design differences may be acceptable as long as they do not significantly alter product performance or operating principles and do not result in impermissible differences in labeling." *Id.* The FDA's letter also explained: "Clinical usability or human

[21] A citizen petition is a document that anyone may submit to the FDA asking it "to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.25(a).

[22] Again, plaintiffs object to this exhibit as inadmissible hearsay to which no exception applies. Doc. 2190-1 at 77. Defendants respond that this FDA response letter is a public record that qualifies for admission under Fed. R. Evid. 803(8)'s exception to the hearsay rule. Doc. 2226-1 at 21. The court agrees. Defendants' Exhibit 99 falls within the public records exception to the hearsay rule in Fed. R. Evid. 803(8) because it is a record of a public office setting out its activities and plaintiffs have not shown any circumstances indicating a lack of trustworthiness with the document.

factor studies may also be required," and such studies "are beyond the scope of studies that can be reviewed and approved in an ANDA." *Id.* at 8. And, the FDA stated: "For products that require physician training before unsupervised patient use, differences in operation that require retraining prior to use are not expected to be acceptable in an ANDA." *Id.* at 11–12. In addition to the Citizen Petition, Meridian's Director of Regulatory Affairs, Dr. Thomas G. Fruend, wrote letters to the FDA on December 5, 2012 and May 7, 2013, about Teva's pending ANDA. Doc. 2204-3 at 2–7 (Pls.' Ex. 324).

In December 2009, Dey submitted a citizen petition (the "Dey Petition") asking the FDA to apply certain conditions to its approval of a generic EAI. Doc. 2167-2 at 2 (Defs.' Ex. 100) (describing Dey Petition in FDA response letter).[23] Specifically, Dey asked that the FDA "[d]ecline to approve any ANDA . . . and decline to assign an 'AB' rating for a generic product that is not the same as the currently marketed EpiPen auto-injector[.]" *Id.* Also, Dey asked that the FDA "[d]etermine that generic versions of EpiPen auto-injector must have the same design, operation, and function of the RLD[.]" *Id.* at 8. King and Meridian employees provided comments and input on Dey's Citizen Petition. Doc. 2204-2 at 2 (Pls.' Ex. 323).

On May 27, 2010, the FDA denied Dey's Citizen Petition. Doc. 2167-2 at 2 (Defs.' Ex. 100). In its response to the Dey Petition, the FDA noted that the "King Petition response specifically addressed situations such as the one the [Dey] Petition addresses" and that "there is no requirement in the Act, implementing regulations, guidance, or Agency precedent that would

[23] The court rejects plaintiffs' objection that defendants' Exhibit 100 is inadmissible hearsay to which no exception applies. The court finds that this document arguably qualifies for admission under Fed. R. Evid. 803(8)'s public record exception to the hearsay rule. Also, it qualifies as a business record under Fed. R. Evid. 803(6)'s exception to the hearsay rule. And, plaintiffs have submitted the exact same document as part of an exhibit supporting their own asserted summary judgment facts. Doc. 2190-1 at 69 (Statement of Additional Material Fact ¶ 147) (citing Pls.' Ex. 322 (Doc. 2207-14 at 2–15)). This ploy is no more impressive than plaintiffs' other similar attempts to enforce a "heads I win, tails you lose" paradigm.

mandate as narrow an interpretation of sameness as [Dey] would have the [FDA] adopt." *Id.* at 9–10. The letter also recognized that because EAIs are emergency-use products, the FDA must use "particular vigilance" in ensuring product safety. *Id.* at 9.

On November 1, 2010, Teva submitted a Paragraph IV certification concerning an additional Pfizer EpiPen patent: U.S. Patent No. 7,794,432B2 (the "'432 Patent"). First Amended Complaint ¶ 21, *King Pharms., Inc. v. Teva Parenteral Meds., Inc.*, No. 1:09-cv-00652-GMS (D. Del. Nov. 11, 2010), ECF No. 37-1 at 5. On November 11, 2010, King and Meridian amended their Complaint in the Delaware suit against Teva to enforce the second patent. *See generally id.* Both the '012 and '432 Patents are listed in the FDA Orange Book and expire in September 2025. Doc. 2169 at 4 (Pretrial Order ¶ 2.a.27.).

As the patent litigation progressed, Teva continued to pursue FDA approval of its generic EAI. *See, e.g.*, Doc. 2145-2 at 2–4 (Defs.' Ex. 113) (correspondence between Teva and the FDA about the ANDA application).[24] In March 2010, the FDA sent Teva a "bioequivalence" deficiency letter. *Id.* In an internal e-mail, the Teva project manager overseeing the product stated that this deficiency was primarily concerned with the fact that the Teva device was not "similar enough" to the RLD, *i.e.*, the EpiPen and EpiPen Jr Auto-Injectors. Doc. 2145-3 at 3 (Defs.' Ex. 114).

[24] The court rejects plaintiffs' objection to defendants' Exhibit 113 as inadmissible hearsay to which no exception applies. Doc. 2190-1 at 20. Defendants assert that this exhibit doesn't qualify as hearsay because it's not offered to prove the truth of the matter asserted. Doc. 2226-1 at 21. The court agrees. Defendants don't offer this exhibit to prove the truth of any of its contents. Instead, it is offered to show that Teva was communicating with the FDA about its ANDA for its proposed generic EAI. So, this exhibit isn't inadmissible hearsay under Fed. R. Evid. 801(c).

Then, in February 2011, the FDA cited differences between Teva's EAI and EpiPen in a "labeling deficiency" letter. Doc. 2145-4 (Defs.' Ex. 115).[25] Among other comments, the FDA noted that Teva's proposed device instructions did "not read the same as the innovator" and were "difficult to follow and to ensure that the sequence of steps match the innovator." *Id.* at 4. Thus, the FDA predicted that the proposed instructions "may present confusion for customers that have used the innovator's product." *Id.*

In a March 2011 internal e-mail exchange, Teva personnel discussed these and other deficiency communications that the FDA had sent to Teva, including a chemistry deficiency that requested "stability data" for the stability of the epinephrine inside Teva's device. Doc. 2145-3 at 3 (Defs.' Ex. 114). The Teva correspondence concluded with a March 15, 2011 e-mail stating: "This product needs a reformulation as well as a new device." *Id.*

Also in March 2011, Teva and Pfizer discussed in an email titled "Fre 408: couple of things" setting up a phone call to discuss the Teva/EpiPen patent infringement litigation. Doc. 2203-11 at 2 (Pls.' Ex. 304).

On May 17, 2011, Teva received another deficiency letter from the FDA. Doc. 2145-5 at 2 (Defs.' Ex. 116).[26] This letter asked Teva to "conduct a design validation (human factors) study" and stated that the FDA "recommend[s] that you submit a draft of the test protocol before you implement it for our review and feedback to ensure that your methods will be acceptable."

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[25] The court rejects plaintiffs' objection to defendants' Exhibit 115 as inadmissible hearsay to which no exception applies. Doc. 2190-1 at 20. Defendants assert that this exhibit qualifies as a public record subject to Fed. R. Evid. 803(8)'s exception to the hearsay rule. Doc. 2226-1 at 21. The court agrees for the same reasons discussed *supra* note 17.

[26] The court rejects plaintiffs' objection to defendants' Exhibit 116 as inadmissible hearsay to which no exception applies. Doc. 2190-1 at 20. Defendants assert that this exhibit qualifies as a public record subject to Fed. R. Evid. 803(8)'s exception to the hearsay rule. Doc. 2226-1 at 21. The court agrees for the same reasons discussed *supra* n.17.

Id. at 3. A human factors study is a study "conducted with representative users to assess[,]" among other things, "the ability of the user" to operate the device safely and effectively. Doc. 2144-17 at 10 (Defs.' Ex. 103) (Weisman Expert Report ¶ 30).

On the same day—May 17, 2011—Teva's "epinephrine core team" met. Doc. 2145-6 at 2 (Defs.' Ex. 117). The meeting minutes reflect that Teva's device manufacturer had received a warning letter from the FDA, and Teva was in the process of evaluating potential alternative manufacturing sites. *Id.* at 3–5. The minutes also note that "[n]o [epinephrine] batches made so far have met shelf life requirements." *Id.* at 2. Also, Teva experienced additional manufacturing problems with needle corrosion, needle separation, fill volume, dosage delivery, stopper placement, and impurities. Docs. 2145-7–2145-14 (Defs.' Exs. 118–125).

In the summer of 2011, Teva decided to amend and resubmit its ANDA with changes to both the epinephrine formulation and the device itself. Doc. 2145-15 at 8 (Defs.' Ex. 126). In a September 8, 2011 internal e-mail, Cory Wohlbach, the Teva regulatory affairs employee assigned to the epinephrine project, estimated that the "probability of success for the approval of the Epinephrine drug product is around 60%." Doc. 2144-20 at 2 (Defs.' Ex. 108). Mr. Wolhbach explained that "differences in the RLD device [EpiPen] to the [Teva] device . . . add[ ] to the complexity of the approval." *Id.* He noted the two devices "are not exactly the same[,]" and because "[e]pinephrine is a rescue product, similarities between the RLD and the [Teva] devices are critical." *Id.* In January 2012, Teva informed Pfizer that "it is modifying its proposed epinephrine auto-injector and that it intends to submit an amendment to its ANDA after the trial in this matter." Proposed Joint Pretrial Order, Ex. 21 ¶ 2, *King Pharms., Inc. v. Teva Parenteral Meds., Inc.*, No. 1:09-cv-00652-GMS (D. Del. Jan. 24, 2012), ECF No. 142-1 at 291.

Teva began testing new batches of its product in December 2011, but at an April 17, 2012 meeting, it was reported that these batches had failed because of a "needle separation issue." Doc. 2145-16 at 3 (Defs.' Ex. 127). Also, Teva meeting minutes from February 10, 2012 reported "several technical issues" that occurred "during testing of the Epinephrine stability batches[.]" Doc. 2145-17 at 2 (Defs.' Ex. 128). Six days later, on February 16, 2012, the EpiPen bench trial began. Day 1 of Trial Transcript, *King Pharms., Inc. v. Teva Parenteral Meds., Inc.*, No. 1:09-cv-00652-GMS (D. Del. July 25, 2012), ECF No. 150 at 1 (transcript dated "Thursday, February 16, 2012").

Settlement of the Teva Patent Litigation

After Pfizer rested its case-in-chief in the bench trial, Teva moved for judgment as a matter of law. Day 2 of Trial Transcript, *King Pharms., Inc. v. Teva Parenteral Meds., Inc.*, No. 1:09-cv-00652-GMS (D. Del. July 25, 2012), ECF No. 151 at 140–64 (Tr. 363:12–387:2). The presiding Judge, The Honorable Gregory M. Sleet, denied the motion. *Id.*

During the trial, Pfizer and Teva simultaneously engaged in settlement negotiations in Judge Sleet's chambers. Day 4 of Trial Transcript, *King Pharms., Inc. v. Teva Parenteral Meds., Inc.*, No. 1:09-cv-00652-GMS (D. Del. July 25, 2012), ECF No. 154 at 85 (Tr. 750:1–11). On March 9, 2012, at the end of the fourth and last day of trial, Judge Sleet told the parties that he would hold off on issuing an opinion for "as long as it takes—and I really mean that, as long as it takes" to allow the parties to pursue settlement negotiations. *Id.* Pfizer and Teva continued settlement talks through March and April 2012. Letter to The Honorable Gregory M. Sleet, *King Pharms., Inc. v. Teva Parenteral Meds., Inc.*, No. 1:09-cv-00652-GMS (D. Del. Mar. 30, 2012), ECF No. 144.

At the same time, Teva's regulatory team "d[id] not believe FDA would approve the product." Doc. 2145-20 at 3 (Defs.' Ex. 131) (noting in April 3, 2012 meeting minutes that that the FDA likely wouldn't approve the product even if Teva "highlight[ed] [its] intent to amend the application"). The position of Teva's Quality Team was: "With a critical defect such as this (needle dislodgement) the amendment should not be filed and new syringes should not be ordered or new batches made until root cause has been identified and corrective and preventative actions put in place[.]" *Id.* Then President and CEO of Teva-Americas William Marth acknowledged in an April 2012 internal e-mail that "[t]he product is challenging[.]" Doc. 2145-21 at 2 (Defs.' Ex. 132). Mr. Marth was willing to negotiate "any date in 2016 or earlier." Doc. 2145-22 at 2 (Defs.' Ex. 133).

Also, while the Teva litigation was pending, two additional EpiPen patents were pending approval by the U.S. Patent and Trademark Office ("USPTO"). Doc. 2146-1 at 2 (Defs.' Ex. 134); Doc. 2146-2 at 4 (Defs.' Ex. 135);[27] *see also* Doc. 2169 at 5–6 (Pretrial Order ¶¶ 2.a.38., 2.a.39.). In December 2010, the application for what would become U.S. Patent No. 8,870,827 (the "'827 Patent") was made publicly available. Doc. 2146-1 at 2 (Defs.' Ex. 134). Then, in October 2014, the USPTO issued the '827 Patent. *Id.* In November 2011, the USPTO issued another EpiPen-related patent, U.S. Patent No. 8,048,035 ("'035 Patent"). Doc. 2146-2 at 4 (Defs.' Ex. 135). The disputes at issue in the Teva litigation did not involve either the '827 and '035 Patents. Days 1–4 of Trial Transcript, *King Pharms., Inc. v. Teva Parenteral Meds., Inc.*,

[27] The court rejects plaintiffs' objections to defendants' Exhibits 134 and 135 as inadmissible hearsay to which no exception applies. Doc. 2190-1 at 77. Exhibit 134 is a patent which likely doesn't qualify as hearsay because defendants don't offer the '827 Patent to prove any of its contents. But even if they had offered the exhibit to prove the truth of its contents, the '827 Patent is a public record that qualifies for admission under Fed. R. Evid. 803(8). *See supra* n.20. And Exhibit 135 is a Mylan business record that qualifies for admission under Fed. R. Evid. 803(6)'s business records exception.

No. 1:09-cv-00652-GMS (D. Del. July 25, 2012), ECF Nos. 150–51, 153–54. These two patents do not expire until 2025. Doc. 2169 at 4 (Pretrial Order ¶ 2.a.27.) (explaining that the EpiPen Device Patents expire in 2025).

On April 26, 2012, Pfizer and Teva executed a binding term sheet that granted Teva a license to launch its EAI by June 22, 2015, subject to FDA approval. Doc. 2146-3 at 14–20 (Defs.' Ex. 136). The term sheet did not include any monetary payment between Pfizer and Teva. *Id.* The draft settlement agreements exchanged by the parties never proposed a licensed entry date earlier than June 2015. Doc. 2145-18 at 7–9 (Defs.' Ex. 129) (Myers Dep. 93:15–95:11).

On July 20, 2012, Pfizer and Teva executed the final Settlement and License Agreement to resolve the EpiPen litigation. Doc. 2146-3 at 2–29 (Defs.' Ex. 136). On that same date, Mylan executed a Covenant Not to Sue Teva with respect to any patents in the ownership or control of Mylan. *Id.* at 28–29. By settling, the parties to the Teva litigation avoided litigation risk and millions of dollars in expected litigation costs. Doc. 2146-5 at 74–75 (Defs.' Ex. 138) (Torrance Expert Report ¶ 146).

Mylan was not a signatory to the binding term sheet or the Settlement and License Agreement. Doc. 2146-3 at 10–12, 19–20 (Defs.' Ex. 136). But, as discussed, Mylan signed a Form of Covenant Not to Sue and Mutual Releases, which was attached to the settlement agreement. *Id.* at 24–29. A Mylan witness testified that Mylan signed the covenant "to appease Teva" though Mylan "didn't think [it] was necessary given that these weren't [Mylan's] patents." Doc. 2146-6 at 6–7 (Defs.' Ex. 139) (Jenkins Dep. 116:13–117:5).

Mylan witnesses testified that Mylan received updates from Pfizer about the Teva litigation, including during trial and settlement negotiations, but as one witness put it, Mylan

"played no active role in the case itself." Doc. 2146-7 at 5–6 (Defs.' Ex. 140) (Ondos Dep. 63:23–64:2); *see also* Doc. 2146-6 at 6 (Defs.' Ex. 139) (Jenkins Dep. 116:13–25) (testifying that "Pfizer was the party responsible for the negotiation and settlement" and that "[u]ltimately it was their call whether to settle or not settle"). Some witnesses testified that Mylan had no decision-making rights in the litigation. Doc. 2146-7 at 4 (Defs.' Ex. 140) (Ondos Dep. 60:14–23); Doc. 2145-18 at 13 (Defs.' Ex. 129) (Myers Dep. 127:2–12). One witness testified that Mylan didn't provide any legal or business advice to Pfizer about the settlement, including the agreed licensing date for the Teva generic found in the binding term sheet. Doc. 2146-6 at 3–5 (Defs.' Ex. 139) (Jenkins Dep. 96:6–9, 99:1–8, 15:1–8); Doc. 2145-18 at 20 (Defs.' Ex. 129) (Myers Dep. 209:7–14). Also, Pfizer's counsel testified that it didn't need Mylan's consent to settle the litigation. Doc. 2145-18 at 7–9 (Defs.' Ex. 129) (Myers Dep. 208:18–20).

But, in email correspondence dated March 8, 2012 (the day before the last day of the Teva/EpiPen bench trial), William Marth noted that he had "talked to Heather yesterday throughout the afternoon and evening about settlement" and that "[s]he (Heather) wants to give [Teva] a 2018 entry date but would likely agree to 2017." Doc. 2201-21 at 2 (Pls.' Ex. 255). Also, Mylan and Pfizer's Supply Agreement requires the parties to notify each other of potential infringement and "jointly determine in good faith the appropriate course of action[.]" Doc. 2201-7 at 27 (Pls.' Ex. 256). And, several documents reference that Mylan's lawyers spoke with Teva and Pfizer about the settlement. Doc. 2201-11 at 2 (Pls.' Ex. 260) (explaining that Mylan General Counsel had called Teva "to ask if there is anything we can do to get Epi back on track"); Doc. 2201-13 at 2 (Pls.' Ex. 262) (stating that Teva had called Mylan's Deputy General Counsel and "relayed the following proposal: epipen in 2014 and nuvigil in 2018"); Doc. 2201-14 at 2 (Pls.' Ex. 263) (scheduling telephone conference with Teva, Mylan, and Pfizer); Doc.

2201-22 at 3 (Pls.' Ex. 266) (Haggerty Dep. 78:8–24) (Mylan's General Counsel testifying that he can't confirm or dispute entries on a privilege log showing that he spoke with Pfizer about the EpiPen litigation 56 times in March and April 2012).

On April 26, 2012, Mylan and Pfizer issued a joint press release announcing that "Meridian Medical Technologies, a Pfizer subsidiary, has entered into a settlement agreement with Teva that will resolve pending patent litigation related to [the Teva/EpiPen litigation]." Doc. 2146-9 at 2 (Defs.' Ex. 142).[28] The press release doesn't say that Mylan was a party to the suit or settlement. *Id.* Mylan's Nina Devlin drafted the press release. Doc. 2201-20 at 2–4 (Pls.' Ex. 269). And, others within Mylan reviewed and provided comment on the press release. Doc. 2202-2 at 2 (Pls.' Ex. 271); Doc. 2202-3 at 2 (Pls.' Ex. 272); Doc. 2202-1 at 2–3 (Pls.' Ex. 270). Also, several months after the settlement, in a July 2012 earnings call, Heather Bresch commented that "the runway was absolutely clear . . . through 2015, through *our settlement* with Teva[.]" Doc. 2207-4 at 12 (Pls.' Ex. 273) (emphasis added).

The settlement agreement gave Teva a license to all issued patents and a covenant not to sue based on any current or future patents covering EpiPen devices (including the '035 Patent not at issue in the litigation, and any future patents like the '827 Patent). Doc. 2146-3 at 3, 14–15 (Defs.' Ex. 136). It did not contain any monetary payment. *See generally id.*

Plaintiffs' expert Dr. Carl Peck testified that he has no opinion whether the settlement agreement caused any delay in Teva's product development or FDA approval. Doc. 2142-3 at 9 (Defs.' Ex. 1) (Peck Dep. 115:14–116:2) (testifying that he was not giving a "casual

[28] Plaintiffs object that this exhibit is inadmissible hearsay for which no exception applies. Doc. 2190-1 at 77. But, plaintiffs don't controvert the statement of fact that relies on it. *Id.* at 20; *see also* Doc. 2226-3 at 34 (discussing "SMF ¶ 93"). And, as defendants respond, Exhibit 142 is admissible because it's not hearsay. Doc. 2226-1 at 21. Defendants don't offer the press release to prove the truth of the matter of any of the contents in the press release. And, even if it is hearsay, the Mylan press release likely qualifies as a business record subject to Fed. R. Evid. 803(6)'s exception to the hearsay rule.

explanation" for why it took Teva so long to achieve FDA approval). Also, he testified that Teva's generic device did not satisfy the requirements for FDA approval until around August 2018. *Id.* at 12 (Peck Dep. 121:9–11); *see also* Doc. 2191-7 at 8 (Pls.' Ex. 30) (Peck Expert Report ¶ 16). But, he also opines about the issue "whether the FDA caused delays in the review and approval of [Teva's] ANDA[,]" concluding "based on [his] independent review and analysis of materials identified in [his] report, [his] expertise, and [his] knowledge of the FDA drug-approval process . . . that these delays were not due to the FDA's conduct or inaction." Doc. 2191-7 at 8 (Pls.' Ex. 30) (Peck Expert Report ¶ 17).

Teva's Continued Attempts to Secure FDA Approval

As defendants' expert testified, Teva is a large, sophisticated pharmaceutical company "skilled in the art" of drug development. Doc. 2203-6 at 3–4 (Pls.' Ex. 298) (Weisman Dep. 42:24–45:6). Internal Teva documents from late 2011 and early 2012 projected that Teva would launch its generic EAI by 2014. Doc. 2203-20 at 5 (Pls.' Ex. 317); Doc. 2203-21 at 3–5 (Pls.' Ex. 318).

On July 31, 2013, Teva sent a letter to the FDA responding to a deficiency letter dated March 29, 2010—more than three years earlier. Doc. 2203-13 at 2 (Pls.' Ex. 309). On August 29, 2013, Teva submitted its first human factors study to the FDA—responding to the FDA's deficiency letter of May 17, 2011. Doc. 2146-11 at 2–5 (Defs.' Ex. 144). Earlier, in January 2012, Teva had submitted a draft protocol for this study to the FDA and requested feedback "within one month to enable Teva to proceed with the study and promptly respond to the rest of requests contained in the deficiency letter." Doc. 2146-12 at 2 (Defs.' Ex. 145). More than one and a half years later, and after Teva followed up at least three times, the FDA still had not provided feedback about the protocol. Doc. 2146-13 at 2 (Defs.' Ex. 146); Doc. 2146-14 at 1–2

(Defs.' Ex. 147); *see also* Doc. 2142-3 at 34 (Defs' Ex. 1) (Peck Dep. 208:6–10) (agreeing that Teva "went ahead and did the human factors study even though FDA had not yet gotten back to it about the draft protocol").

In 2013, Teva discovered that when the device "was dropped without the safety cap, [it] had a tendency to fire, yet it wasn't evident to the end user that the device had in fact fired." Doc. 2146-15 at 2 (Defs.' Ex. 148). So, Teva had to redesign its device again "so that the user clearly knows the device has been fired[.]" *Id.* Teva recognized that the device, "being a life saving product[,]" made it "critical [for Teva] to make this change." *Id.*

Teva recognized that "a new Human factor study will be required for this device modification[.]" *Id.* at 3. In 2014, Teva completed a new human factors study. Doc. 2146-16 at 2 (Defs.' Ex. 149). That same year, an internal Teva document estimated the net present value of the EpiPen generic at $193 million—$70 million more than any other product Teva was working to develop. Doc. 2146-17 at 4 (Defs.' Ex. 150).

As it worked to secure FDA approval, Teva implemented a "Tiger Team" to work on its generic EAI. Doc. 2205-1 at 7 (Pls.' Ex. 344); Doc. 2205-2 at 2–3 (Pls.' Ex. 345). One Teva communication defined a "Tiger Team" as "a group of experts assembled to solve a crisis or to have a reliable/predictable performance on important projects and/or tasks with high priorities." Doc. 2205-2 at 3 (Pls.' Ex. 345). In May 2014, Rosario Lobrutto asked for "more resources (and the right resources/best experts) to address current issues[.]" Doc. 2205-3 at 3 (Pls.' Ex. 346). She asked for 8.5 additional persons "to backfill the resource gaps[.]" Doc. 2205-4 at 7 (Pls.' Ex. 347). Teva agreed to "reallocate [its] existing resources from agreed upon other projects (with portfolio) to Epi[.]" *Id.* at 4.

On August 1, 2014, Teva responded to the FDA's deficiency letter dated February 2, 2011. Doc. 2203-18 at 2 (Pls.' Ex. 314). On December 30, 2014, Teva submitted an amended ANDA to the FDA that one Teva executive described as "basically . . . a completely new ANDA." Doc. 2146-18 at 2 (Defs.' Ex. 151). Teva's submission stated that it was prepared in response to the FDA's March, 2, 2010 deficiency letter. Doc. 2146-19 at 2 (Defs.' Ex. 152). Also, this response explained that Teva had "changed the site of the drug product manufacture/testing . . . and device assembly[,]" "changed the formulation" of epinephrine, and "changed the device to improve the design to ensure the user will not be presented with a device that has delivered the drug product but has not engaged the safety guard." *Id.* Teva asked the FDA to review its ANDA on an "expedited" basis. *Id.* Dr. Peck asserts that Teva could have requested "expedited review" as early as "April 2012" when the Teva/EpiPen litigation settled because "by that time . . . there were no blocking patents or exclusivities based on the Agreement." Doc. 2191-7 at 15–16 (Pls.' Ex. 30) (Peck Expert Report ¶¶ 33–34). Defendants' expert, Dr. Steven M. Weisman, agreed that Teva "theoretically could have requested expedited review at any point in time; however, [Teva] didn't have an application . . . that was likely to be approved within that time frame, so that would have certainly frustrated the FDA and not have been an appropriate request." Doc. 2203-6 at 5 (Pls.' Ex. 298) (Weisman Dep. 289:17–25). Also, Dr. Weisman testified that Teva had "deficiencies throughout a large part of the development program that weren't entirely addressed until the complete response in 2014." *Id.* at 6 (Pls.' Ex. 298) (Weisman Dep. 309:13–20).

Also, Dr. Peck opines that when "Teva finally did submit its major amendment" on December 30, 2014, "as Teva was aware, the FDA would have reviewed it under the more stringent data requirements that went into effect in mid-2014." Doc. 2191-7 at 26 (Pls.' Ex. 30)

(Peck Expert Report ¶ 56.d.). Dr. Peck explains that "a new standard policy went into effect on June 20, 2014, under which generic drugs now had to follow ICH drug product stability requirements in their ANDA filings[,]" where "both ANDAs and NDAs had the same CMC requirements for approval." *Id.* at 17 (¶ 37). Before June 2014, "generics only had to file minimal CMC data." *Id.*

Defendants did not know about the interactions between Teva and the FDA. Doc. 2143-14 at 11 (Defs.' Ex. 33) (Graham Dep. 318:21–25). So, Mylan wouldn't have known that the FDA had asked Teva to conduct a human factors study. *Id.*; *see also* Doc. 2146-20 at 20 (Defs.' Ex. 153) (Peck Rebuttal Expert Report ¶ 43).

On January 16, 2015, Mylan Specialty submitted a citizen petition to the FDA about the Teva ANDA. Doc. 2146-21 (Defs.' Ex. 154).[29] The citizen petition asked the FDA to "refrain from approv[ing] the Teva ANDA unless . . . the agency concludes that the proposed product is the 'same as' the EpiPen auto-injector." *Id.* at 2. Also, Mylan's citizen petition noted that "[p]ublicly available (and recently confirmed) information indicates that the design and operating principles of the Teva proposed product differ significantly from those of the EpiPen® auto-injector." *Id.* at 3. Based on these differences, the petition stated that Teva should provide, "at a minimum, very carefully designed human factors studies that would demonstrate the Teva product's safety and effectiveness and its comparability to the EpiPen® auto-injector." *Id.* at 4.

[29] The court rejects plaintiffs' objection to Exhibit 154—as well as Exhibits 155 and 156—based on inadmissible hearsay. Doc. 2190-1 at 77. As defendants correctly argue, these exhibits don't qualify as hearsay under Fed. R. Evid. 801(c)(2)'s definition of hearsay evidence because defendants don't offer the exhibits to prove the truth of the matters asserted in the documents. Instead, they offer the exhibits to show that Mylan communicated with the FDA about Teva's ANDA. Also, again, the court notes that plaintiffs have objected to defendants' Exhibit 154, but yet plaintiffs rely on the very same document—plaintiffs' Exhibit 325—as support for one of their summary judgment facts. Doc. 2190-1 at 70 (plaintiffs' Statement of Additional Material Fact ¶ 152 (citing Pls.' Ex. 325 (Doc. 2204-4))).

On April 28, 2015, Mylan Specialty submitted a supplement to its January 16, 2015 citizen petition. Doc. 2167-8 (Defs.' Ex. 155). It included a report from a study that Mylan cited as further support for its argument that the FDA should require Teva to submit a human factors study. Doc. 2147-1 (Defs.' Ex. 156). On June 15, 2015, the FDA "den[ied] without comment" Mylan's citizen petition. Doc. 2147-2 at 2 (Defs.' Ex. 157).[30]

After the FDA denied Mylan's citizen petition, Mylan's counsel sent a letter to the FDA. Doc. 2206-9 (Pls.' Ex. 38). Among other things, the correspondence noted that "Mylan is considering its options for seeking judicial review of FDA's decision" due to "the lack of guidance and clarity from the Agency on how it is ensuring sameness[.]" *Id.* at 12.

Plaintiffs' expert Dr. Peck testified that he was not offering an opinion whether Mylan Specialty's citizen petition caused any delay in Teva's FDA approval process, but he agreed that "citizen petitions rarely delay generic drug approvals." Doc. 2142-3 at 66 (Defs.' Ex. 1) (Peck Dep. 346:14–17). However, in his Rebuttal Expert Report, Dr. Peck describes how citizen petitions may delay generic entry, and he cites an empirical study. Doc. 2191-3 at 18–19 (Pls.' Ex. 25) (Peck Rebuttal Expert Report ¶¶ 38–41) (citing an empirical study that analyzed citizen petitions filed close to the approval date of generic drug applications).

On February 23, 2016, the FDA issued a "complete response letter"[31] denying Teva's ANDA application. Doc. 2147-3 (Defs.' Ex. 158). The complete response letter cited

[30] The court rejects plaintiffs' objection to Exhibit 157—as well as Exhibits 158 and 160—based on inadmissible hearsay. Doc. 2190-1 at 77. As defendants correctly argue, these exhibits are public records that qualify for admission under Fed. R. Evid. 803(8)'s exception to the hearsay rule.

[31] A complete response letter is a letter the FDA sends to an applicant "if the agency determines that [it] will not approve the application or abbreviated application in its present form[.]" 21 C.F.R. § 314.110(a).

"MAJOR" deficiencies with product quality, bioequivalence, microbiology, and labeling. *Id.* at 11. The FDA also criticized Teva's human factors study, stating:

> The human factors study data that you provided with respect to your proposed epinephrine auto-injector (AJE) device, which differs in a critical design attribute from EpiPen (use of a twist-off cap rather than a removable carrier tube), is insufficient to support a conclusion that your product can be substituted for EpiPen without additional training or physician intervention before use of the AJE.

Id. at 7.

Teva never re-performed its human factors study. Doc. 2191-3 at 7–8 (Pls.' Ex. 25) (Peck Rebuttal Expert Report ¶ 14) (recognizing that Teva's last human factors study "was completed years before the Human Factors Guidance was issued"). But, on August 15, 2018, the FDA alerted Teva that it had found its 2014 Teva human factors study adequate—the same study it had rejected in the 2016 complete response letter. Doc. 2147-4 at 2–3 (Defs.' Ex. 159).

The next day, August 16, 2018, the FDA approved Teva's ANDA. Doc. 2147-5 at 2 (Defs.' Ex. 160). The FDA approval letter noted that it had found Teva's generic EAI "therapeutically equivalent to the referenced listed drug (RLD), EpiPen Jr. Auto-Injector, 0.12 mg and EpiPen Auto-Injector, 0.3 mg, of Mylan Specialty L.P. (Mylan)." *Id.*

The FDA issued a press release announcing the approval. *FDA Approves First Generic Version of EpiPen*, FDA (Aug. 16, 2018), https://www.fda.gov/news-events/press-announcements/fda-approves-first-generic-version-epipen. It noted: "The development of generic combination products" like an EAI "can be more challenging than typical drug products." *Id.*

Although Teva received FDA approval in August 2018, the company did not launch its generic EAI at that time. Instead, it launched the 0.3 mg strength product (corresponding to EpiPen Auto-Injector in limited quantity) on November 27, 2018, and the 0.15 mg strength

(corresponding to EpiPen Jr Auto-Injector) on August 20, 2019. *See Teva's Generic Version of EpiPen® Auto-Injector 0.3mg Now Available in Limited Quantity in the United States*, Business Wire (Nov. 27, 2018), https://www.businesswire.com/news/home/20181127005573/en/Teva%E2%80%99s-Generic-Version-EpiPen%C2%AE%C2%A0-Epinephrine-Injection-USP; *see also Teva Announces Availability of a Generic Equivalent of EpiPen Jr® Auto-Injector, 0.15mg in the United States*, Business Wire (Aug. 20, 2019), https://www.businesswire.com/news/home/20190820005419/en/Teva-Announces-Availability-Generic-Equivalent-EpiPen-Jr%C2%AE.[32]

Plaintiff's expert, Dr. Carl Peck, calculates that it took Teva "9 years and 9 months" to secure FDA approval. Doc. 2191-7 at 26–27 (Pls.' Ex. 30) (Peck Expert Report ¶ 58 & Table 2). He measures that time starting on November 21, 2008—when the FDA accepted Teva's ANDA for filing—and ending on August 16, 2018—the date the FDA approved Teva's generic. *Id.* Dr. Peck compared the time it took Teva to secure FDA approval to those of other EAI manufacturers, and he opines that "none have required the lengthy time for review and approval exhibited by the Teva generic EAI." *Id.* at 26 (¶ 58). He asserts that "the other EAIs all were subject to the more stringent NDA standards (as opposed to ANDA standards)" yet "most were approved in 2–3 years, while the longest review and approval time was 6.5 years from initial filing." *Id.*

[32] To the extent plaintiffs challenge defendants' citation to these news articles because they aren't attached as summary judgment exhibits, *see* Doc. 2190-1 at 76–77, the court rejects that challenge because plaintiffs don't controvert the summary judgment facts cited in this statement of fact, *see* Doc. 2190-1 at 20.

Also, Dr. Peck reviewed the approval time for other auto-injector products. *Id.* at 27–28 (¶ 59 & Table 3); *see also* Doc. 2191-3 at 16–17 (Peck Rebuttal Expert Report ¶ 35 & Table 3). He notes that with other auto-injector products that "[a]gain, none have required the lengthy time for review and approval exhibited by the Teva generic epinephrine autoinjector." Doc. 2191-7 at 27 (¶ 59). Instead, the approval time for other auto-injector products has ranged from six months to 69 months. *Id.* at 28 (Table 3). Dr. Peck asserts that this data shows "autoinjectors are common, their technology is well-developed, and that all of the autoinjectors on the market today were reviewed and approved in less than half the time of the Teva EAI." Doc. 2191-3 at 16 (¶ 35). Also, "at least six of the EAIs" that Dr. Peck lists "required an HFS[,]" which, he asserts, "shows that Teva had the same opportunity as other EAI manufacturers to develop and prosecute ANDA and NDA injectable products within a reasonable time period." *Id.*

Last, Dr. Peck reviewed other Teva injectable products and opines that "on average, they were approved in under 30 months." Doc. 2191-7 at 29 (¶ 60 & Table 4). He notes that "the longest submission to approval time" for the other Teva injectable products "was 48 months or about one half the time" that it took Teva to secure approval of its generic EAI. *Id.* at 29 (¶ 60).

Dr. Peck opines that "the FDA review and guidance did not delay the approval of Teva's application." *Id.* at 9 (¶ 18). "On the contrary," he asserts, "the evidence confirms that the FDA treated this as a priority application and was responsive well within the metrics for review time of the application." *Id.* But, he opines that "Teva 'dropped the ball' in the 2011–2014 time frame by not pursuing the application aggressively or responding to the FDA[.]" *Id.* at 25 (¶ 56(c)). Based on his review of Teva's communications with the FDA, he concludes that "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 10 (¶ 21).

Cephalon's Lawsuit Against Mylan Involving Unrelated Drug Nuvigil

On December 11, 2009, pharmaceutical company Cephalon, Inc. filed a lawsuit in the District of Delaware alleging patent infringement against Mylan based on Mylan's ANDA to manufacture and sell a generic version of the pharmaceutical product Nuvigil (armodafinil). *See generally*, Complaint, *Cephalon, Inc. v. Mylan Pharms., Inc.*, No. 1:09-cv-00954 (D. Del. Dec. 11, 2009), ECF No. 1. Nuvigil is a "prescription drug" used to "improve wakefulness in patients with excessive sleepiness[.]" *Id.* at 1. Cephalon sued six other generic manufacturers, along with Mylan, who were seeking ANDA approval to manufacture and sell armodafinil tablets. *See* Transfer Order at Schedule A, *In re: Armodafinil Patent Litig.*, No. 1:10-md-02200 (D. Del. Dec. 8, 2010), ECF No. 1. In December 2010, the Judicial Panel on Multi-District Litigation consolidated the cases into a multidistrict litigation in the District of Delaware before Judge Sleet. *Id.* In this MDL, the Nuvigil defendants advanced similar defenses and relied on the same experts. *See* Doc. 2147-6 at 50–51 (Defs.' Ex. 161) (Folsom Rebuttal Expert Report ¶ 142).

In October 2011, while the Nuvigil litigation was pending, Teva acquired Cephalon.[33] *Press Release Details: Teva Completes Acquisition of Cephalon*, Teva Pharm. (Oct. 14, 2011), https://ir.tevapharm.com/news-and-events/press-releases/press-release-details/2011/Teva-Completes-Acquisition-of-Cephalon/default.aspx.

As discussed above, after Teva filed the Nuvigil lawsuits, the Hatch-Waxman Act triggered a 30-month stay for each Nuvigil defendant's ANDA, meaning the FDA couldn't finally approve those ANDAs while the Nuvigil litigation was ongoing. 21 U.S.C. §

[33] Cephalon continued to litigate the Nuvigil litigation as Cephalon even after Teva acquired it. The parties refer to Cephalon as Teva going forward, and the court adopts that convention.

355(j)(5)(B)(iii); *Id.* § 355(c)(3)(C). But, during the 30-month stay, the FDA tentatively had approved Mylan's ANDA, Doc. 2147-7 at 2 (Def's Ex. 162), which meant that the ANDA met substantive requirements for final approval, *ANDA Submissions-Amendments and Requests for Final Approval to Tentatively Approved ANDAs Guidance for Industry*, FDA (Sept. 2020), https://www.fda.gov/media/119718/download. Mylan's stay was set to expire on May 3, 2012, which meant that the FDA potentially could have granted final approval on that day. Letter to Judge Sleet, *In re: Armodafinil Patent Litig.*, No. 1:10-md-02200 (D. Del. Mar. 13, 2012), ECF No. 225 at 1–2. Teva asserted in a brief seeking a temporary restraining order and a preliminary injunction, filed in the Nuvigil litigation that: "Other than this patent litigation, there are likely to be no legal impediments to Mylan's launching of its products on or after May 3[, 2012]." Plaintiffs' Memorandum of Law in Support of Their Motion for a Temporary Restraining Order and Preliminary Injunction at 1, *In re: Armodafinil Patent Litig.*, No. 1:10-md-02200 (D. Del. Apr. 10, 2012), ECF No. 270 at 5. In contrast, the FDA never granted tentative approval to Teva's ANDA for a generic EAI while the Teva/EpiPen litigation was pending. *See* Doc. 2147-3 (Defs.' Ex. 158) (explaining the deficiencies with Teva's ANDA identified in the FDA's February 23, 2016 complete response letter).

Mylan refused to agree to forgo launching its product on May 3, 2012. Letter to Judge Sleet at 1, *In re: Armodafinil Patent Litig.*, No. 1:10-md-02200 (D. Del. Mar. 13, 2012), ECF No. 225 at 1. And, on March 30, 2012, as the parties were in settlement negotiations, Mylan rejected Teva's request to extend the stay until May 15, 2012. Doc. 2147-8 at 2 (Defs.' Ex. 163). The next day, Teva sent a draft term sheet to Mylan. Doc. 2147-9 at 2 (Defs.' Ex. 164); Doc. 2147-10 at 2–11 (Defs.' Ex. 165).[34]

[34] The court rejects plaintiffs' objection to Exhibits 164 and 165 based on inadmissible hearsay. Doc. 2190-1 at 77. As defendants correctly argue, these exhibits don't qualify as hearsay under

On April 26, 2012, Mylan and Teva executed a binding term sheet to resolve the claims against Mylan in the Nuvigil litigation. Doc. 2147-11 at 2–18 (Defs.' Ex. 166). As already discussed, this was the same day that Pfizer and Teva executed a binding term sheet that resolved the Teva/EpiPen litigation. Doc. 2146-3 at 14–20 (Defs.' Ex. 136).

Under the agreement to resolve the Nuvigil litigation, Mylan acquired the right to launch certain armodafinil products on June 1, 2016 (50mg, 150mg, and 250mg strength tablets) and others on June 1, 2019 (100mg and 200mg strength tablets) without infringing Teva's patents, which were set to expire in 2024. Doc. 2147-11 at 3–4, 6–7; *see also* Doc. 2147-16 at 3 (Defs.' Ex. 171) (listing the Nuvigil patents' 2024 expiration dates).[35] The settlement did not include any monetary payment between Mylan and Teva. *See generally* Doc. 2147-11 (Defs.' Ex. 166). By settling, both Mylan and Teva avoided litigation risk and millions of dollars in expected litigation costs. Doc. 2146-5 at 103 (Defs.' Ex. 138) (Torrance Expert Report ¶ 214). Pfizer, King, and Meridian were not parties to the Nuvigil MDL or settlement. *See generally* Doc. 2147-11 (Defs.' Ex. 166).

The other defendants in the Nuvigil MDL went to trial in July 2012 and didn't prevail. Memorandum at 1, *In re: Armodafinil Patent Litig.*, No. 1:10-md-02200 (D. Del. Mar. 30, 2013), ECF No. 329 at 1; *see also* Doc. 2147-12 at 13 (Defs.' Ex. 167) (admitting in response to defendants' request for admission that "Mylan's non-settling codefendants . . . did not prevail at trial"). The non-prevailing defendants appealed. Notices of Appeal, *In re: Armodafinil Patent*

Fed. R. Evid. 801(c)(2)'s definition of hearsay because defendants don't offer the exhibits to prove the truth of the matters asserted in the documents. Instead, they offer the exhibits to show Mylan and Teva exchanged a binding term sheet.

[35] The court rejects plaintiffs' objection to Exhibit 171 based on inadmissible hearsay. Doc. 2190-1 at 77. As defendants correctly argue, this letter from the FDA qualifies as a business record under Fed. R. Evid. 803(6)'s exception to the hearsay rule. Also, this exhibit—a letter from the FDA—likely is a public record that qualifies for admission under Fed. R. Evid. 803(8)'s exception to the hearsay rule.

Litig., No. 1:10-md-02200 (D. Del. Mar. 30, 2013), ECF Nos. 331, 332, 334, & 336. While the appeal was pending, the parties settled. *See* Doc. 2202-4 (Pls.' Ex. 274); Doc. 2202-5 (Pls.' Ex. 275); Doc. 2202-6 (Pls.' Ex. 276); Doc. 2202-7 (Pls.' Ex. 277).

The draft agreements granted defendants a "License Effective Date" for their generic Nuvigil products that was at least 180 days after Mylan's first sale of a generic product. *See* Doc. 2202-4 at 5 (Pls.' Ex. 274); Doc. 2202-5 at 3 (Pls.' Ex. 275); Doc. 2202-6 at 3 (Pls.' Ex. 276); Doc. 2226-10 at 3 (Defs.' Ex. 381). And, some of the draft settlement agreements required Teva to pay defendants for their legal fees. *See* Doc. 2202-4 at 6 (Pls.' Ex. 274); Doc. 2202-5 at 5 (Pls.' Ex. 275); Doc. 2202-6 at 6 (Pls.' Ex. 276).

Then President and CEO of Teva-Americas William Marth had discussions with Heather Bresch about both the Teva/EpiPen settlement and the Nuvigil settlement. *See* Doc. 2201-21 at 2 (Pls.' Ex. 255) (explaining that Mr. Marth had "talked to Heather . . . about settlement" of the EpiPen litigation and that "[s]he (Heather) wants to give us a 2018 entry date but would likely agree to 2017" and noting that "[j]ointly but not directly connected is the Nuvigil litigation" where Mr. Marth "offered a 2018 entry date"); *see also* Doc. 2202-20 at 2 (Pls.' Ex. 278) (stating in first email that "Bill [Marth] got a call from Heather at Mylan" and asking what "exactly did we propose re epi and nuvigil?" and responding in another email with "2014 for epi and 2018 for nuvigil. No months specified."); Doc. 2202-9 at 2 (Pls.' Ex. 279) (sending the Nuvigil term sheet and discussing changes that were "agreed to between Heather and Mr. Marth"). Also, other Mylan and Teva employees discussed the EpiPen and Nuvigil settlements in the same communications. *See* Doc. 2201-13 at 2 (Pls.' Ex. 262) (stating that Teva had called Mylan's Deputy General Counsel and "relayed the following proposal: epipen in 2014 and nuvigil in 2018"); *see also* Doc. 2202-13 at 2 (Pls.' Ex. 283) (noting that "the signed Nuvigil deal was"

complete and "language w Pfizer on Epipen is done"); Doc. 2201-20 at 2 (Pls.' Ex. 269) (Mylan employees emailing with the subject line "Epipen—Teva/Potential Settlement" and attaching a "Nuvigil Settlement DRAFT").

On April 30, 2012, Mylan issued a press release announcing the Nuvigil settlement.[36] On May 10, 2012, Mylan's outside counsel sent a letter to the FTC and DOJ providing copies of the Nuvigil Settlement and EpiPen Settlement agreements. Doc. 2147-13 at 2 (Defs.' Ex. 168). The letter stated: "While Mylan does not believe it is required to file the EpiPen Settlement in connection with the Nuvigil Settlement, it nonetheless files this agreement as a potentially 'related' agreement solely out of an abundance of caution." *Id.* Mylan's 30(b)(6) witness testified that it submitted the settlements to the FTC and DOJ "solely out of an abundance of caution. We certainly don't believe they actually are related." Doc. 2146-6 at 10 (Defs.' Ex. 139) (Jenkins Dep. 136:23–137:23).

On July 3, 2012, the FTC responded, stating that while it reserved the right to investigate, "nothing in this letter should be construed to indicate that a violation of law has occurred." Doc. 2147-14 at 2 (Defs.' Ex. 169).[37] But, the FTC noted that its "Bureau of Competition is concerned that the Teva-Mylan agreement on [another drug product,] generic Provigil[,] may be related to delayed generic Nuvigil entry and/or delayed generic EpiPen entry." *Id.*

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[36] The citation defendants provide for this statement of fact is no longer available online, but plaintiffs don't controvert this statement of fact. *See* Docs. 2142-1 at 50, 2190-1 at 20; *see also* Doc. 2226-3 at 40 (discussing "SMF ¶ 118"). So, the court accepts it for purposes of this summary judgment motion.

[37] The court rejects plaintiffs' objection to Exhibit 169 based on inadmissible hearsay. Doc. 2190-1 at 77. As defendants correctly argue, this letter from the FDA qualifies as a public record that is admissible under Fed. R. Evid. 803(8)'s exception to the hearsay rule. Also, plaintiffs quote language from this letter to support one of their own statements of fact. Doc. 2190-1 at 63 (plaintiffs' Statement of Additional Material Fact ¶ 118). While the court understands that some hearsay issues can turn on the identity of the offering party, *see* Fed. R. Evid. 801(d)(2), that isn't the case here. Plaintiffs have used the same FDA letter to support their facts, but also they object to defendants using it. This tact is not impressive.

A few years later, in May 2015, the FTC announced that it had "entered into a landmark settlement with Cephalon, Inc. and its parent company, Teva . . . to resolve its action against Cephalon for illegally monopolizing the market for the sale of its blockbuster sleep-disorder drug Provigil." Doc. 2207-5 at 2 (Pls.' Ex. 295). The FTC said it "was prepared to prove that Cephalon paid four generic competitors to abandon their challenges to Cephalon's Provigil patent and stay off the market for six years in violation of the antitrust laws, resulting in significantly higher prices for the drug and substantial consumer harm." *Id.* Then, in February 2017, Mylan "agreed to pay $96.5 million to settle claims by drug purchasers that it delayed launching a generic version of Cephalon Inc.'s narcolepsy drug Provigil in exchange for payment from Cephalon." Doc. 2207-6 at 2 (Pls.' Ex. 296). And, in January 2017, Mylan reported that it had "received a 'preliminary' inquiry from" the FTC "asking about the company's commercial practices for its EpiPen severe-allergy treatments." Doc. 2207-7 at 2 (Pls.' Ex. 297). As of August 2019, the FTC investigation still was pending. Doc. 2191-15 at 5 (Pls.' Ex. 44) (Ondos Dep. 89:14–17).

The Pfizer attorneys who handled the EpiPen litigation testified that they never had heard of the Nuvigil litigation, or even the Nuvigil product, until after the present lawsuit was filed. Doc. 2145-18 at 16–17 (Defs.' Ex. 129) (Myers Dep. 205:16–206:7) (testifying that the "first time [he] heard of Nuvigil" was in "connection with" this lawsuit); Doc. 2146-8 at 5 (Defs.' Ex. 141) (Rennecker Dep. 164:8–13) (testifying that he "never heard of Nuvigil prior to this litigation"). Also, they testified that they were not aware of anyone at Pfizer who had any involvement with the Nuvigil litigation and that the Nuvigil litigation was not discussed in any joint Pfizer-Mylan telephone conferences. Doc. 2145-18 at 12 (Defs.' Ex. 129) (Myers Dep. 115:4–13); Doc. 2146-8 at 6–7 (Defs.' Ex. 141) (Rennecker Dep. 167:10–18, 168:4–7). Some

Mylan witness likewise testified that the Nuvigil and EpiPen settlements were independent, and that Mylan played no role in directing or managing the Teva/EpiPen litigation or settlement. Doc. 2146-7 at 89–90 (Defs.' Ex. 140) (Ondos Dep. 89:18–90:9) (testifying that "both lawsuits had separate, independent tracks and negotiations" and "their terms were not linked"); *see also id.* at 3–4 (Ondos Dep. 59:17–60:23) (testifying that Mylan had no "decisionmaking right" in the Teva/EpiPen litigation); Doc. 2150-1 at 3–4 (Def's Ex. 174) (Bresch Dep. 57:17–58:23) (testifying that "even though the settlements occurred on the same date" there "was no linkage between EpiPen and Nuvigil").

Other Patent Litigation

In 2011, Pfizer—through its subsidiaries—filed a patent infringement lawsuit against Intelliject after it sought to secure FDA approval to market "e-cue," the predecessor to competing EAI, Auvi-Q. Complaint, *King Pharms. Inc. v. Intelliject Inc.*, No. 1:11-cv-00065-GMS (D. Del. Jan. 19, 2011), ECF No. 1. Pharmaceutical company Sanofi-Aventis later secured the rights to the Auvi-Q device. Doc. 2169 at 6 (Pretrial Order ¶ 2.a.46.). After that acquisition of rights, Sanofi executed a settlement with Pfizer to resolve the case. Doc. 2191-16 at 2 (Pls.' Ex. 45). Mylan wasn't a party to the agreement, but yet, Mylan drafted the press release announcing the settlement and the initial draft didn't include references to Pfizer's involvement. *See id.* ("Mylan [and Pfizer] Announce Epinephrine Auto-Injector Settlement Agreement"). The agreement allowed Sanofi to launch "e-cue" in November 2012. *Id.*

EAIs in the United States

When Mylan acquired Dey in 2007, another branded EAI called Twinject was available for purchase in the United States in both .3mg and .15mg doses. Doc. 2150-3 at 9 (Defs.' Ex.

176).[38] Twinject's name is a reference to the fact that each device contained two doses. *Id.* at 6. It was removed from the market in 2012. Doc. 2150-4 at 12 (Defs.' Ex. 177). Another branded product, Adrenaclick, secured FDA approval under a modified version of the Twinject NDA and launched in 2009 in both .3mg and .15mg doses. Doc. 2150-3 at 9 (Defs.' Ex. 176). In 2010, an authorized generic to the Adrenaclick product became available in both .3mg and .15mg doses. *Id.*; *see also* Doc. 2150-5 (Defs.' Ex. 178); Doc. 2150-6 (Defs.' Ex. 179).

In January 2013, Sanofi launched a branded EAI called Auvi-Q. Doc. 2169 at 6 (Pretrial Order ¶ 2.a.46.). In October 2015, Sanofi issued a Class I voluntary recall of all Auvi-Q devices in the United States. *Id.* (Pretrial Order ¶ 2.a.47.).

Some named plaintiffs continued to purchase EpiPens after filing this lawsuit. Doc. 2144-16 at 11–13 (Defs.' Ex. 102) (citing Defs.' Ex. 102-A). And, some named plaintiffs testified that they purchased EpiPen products even though a generic or other alternative was available for purchase. *Id.*

Sale of Pharmaceutical Products in the United States

Pharmaceutical manufacturers sell prescription drugs through a multi-step distribution chain—from manufacturer to wholesaler to pharmacy to patient. Doc. 2150-9 at 14–18 (Defs.' Ex. 182) (Navarro Expert Report ¶ 23). For patients with insurance, the price at the pharmacy depends on the terms of their insurance coverage, among other factors. *Id.* at 20, 29–30 (¶¶ 36, 51). Uninsured patients generally pay the price set by the pharmacy, although patients can lower the pharmacy price by using discount cards and coupons. *Id.* at 19–20 (¶ 35).

[38] The court rejects plaintiffs' objection to Exhibit 176—as well as Exhibits 177, 178, 179, 180, & 181—based on plaintiffs' argument that the documents are inadmissible hearsay to which no exception applies. Doc. 2190-1 at 77. These documents produced by Mylan qualify for admission as business records under Fed. R. Evid. 803(6)'s exception to the hearsay rule. Doc. 2226-1 at 21; *see also* Doc. 2227-1 at 11–12 (Cuthbertson Decl.).

The term "formulary" refers to a published list of prescription drugs covered by a health plan. *Id.* at 28 (¶ 48). Another name for a "formulary" is a "preferred drug list." *Id.* Pharmacy Benefit Managers ("PBMs") develop, manage, and administer prescription drug benefit programs for commercial payors and other insurance programs, including Medicare and Medicaid. *Id.* at 12 (¶ 18). Among other things, PBMs create formularies for insurance companies and payors. *Id.* at 28 (¶¶ 48–71).

Formularies organize drugs by therapeutic category and are designed to include a selection of medicines to satisfy the needs of insured customers. *Id.* at 29 (¶¶ 49–50). Formularies change over time as drugs enter or leave the market, and as new data becomes available. *Id.* (¶ 49). Formularies also use different levels of "control," referring to how strictly the plan enforces the list of covered drugs. *Id.* at 32–33 (¶ 57). With an "open" or "low control" plan design, a health plan typically covers many (sometimes all) of the drugs on the formulary, or covers at least some portion of the cost of drugs that are not included on the formulary. *Id.* In contrast, with a "closed" or "high control" plan design, a health plan typically covers only the products listed on the formulary. *Id.*

PBMs typically develop standard formularies, giving their clients options from which to choose. Doc. 2150-11 at 25, 35 (Defs.' Ex. 184) (Kautzner (ESI) Dep. 190:2–21, 273:5–19). Also, some PBMs allow health-plan and large-employer clients to customize drug formularies. Doc. 2150-10 at 5–6 (Defs.' Ex. 183) (Anderson (CVS) Dep. 67:15–68:7); Doc. 2150-11 at 35 (Defs.' Ex. 184) (Kautzner (ESI) Dep. 273:5–19). Some of the largest PBMs maintain hundreds or thousands of formularies. Doc. 2150-10 at 3–4 (Defs.' Ex. 183) (Anderson (CVS) Dep. 35:17–36:5); Doc. 2150-11 at 18 (Defs.' Ex. 184) (Kautzner (ESI) Dep. 178:5–20); Doc. 2150-12 at 3 (Defs.' Ex. 185) (Rogers (OptumRx) Dep. 36:7–21).

Also, PBMs use "Utilization Management" techniques—such as copayments and tiering, step edits, prior authorization, and benefit exclusion—to incentivize the use of one drug over another. Doc. 2150-9 at 33–37 (Defs.' Ex. 182) (Navarro Expert Report ¶¶ 58–60). Payors use these techniques to encourage patients to use more cost-effective products. *Id.* at 36 (¶ 59). They also use these tools to negotiate lower prices from manufacturers by offering preferred formulary placement in exchange for greater rebates. *See* Doc. 2150-16 at 3 (Defs.' Ex. 189) (Stein (Humana) Dep. 210:1–8); *see also* Doc. 2150-11 at 28 (Defs.' Ex. 184) (Kautzner (ESI) Dep. 197:7–18).

The use of copayments and tiering involves a payor requiring patients to pay a portion of the cost for a prescription drug, either a fixed-dollar copayment or a percentage-based coinsurance. Doc. 2150-9 at 29–30 (Defs.' Ex. 182) (Navarro Expert Report ¶ 51). The most common formularies have three or more "tiers" with increasing copayments. *Id.* Copayment differentials encourage patients to purchase lower-tier drugs, *e.g.*, to purchase a preferred Tier 2 brand over a non-preferred Tier 3 brand. *See, e.g.*, Doc. 2150-17 at 5–7 (Defs.' Ex. 190) (Kronberg (Cigna) Dep. 58:17–60:4); Doc. 2150-12 at 10 (Defs.' Ex. 185) (Rogers (OptumRx) Dep. 43:13–24).

A "step edit" or "step therapy" requirement usually requires a patient to fill a prescription for a preferred drug before the plan will reimburse for purchasing a branded alternative. Doc. 2150-9 at 35 (Defs.' Ex. 182) (Navarro Expert Report ¶ 58(c)); *see also* Doc. 2197-12 at 3 (Pls.' Ex. 176) (Brodeur Dep. 32:7–13) (explaining that a step edit requires a patient "to have the trial or failure or a reason [the patient] can't take the" preferred drug before the payor will cover the alternative drug).

Prior authorization requirements mean a plan will cover a drug product only if the patient's physician formally requests the payor to approve coverage. *Id.* at 35–36 (¶ 59(d)). Each payor determines the approval criteria for a prior authorization. *Id.* If a Tier 3 drug has a prior authorization requirement, the patient must secure that authorization and then pay the Tier 3 copayment. *Id.*

A benefit exclusion excludes a drug from coverage altogether. *Id.* at 34 (¶ 58(a)). Since 2012, payors increasingly have excluded drugs from coverage (rather than covering them on a higher copay tier), sometimes covering only one branded product per therapeutic class of drugs. *Id.* at 53–54 (¶¶ 95–97).

A PBM's ability to promote or prefer drugs to prescribers and patients gives it leverage when negotiating price discounts from branded drug manufacturers. *Id.* at 52 (¶ 89). Manufacturers set a WAC (or list price) for their prescription drugs. *Id.* at 13–14 (¶ 22). But, they also may offer retrospective rebates to PBMs. *Id.* at 45 (¶¶ 75–77). A retrospective rebate is what a manufacturer pays to a PBM after the PBM reimburses a pharmacy for the balance of the cost of a prescription drug that the pharmacy sold to an insured consumer. *Id.* Defendants' expert opines that "most of the rebate value (approximately 90%) paid to PBMs is transferred back to the purchaser or insured individual to reduce pharmacy costs." *Id.* at 52 (¶ 90). Rebates are common in the pharmaceutical industry. *Id.* at 45–46 (¶ 78).

Many PBMs solicit rebates from manufacturers by inviting manufacturers to fill out "bid grids." *Id.* at 55 (¶ 98). A bid grid is a table with blank cells corresponding to different levels of control. *Id.* at 56–57 (¶ 100 & Fig. 6). Manufacturers fill out the blank cells of the bid grid with rebate percentages that represent their bids for various formulary placements. *Id.* Often, after submitting a bid grid with proposed rebate percentages, the manufacturers and PBMs enter

negotiations where the PBMs try to secure the highest possible rebates, sometimes by pitting competing manufacturers against each other. *See, e.g.*, Doc. 2150-11 at 6–7 (Defs.' Ex. 184) (Kautzner (ESI) Dep. 119:18–120:8) (testifying about how Express Scripts, Inc. "continu[es] to try to push rebates up" with manufacturers); Doc. 2150-15 at 12 (Defs.' Ex. 188) (Hall (Prime) Dep. 58:12–17) (testifying how the entry of a competing drug gave Prime "the opportunity . . . to renegotiate improved rates"); Doc. 2150-19 at 5 (Defs.' Ex. 192) (Minton (Anthem) Dep. 75:1–14) (testifying about how Anthem goes "back to the manufacturers to press" for higher rebates).

If negotiations are successful, PBMs and manufacturers enter rebate agreements. *See e.g.*, Doc. 2152-1 at 2–5 (Defs.' Ex. 201) (Mylan/ESI Rebate Agreement); Doc. 2152-2 at 2–22 (Defs.' Ex. 202) (Mylan/CVS Agreement). Often, the rebate agreements contain a menu of options from which a PBM's clients can choose. *See e.g.*, Doc. 2152-1 at 4–5 (Defs.' Ex. 201); Doc. 2152-2 at 19–21 (Defs.' Ex. 202). As one example, in 2015, Mylan and Express Scripts, Inc. ("ESI") entered a Rebate Agreement that contained a menu of rebate opinions. Doc. 2152-5 at 4 (Defs.' Ex. 205). This Agreement memorialized Mylan's offer of up to a 50.625% rebate for exclusive position for EpiPen. *Id.* But, Mylan also offered up to 40.625% for 1-of-2 placement, meaning that health plans could access both EpiPen and competing EAI Auvi-Q and still realize about 80% of the discount that Mylan offered for exclusivity. *Id.* So, depending on what the payor preferred, it could select EpiPen as the exclusive product for a 10% increase in the rebate Mylan was offering. *Id.* Or, it could offer both products and receive the 40.635% rebate.

Mylan's rebate agreements with payors typically specified a term of three years or less. Doc. 2152-8 at 2, 9 (Defs.' Ex. 208) (Mylan/MedImpact Rebate Agreement with two year term); Doc. 2152-9 at 2 (Defs.' Ex. 209) (Mylan/Aetna Rebate Agreement with two year term); Doc. 2152-10 at 2–3 (Defs.' Ex. 211) (Mylan/OptumRx Rebate Agreement with two year term); Doc.

2192-8 at 11 (Pls.' Ex. 57) (Mylan/CVS Rebate Agreement with three year term). And, PBMs typically renegotiate their rebate agreements at least annually. *See* Doc. 2150-16 at 6 (Defs.' Ex. 189) (Stein (Humana) Dep. 228:1–5) (testifying that rebates were renegotiated annually); *see also* Doc. 2150-11 at 23–24 (Defs.' Ex. 184) (Kautzner (ESI) Dep. 185:24–186:22). Also, Sanofi's rebate agreements typically "were annual contracts" and sometimes were renegotiated midterm. Doc. 2152-11 at 3–4 (Defs.' Ex. 212) (Borneman Dep. 28:9–29:17). Most of Mylan's rebate agreements with payors allowed termination without cause on 90 days' notice or less. *See, e.g.*, Doc. 2152-8 at 9 (Defs.' Ex. 208) (Mylan/MedImpact Rebate Agreement with 90 days' notice provision); Doc. 2152-12 at 5 (Defs.' Ex. 213) (Mylan/Aetna Rebate Agreement with 90 days' notice provision); Doc. 2155-1 at 3 (Defs.' Ex. 215) (Mylan/CIGNA Rebate Agreement with 60 days' notice provision).

Mylan's rebate agreements generally reserve to PBMs the right to alter their commercial formularies at any time. *See* Doc. 2155-2 at 4 (Defs.' Ex. 216) (Mylan/ESI rebate agreement) ("Nothing in this Agreement shall be construed to limit the ability of ESI or any ESI Client to remove a Product from formulary."); *see also* Doc. 2155-3 at 8 (Defs.' Ex. 217) (Mylan/CVS rebate agreement containing similar language); Doc. 2155-4 at 8 (Defs.' Ex. 218) (Mylan/OptumRx rebate agreement containing similar language); Doc. 2155-5 at 7 (Defs.' Ex. 219) (Mylan/Prime rebate agreement containing similar language). And, Mylan has renegotiated its rebate agreement with a PBM during a contract term when the PBM initiated negotiations as a way to seek better rebates. *See, e.g.*, Doc. 2150-10 at 34–37 (Defs.' Ex. 183) (Anderson (CVS) Dep. 231:2–234:3) (describing how CVS asked Sanofi and Mylan for better rebate offers mid-contract term).

Pfizer asserts that neither it nor its subsidiaries played any role in negotiating contracts, rebates, formulary placement, or discounts with wholesalers, payors, PBMs, or other industry partners. Doc. 2143-31 at 3, 6–8 (Defs.' Ex. 64) (Handel Dep. 138:9–12, 151:10–153:5); *see also* Doc. 2155-6 at 3 (Defs.' Ex. 220). Mylan's CEO Heather Bresch testified that she was not involved in the "day to day" negotiations and contract strategies with PBMs. Doc. 2143-3 at 17 (Defs.' Ex. 21) (Bresch Dep. 316:19–317:17). But Mylan documents show that Ms. Bresch was involved in discussions about EpiPen formulary placements and exclusions as Mylan negotiated these terms with PBMs. Doc. 2206-13 at 2 (Pls.' Ex. 61); Doc. 2206-14 at (Pls.' Ex. 62).

Sanofi Launches Auvi-Q

In 2013, Sanofi's revenue exceeded $43 billion. *See* Sanofi, Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, at 2–3 (Form 20-F) (Mar. 6, 2014), https://www.sec.gov/Archives/edgar/data/1121404/000104746914001951/a2217900z20-f.htm (reporting almost $44 billion, calculated using average exchange rate for 2013). Around the same time, Mylan's revenue was less than $7 billion. *See* Mylan Inc., Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, at 46 (Form 10-K) (Feb. 27, 2014), https://www.sec.gov/Archives/edgar/data/69499/000006949914000007/myl10k_20131231xdoc.htm (listing "Total revenues" as more than $6.9 billion).

In 2009, Sanofi secured a license to market and sell Auvi-Q. Doc. 2155-8 (Defs.' Ex. 222).[39] And, in January 2013, Sanofi launched Auvi-Q in the U.S. Doc. 2169 at 6 (Pretrial

[39] Once again, plaintiffs assert an objection to defendants' exhibit offered as evidentiary support for this factual statement. Defendants' Exhibit 222 is Sanofi's License and Development Agreement with Intelliject that granted Sanofi the right to market and sell Auvi-Q. Plaintiffs assert this Agreement is inadmissible hearsay to which no exception applies. Doc. 2190-1 at 77. Defendants respond that this document qualifies as a business record that is admissible under Fed. R. Evid. 803(6)'s exception to the hearsay rule. Doc. 2226-1 at 21. The court agrees. This document was produced by Sanofi. *See generally* Doc. 2155-8 (Sanofi Bates-numbered document). It's an Agreement that it entered in the course of its business. And, it likely qualifies as a business record that is admissible under the

Order ¶ 2.a.46.). The Auvi-Q was the first and only EAI drug device with audiovisual cues to guide patients how to administer epinephrine. Doc. 2206-18 at 2–3 (Pls.' Ex. 150).

Mylan's Response to Auvi-Q

Before Auvi-Q's launch, Mylan internally referred to EpiPen as having "100% market share." Doc. 2192-17 at 3 (Pls.' Ex. 68). Mylan recognized there was a "strong interest" in Auvi-Q "due to is size shape and advanced technology." Doc. 2196-8 at 3 (Pls.' Ex. 151). And, Pfizer recognized that Auvi-Q posed "a significant threat to [its] EpiPen business." Doc. 2196-15 at 2 (Pls.' Ex. 158); *see also* Doc. 2196-10 at 3 (Pls.' Ex. 153) ("Auvi-Q represents a significant threat to EpiPen market share[.]").

So, Mylan decided to implement a "proactive" response to Auvi-Q that included using "[e]xclusivity language" in rebate agreements. Doc. 2196-19 at 35 (Pls.' Ex. 162). One Mylan employee suggested "only pay[ing] rebates if a client is willing to exclude Auvi[-]Q." Doc. 2206-19 at 2 (Pls.' Ex. 165). Mylan also proposed a strategy of using prior authorization and step edits against Auvi-Q. Doc. 2197-10 at 34 (Pls.' Ex. 174). Mylan referred to these strategies as "high controls." Doc. 2197-16 at 10 (Pls.' Ex. 180). Plaintiffs' expert opines that Mylan's use of "all three of these restrictive coverage statuses [*i.e.*, exclusive rebating, prior authorization, and step edits] significantly restrained the usage of rival EAIs." Doc. 2193-4 at 82 (Pls.' Ex. 85) (Elhauge Expert Report ¶ 155).

Some PBMs testified that EAIs were not "historically managed aggressively" before Auvi-Q's launch. Doc. 2192-5 at 6 (Pls.' Ex. 54) (Minton (Anthem) Dep. 279:3–13); *see also*

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exception to the hearsay rule. Fed. R. Evid. 803(6). Also, because this exhibit is a contract, it isn't hearsay because it has independent legal significance. *See Kepner-Tregoe, Inc. v. Leadership Software, Inc.*, 12 F.3d 527, 540 (5th Cir. 1994) ("Signed instruments such as wills, contracts, and promissory notes are writings that have independent legal significance and are not hearsay." (citation and internal quotation marks omitted)). The court rejects plaintiffs' objection as utterly baseless.

Doc. 2192-13 at (Pls.' Ex. 64) (Jan (Horizon) Dep. 143:23–144:2) (testifying that rebates weren't restrictive in the EAI class before 2013). Other witnesses recognized that the EAI market was "unique" but they provided different reasons for that conclusion. Doc. 2192-1 at 4 (Pls.' Ex. 50) (Eaton Dep. 122:13–123:25) (testifying that the EAI was "unique" because "patients get one prescription per year" and the product involves "a life-and-death situation" so "people are adamant [and] want to get [the] prescription filled"); Doc. 2192-2 at 3 (Pls.' Ex. 51) (Rogers Dep. 333:5–9) (testifying that the EAI category was "unique" because "market share for EpiPen was so dominant"); Doc. 2194-9 at 6 (Pls.' Ex. 109) (Bresch Dep. 248:3–18) (testifying that the EAI market was "unique" because it had a need to "expand the market"); Doc. 2197-6 at 3 (Pls.' Ex. 170) (Loreaux Dep. 213:12–214:15) (testifying that the EAI market was "unique" because it "predominately had one market player [with] nearly a hundred percent of the market share").

Before 2013, Mylan typically offered rebates below 10 percent. *See* Doc. 2155-9 at 5 (Defs.' Ex. 224);[40] *see also* Doc. 2197-7 at 3–4 (Pls.' Ex. 171) (Foster Dep. 212:17–213:8) (testifying that Mylan rebates were in the range of "3 to 5 percent"); Doc. 2197-8 at 3 (Pls.' Ex. 172) (Jordan Dep. 39:2–8) (testifying that, in 2011, Mylan rebates were in the single digits).

As Auvi-Q prepared to launch, Mylan implemented a strategy to "negotiate, where possible, language requiring plans to put EpiPen in sole preferred position and no restrictions." Doc. 2197-17 at 4 (Pls.' Ex. 181) (Korczynski Dep. 254:3–10). Mylan also sought to require

[40] It's like a broken record. Plaintiffs assert an objection to defendants' Exhibit 224 based on inadmissible hearsay to which no exception applies. Doc. 2190-1 at 77. Yet, plaintiffs also don't dispute this statement of fact. *Id.* at 20; *see also* Doc. 2226-3 at 52 (discussing "SMF ¶ 156"). Defendants respond that this document qualifies as a business record that is admissible under Fed. R. Evid. 803(6)'s exception to the hearsay rule. Doc. 2226-1 at 21. The court agrees. As defendants have shown, this document, produced by Mylan, qualifies for admission as a business record under Fed. R. Evid. 803(6)'s exception to the hearsay rule. Doc. 2226-1 at 21; *see also* Doc. 2227-1 at 11–12 (Cuthbertson Decl.). The court thus overrules this objection, yet another of plaintiffs' meritless and needless evidentiary objections.

prior authorizations and step edits. Doc. 2197-19 at 2 (Pls.' Ex. 183). Mylan told PBMs that, if they wanted to secure larger rebates, Mylan would require restrictions on Auvi-Q. Doc. 2197-13 at 3 (Pls.' Ex. 177) (Willing Dep. 63:17–25).

Mylan sought to "hammer Sanofi at launch." Doc. 2197-20 at 4 (Pls.' Ex. 184). Mylan proposed "strategic imperatives" that would "[p]reemptively blunt adoption of new entrants (branded and generic)[.]" Doc. 2198-1 at 132 (Pls.' Ex. 185). Robert Coury, then Mylan's CEO, instructed the marketing team to "pre-empt any new market entry[.]". Doc. 2198-2 at 2 (Pls.' Ex. 186). And, Mylan's Director of National Accounts expressed a desire to "block further competition." Doc. 2198-3 at 3 (Pls.' Ex. 187); *see also* Doc. 2206-20 at 2 (Pls.' Ex. 189) (discussing Mylan's efforts of "locking [Auvi-Q] out").

Also in anticipation of Auvi-Q's launch, Mylan increased the WAC price on the EpiPen several times. *See* Doc. 2198-16 at 15 (Pls.' Ex. 202) (recommending an "increase" of EpiPen's "WAC price [by] 19.9%" because there was an opportunity to "[g]ain incremental revenue on current volume before competition comes to market"); Doc. 2199-4 at 7 (Pls.' Ex. 210) (recommending "an immediate price increase on EpiPen, the size" of which "should depend on the launch timing of" Auvi-Q); Doc. 2199-5 at 16 (Pls.' Ex. 211) (noting that EpiPen price increases "now will elevate the overall market price giving the ability to take a discount off a higher WAC"). EpiPen's WAC price rose from a little over $100 for two EpiPens in 2007 to more than $600 for two EpiPens in 2016. Doc. 2199-6 at 2 (Pls.' Ex. 212). When one PBM complained that the EpiPen price increases were "not sustainable or acceptable[,]" a Mylan executive commented that a "reason for the higher WAC is these massive rebates" Mylan was paying. Doc. 2199-7 at 2 (Pls.' Ex. 213).

Mylan told various PBMs, including ESI, MedImpact, and Humana, that it would offer higher rebates but conditioned those rebates on excluding or restricting Auvi-Q from their formularies. *See* Doc. 2198-6 at 2 (Pls.' Ex. 191) (discussing with ESI that Mylan would not offer more rebates unless ESI was willing to block or restrict Auvi-Q); *see also* Doc. 2198-11 at 3 (Pls.' Ex. 197) (discussing that MedImpact cannot have access to rebates unless it controls the EAI class); Doc. 2198-12 at 2 (Pls.' Ex. 198) (offering Humana "more rebate" if it makes EpiPen "1 of 1 and block[s] competitors"). As plaintiffs' expert explains, the "PBM industry is highly concentrated" and the "large PBMs generally offer the same set of pharmacy benefit formularies to many different insurers," so, as a consequence, "a single contract between a manufacturer and a PBM can affect the pharmacy benefit formularies of many different insurers." Doc. 2193-4 at 81 (Pls.' Ex. 85) (Elhauge Expert Report ¶ 153).

By mid-November 2013, Mylan reported that its "[m]ajor wins have resulted in Auvi-Q not being covered or requiring patients to try EpiPen before Auvi-Q in about 20% (87 million) of the US population." Doc. 2199-1 at 4 (Pls.' Ex. 207). One of Mylan's consultants commented that Mylan would "go down in pharma history" because Auvi-Q was offering a "better mousetrap" but was "at 7% share 1 year post launch—unheard of." Doc. 2199-2 at 2 (Pls.' Ex. 208). By June 2015, Mylan's Pricing Committee had approved Mylan offering rebates in the range of 50% to 60% off the EpiPen WAC for the largest PBMs and up to 30% for specifically targeted managed care accounts, conditioned on exclusive or preferred formulary coverage for EpiPen. Doc. 2199-3 at 2–5 (Pls.' Ex. 209).

After Auvi-Q entered the market, Mylan trained its sales force to understand "the 'spillover' effect[,]" meaning that in territories where Mylan was preferred on a majority of plans, the sales force should "emphasize the preferred plans[.]" Doc. 2199-9 at 2 (Pls.' Ex. 215);

see also Doc. 2197-7 at 5 (Pls.' Ex. 171) (Foster Dep. 278:1–9) (explaining that the "concept of spillover typically refers to when a doctor is used to writing [a] product" because the manufacturer has "strong formulary positions" and "then it tends to have a spillover effect where the doctor just gets patterned into" prescribing the product). And, Mylan's sales force sought to "leverage EpiPen's superior formulary coverage" when competing against Auvi-Q. Doc. 2199-12 at 2 (Pls.' Ex. 218) (urging team to "put Sanofi out of business!"); *see also* Doc. 2197-15 at 8 (Pls.' Ex. 179) (noting in an email that recent "wins are HUGE!" and Mylan should "leverage them beyond belief!").

Mylan also listed as one of its "Message Areas with the most expansion potential" as "anti-competitive messages" about Auvi-Q. Doc. 2199-10 at 9 (Pls.' Ex. 216). It noted that "[b]undling of anticompetitive messages can move physicians, even if individual anticompetitive messages may not[.]" *Id.* at 11; *see also* Doc. 2199-11 at 6 (Pls.' Ex. 217) (suggesting that physicians "need to hear anticompetitive messages" about Auvi-Q).

Mylan marketed to physicians that EpiPen was "preferred" on many health plans while Auvi-Q was restricted. Doc. 2200-1 at 3 (Pls.' Ex. 227) (stating for "the 95 million patients in these major plans," EpiPen "is the preferred brand"). Mylan's marketing materials noted that "[h]ealth plans and PBMs make formulary decisions based on internal clinical and financial recommendations." *Id.* In one email, Mylan noted that "[f]rom a clinical perspective the plans have 'spoken' by selecting EpiPen over Auvi-[Q]" and encouraged sales people to "understand and leverage that [message] with their customers." Doc. 2199-9 at 2 (Pls.' Ex. 215). But, Mylan is not aware of any payor who chose EpiPen over Auvi-Q based on "clinical or superiority" reasons because that's not information that payors share with Mylan. Doc. 2200-3 at 3 (Pls.' Ex. 229) (Graham Dep. 179:15–21). And, as Mylan's expert testified, he is unaware of any PBM or

payor refusing to cover Auvi-Q for "clinical reasons" because "both products have the same amount of epinephrine and [are] deemed bioequivalent by the FDA." Doc. 2200-4 at 3 (Pls.' Ex. 230) (Zieziula Dep. 26:13–20).

Also, Mylan funded and presented a study titled: "Auvi-Q Versus EpiPen Auto-Injectors: Failure to Demonstrate Bioequivalence of Epinephrine Delivery Based on Partial Area Under the Curve." Doc. 2200-5 at 3–5 (Pls.' Ex. 231). But, Mylan also recognized that the FDA had reviewed Auvi-Q and concluded that the epinephrine "demonstrat[ed] bioequivalence" with the epinephrine in EpiPen. *Id.* at 31.

Pfizer was apprised of Mylan's strategies for competing against Auvi-Q through its participation in the JCC. *See* Doc. 2199-14 at 89 (Pls.' Ex. 220) (JCC presentation discussing "a pre-emptive and launch action plan for future competition"). Also, Pfizer learned through its participation in the JCC about Mylan's success in blocking Auvi-Q from formulary access. Doc. 2199-15 at 44 (Pls.' Ex. 221) (JCC presentation discussing competitive intelligence about Auvi-Q and noting that "[m]ajor wins have resulted in Auvi-Q not being covered or requiring patients to try EpiPen before Auvi-Q in about 31% (93 million in the US population)").

Pfizer "raised concerns about EpiPen pricing" with Mylan. Doc. 2199-19 at 2 (Pls.' Ex. 225). Meridian's General Manager and President testified that he "didn't think" it "was an accurate description for the cost drivers" of EpiPen to say that the "wholesale price has changed over time to better reflect the multiple important product features and the value the product provides." Doc. 2194-1 at 3 (Pls.' Ex. 101) (Handel Dep. 163:15–164:22).

Sanofi's Rebate Agreements with PBMs

Sanofi's pricing strategy was to launch Auvi-Q at parity with EpiPen and then price at a premium because Sanofi felt that it "had the better product." *See also* Doc. 2150-24 at 3–4, 12

(Defs.' Ex. 197) (Viehbacher Dep. 93:14–94:6, 210:8–16). In January 2013, Sanofi launched Auvi-Q at a WAC of $241.00 per two-pack—just slightly above the $240.66 WAC for an EpiPen two-pack. Doc. 2143-13 at 2 (Defs.' Ex. 32).[41]

In July 2013, Mylan increased the WAC for EpiPen devices by 9.9%. Doc. 2157-1 at 3 (Defs.' Ex. 225). Sanofi adopted a "fast follower strategy," where it quickly followed any EpiPen WAC increases by raising the Auvi-Q WAC even higher. Doc. 2157-2 at 5 (Defs.' Ex. 226).[42] Sanofi increased Auvi-Q's WAC six times during the 33 months it marketed Auvi-Q, maintaining a premium over EpiPen for most of the period. Doc. 2157-3 at 3 (Defs.' Ex. 227).

Sanofi initially decided that it would not compete with Mylan on price, instead pursuing a "Mix of T2 and T3 access (not T2 at all cost)." Doc. 2157-4 at 5 (Defs.' Ex. 228). Sanofi's Vice President in charge of Auvi-Q, Bryan Downey, testified that Sanofi was "not planning for a lot of tier two access" for Auvi-Q and was "perfectly fine with tier two or tier three" placement for Auvi-Q. Doc. 2157-5 at 5–6 (Defs.' Ex. 229) (Downey Dep. 8:8–9:7). The head of Sanofi's allergy division agreed that Sanofi was "trying to really negotiate . . . for tier three coverage."

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[41] The court rejects plaintiffs' objection to defendants' Exhibit 32—as well as their objection to Exhibit 225 cited in the first sentence of the next paragraph—based on inadmissible hearsay to which no exception applies. Doc. 2190-1 at 77. Plaintiffs don't dispute these statements of fact. *Id.* at 20; *see also* Doc. 2226-3 at 52 (discussing "SMF ¶¶ 156–157"). And, in any event, defendants correctly explain that these Mylan-produced documents qualify as business records that are admissible under Fed. R. Evid. 803(6)'s exception to the hearsay rule. Again, the court is perplexed by plaintiffs' purposeless objection tactics.

[42] Plaintiffs object to defendants' Exhibits 226 and 227 as inadmissible hearsay to which no exception applies. Doc. 2190-1. But, plaintiffs also don't dispute the factual statements that the exhibits support. *Id.* at 20; *see also* Doc. 2226-3 at 52–53 (discussing "SMF ¶ 158"). Nevertheless, defendants correctly explain that these Sanofi-produced documents qualify as business records that are admissible under Fed. R. Evid. 803(6)'s exception to the hearsay rule. For the same reasons, the court rejects all of plaintiffs' other objections to Sanofi-produced documents as inadmissible hearsay because the Sanofi documents qualify as business records that fall outside the definition of hearsay under Fed. R. Evid. 803(6). Also, plaintiffs' objections fail the sincerity standard because plaintiffs themselves rely on Sanofi-produced business records as summary judgment evidence to support their own factual statements. *See, e.g.*, Doc. 2190-1 at 34 (citing Doc. 2192-12 (Pls.' Ex. 63) (Sanofi-produced internal email)).

Doc. 2157-7 at 3 (Defs.' Ex. 231) (Barry Dep. 156:2–12). And Sanofi's former Head of North America testified that Sanofi's strategy for Auvi-Q was to "get[] Tier 3 access so patients would have the product available versus going to Tier 2." Doc. 2157-8 at 3–4 (Defs.' Ex. 232) (Whitaker Dep. 45:16–46:3).

Sanofi's initial contracting guidelines for Auvi-Q rebates were "pretty small"—in the range of 3–10% for Tier 2. Doc. 2157-10 at 3–4 (Defs.' Ex. 234) (Denney Dep. 99:25–100:13). But, Sanofi's account executives reported that PBMs and payors were rejecting offers in this range as "not competitive" and even "laughable." *See, e.g.*, Doc. 2157-12 at 2 (Defs.' Ex. 236) (explaining Auvi-Q offer rejected by PBM as "inadequate"); Doc. 2157-13 at 2 (Defs.' Ex. 237) (informing Sanofi that its offer to PBM was "not competitive"); Doc. 2157-14 at 2 (Defs.' Ex. 238) (reporting that PBM called Auvi-Q offer "'laughable'"). Within a few months of launch, Mr. Downey questioned whether Sanofi was "being aggressive enough." Doc. 2157-15 at 3 (Defs.' Ex. 239).

PBMs' Coverage Decisions

When Auvi-Q launched, many PBMs and commercial insurers determined that either EpiPen or Auvi-Q devices were clinically adequate to treat anaphylaxis. *See, e.g.*, Doc. 2157-16 at 4 (Defs.' Ex. 240) (noting that ESI's Pharmacy & Therapeutics ("P&T") review committee had recommended Auvi-Q as an "optional" treatment for anaphylaxis); Doc. 2157-17 at 22 (Defs.' Ex. 241) (explaining that CVS had identified Auvi-Q and EpiPen as part of a "[t]herapeutically interchangeable class"); Doc. 2157-18 at 13 (Defs.' Ex. 242) (stating that Prime would choose "one epinephrine product" to cover); Doc. 2159-1 at 20 (Defs.' Ex. 243) (asserting that UnitedHealthcare's P&T committee "determined Auvi-Q to be therapeutically equivalent . . . to EpiPen"); Doc. 2159-2 at 5–6 (Defs.' Ex. 244) (Shia (Kaiser) Dep. 95:14–96:7)

(testifying that Kaiser determined the "clinical efficacy would be the same" for Auvi-Q and EpiPen).[43] *But see* Doc. 2192-13 at 3 (Pls.' Ex. 64) (Jan (Horizon) Dep. 56:11–57:10) (testifying that Auvi-Q and EpiPen were "clinically . . . the same" but noting a "preference" for Auvi-Q because of its "convenience" and because it was a "more-consumer-friendly device").

Several large PBMs and payors told both Sanofi and Mylan that they might cover or prefer only one EAI product on their formularies. *See, e.g.*, Doc. 2159-3 at 3 (Defs.' Ex. 245) (stressing the "need to raise the level of importance with the brand team around CVS Caremark's plan to review the [EAI] class and choose an exclusive product"); Doc. 2159-4 at 2 (Defs.' Ex. 246) (reporting that Kaiser has "suggested that [it] only want[s] one product" and "there has been discussion of replacing Epi-Pen"); Doc. 2159-5 at 2 (Defs.' Ex. 247) (reporting that "MedImpact likes the Auvi-Q product but wishes to have only one product in the category"); Doc. 2159-6 at 2 (Defs.' Ex. 248) (reporting that OptumRx asked whether Mylan was "interested in a guaranteed exclusive position for EpiPen in exchange for the addition of 10% price protection").

For example, in late 2012, OptumRx warned Mylan that "EpiPen is at risk" if it didn't offer price protection because the PBM was "well aware of the price increases Mylan [had] taken." Doc. 2159-7 at 3 (Defs.' Ex. 249). OptumRx also gave Mylan an example where "the benefit exclusion can be flipped to exclude the prominent brand." *Id.* About a month later, OptumRx told Mylan that it expected Sanofi to make a "strong rebate offer to gain coverage and potentially displace EpiPen[,]" so it was seeking a "competitive bid" from Mylan "to maintain [its] current positioning." Doc. 2159-8 at 2 (Defs.' Ex. 250). In early 2013, Cigna told Mylan

[43] The court rejects plaintiffs' objections to all of these third-party produced documents as inadmissible hearsay to which no exception applies. Doc. 2190-1 at 77 (objecting to defendants' Exhibits 235 through 243). Defendants assert that these documents—produced by PBMs—qualify as business records subject to Fed. R. Evid. 803(6)'s hearsay exception. Doc. 2226-1 at 21. The court agrees and thus overrules plaintiffs' objections.

that it "can use tier differential and step therapy" with the EAI class and that it was "looking for an offer for exclusive epinephrine positioning." Doc. 2159-9 at 2 (Defs.' Ex. 251).

But not all PBMs sought to manage the EAI class by excluding products from coverage. *See* Doc. 2192-13 at 3 (Pls.' Ex. 64) (Jan (Horizon) Dep. 56:11–57:23) (testifying that Auvi-Q and EpiPen both were offered on the "preferred tier" of the formulary); *see also* Doc. 2192-5 at 6 (Pls.' Ex. 54) (Minton (Anthem) Dep. 280:1–25) (testifying that Anthem was willing to cover multiple EAIs and not "seeking out exclusive offers"). And, some PBMs expressed concern about excluding EpiPen because of its large market share. *See* Doc. 2198-14 at 2 (Pls.' Ex. 200) (noting that, if forced to switch to Auvi-Q, patient disruption at Optum "would be really significant"); Doc. 2198-15 at 2 (Pls.' Ex. 201) (recognizing that, at MedImpact, it "would be very difficult for Sanofi to neutralize that savings advantage given [EpiPen's] current share"); Doc. 2192-5 at 7 (Pls.' Ex. 54) (Minton (Anthem) Dep. 292:22–293:5) (testifying that Mylan's market share had an impact in Anthem's decision to accept Mylan's offer because "the more share [Mylan] had, the more the rebate was attributable to that share" and "the value of selecting that scenario where [Anthem] would edit Auvi-Q was increased").

Also, Mylan recognized that PBMs would be "heavily impacted" if they worked against Mylan because of the large amount of administrative fees Mylan had paid them. Doc. 2198-16 at 15 (Pls.' Ex. 202). And, at least one PBM recognized that "with EpiPen's presence in the market and being established . . . there's basically going to be no way you could get everybody off of EpiPen" because that would require "mov[ing] at least 60 percent of [the] market share just to break even." Doc. 2192-20 at 65 (Pls.' Ex. 71).

When Auvi-Q launched in January 2013, many PBMs, including ESI, CVS, Prime, Aetna, and Cigna—covered Auvi-Q on Tier 3 by default before any review by their P&T

Committees. Doc. 2157-4 at 17–18 (Defs.' Ex. 228). However, United, following its standard policy "not [to] cover new products . . . with the same active ingredients as other covered products" before P&T review, did not cover Auvi-Q at launch. Doc. 2150-13 at 10 (Defs.' Ex. 186) (Etemad (United) Dep. 84:9–16); *see also* Doc. 2159-8 at 2 (Defs.' Ex. 250).

PBMs and payors then solicited rebate offers from Mylan and Sanofi, giving them the opportunity to compete through rebates or other discounts, and with some payors suggesting a willingness to exclude or place restrictions on one of the products. *See, e.g.*, Doc. 2159-3 at 3 (Defs.' Ex. 245) (discussing "CVS Caremark's plan to review the [EAI] class and choose an exclusive product"); Doc. 2159-11 at 2 (Defs.' Ex. 253) (noting in CVS's bid solicitation letter to Mylan the availability of "exclusion opportunities"); Doc. 2159-13 at 5 (Defs.' Ex. 255) (explaining that OptumRx "intends to manage the products" in the EAI class "using a combination of tier placement and product exclusion"); Doc. 2160-1 at 2 (Defs.' Ex. 257) (explaining MedImpact was "looking for a 1 or 1 offer for the" EAI class); Doc. 2159-9 at 2 (Defs.' Ex. 251) (asserting that Cigna was "looking for an offer for exclusive epinephrine positioning"). When payors asked for non-exclusive rebate offers—or several rebate options—Mylan provided them. *See, e.g.*, Doc. 2152-1 at 4 (Defs.' Ex. 201) (providing several rebate offers to ESI but also providing "no bid" for several categories); Doc. 2152-2 at 19 (Defs.' Ex. 202) (same to CVS); Doc. 2160-3 at 2 (Defs.' Ex. 260) (same to OptumRx); Doc. 2160-4 at 5, 7 (Defs.' Ex. 261) (same to Prime); Doc. 2160-5 at 2–5 (Defs.' Ex. 262) (same to MedImpact).

Several PBMs testified that, after negotiating with both Mylan and Sanofi, each PBM and payor made its own independent formulary determinations for the EAI class and that Mylan never threatened to cut off EpiPen supply based on a PBMs' formulary decisions.[44] *See, e.g.*,

[44] Plaintiffs attempt to controvert the statement that Mylan never threatened to cut off supply by citing two Mylan documents. But neither document, even when construed in plaintiffs' favor,

Doc. 2160-7 at 3–5 (Defs.' Ex. 264) (Cunico (Presbyterian) Dep. 148:17–150:24, 178:21–179:5); Doc. 2150-16 at 8–10 (Defs.' Ex. 189) (Stein (Humana) Dep. 282:7–284:2); Doc. 2160-6 at 3–4 (Defs.' Ex. 263) (Brodeur (Aetna) Dep. 130:3–131:7); Doc. 2150-15 at 28 (Defs.' Ex. 188) (Hall (Prime) Dep. 150:11–25); Doc. 2152-13 at 6–7 (Defs.' Ex. 214) (Vargo (Aetna) Dep. 130:17–131:9); Doc. 2150-11 at 30–34 (Defs.' Ex. 184) (Kautzner (ESI) Dep. 204:4–211:23); Doc. 2150-19 at 141 (Defs.' Ex. 192) (Minton (Anthem) Dep. 141:19–24). With the PBMs that chose to cover Auvi-Q, Mylan still paid rebates to those PBMs which covered both EpiPen and Auvi-Q. *See, e.g.*, Doc. 2152-2 at 2–22 (Defs.' Ex. 202) (Mylan/CVS Agreement); Doc. 2152-4 at 2–5 (Defs.' Ex. 204).

Three PBMs—CVS, Prime, and Cigna—never restricted or excluded Auvi-Q, covering it on Tier 2 or Tier 3 without restriction. Doc. 2150-10 at 9–13 (Defs.' Ex. 183) (Anderson (CVS) Dep. 112:12–116:23); Doc. 2150-15 at 16–17, 23–24 (Defs.' Ex. 188) (Hall (Prime) Dep. 110:22–111:9, 129:24–130:7); Doc. 2150-17 at 18–22 (Defs.' Ex. 190) (Kronberg (Cigna) Dep. 79:3–83:8). Also, with MedImpact, EpiPen had an exclusive Tier 2 position with a step-edit placed on Auvi-Q on MedImpact's three standard commercial formularies, but MedImpact's custom clients remained eligible for rebates from Sanofi if they covered Auvi-Q. Doc. 2160-9 at 2 (Defs.' Ex. 266). For example, MedImpact client University of Michigan added Auvi-Q in a Tier 2 position. Doc. 2160-10 at 2 (Defs.' Ex. 267). Also, on open plans—about 15% of

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suggests that Mylan threatened to cut off supply of EpiPens. *See* Doc. 2192-17 at 2–3 (Pls.' Ex. 68) (listing as a "talking point" for a meeting with MedImpact that "Mylan will terminate its current contract if MedImpact implements a step edit *against EpiPen*[,]" meaning that Mylan will withdraw its current rebates if the PBM imposed a restriction on EpiPen but never saying anything about cutting off EpiPen supply (emphasis added)); Doc. 2192-18 at 2 (Pls.' Ex. 69) (informing OptumRx that "[i]f for some reason, [OptumRx/UnitedHealthcare] decides *to exclude EpiPen* in 2014, we will not pay any enhanced rebates in 2013[,]" but never mentioning that Mylan would cut off EpiPen supply (emphasis added)).

MedImpact's clients—Auvi-Q had equal preferred positioning with EpiPen. Doc. 2160-9 at 2 (Defs.' Ex. 266).

PBMs made different decisions about how they would cover EpiPen and Auvi-Q. For example, Blue Cross Blue Shield of California covered both EpiPen and Auvi-Q on the preferred brand tier. Doc. 2160-11 at 2 (Defs.' Ex. 268). Humana covered EpiPen on the preferred tier, and Auvi-Q as non-preferred. *See* Doc. 2160-12 at 3 (Defs.' Ex. 269); *see also* Doc. 2160-16 at 3 (Defs.' Ex. 270). Presbyterian Health covered Auvi-Q on the preferred tier and EpiPen as non-preferred. Doc. 2160-14 at 2 (Defs.' Ex. 271).[45] Anthem/Wellpoint covered EpiPen as the preferred brand and placed a restriction on Auvi-Q. Doc. 2161-1 at 2 (Defs.' Ex. 274). Kaiser Permanente chose to cover only just one device and selected EpiPen.[46] Doc. 2161-5 at 3–4 (Defs.' Ex. 278). And, Geisinger Health Plan restricted EpiPen in favor of Auvi-Q. Doc. 2161-6 at 2 (Defs.' Ex. 279).

By the beginning of 2014, Sanofi recognized that Mylan's "very aggressive approach on pricing to try to exclude Auvi-Q" was affecting Auvi-Q's sales, so "it became clear" to Sanofi that it had "no choice but to try to gain access to the marketplace by significantly discounting" Auvi-Q. Doc. 2150-24 at 5–6 (Viehbacher Dep. 121:18–122:10). In January 2014, Sanofi's CEO suggested "mak[ing] an offer that kicks [Mylan] off a formulary. If Mylan knows we can be aggressive it may help." Doc. 2161-7 at 2 (Defs.' Ex. 280). Sanofi's Head of North America agreed that Sanofi should "get aggressive." Doc. 2161-8 at 2 (Defs.' Ex. 281).

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[45] Sanofi offered 25% rebates to Presbyterian Health, Doc. 2160-15 at 3 (Defs.' Ex. 272), while Mylan offered 15.5% rebates, Doc. 2160-16 at 2 (Defs.' Ex. 273).

[46] A Kaiser Permanente witness testified that the company usually contracts for one drug and it solicits up-front discounts instead of rebates. Doc. 2159-2 at 3–4, 14–15 (Defs.' Ex. 244) (Shia (Kaiser) Dep. 82:14–83:3, 264:14–265:19). The witness further testified that when it chose to stay with EpiPen Auvi-Q launched because Mylan offered "the better price." *Id.* at 7–9 (Defs.' Ex. 244) (Shia (Kaiser) Dep. 106:11–108:1).

Sanofi succeeded in reversing its exclusion from ESI's national formulary. Doc. 2161-10 at 2 (Defs.' Ex. 283). As part of its negotiations with ESI to achieve coverage for Auvi-Q, Sanofi offered additional rebates on its insulin drug Lantus. *See* Doc. 2192-23 at 3 (Pls.' Ex. 74); *see also* Doc. 2192-14 at 2 (Pls.' Ex. 75). As a Sanofi witness testified, the Lantus offers were an "unprecedented" and "desperate move" by Sanofi to secure more formulary access for Auvi-Q. Doc. 2192-4 at 3 (Pls.' Ex. 53) (Borneman Dep. 138:18–139:17).

ESI then approached Mylan for a better rebate offer, and initially, Mylan offered just a 2% enhancement. Doc. 2161-9 at 8 (Defs.' Ex. 282). ESI responded by telling Mylan that it would switch to covering Auvi-Q as a preferred product in 2015. *Id.* ESI then gave Mylan an ultimatum: Either offer a 45% rebate to share Tier 2 with Auvi-Q or offer a 58% rebate to remain exclusive. *Id.* Mylan responded by offering a 45% rebate to share Tier 2 with Auvi-Q but offered just a 55% rebate to remain exclusive. Doc. 2161-11 at 3 (Defs.' Ex. 284). ESI accepted Mylan's 45% rebate offer and covered both EpiPen and Auvi-Q on its main formulary in 2015. Doc. 2161-10 at 2 (Defs.' Ex. 283). But, it excluded EpiPen on its High Performance formulary in favor of Auvi-Q. Doc. 2161-12 at 3 (Defs.' Ex. 285).

Sanofi had success with Aetna too. It offered Aetna a 65% rebate for exclusivity for 2015. Doc. 2161-13 at 2 (Defs.' Ex. 286). Aetna then used Sanofi's offer to push Mylan to offer a 45% rebate for EpiPen to be co-preferred on Tier 2. Doc. 2161-14 at 2 (Defs.' Ex. 287). Ultimately, Sanofi agreed to a 30% rebate for Auvi-Q to be co-preferred on Tier 2 (a lower rebate than Mylan for the same access). Doc. 2162-1 at 7–9 (Defs.' Ex. 289). Aetna then made EpiPen and Auvi-Q co-preferred on its value and premier formularies effective January 1, 2015. Doc. 2162-3 at 2 (Defs.' Ex. 291).

Also, Sanofi improved its coverage at CVS by offering rebates of 40% for unrestricted coverage, 50% for exclusive preferred coverage, and 65% for exclusive formulary coverage with EpiPen and Adrenaclick excluded. Doc. 2162-4 at 19–20 (Defs.' Ex. 292).[47] The parties memorialized the rebate menu in a rebate agreement effective July 1, 2014, through December 31, 2015. Doc. 2162-5 at 2–28 (Defs.' Ex. 293). With this offer, Sanofi not only secured co-preferred Tier 2 formulary coverage for Auvi-Q on CVS's Preferred Drug List, but it also became the sole preferred drug (with EpiPen excluded) on CVS's Value Based Formulary beginning July 1, 2014, and CVS's Advanced Control Formulary beginning October 1, 2014. Doc. 2162-6 at 2 (Defs.' Ex. 294). And, CVS then used this offer to persuade Mylan to offer increased rebates to avoid exclusion on its Preferred Drug List. Doc. 2162-7 at 3–4 (Defs.' Ex. 295); Doc. 2162-8 at 6 (Defs.' Ex. 296); Doc. 2162-9 at 3–5 (Defs.' Ex. 297). CVS continued to exclude EpiPen devices on the Value Based Formulary and Advanced Control Formulary until Sanofi recalled Auvi-Q from the market. Doc. 2162-12 at 2–3 (Defs.' Ex. 300); *see also* Doc. 2150-10 at 38–39 (Anderson (CVS) Dep. 252:16–253:22).

Sanofi also maintained coverage it had previously secured at Prime and Cigna, among others. Doc. 2162-13 at 7 (Defs.' Ex. 301). An August/September 2014 internal Sanofi document recognized the advances it had made in coverage by stating, "Thanks for Your Tremendous Efforts to Recapture and Secure Access[,]" and then listing "Great Recent Auvi-Q Decisions" with 10 PBMs. *Id.*

But Sanofi wasn't able to secure favorable coverage with every PBM in 2015. For example, United gave Sanofi the opportunity to renegotiate. Doc. 2162-14 at 3 (Defs.' Ex. 302). United expressly requested an offer for exclusive coverage, and it told Sanofi its target rebate

[47] The percentages include base rebates, incremental rebates, and a 4% administrative fee.

was 60%. *Id.* Sanofi did not make an exclusive offer, offering instead a lower rebate (35%) for coverage at any tier. Doc. 2162-15 at 5 (Defs.' Ex. 303). In contrast, Mylan offered a higher rebate (37%) for exclusive coverage and maintained its exclusive position. Doc. 2163-1 at 10 (Defs.' Ex. 304).

Similarly, in March 2014, Sanofi approached MedImpact about removing a step-edit on Auvi-Q. Doc. 2163-2 at 3 (Defs.' Ex. 305). MedImpact told Sanofi it "would need to offer a discount in the upper 30s to low 40s . . . to even open the conversation." *Id.* at 2. And, MedImpact recognized that it "would be very difficult for Sanofi to neutralize that [EpiPen] savings advantage given [EpiPen's] current share." *Id.* at 2. Sanofi declined to offer the requested discount. Doc. 2163-3 at 2 (Defs.' Ex. 306); Doc. 2163-4 at 2 (Defs.' Ex. 307).

A 2016 Pfizer email identified the "cost of goods sold" for an EpiPen 2-Pak as $18.32. Doc. 2193-9 at 2 (Pls.' Ex. 90). Mylan never sold EpiPen devices at a price below production costs. Doc. 2163-5 at 9–10, 39–55 (Defs.' Ex. 308) (Willig Expert Report ¶¶ 14, 89–122) (concluding that "Mylan's prices, taking full account of rebates and price protection, were above an appropriate measure of its cost" in analysis of PBM contracts).[48] Also, there is no evidence that a PBM or payor ever excluded Sanofi when it offered a lower per-unit price than Mylan. *See id.* at 64 (¶ 142) (emphasizing that plaintiffs' expert had failed to identify "a single instance where Auvi-Q was offered at a lower net price per unit than EpiPen" and still "a plan 'restricted' Auvi-Q on its formulary"). There are, however, examples where Sanofi offered higher rebates

[48] Plaintiffs try to controvert this fact by citing their own expert's opinion that Mylan's rebate agreements violate the discount attribution test. Doc. 2192-6 at 237–38, 247–50 (Pls.' Ex. 55) (Elhauge Reply Expert Report ¶¶ 402, 419–22). As Prof. Elhauge explains, the discount attribution test "shows that [Mylan's rebate agreements] have the potential to force an equally efficient rival to exit the market." *Id.* at 237–38 (¶ 402). And, applying that test to rebate agreements at issue here, he concludes that "many or most of Mylan's agreements did in fact fail the discount attribution test by resulting in below-cost incremental prices." *Id.* But, as defendants correctly explain, Prof. Elhauge's analysis isn't evidence that Mylan sold an EpiPen device at a price below its production cost.

and price protection to PBMs, but it was unable to secure exclusivity for Auvi-Q over EpiPen. *See, e.g.*, Doc. 2193-1 at 4 (Defs.' Ex. 82) (showing Sanofi's offer to ESI of a 60.625% rebate with 10% price protection for exclusivity); *see also* Doc. 2193-3 at 2 (showing Sanofi offer Aetna 65% rebates for exclusive coverage compared to Mylan's 55% exclusive offer).

Prof. Elhauge performed an analysis showing the percentage of Auvi-Q foreclosure to consumers—both insured and uninsured. Doc. 2192-6 at 90 (Pls.' Ex. 55) (Elhauge Reply Expert Report Fig. 104). His analysis shows that, in 2013, about 80% of consumers had access to Auvi-Q. *Id.* In 2014, that number fell to around 65%, but it grew again in 2015, to about 69%, meaning that Auvi-Q was foreclosed from about 31% of consumers. *Id.* In Canada, where Auvi-Q had access equal to EpiPen, Auvi-Q reached a 30% market share within at least three years of launch. Doc. 2200-12 at 4 (Pls.' Ex. 240) (Fairest Dep. 236:20–237:24); Doc. 2200-13 at 2 (Pls.' Ex. 241).

PBM Negotiations

Pfizer played no role in PBM negotiations.[49] Several PBMs testified that their negotiations with Mylan were "spirited" and even "contentious." *See, e.g.*, Doc. 2150-11 at 30–31 (Defs.' Ex. 184) (Kautzner (ESI) Dep. 207:7–208:8); Doc. 2150-16 at 7 (Defs.' Ex. 189) (Stein (Humana) Dep. 229:1–4). PBMs and drug manufacturers have "competing priorities" where the manufacturer is trying to secure the lowest rebates but also with favorable formulary position while PBMs are trying to secure larger rebate offers on drug products. Doc. 2150-11 at 29 (Defs.' Ex. 184) (Kautzner (ESI) Dep. 206:2–20); Doc. 2150-16 at 7 (Defs.' Ex. 189) (Stein (Humana) Dep. 229:6–13); Doc. 2150-10 at 29–30 (Defs.' Ex. 183) (Anderson (CVS) Dep. 209:21–210:1). Several PBMs and payors testified that they never conspired with Mylan to

[49] Plaintiffs don't dispute this fact. Doc. 2190-1 at 20 (noting that defendants' SMF ¶ 179 is undisputed).

exclude Auvi-Q. Doc. 2150-11 at 30–31 (Defs.' Ex. 184) (Kautzner (ESI) Dep. 207:7–208:8); Doc. 2150-16 at 7 (Defs.' Ex. 189) (Stein (Humana) Dep. 229:14–17); Doc. 2159-2 at 10 (Shia (Kaiser) Dep. 154:3–9).

Some PBMs and payors testified that they used exclusivity to extract higher rebates from both Mylan and Sanofi. *See, e.g.*, Doc. 2150-14 at 6–7, 9 (Defs.' Ex. 187) (Ayers (MedImpact) Dep. 150:18–151:2, 162:1–22) (agreeing that MedImpact sought "to create the perception within Mylan" that Auvi-Q "could be a formidable challenger" to EpiPen in order "to induce Mylan to provide a larger rebate[,]" and that MedImpact asked both Sanofi and Mylan for 1-of-1 (exclusive position) proposals); Doc. 2150-19 at 7 (Defs.' Ex. 192) (Minton (Anthem) Dep. 281:17–25) (testifying that Auvi-Q was "the highest costing product" and Anthem was "looking to see how we could bring down a cost in the class by making EpiPen more preferred").

Several payors testified that—despite EpiPen's market share—they could have excluded EpiPen because they could shift product use from EpiPen to Auvi-Q. *See, e.g.*, Doc. 2150-17 at 26–27 (Defs.' Ex. 190) (Kronberg (Cigna) Dep. 148:19–149:14) (testifying that "people will be okay with moving" products when "they're clinically equivalent"); Doc. 2150-13 at 13 (Defs.' Ex. 186) (Etemad (United) Dep. 115:21–23) (testifying that "it was a possibility to exclude" EpiPen from coverage); Doc. 2159-2 at 10–11 (Shia (Kaiser) Dep. 260:36–261:13) (testifying that "it would not be difficult" to move consumers from "one branded EAI device to another branded EAI device"). ESI implemented a strategy that sought "to make the product that has lots of market share [*i.e.*, EpiPen] feel threatened" by potential exclusion "to get the lowest net cost." Doc. 2150-11 at 12 (Defs.' Ex. 184) (Kautzner (ESI) Dep. 154:18–24). Sanofi reported internally that "Aetna believe[d] Auvi-Q would see an 80% shift of utilization from Epi-Pen in [Year] 1" if Aetna accepted Sanofi's exclusive offer. Doc. 2161-13 at 3 (Defs.' Ex. 286).

CVS serves as an example of a PBM who successfully shifted patients to Auvi-Q after it excluded EpiPen from its Advanced Control Formulary ("ACF"). Doc. 2163-11 at 2–3 (Defs.' Ex. 314). On this plan, EpiPen's market share went from 92% in Q4 2014 to 0.2% by Q2 2015. *Id.* CVS told Mylan in 2015 that its market share on that formulary was "all but gone." *Id.* at 3. CVS also noted that EpiPen's market share on CVS's Value Based Formulary was "still holding share." *Id.* But, it warned Mylan that it "view[ed] the ACF as a trial balloon" and that there had "been no noise or complaints . . . which would indicate not a big deal excluding epipen." *Id.* Mylan confirmed that EpiPen utilization on the plans that adopted the CVS Value Formulary, including plans of large corporations like Comcast and Home Depot, "completely disappeared in Q4 2014," necessitating an enhanced rebate offer to "reverse the exclusion." Doc. 2163-12 at 11–12 (Defs.' Ex. 315). CVS projected that EpiPen's share, if CVS excluded EpiPen in favor of Auvi-Q on its national template formulary, would drop from 66% to 7%, with Auvi-Q's share increasing from 10% to 75%. Doc. 2163-13 at 3 (Defs.' Ex. 316). West Virginia's Medicaid program also shifted 90% of its market share to Auvi-Q in just two quarters. Doc. 2163-14 at 2 (Defs.' Ex. 317). Also, some PBMs testified about past success in other markets shifting patient volume from market leading drugs to upstart competitors for other products. *See, e.g.*, Doc. 2150-10 at 26–28 (Defs.' Ex. 183) (Anderson (CVS) Dep. 200:18–202:1); Doc. 2150-11 at 26–27 (Defs.' Ex. 184) (Kautzner (ESI) Dep. 191:21–192:15).

As an ESI witness testified, the increased rebates ESI negotiated from Mylan and Sanofi produced lower net prices for EAI devices. Doc. 2150-11 at 13 (Defs.' Ex. 184) (Kautzner (ESI) Dep. 155:7–11) (testifying that, by 2015, ESI was "highly effective in making this a very competitive class and bringing the rates down, lowering that cost, both for our plans and ultimately for many members").

Sanofi Recalls Auvi-Q and Returns Its Rights

In the summer of 2015, Sanofi learned that some of its Auvi-Q devices may fail to inject epinephrine. Doc. 2163-15 at 2 (Defs.' Ex. 318); Doc. 2163-16 at 4–6 (Defs.' Ex. 319). On October 22, 2015, the FDA conducted a surprise inspection at Sanofi's manufacturing facility. Doc. 2163-17 at 2–4 (Defs.' Ex. 320). A few days later, Sanofi issued a Class I voluntary recall of all Auvi-Q devices in the United States and discontinued Auvi-Q manufacturing operations. Doc. 2169 at 6 (Pretrial Order ¶ 2.a.47.). The FDA reserves a Class I recall for cases involving "a reasonable chance that a product will cause serious health problems or death." *What is a Medical Device Recall?*, FDA (current as of Sept. 26, 2018), https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall. In a letter to the FDA, Sanofi explained that its recall was "[b]ased on the complexity of the Auvi-Q device (27 components, including an audio device) and the occurrence of three distinct potential quality events over the past four months." Doc. 2164-1 at 3 (Defs.' Ex. 322).

Sanofi considered renegotiating its contract rights with kaléo. Doc. 2200-15 at 4–28 (Pls.' Ex. 243). In a presentation discussing that strategy, Sanofi noted that when it "signed the deal 5 years ago, the market was quite different and neither company anticipated the managed care response or the aggressive tactics that Mylan would employ." *Id.* at 7; *see also* Doc. 2200-16 at 3 (Pls.' Ex. 244) (assuming that Auvi-Q would have strong formulary access at launch).

On December 7, 2015, Sanofi advised kaléo it would return the rights for Auvi-Q and terminate the license agreement. Doc. 2164-2 at 3–7 (Defs.' Ex. 323) (Barry Dep. 21:8–25:3). On February 24, 2016, Sanofi and kaléo signed a termination agreement. Doc. 2164-3 at 2 (Defs.' Ex. 324). Sanofi's then-Head of Global Commercial Operations testified that "the recall

was the single and only reason" that Sanofi returned its rights to Auvi-Q. Doc. 2163-6 at 5–6 (Defs.' Ex. 309) (Guenter Dep. 327:23–328:6). Also, he testified:

> So the only reason why [Sanofi] decided to [return the Auvi-Q rights] was a potential relaunch after whatever it would be, 12, 15 months, would have been a very, very costly endeavor because we would anticipate that Mylan would of course be at least as aggressive in the second potential relaunch period as compared to the first. So that's what made us decide that given the recall of the product that it didn't make economic sense to relaunch the product.

Doc. 2193-6 at 5 (Pls.' Ex. 87) (Guenter Dep. 358:17–359:15); *see also* Doc. 2200-17 at 4–5 (Pls.' Ex. 245) (Barry Dep. 37:24–38:14) (testifying that after "[c]onsidering the market environment" and "the behaviors of the competitor, and assuming that there was a likelihood that [Mylan] would continue to try to blunt our launch in terms of using their lion's share of the market inappropriately and the level of investment that would be required to achieve a relaunch," Sanofi "determined that based on the pro forma of the general medicines team that it would be best to put those investments somewhere else and then . . . transition the product back to" kaléo).

Shortly after Sanofi removed Auvi-Q from the market in October 2015, Mylan "took a 14.9% WAC increase on" November 21, 2015, "increasing the WAC/pen to $264.85." Doc. 2200-21 at 3 (Pls.' Ex. 249). And, Mylan began "evaluating all contracts (both with the States and Payors) now that Auvi-Q [had] exited the market" and "working [to] improve these rates for 2016[.]" *Id.* In negotiations with a PBM, Mylan's Bruce Foster noted that Mylan was "hoping to reduce [its] average rebate percentage" based on a "directive [that came] down from the very top leadership at Mylan." Doc. 2201-1 at 2 (Pls.' Ex. 250). As PBM Magellan recognized, now that "EpiPen is the only game in town[,]" Mylan didn't "need to be as aggressive with rebates to compete. It's that simple." Doc. 2201-2 at 2 (Pls.' Ex. 251).

In February 2017, kaléo reintroduced Auvi-Q in the United States. Doc. 2169 at 6 (Pretrial Order ¶ 2.a.48.). It offered Auvi-Q at a WAC of $4,500. Matthew Herper, *In Rube*

Goldberg Price Scheme, EpiPen Competitor Auvi-Q To Be Free For Patients, $4,500 For Their Insurers, Forbes (Jan. 19, 2017), https://www.forbes.com/sites/matthewherper/2017/01/19/epipen-competitor-auvi-q-to-be-free-for-most-patients-but-cost-4500-for-insurers-in-rube-goldberg-scheme/#3ea207ae3fe6.[50]

Mylan Enters Settlement Agreement with DOJ

In 2017, Mylan agreed to pay $465 million to the Department of Justice to resolve claims that it knowingly misclassified the EpiPen as a generic drug to avoid paying rebates owed to Medicaid. Doc. 2207-3 at 2 (Pls.' Ex. 238). "The claims settled by [the] agreement [were] allegations only, and there [was] no determination of liability." *Id.* But, at least one payor recognized that Mylan was paying lower rebates on Medicaid plans based on its classification of EpiPen as a generic. *See* Doc. 2200-11 at 3 (Pls.' Ex. 239) (noting that "[e]very data point we have suggest[s] the Epipen is a brand (because it is); however; [Mylan has] been paying federal rebates at 13% of AMP as if it was a generic" and recognizing that "[i]f CMS requires Mylan to recalculate their rebates to reflect a branded status as we are expecting, the federal rebate has the potential to increase drastically").

II. Summary Judgment Standard

The standard for deciding summary judgment under Federal Rule of Civil Procedure 56 is well-known. Summary judgment is appropriate if the moving party demonstrates that "no genuine dispute" exists about "any material fact[,]" and the moving party is "entitled to judgment

[50] As noted previously, *see supra* note 9, plaintiffs assert a blanket objection to documents that defendants cite as summary judgment evidence but which they didn't submit as exhibits to their summary judgment motion. Doc. 2190-1 at 76–77. The above-cited *Forbes* article is one of the citations to which plaintiffs object. *Id.* at 77 n.439 (asserting that the court can't consider the citation in defendants' footnote 429). But, plaintiffs also don't dispute defendants' factual assertion that defendants support with the exhibit. *See* Doc. 2190-1 at 20 (noting that plaintiffs don't dispute defendants' SMF ¶ 188). So, the court includes the above-recited fact because plaintiffs don't controvert it.

as a matter of law." Fed. R. Civ. P. 56(a); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). When the court applies this standard, it views the evidence and draws reasonable inferences in the light most favorable to the non-moving party. *Scott v. Harris*, 550 U.S. 372, 378 (2007). An issue of "material fact is 'genuine' . . . if the evidence is such that a reasonable jury could return a verdict for the nonmoving party" on that issue. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). And, an issue of fact is "material" if it has the ability to "affect the outcome of the suit under the governing law[.]" *Id.*

The party moving for summary judgment bears the initial burden of showing "the basis for its motion." *Celotex*, 477 U.S. at 323; *Kannady v. City of Kiowa*, 590 F.3d 1161, 1169 (10th Cir. 2010) (explaining that the moving party bears "'both the initial burden of production on a motion for summary judgment and the burden of establishing that summary judgment is appropriate as a matter of law'" (quoting *Trainor v. Apollo Metal Specialties, Inc.*, 318 F.3d 976, 979 (10th Cir. 2002))). A summary judgment movant can satisfy this burden by demonstrating "there is an absence of evidence to support the nonmoving party's case." *Celotex*, 477 U.S. at 325; *see also Kannady*, 590 F.3d at 1169 (explaining that the moving party, to meet its summary judgment burden, "need not negate the non-movant's claim, but need only point to an absence of evidence to support the non-movant's claim" (citation and internal quotation marks omitted)).

If the moving party satisfies its initial burden, the non-moving party "must set forth specific facts showing that there is a genuine issue for trial." *Anderson*, 477 U.S. at 250 (citation and internal quotation marks omitted); *see also Kannady*, 590 F.3d at 1169 ("If the movant carries [the] initial burden, the nonmovant may not rest on its pleadings, but must bring forward specific facts showing a genuine issue for trial [on] those dispositive matters for which it carries the burden of proof." (citation and internal quotation marks omitted)). To satisfy this

requirement, the nonmoving party must "go beyond the pleadings and by [its] own affidavits, or by the depositions, answers to interrogatories, and admissions on file, designate specific facts showing that there is a genuine issue for trial." *Celotex*, 477 U.S. at 324 (citation and internal quotation marks omitted). When deciding whether a party has shouldered its summary judgment burden, "the judge's function" is not "to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Anderson*, 477 U.S. at 249.

Summary judgment is not a "disfavored procedural shortcut[.]" *Celotex*, 477 U.S. at 327. Instead, it is an important procedure "designed 'to secure the just, speedy and inexpensive determination of every action.'" *Id.* (quoting Fed. R. Civ. P. 1).

Just recently, our Circuit[51] has reiterated that "'summary judgment should be used sparingly in antitrust cases[.]'" *N.M. Oncology & Hematology Consultants, Ltd. v. Presbyterian Healthcare Servs.*, 994 F.3d 1166, 1174 (10th Cir. 2021) (quoting *Bell v. Fur Breeders Agric. Co-op.*, 348 F.3d 1224, 1229 (10th Cir. 2003)). But still, a court must apply "'the usual rules governing summary judgment'" to antitrust cases. *Id.* (quoting *Bell*, 348 F.3d at 1229); *see also id.* at 1172 (affirming trial court's decision granting summary judgment against plaintiff's Sherman Act § 2 claims because plaintiff "failed to establish that Defendants had engaged in exclusionary or anticompetitive conduct"). Like "any Rule 56 motion," an antitrust plaintiff "has the burden 'to set forth specific facts showing that there is a genuine issue for trial.'" *Id.*

[51] Our court has held that "an MDL transferee court applies the law of the circuit in which it sits." *In re: Syngenta AG Mir 162 Corn Litig.*, No. 14-md-2591-JWL, 2016 WL 5481997, at *1 n.1 (D. Kan. Sept. 29, 2016). Although the Tenth Circuit hasn't addressed this question, our court has explained that this "ruling is consistent with the rule followed by a number of circuit courts that have considered the question." *Id.* (first citing *Murphy v. FDIC*, 208 F.3d 959, 965–66 (11th Cir. 2000); then citing *In re U.S. Dep't of Defense & U.S. EPA Final Rule*, 817 F.3d 261, 272 (6th Cir. 2016)); *see also AER Advisors, Inc. v. Fid. Brokerage Servs., LLC*, 921 F.3d 282, 288–89 (1st Cir. 2019) (joining every Circuit that has considered the issue by holding that "the transferee court applies its own Circuit's cases on the meaning of federal law"); *In re Takata Airbag Prods. Liab. Litig.*, 464 F. Supp. 3d 1291, 1300 (S.D. Fla. 2020) ("Questions of federal law in cases transferred under 28 U.S.C. Section 1407 are governed by the clearly settled law of the transferee court's circuit.").

(quoting *In re Rumsey Land Co.*, 944 F.3d 1259, 1270 (10th Cir. 2019)). And, as the Supreme Court has recognized, "[s]ummary judgments have a place in the antitrust field" because "[s]ome of the law in this area is so well developed that [when] the gist of the case turns on documentary evidence, the rule at times can be divined without a trial." *White Motor Co. v. United States*, 372 U.S. 253, 259 (1963); *see also SEC v. Geyser Mins. Corp.*, 452 F.2d 876, 881 (10th Cir. 1971) (explaining that "even in antitrust litigation, if the pertinent area of law is well developed and the case turns on documentary evidence, disposition by summary judgment may be appropriate" (citing *White Motor Co.*, 372 U.S. at 259)).

With this governing legal standard explained, the court now turns to defendants' arguments supporting summary judgment against plaintiffs' claims.

III. Analysis

Defendants move for summary judgment against plaintiffs' two claims—one asserting antitrust claims violations and the other claiming RICO violations. The court addresses defendants' summary judgment arguments, below. *First*, the court addresses whether the summary judgment facts present any triable issue for plaintiffs' antitrust claims. *Second*, the court decides whether the undisputed facts warrant summary judgment against plaintiffs' RICO claims.

A. Antitrust Claims

Plaintiffs assert state antitrust conspiracy and monopolization claims under certain state laws. Doc. 2169 at 42, 44–45 (Pretrial Order ¶¶ 4.a., 4.d.).

Generally, an antitrust conspiracy requires the plaintiff to establish: "(1) concerted action in the form of a contract, combination, or conspiracy, and (2) an unreasonable restraint of trade." *Systemcare, Inc. v. Wang Labs. Corp.*, 117 F.3d 1137, 1139 (10th Cir. 1997) (citing 15 U.S.C. §

1); *see also Bushnell Corp. v. ITT Corp.*, 973 F. Supp. 1276, 1285 (D. Kan. 1997) (Lungstrum, J.) (citing 15 U.S.C. § 1).[52] And, to prevail on a monopolization claim, a plaintiff must prove: (1) defendants have "monopoly power in a properly defined relevant market;" and (2) that defendants "willfully acquired or maintained this power by means of anticompetitive conduct." *United States v. AMR Corp.*, 335 F.3d 1109, 1113 (10th Cir. 2003) (citing 15 U.S.C. § 2 (further citation omitted)).

Here, plaintiffs allege two theories to support their conspiracy and monopolization claims under the antitrust laws. *First*, they allege that defendants entered a "reverse payment" settlement that unlawfully delayed generic competition from entering the market and competing against the EpiPen. *Second*, they allege that defendants foreclosed competition by entering unlawful exclusive dealing arrangements in the form of Mylan's rebate agreements with PBMs. Defendants challenge both theories on summary judgment. The court addresses each theory, in turn, below.

1. Generic Delay Theory

Plaintiffs' first antitrust theory asserts that defendants and Teva entered settlement agreements in "tandem" that resolved the EpiPen and Nuvigil patent litigations. Doc. 2169 at 16 (Pretrial Order ¶ 3.a.1.b.). Plaintiffs contend that "[n]either settlement, viewed independently, was economically rational[,]" but "through the tandem EpiPen and Nuvigil settlements, Mylan and Teva guaranteed that they would both profit by limiting competition in their respective monopoly marketplaces rather than compete." *Id.* Plaintiffs assert that the settlements

[52] Although plaintiffs assert their antitrust claims under particular state laws, they ask the court to evaluate them "under the same legal standards as Sherman Act Section One (Conspiracy)" and "Sherman Act Section Two (Monopolization)[.]" Doc. 2169 at 43 (Pretrial Order ¶¶ 4.b.3.–4.). Defendants agree for "the purpose of summary judgment." Doc. 2142-1 at 69 n.431. So, consistent with the parties' agreement, the court evaluates plaintiffs' antitrust claims on summary judgment under the legal standards that apply to the Sherman Act.

"effectively precluded generic competition for at least 3 years" in the EAI market and "allowed Mylan to raise the EpiPen's price without fear of generic competition and ensured that Pfizer and Mylan would continue to share millions of dollars in unlawful monopoly profits." *Id.*

The Supreme Court has recognized that a patent settlement involving a "large [and] unjustified reverse payment" can violate the antitrust laws if its "objective is to maintain supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market" because that objective is "the very anticompetitive consequence that underlies the claim of antitrust unlawfulness." *FTC v. Actavis, Inc.*, 570 U.S. 136, 157–58 (2013). But here, defendants assert, plaintiffs' antitrust claims premised on a generic delay theory cannot survive summary judgment for four reasons. Defendants say that the undisputed summary judgment facts establish that: (1) the EpiPen settlement never caused any delay in Teva's generic entry; (2) the EpiPen and Nuvigil settlements were independent and lawful settlements; (3) the summary judgment evidence doesn't support a triable issue whether defendants made a "reverse payment"; and (4) both the EpiPen and Nuvigil settlements were procompetitive.

Below, the court addresses all four arguments. Before turning to them, however, the court recognizes that defendants' arguments call on the court to analyze and consider the underlying facts of the EpiPen and Nuvigil patent litigation and eventual settlements. When presented with a similar scenario involving a reverse payment settlement claim, the Eleventh Circuit's Judge Carnes observed the work of "deciding a patent case within an antitrust case about the settlement of the patent case" is something he called "a turducken task."[53] *FTC v.*

[53] For those who don't recall John Madden's telestrated explanation on Thanksgiving Day broadcasts of NFL games, a turducken is a deboned chicken stuffed inside a deboned duck, the two then stuffed inside a deboned turkey. The British sometimes replace the turkey with a goose, producing a

Watson Pharms., Inc., 677 F.3d 1298, 1315 (11th Cir. 2012). But, on appeal, the Supreme Court disagreed, finding that "an antitrust action" based on a reverse payment settlement "is likely to prove more feasible administratively than the Eleventh Circuit believed." *Actavis*, 570 U.S. at 157. In reverse payment settlement claims, the Supreme Court ruled, "it is normally not necessary to litigate patent validity to answer the antitrust question (unless, perhaps, to determine whether the patent litigation is a sham)." *Id.* (citation omitted). Following that guidance from the Supreme Court, the court now endeavors to decide this question: Does this case's summary judgment facts present a triable question whether defendants violated the antitrust laws by entering into a reverse payment settlement to resolve the EpiPen litigation with Teva?

a. Whether EpiPen Settlement Delayed Teva's Generic Entry

First, defendants argue, plaintiffs' generic delay claims fail because the summary judgment facts present no triable issue of causation. More specifically, defendants contend that no reasonable jury could find or infer from the undisputed summary judgment facts that the EpiPen settlement caused any delay in the entry of Teva's competing generic EAI.

The Sherman Act requires an antitrust plaintiff to show that its injury was caused "by reason of" the defendant's anticompetitive conduct. 15 U.S.C. § 15(a); *see also Aspen Highlands Skiing Corp. v. Aspen Skiing Co.*, 738 F.2d 1509, 1519 n.12 (10th Cir. 1984) ("Of course, the fact of injury and damages suffered *by reason of a violation of the antitrust laws* must also be shown for a private litigant to recover on a claim of monopolization." (emphasis added)). Thus, "to recover under the antitrust laws[,]" an antitrust plaintiff must "establish that defendant's unlawful conduct caused plaintiff injury in its business or property." *Aspen Highlands*, 738 F.2d at 1522–23; *see also Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429

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gooducken. Will Iredale, *Three in One Bird is Big This Christmas*, Times (London), Nov. 21, 2004, https://www.thetimes.co.uk/article/three-in-one-bird-is-big-this-christmas-8569w2jppgg.

U.S. 477, 489 (1977) (explaining that an antitrust plaintiff "must prove antitrust injury, which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful").

An antitrust plaintiff cannot shoulder its burden to prove an antitrust violation if the injury is "attributable to its lack of desire, its limited production capabilities, or to other factors independent of [the alleged] unlawful conduct[.]" *Zenith Radio Corp. v. Hazeltine Rsch., Inc.*, 395 U.S. 100, 126–27 (1969). But, at the same time, an antitrust plaintiff need not show that defendant's conduct was the exclusive cause of plaintiff's injury. *Id.* at 114 n.9 (A "plaintiff need not exhaust all possible alternative sources of injury in fulfilling his burden of proving compensable injury[.]"). Instead, it "is enough that the illegality is shown to be a *material cause* of the injury[.]" *Id.* (emphasis added); *see also In re Actos End-Payor Antitrust Litig.*, 848 F.3d 89, 97 (2d Cir. 2017) ("An antitrust plaintiff must show that a defendant's anticompetitive act was a 'material' and 'but-for' cause of plaintiff's injury, although not necessarily the sole cause.").

A "material cause" is "often interpreted as proximate cause" of an antitrust violation. *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-md-02503, 2018 WL 563144, at *13 (D. Mass. Jan. 25, 2018); *see also In re Flonase Antitrust Litig.*, 798 F. Supp. 2d 619, 627 (E.D. Pa. 2011) ("An antitrust violation is a 'material cause' of an injury if it is a proximate cause of that injury." (citation omitted)). "The doctrine of proximate cause in the antitrust context considers whether the alleged injury is too remote to be fairly attributed to the asserted antitrust violation." *In re Flonase Antitrust Litig.*, 798 F. Supp. 2d at 627.

As our Circuit has explained, an antitrust plaintiff demonstrates "proximate cause" by showing "'there is a causal connection between an antitrust violation and an injury sufficient to

establish the violation as a substantial factor in the occurrence of damage.'" *Motive Parts Warehouse v. Facet Enters.*, 774 F.2d 380, 389 (10th Cir. 1985) (quoting *Reibert v. Atl. Richfield Co.*, 471 F.2d 727, 731 (10th Cir. 1973)). But, if "an independent cause fully accounts for the plaintiff's alleged injury[,]" then that intervening, independent cause "breaks the causal connection between the alleged antitrust violation and the plaintiff's injury." *In re Flonase Antitrust Litig.*, 798 F. Supp. 2d at 627 (citation and internal quotation marks omitted). "'Proximate cause and intervening cause are usually issues for the jury to decide.'" *Id.* at 628 (quoting *Wortley v. Camplin*, 333 F.3d 284, 295 (1st Cir. 2003)); *see also In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2018 WL 563144, at *13 ("[C]ausation is generally a question best left for the jury to decide.").

Defendants argue that the summary judgment facts here present no triable issue of causation. That is, defendants argue, plaintiffs haven't adduced any evidence from which a jury rationally could find or infer that, but for the Teva/EpiPen settlement, Teva would have launched its generic EAI before June 2015—the date the settlement agreement allowed Teva to launch its generic product. Instead, defendants contend, the undisputed facts establish, as a matter of law, that other, intervening causes prevented Teva from launching its product before the settlement's agreed-to generic entry date. Defendants assert three reasons why this is so: (a) Teva didn't have FDA approval of its generic EAI by that date, (b) Teva had difficulties developing its generic EAI, and (c) other EpiPen patents would have blocked Teva's entry into the market without a settlement. The court considers these three arguments in subsections i, ii, and iii, following.

i. Teva's FDA Approval

First, defendants assert that plaintiffs present no triable issue whether the Teva/EpiPen settlement delayed generic entry because it's undisputed that Teva didn't secure FDA approval to launch its product by the settlement's agreed-to entry date of June 22, 2015. It's undisputed that the Teva/EpiPen settlement agreement granted Teva a license to launch its EAI by June 22, 2015, subject to FDA approval. Doc. 2146-3 at 14–20 (Defs.' Ex. 136). Also, the summary judgment facts establish that Teva didn't secure FDA approval for its generic until August 2018—more than three years after the settlement's agreed-to generic entry date. Doc. 2147-5 at 2, 6 (Defs.' Ex. 160). So, defendants argue, the FDA's independent action of withholding approval of Teva's generic until 2018 was an intervening and independent cause that breaks any causal chain between the EpiPen settlement and Teva's generic entry.

For support, defendants cite the summary judgment facts showing that the FDA repeatedly expressed concerns about Teva's generic EAI by sending Teva deficiency letters. In one letter, dated May 17, 2011, the FDA told Teva that it must conduct a human factors study and the same letter recommended Teva submit a draft of its test protocol before implementing the study so that the FDA could review and provide feedback. Doc. 2145-5 at 2–3 (Defs.' Ex. 116). In January 2012, Teva sent its draft protocol and requested feedback within one month of the letter's date so that it could proceed with the study. Doc. 2146-12 at 2 (Defs.' Ex. 145). More than a year and a half later, the FDA still never had provided Teva any feedback, as requested. Doc. 2146-13 at 2 (Defs.' Ex. 146); Doc. 2146-14 at 1–2 (Defs.' Ex. 147). So, on August 29, 2013, Teva, without any feedback from the FDA on Teva's draft protocol, submitted its first human factors study to the FDA—in response to the deficiency letter the FDA had sent Teva on May 17, 2011. Doc. 2146-11 (Defs.' Ex. 144). And, in 2014, Teva completed a new

human factors study. Doc. 2146-16 at 2 (Defs.' Ex. 149). Then, on February 23, 2016, the FDA issued a complete response letter denying Teva's ANDA application and citing "MAJOR" deficiencies with Teva's generic EAI, including, among other things, deficiencies with the human factors study. Doc. 2147-3 at 7, 11 (Defs.' Ex. 158). Teva never re-performed its human factors study. Doc. 2191-3 at 7–8 (Pls.' Ex. 25) (Peck Rebuttal Expert Report ¶ 14). But then, in August 2018, the FDA changed its position telling Teva that it had found the 2014 Teva human factors study adequate—the same study it had rejected in the 2016 complete response letter. Doc. 2147-4 at 2–3 (Defs.' Ex. 159). And, the very next day, the FDA approved Teva's ANDA. Doc. 2147-5 at 2 (Defs.' Ex. 160).

Defendants assert that these independent actions taken by the FDA—*i.e.*, first rejecting Teva's ANDA and then granting approval of its generic product in August 2018—qualify as intervening causes that "'cut[] off' the 'requisite chain of causation' and doom Plaintiffs' generic delay claims." Doc. 2142-1 at 72 (quoting *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 768 (E.D. Pa. 2015)).

Plaintiffs disagree. Plaintiffs assert that, but for the EpiPen settlement, Teva would have entered the EAI market in either March 2014 or January 2015—months before the settlement's agreed-to licensing date. Doc. 2169 at 16, 55 (Pretrial Order ¶¶ 3.a.1.b., 5.a.B.). And, they cite several summary judgment facts from which, they contend, a reasonable jury could find that defendants' actions—through an allegedly unlawful reverse payment settlement with Teva—were the "but for" cause of Teva's delay in securing FDA approval of its generic, thereby resulting in an approval date beyond the settlement's agreed-to launch date of June 2015.

First, plaintiffs cite Teva's internal documents from late 2011 and early 2012 showing that it projected that it would launch its generic EAI by 2014. Doc. 2203-20 at 5 (Pls.' Ex. 317);

Doc. 2203-21 at 3–5 (Pls.' Ex. 318). Defendants respond that these internal projections are nothing more than predictions made before Teva encountered various development issues with its product. So, defendant argue, plaintiffs can't rely on this evidence to avoid summary judgment because it's just speculative. *See Pioneer Ctrs. Holding Co. Emp. Stock Ownership Plan & Tr. v. Alerus Fin., N.A.*, 858 F.3d 1324, 1334 (10th Cir. 2017) (explaining that, to avoid summary judgment, the non-moving party must adduce evidence that is "based on more than mere speculation, conjecture, or surmise" (citation and internal quotation marks omitted)). If these internal projections were the only evidence plaintiffs adduced to show that Teva could have launched its generic EAI on an earlier date, the court might side with defendants' argument. But, there's far more than just these projections.

Second, plaintiffs offer the analysis of their expert, Dr. Carl Peck, who reviewed Teva's communications with the FDA. Dr. Peck opines that Teva slowed its responsiveness to the FDA's requests during "the 2011–2014 time frame by not pursuing its application aggressively or responding to the FDA[.]" Doc. 2191-7 at 25 (Pls.' Ex. 30) (Peck Expert Report ¶ 56(c)). Based on his analysis of the communications, Dr. Peck concludes that "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 10 (¶ 21). Importantly, plaintiffs assert, the 2011–14 time period corresponds with the time when Pfizer and Teva commenced settlement negotiations and eventually agreed to resolve the EpiPen litigation through an agreement that, among other terms, granted Teva a license to launch its EAI by June 22, 2015. *See* Doc. 2146-3 at 14–20 (Defs.' Ex. 136) (binding term sheet executed on April 26, 2012); *see also id.* at 2–29 (final Settlement and License Agreement executed on July 20, 2012).

Indeed, the summary judgment facts establish that Teva initially responded to the FDA's requests for information within a few weeks or months. *See* 2203-7 at 2 (Pls.' Ex. 299) (Teva's May 22, 2009 response to FDA's May 1, 2009 deficiency letter); Doc. 2203-10 at 2 (Pls.' Ex. 302) (Teva's September 8, 2009 ANDA amendment responding to FDA's July 6, 2009 deficiency letter). But then, during the 2011–14 time frame, Teva took noticeably longer to respond to the FDA's requests. *See* Doc. 2203-13 at 2 (Pls.' Ex. 309) (Teva's July 31, 2013 letter responding more than three years later to FDA's March 29, 2010 deficiency letter); Doc. 2203-18 at 2 (Pls.' Ex. 314) (Teva's August 1, 2014 letter responding more than three years later to FDA's February 2, 2011 deficiency letter); Doc. 2146-19 at 2 (Defs.' Ex. 152) (Teva's December 30, 2014 amended ANDA submitted in response to the FDA's deficiency letter sent more than four years earlier on March, 2, 2010).

Plaintiffs argue that it's wrong for defendants to focus on the FDA's initial rejection and later acceptance of Teva's human factors study as an intervening cause that breaks the causal chain. As discussed, Teva submitted its first human factors study more than two years after the FDA had requested it. Doc. 2146-11 at 2–5 (Defs.' Ex. 144) (Teva's August 29, 2013 response to the FDA's May 17, 2011 deficiency letter). Defendants argue Teva was waiting to submit the study until after the FDA provided feedback on its draft protocol, and when Teva still hadn't received that feedback by August 2013, it submitted the human factors study anyway. Then, the FDA rejected the human factors study in 2016, but later accepted the same study in 2018 when it approved Teva's ANDA. But, as defendants concede, it wasn't just the deficient human factors study that the FDA identified in its February 23, 2016 denial of Teva's ANDA application as a deficiency with Teva's proposed generic EAI. The letter also identified "MAJOR" deficiencies with product quality, bioequivalence, microbiology, and labeling. Doc. 2147-3 at 11 (Defs.' Ex.

158). Plaintiffs argue, it wasn't until Teva cured those other deficiencies by 2018 that the FDA approved Teva's ANDA. As Dr. Peck opines, "Teva submitted an application that had a sufficient HFS in 2013 and 2014" but "the ANDA ultimately was not approved until 2018 because further review on other parts of the applications was required based on Teva's other submissions." Doc. 2191-3 at 9 (Pls.' Ex. 25) (Peck Rebuttal Expert Report ¶ 16).

Plaintiffs argue that a reasonable jury could find or infer from the summary judgment facts that Teva did not act diligently in responding to each of the deficiencies that the FDA identified which, in turn, delayed FDA approval until 2018. The court agrees. Ultimately, a jury might accredit defendants' position that the FDA's actions were an intervening cause that cuts off the causal chain between the EpiPen settlement and Teva's delayed generic entry. But the court cannot find that the summary judgment facts require that finding as a matter of law. Instead, a reasonable jury also could find or infer from Teva's fluctuating responsiveness to the FDA's requests—and Dr. Peck's opinion that its responsiveness slowed between 2011–14, thereby delaying FDA approval—that the EpiPen settlement delayed Teva's efforts to secure FDA approval, which, in turn, delayed its launch of a generic EAI to compete with EpiPen.

Third, plaintiffs argue that a jury could infer that the EpiPen settlement delayed Teva's generic entry based on Dr. Peck's analysis comparing the "9 years and 9 months" it took Teva to secure FDA approval to the time it took other EAIs to achieve FDA approval. Doc. 2191-7 at 26–27 (Pls.' Ex. 30) (Peck Expert Report ¶ 58 & Table 2) (concluding that "none [of the other EAIs] have required the lengthy time for review and approval exhibited by the Teva generic EAI" but instead "most were approved in 2–3 years, while the longest review and approval time was 6.5 years from initial filing"). Also, Dr. Peck's analysis shows that Teva's approval time for its generic exceeded the approval times for other auto-injector products and other Teva injectable

products. *See id.* at 27–28 (¶ 59 & Table 3) (concluding that approval time for other auto-injector products has ranged from six months to 69 months); *see also id.* at 29 (¶ 60 & Table 4) (concluding that other Teva injectable products "on average . . . were approved in under 30 months"). The court recognizes that defendants dispute that these other products are proper comparisons to the Teva generic. At trial, defendants can cross-examine Dr. Peck and attack his opinions with contrary evidence. And, in the end, the trier of fact might not find Dr. Peck's analysis credible or germane to the causation analysis. But, the court can't make that finding on summary judgment.

Fourth, plaintiffs assert that a reasonable jury could infer from the summary judgment facts that Teva knew the EpiPen settlement did not permit it to enter the market for more than three years after Teva had settled the litigation in 2012, which, in turn, reduced Teva's incentive to continue pursuing the ANDA actively. Defendants assert that—after the settlement—the ball was in Teva's court to secure FDA approval. And, to the extent Teva delayed its FDA approval efforts, defendants can't be held responsible for it. Also, defendants argue, it wasn't foreseeable to them that the EpiPen settlement would delay Teva's FDA approval until 2018. Again, a reasonable jury might agree with defendants' assessment of the summary judgment facts here. But, an equally reasonable jury might conclude that defendants' actions—by settling the EpiPen litigation and agreeing to a 2015 generic entry date—caused Teva to slow its efforts to secure FDA approval during the 2011–14 time frame which, in turn, delayed the FDA's approval until 2018. So, the court cannot find—as a matter of law—that either the FDA's actions or Teva's efforts to secure FDA approval serve as an intervening or unforeseeable cause that breaks the requisite chain of causation. *See In re Flonase Antitrust Litig.*, 798 F. Supp. 2d 619, 628 (E.D. Pa. 2011) ("Whether conduct constitutes intervening conduct that breaks the chain of causation

and whether intervening conduct is a foreseeable consequence of a defendant's actions are questions of fact to be submitted to the jury" (citing *Marshall v. Mintz*, 386 F.2d 415, 416 (5th Cir. 1967)).

Last, plaintiffs contend that a reasonable jury could find that Mylan submitted a sham Citizen Petition to the FDA and such a jury also could infer that the sham Citizen Petition delayed Teva's FDA approval.[54] Defendants disagree. They contend that the filing of the Citizen Petition can't subject them to antitrust liability under the *Noerr-Pennington* doctrine. The *Noerr-Pennington* doctrine "exempts from antitrust liability any legitimate use of the political process by private individuals, even if their intent is to eliminate competition." *Tal v. Hogan*, 453 F.3d 1244, 1259 (10th Cir. 2006) (citation and internal quotations marks omitted). But *Noerr-Pennington* immunity does not apply to "sham" activities. *Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60–61 (1993). Petitioning the government is a "sham" activity if: (1) it is "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits[,]" and (2) it "use[s] the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon." *Id.* (citations and internal quotation marks omitted).

[54] Defendants argue that plaintiffs' assertions about the Citizen Petition have no connection to the EpiPen settlement which, under plaintiffs' theory, produced the generic delay. Doc. 2142-1 at 74 n.438. So, defendants argue, the Citizen Petitions can't present a triable issue whether the settlement delayed generic entry. *Id.* But, defendants ignore that plaintiffs have alleged that defendants engaged in a "scheme . . . to stifle all generic competition in the EAI market." Doc. 2169 at 15 (Pretrial Order ¶ 3.a.1.b.). And, they allege that defendants' scheme included both (1) entering unlawful reverse payment settlements, and (2) "filing a baseless Citizen Petition and a supplement mere weeks before the entry date agreed upon in the settlement." *Id.* at 15–17 (Pretrial Order ¶ 3.a.1.b.). Also, plaintiffs assert their argument about the Citizen Petition in response to defendants' contention that the FDA's actions constitute an intervening and independent cause of the generic delay cutting off any causal connection between the EpiPen settlement and the delayed generic entry. As discussed in the above-section, plaintiffs present a triable issue whether the Citizen Petition delayed Teva's FDA approval. So, because a reasonable jury could find from the summary judgment facts that defendants' actions caused delay in the FDA's approval, the court can't find as a matter of law that the FDA's approval—which didn't come until 2018—was an *independent* and intervening cause of the generic delay.

Defendants assert that the Citizen Petition wasn't objectively baseless because it suggested the FDA should require Teva to perform a human factors study—something that the FDA also required of Teva. *Compare* Doc. 2146-21 at 4 (Defs.' Ex. 154) (Mylan's Citizen Petition asking the FDA to require "at a minimum, very carefully designed human factors studies that would demonstrate the Teva product's safety and effectiveness and its comparability to the EpiPen® auto-injector"), *with* Doc. 2145-5 at 3 (Defs.' Ex. 116) (FDA letter to Teva asking it to "conduct a design validation (human factors) study"). But, plaintiffs argue, a reasonable jury could disagree with that conclusion because the FDA denied Mylan's Citizen Petition "without comment[.]" Doc. 2147-2 at 2 (Defs.' Ex. 157). Also, plaintiffs argue, a rational trier of fact could find or infer that the Mylan's Citizen Petition was objectively baseless because, as Dr. Peck opines, it "contained no new information for the FDA to consider" and didn't "raise novel concerns[.]" Doc. 2191-3 at 21 (Pls.' Ex. 25) (Peck Rebuttal Expert Report ¶ 44). Instead, Dr. Peck opines, the Citizen Petition "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.* Dr. Peck further opines that the Citizen Petition was one of several "inappropriate" actions taken by defendants that "occupied a great deal of time at the FDA[.]" Doc. 2191-7 at 34 (Pls.' Ex. 30) (Peck Expert Report ¶ 71). And, he describes the filing of the Citizen Petition as an "anticompetitive tactic[ ]" that "burden[ed] the agency, if not also delay[ed] approval." *Id.* (Peck Expert Report ¶ 72). Plaintiffs also assert that a reasonable jury could infer from the timing of the Citizen Petition that defendants intended for it to delay generic approval because Mylan submitted the Citizen Petition to the FDA on January 6, 2015, just six months before Teva was permitted to enter the EAI market under the EpiPen settlement agreement. The court agrees that

these summary judgment facts together present a triable issue whether the Citizen Petition was objectively baseless, and thus a sham activity.[55]

Defendants also argue that the summary judgment facts establish that the Citizen Petition caused no delay in Teva's application. For support, they cite the FDA's Report to Congress for fiscal year 2018, arguing that it confirms that Mylan's Citizen Petition caused no delay in the FDA's approval of the Teva generic. The FDA's 2018 Report states, "No 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. As discussed in the court's contemporaneously-filed Order ruling defendants' Motion to Exclude the Testimony and Report of Dr. Peck, the FDA's Report isn't clear whether this statement means no FDA approvals in 2018 (which would include the approval of Teva's generic EAI) were delayed because of a Citizen Petition, or whether it means that no Citizen Petitions filed in 2018 (which wouldn't include the 2015

[55] Defendants assert that, because the Citizen Petition's contents are undisputed, the question whether the Citizen Petition is objectively baseless is a question of law for the court to decide. Doc. 2226-1 at 26 & n.50. The court disagrees. The question "[w]hether petitioning activity is a sham is generally [one] for the jury." *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 689 (E.D. Pa. 2014) (citing *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 310 (E.D. Pa. 2011)); *see also Catch Curve, Inc. v. Venali, Inc.*, 519 F. Supp. 2d 1028, 1037 (C.D. Cal. 2007) ("'[W]hether something is a genuine effort to influence governmental action, or a mere sham, is a question of fact.'" (quoting *Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau, Inc.*, 690 F.2d 1240, 1253 (9th Cir. 1982)). A court can rule the objectively baseless question as a matter of law where "there is no dispute over the predicate facts of the underlying . . . proceeding[.]" *Pro. Real Est. Invs., Inc.*, 508 U.S. at 63. But, here, there is a dispute about the predicate facts of the underlying proceeding—namely, whether Mylan's Citizen Petition raised issues that the FDA already had received and rejected in other Citizen Petitions, whether it occupied the FDA's time thus delaying the approval process, and whether the timing of the filing in January 2015 supports a finding or inference that defendants submitted the Citizen Petition as a way to delay Teva's generic entry as the settlement's agreed-to entry date approached. The court can't make that determination as a matter of law on these facts. It's a jury question.

Citizen Petition) delayed any FDA approval. Thus, the court can't find, as a matter of law, that the Report conclusively establishes that Mylan's Citizen Petition never delayed the FDA's approval of the Teva generic.

Also, defendants argue that no reasonable jury could find that the Citizen Petition delayed FDA approval when the FDA denied the Petition "without comment" in June 2015, Doc. 2147-2 at 2 (Defs.' Ex. 157), but then didn't approve the Teva generic until 2018. A reasonable jury might adopt the inference that this argument presupposes. But, a reasonable jury also might find Dr. Peck's opinions credible and agree with his conclusions that the Citizen Petition took time and resources from the FDA, thus burdening the agency and likely delaying approval. So, the court agrees with plaintiffs. Genuine issues of fact exist whether the filing of the Citizen Petition delayed Teva's FDA approval.

In sum, the court finds that plaintiffs have adduced sufficient evidence from which a reasonable jury could conclude that the EpiPen settlement delayed generic entry by slowing Teva's efforts to secure FDA approval before the settlement's agreed-to entry date of June 22, 2015. And, from those facts, a reasonable jury also could conclude that the FDA's actions in refusing to approve the Teva generic until 2018 aren't an intervening cause breaking the requisite chain of causation between the EpiPen settlement and delayed generic entry. *See In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 287–89 (D. Mass. 2014), *aff'd* 842 F.3d 34 (1st Cir. 2016) (denying summary judgment motion on causation grounds based on the argument that a pharmaceutical company's failure to achieve FDA approval for its generic was "the sole and direct cause of [the] failure to enter the generic Nexium market" because plaintiffs "marshaled sufficient evidence in the record to demonstrate genuine and material factual disputes" allowing "a reasonable juror to conclude that [pharmaceutical company] was well on

its way to obtaining tentative approval" of its generic product but "since slowed its progress in response to the terms of its settlement"). *Cf. In re Flonase Antitrust Litig.*, 798 F. Supp. 2d at 629–33 (denying summary judgment against antitrust claims because, among other things, plaintiffs presented sufficient evidence to raise genuine issues of material fact whether the FDA's deficiency notices sent to a potential competing generic were "indeed proximately caused by, or was the foreseeable consequences of, [defendant's] alleged antitrust violations[,]" and thus not "an intervening cause of [the] delayed entry into the market that severs the causal chain beginning with [defendant's] conduct"). So, the court finds here that the summary judgment facts don't permit the court to conclude—as a matter of law—that Teva's failure to secure FDA approval until 2018 was an intervening cause breaking the chain of causation and warranting summary judgment against plaintiffs' antitrust claims premised on their generic delay theory.

ii. Teva's Challenges Developing the Product

Next, defendants assert that the summary judgment facts establish that Teva faced continuous setbacks in its efforts to develop its generic EAI. And, defendants argue, these development issues were another independent and intervening cause of the generic's delay that breaks any chain of causation linking the EpiPen settlement and any delayed generic entry.

For support, defendants rely on summary judgment facts showing that shortly after the settlement—in 2013—Teva discovered that its device had a tendency to fire when dropped but didn't indicate to end users that the device already had dispensed the epinephrine. Doc. 2146-15 at 2 (Defs.' Ex. 148). So, Teva had to redesign its device to correct the problem. *Id.* After making these changes, on December 30, 2014, Teva submitted an amended ANDA to the FDA that one Teva executive described as "basically . . . a completely new ANDA[.]" Doc. 2146-18 at 2 (Defs.' Ex. 151). Teva's submission explained that, among other changes, Teva had

"changed the site of the drug product manufacture/testing . . . and device assembly[,]" "changed the formulation" of epinephrine, and "changed the device to improve the design to ensure the user will not be presented with a device that has delivered the drug product but has not engaged the safety guard." Doc. 2146-19 at 2 (Defs.' Ex. 152). After submitting the amended ANDA in December 2014, the agreed entry date of June 22, 2015 passed without the FDA acting on Teva's application. Then, in February 23, 2016, the FDA issued a complete response letter explaining that it couldn't approve Teva's ANDA application "in its present form" and citing "MAJOR" deficiencies with Teva's generic device. Doc. 2147-3 at 2, 11 (Defs.' Ex. 158). It took two and a half more years for Teva to correct those problems and finally achieve FDA approval in August 2018. Doc. 2147-4 at 2–3 (Defs.' Ex. 159). Defendants assert that these summary judgment facts establish that Teva's product development issues were the intervening cause of the failure to secure FDA approval until 2018. And thus, defendants contend, no causal connection exists between the EpiPen settlement and any delayed generic entry by Teva.

Plaintiffs disagree. Plaintiffs argue that a reasonable jury could infer from the summary judgment facts that the EpiPen settlement caused Teva to slow its efforts to develop its EAI product and correct product development issues which, in turn, produced a delay in Teva achieving FDA approval. Plaintiffs assert that a jury could infer that Teva—which, as defendants' expert testified, is a large, sophisticated pharmaceutical company "skilled in the art" of drug development—had the resources to develop its product much faster than it did. Doc. 2203-6 at 3–4 (Pls.' Ex. 298) (Weisman Dep. 42:24–45:6). Instead, plaintiffs argue, Teva internal documents support a finding or inference that the company didn't make the development of its product a priority during the 2011–13 time frame. Plaintiffs assert that Teva's development meetings were sparsely attended by team members. *See* Doc. 2204-6 at 2 (Pls.' Ex.

329) (May 1, 2012 meeting attended by three out of 18 team members); Doc. 2204-8 at 2 (Pls.' Ex. 331) (June 12, 2012 meeting attended by two out of 16 team members); Doc. 2204-14 at 2 (Pls.' Ex. 337) (November 13, 2012 meeting attended by four out of 16 team members); Doc. 2204-16 at 2 (Pls' Ex. 339) (January 9, 2013 meeting attended by 3 out of 16 team members). Also, plaintiffs argue, the meeting minutes show that Teva failed to take any action on a needle separation issue for at least seven months. *Compare* Doc. 2204-17 at 4 (Pls.' Ex. 340) (April 2012 minutes noting needle separation issue), *with* Doc. 2204-18 at 4 (Pls.' Ex. 341) (November 2012 meeting listing the issue still outstanding). Also, the minutes show that Teva failed to update its quality agreement with the device's manufacturer for two years. *Compare* Doc. 2204-19 at 5 (Pls.' Ex. 342) (March 2011 minutes describing efforts to update to the agreement), *with* Doc. 2204-20 at 5 (Pls.' Ex. 343) (April 2013 minutes showing that agreement updates still in process). But then, in May 2014, with about a year left before the June 2015 agreed-to entry date approached, Teva implemented a "Tiger Team" to work on its generic EAI and began allocating more resources to the project with additional employees. Doc. 2205-1 at 7 (Pls.' Ex. 344); Doc. 2205-2 at 2–3 (Pls.' Ex. 345); Doc. 2205-4 at 4, 7 (Pls.' Ex. 347). Plaintiffs assert that a reasonable jury could infer from these facts that Teva procrastinated in its effort to secure FDA approval until the settlement's agreed-upon date grew nearer. And, plaintiffs argue, a reasonable jury could find or infer that the EpiPen settlement caused that procrastination which, in turn, prevented Teva from securing FDA approval at an earlier date.

The court agrees with plaintiffs. A reasonable jury could infer from these facts that the EpiPen settlement caused Teva to delay its efforts to develop its product and that these delays were a foreseeable consequence of defendants entering a settlement agreement in 2012 that required Teva to wait until 2015 to launch its generic product. Equally, a jury might reach the

opposite conclusion. As defendants argue, Teva's actions developing its product were entirely within Teva's control and defendants played no role in Teva's product development. So, a jury might conclude that any delay in the FDA approval process falls squarely on Teva, making Teva's actions (or inactions) an intervening cause that breaks the causal chain between defendants' settlement of the EpiPen litigation and Teva's generic entry date. But, on these summary judgment facts, the court can't make that finding as a matter of law. So, the court rejects defendants' argument that Teva's failure to develop its product was an intervening cause that precludes a finding that the EpiPen settlement caused Teva's delayed generic entry.

iii. Blocking By Other EpiPen Patents

Last, defendants argue—even if Teva had solved its product development issues and secured FDA approval before June 2015—Pfizer's other EpiPen patents provide another independent and intervening cause precluding a finding of causation between the EpiPen settlement and any delayed generic entry. Defendants contend that these EpiPen patents would have blocked Teva's launch of a generic product in the "but for" world where there was no settlement. Defendants correctly assert that "to withstand summary judgment," plaintiffs "must point to evidence affirmatively showing that [Teva] could have launched" its generic. *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 166 (3d Cir. 2017). "It is not enough" to show that Teva "wanted to launch its drug[.]" *Id.* at 165. Plaintiffs "must also show that the launch would have been legal" because "if the launch were stopped because it was illegal, then the [antitrust] injury (if it could still be called that) would be caused not by the settlement but by the patent laws prohibiting the launch." *Id.*; *see also In re Namenda Indirect Purchaser Antitrust Litig.*, No. 1:15-cv-6549 (CM) (RWL), 2021 WL 2403727, at *26 (S.D.N.Y. June 11, 2021) (explaining if generic drug manufacturer "had won the [patent] challenge, it could

have launched its version of generic Namenda IR earlier than when generics launched in the real world[,]" but if the generic manufacturer "lost the patent challenge, then the date of its generic entry in the but-for world would have been the same as in the real world" which "mean[s] that [defendant's] actions did not depress competition").

It's undisputed that Pfizer owns four patents covering EpiPen devices that expire in 2025. Doc. 2169 at 4 (Pretrial Order ¶ 2.a.27.). Only two of those patents—the '012 and '432 Patents—were at issue in the Teva/EpiPen litigation. First Amended Complaint, *King Pharms., Inc. v. Teva Parenteral Meds., Inc.*, No. 1:09-cv-00652-GMS (D. Del. Nov. 11, 2010), ECF No. 37-1. Neither one of the other two patents—the '827 Patent nor the '035 Patent—was in dispute in the Teva/EpiPen litigation. Days 1–4 of Trial Transcript, *King Pharms., Inc. v. Teva Parenteral Meds., Inc.*, No. 1:09-cv-00652-GMS (D. Del. July 25, 2012), ECF Nos. 150–51, 153–54. But, with the EpiPen settlement, Teva secured a license to all issued patents and a covenant not to sue based on any current or future patents covering EpiPen devices (which would include the '035 and '827 Patents). Doc. 2146-3 at 3, 14–16 (Defs.' Ex. 136).

Defendants argue that, in a "but for" world with no settlement, Teva would have had to overcome the '827 and '035 Patents to launch its generic product. And, defendants assert, plaintiffs offer no evidence showing that Teva could have launched its generic product without infringing the blocking patents—the '827 and '035 Patents—had Teva not settled the EpiPen litigation. So, defendants contend, the summary judgment facts establish that the blocking patents are an independent and intervening cause of any alleged generic delay.

Plaintiffs respond with their own "but for" scenario. Plaintiffs argue that defendants' "but for" world wrongly assumes continued litigation instead of settlement. But, in plaintiffs' "but for" world, defendants and Teva would have settled the EpiPen litigation independently

from the Nuvigil litigation and without joint delayed entry dates for both drug products. Plaintiffs support this theory with the opinion of their expert, Prof. Einer Elhauge. He opines that, had the parties not traded the EpiPen settlement for the Nuvigil settlement, the economically rational "but for" settlement of the EpiPen litigation would have allowed a March 14, 2014 entry date for Teva's generic EAI. Doc. 2192-6 at 9–10 (Pls.' Ex. 55) (Elhauge Reply Expert Report ¶ 3). And, plaintiffs assert, a reasonable jury could infer that the economically rational "but for" settlement would have granted Teva a covenant not to sue based on any current or future EpiPen patents—like the actual agreement did. So, plaintiffs contend, Teva could have launched its generic EAI in this "but for" world without infringing the blocking patents.

Defendants' Reply argues that the summary judgment record contains no evidence suggesting that the parties considered or even discussed an alternative generic entry date. And, defendants argue, Prof. Elhauge's opinion offers only speculation, which isn't evidence sufficient to preclude summary judgment. Doc. 2226-1 at 26 n.53 (quoting *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 407 (3d Cir. 2016) (concluding that Prof. Elhauge's "assumption cannot serve as a substitute for actual evidence at the summary judgment stage")). The court disagrees with defendants' proposition.

As the court has explained in its contemporaneously-filed Order denying defendants' Motion to Exclude the Testimony and Report of Prof. Elhauge, it finds Prof. Elhauge's reverse payment analysis sufficiently reliable and scientifically sound to qualify for admission as evidence. Prof. Elhauge has provided a rational basis for his analysis's assumptions based on his review of documentary and economic evidence. And, consistent with other courts who have considered Prof. Elhauge's proffered expert testimony in pay-for-delay cases, the court finds Prof. Elhauge's analysis qualifies as admissible expert opinion. *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 about Prof. Elhauge's "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").

Defendants' attacks calling his analysis speculative are arguments that go to the credibility of Prof. Elhauge's opinion. On summary judgment, the court can't make this credibility determination or weigh Prof. Elhauge's opinion against other summary judgment facts. Instead, the court must consider the evidence in the light most favorable to plaintiffs, as the non-moving party. So, the court finds, Prof. Elhauge's opinion presents a triable issue of fact whether—in a "but for" world—Teva could have launched its generic product before the agreed-to generic entry date and without infringing the blocking patents (the '827 and '035 Patents). Thus, the court can't find—as a matter of law—that the blocking patents are an independent and intervening cause of any alleged generic delay that warrants summary judgment against plaintiffs' antitrust claims premised on a generic delay theory.

b. Independence of the EpiPen and Nuvigil Settlements

Second, defendants argue that plaintiffs' generic delay claims can't survive summary judgment because the undisputed summary judgment facts establish the EpiPen and Nuvigil settlements were independent and lawful settlements. Thus, defendants contend, the summary judgment facts present no triable issue whether defendants violated the antitrust laws by entering an unlawful pay-for-delay settlement agreement.

Defendants' argument here is two-fold. Defendants' first argument asserts that plaintiffs' antitrust claims are premised on a novel theory alleging that defendants traded the EpiPen settlement (with an agreed-to June 2015 date for Teva's generic EAI to enter the market) in exchange for the Nuvigil settlement (with an agreed 2016 date for Mylan to launch its generic Nuvigil product). It's undisputed that the EpiPen settlement agreement contained no monetary payment. Doc. 2146-3 at 3, 14–15 (Defs.' Ex. 136). Defendants argue, such an agreement is presumptively lawful under *FTC v. Actavis*. 570 U.S. 136, 158 (2013) (explaining that the *Actavis* holding "does not prevent litigating parties from settling their lawsuit" because they may "settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point").

But, plaintiffs respond by citing cases where courts have held that pay-for-delay settlements don't require a monetary payment in the actual settlement agreement when other evidence suggests that the parties to the litigation exchanged some form of consideration in separate, side agreements. *See, e.g.*, *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 258 (3d Cir. 2017) (holding that settlement agreement was "properly subject to antitrust scrutiny" where plaintiffs alleged plausibly that, while pharmaceutical company Ranbaxy gave Pfizer $1 million,

Pfizer's agreement to release its claims involving the drug Accupril was made "[i]n exchange for Ranbaxy's agreement to delay its launch of" another drug product, Lipitor, and "not in exchange for the $1 million" (internal quotation marks omitted)); *In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 198–99 (S.D.N.Y. 2018) (finding genuine issue of fact existed whether an amendment to agreement involving the drug Lexapro was a "side-deal" and part of an agreement to settle the parties' patent dispute over separate drug Namenda); *In re Androgel Antitrust Litig. (No. II)*, No. 1:09-MD-2084-TWT, 2018 WL 2984873, at *4, 10 (N.D. Ga. June 14, 2018) (concluding that, where pharmaceutical companies entered settlement agreements to resolve patent infringement claims and, on the same day, also entered business promotion agreements with profit sharing provisions, plaintiffs' generic delay claims survived summary judgment because plaintiffs had offered "significant evidence from the negotiation of the [patent litigation] settlements to suggest that the services [contracted for in the business promotion agreements] were merely an afterthought to the Defendants, the proverbial lipstick on the pig that was the delay in generic entry[,]" and plaintiffs' experts would "testify that the side agreements did not make much business sense on their own"); *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704, 718 (N.D. Ill. 2016) (rejecting defendants' attempt "to assess the components of the [patent litigation] settlement in piecemeal fashion" and instead finding that plaintiffs plausibly had alleged "when taken as a whole, the total payment" received under several, different agreements was "large and unjustified" and thus pleaded a plausible generic delay claim); *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 408–09, 418 (E.D. Pa. 2015) (finding that the court should consider "the entirety of the reverse payment" made under multiple agreements between the settling parties and concluding that plaintiffs had "presented sufficient evidence to create a genuine dispute . . . whether the reverse payments

exceeded litigation costs and were large enough to induce the Generic Defendants to drop their patent challenge and stay off of the market"); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 752 (E.D. Pa. 2014) (declining defendants' invitation to "examin[e] each of the three settlement agreements in isolation" and, instead, concluding "the Licensing Agreement must be read in conjunction with the Co–Promotion and Manufacturing Agreements executed that same day" to determine whether plaintiffs plausibly had alleged an unlawful reverse payment settlement).

Defendants say that none of plaintiffs' cited cases apply here. Each case, they argue, still involved a monetary payment—either found in the actual settlement agreement or a side agreement. And, defendants assert, plaintiffs offer no cases where, as here, the alleged reverse payment settlement contains no monetary payment but, instead, is premised on the value offered by settling another and different lawsuit. This is a distinction that makes no difference. Here, like the scenarios in other lawsuits, plaintiffs allege that defendants settled the EpiPen case in exchange for the pecuniary value that the Nuvigil settlement offered Teva. Even though plaintiffs haven't provided a case where a court has permitted a generic delay claim premised on a theory that the parties traded settlements in two cases, it would make little sense for the court to preclude this theory simply because the value traded in the settlement didn't include a monetary payment. If the court were to reach that conclusion, the parties to an unlawful reverse payment settlement could avoid antitrust liability so long as they crafted their agreements as exchanging something of value that was delivered by something other than a monetary payment. Nothing in the case law or related antitrust literature embraces defendants' view that money—and money alone—can support reverse payment liabilities.

Also, and as plaintiffs argue, even defendants' expert recognizes that a reverse payment settlement involves the payment of "some form of compensation to the generic manufacturer"

which "can be in the form of cash payments or through a payment associated with some other business transaction (e.g., a cross-licensing agreement) where the brand-name manufacturer might allegedly 'overpay' the generic manufacturer or the generic manufacturer might allegedly 'underpay' the brand-name manufacturer." Bret Dickey, Jonathan Orszag, & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Annals Health L. 367, 385 (2010). Again, plaintiffs allege here that the two settlements entered in "tandem" produced a reverse payment settlement where defendants overpaid Teva in the Nuvigil settlement. Doc. 2169 at 16 (Pretrial Order ¶ 3.a.1.b.) ("Neither settlement, viewed independently, was economically rational."). The court can find no reason to preclude plaintiffs' theory simply because the alleged overpayment was compensation in the form of the value that the Nuvigil settlement provided Teva—and not compensation in the form of money. The court rejects defendants' first argument seeking summary judgment based on the alleged independence of the EpiPen and Nuvigil settlements.

Defendants' second argument asserts that the summary judgment record contains no evidence from which a jury could infer that defendants agreed to trade the EpiPen settlement for the Nuvigil settlement. Plaintiffs disagree. Plaintiffs argue that they have adduced direct evidence of such an agreement. For support, plaintiffs cite two internal Teva documents discussing settlement of both the EpiPen and Nuvigil settlements. *See* Doc. 2201-13 at 2 (Pls.' Ex. 262) (stating that Teva had called Mylan's Deputy General Counsel and "relayed the following proposal: epipen in 2014 and nuvigil in 2018" and "also raised formoterol, which is another of [Mylan's] products [that Teva was] challenging with trial later this year, and threw out a 2018 date"); *see also* Doc. 2202-20 at 2 (Pls.' Ex. 278) (stating in first email that "Bill [Marth] got a call from Heather at Mylan" and asking what "exactly did we propose re epi and nuvigil?"

and responding in another email with "2014 for epi and 2018 for nuvigil. No months specified"). While each communication references negotiations and proposed terms to settle the two separate lawsuits, nothing in them references—explicitly—an agreement to trade one settlement for the other. Instead, a factfinder would have to infer from these communications that the parties, by discussing the two settlements together, entered an agreement to trade one settlement for the other. Thus, these two documents don't capture direct evidence of an agreement. *See Llacua v. W. Range Assoc.*, 930 F.3d 1161, 1177 (10th Cir. 2019) (explaining that the district court "correctly defined direct evidence" of an antitrust conspiracy as "'evidence that is explicit and requires no inferences to establish the proposition or conclusion being asserted. With direct evidence the factfinder is not required to make inferences to establish facts.'" (quoting *Champagne Metals v. Ken-Mac Metals, Inc.*, 458 F.3d 1073, 1083 (10th Cir. 2006))).

But, plaintiffs also assert that they have adduced circumstantial evidence of an agreement to trade the two settlements. Our Circuit has explained, circumstantial evidence "must 'tend[ ] to exclude the possibility' of independent action." *Llacua*, 930 F.3d at 1179 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 554 (2007)). This standard requires an antitrust plaintiff to "show that the inference of conspiracy is reasonable in light of the competing inferences of independent action or collusive action that could not have harmed" plaintiff. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 588 (1986).

But, one cannot infer a conspiracy if "the defendants 'had no rational economic motive to conspire, and if their conduct is consistent with other, equally plausible explanations.'" *Llacua*, 930 F.3d at 1179–80 (quoting *Matsushita*, 475 U.S. at 596). And when considering "circumstantial evidence [that] is just 'as consistent with' unilateral action as with concerted

action, it 'does not, standing alone, support an inference of antitrust conspiracy.'" *Id.* at 1180 (quoting *Matsushita*, 475 U.S. at 588 (further citations omitted)).

Defendants argue that plaintiffs haven't shouldered their burden here to adduce circumstantial evidence that "tend[s] to exclude the possibility" that the EpiPen and Nuvigil settlements were independent actions. *Twombly*, 550 U.S. at 554. Defendants assert that nothing in the language of the EpiPen or Nuvigil settlements connects one to the other. Defendants also cite deposition testimony from defendants' witnesses who testified that there never was any agreement to trade the EpiPen settlement for the Nuvigil settlement. Plaintiffs respond, arguing that the summary judgment record contains plenty of documents from which a jury could infer just the opposite of what defendants' witnesses testified.

To support their argument that they have adduced circumstantial evidence presenting a triable issue that the two settlements were connected to each other, plaintiffs cite the following summary judgment facts:

(1) the parties signed the two binding term sheets agreeing to settle the two lawsuits on the very same day—April 26, 2012; Doc. 2146-3 at 14–20 (Defs.' Ex. 136) (EpiPen settlement); Doc. 2147-11 at 2–18 (Defs.' Ex. 166) (Nuvigil settlement);

(2) internal Teva emails show that Mylan CEO Heather Bresch and Teva CEO Bill Marth negotiated simultaneously the EpiPen and Nuvigil settlements, even though Mylan wasn't a party to the EpiPen litigation; Doc. 2201-21 at 2 (Pls.' Ex. 255) (explaining that Mr. Marth had "talked to Heather . . . about settlement" of the EpiPen litigation and that "[s]he (Heather) wants to give us a 2018 entry date but would likely agree to 2017" and noting that it was

"[j]ointly but not directly connected" to "the Nuvigil litigation" where Mr. Marth "offered a 2018 entry date"); Doc. 2202-20 at 2 (Pls.' Ex. 278) (stating "Bill [Marth] got a call from Heather at Mylan" and asking what "exactly did we propose re epi and nuvigil?"); Doc. 2202-9 at 2 (Pls.' Ex. 279) (sending the Nuvigil term sheet and discussing changes that were "agreed to between Heather and Mr. Marth");

(3) Heather Bresch told Pfizer employees that the EpiPen settlement would include an entry date of June 2015; Doc. 2205-8 at 2 (Pls.' Ex. 360);

(4) internal emails show that the parties discussed, negotiated, and resolved the two cases together; Doc. 2201-13 at 2 (Pls.' Ex. 262) (stating that Teva had called Mylan's Deputy General Counsel and "relayed the following proposal: epipen in 2014 and nuvigil in 2018"); Doc. 2202-13 at 2 (Pls.' Ex. 283) (noting that "the signed Nuvigil deal was" complete and "language w Pfizer on Epipen is done"); Doc. 2201-20 at 2 (Pls.' Ex. 269) (Mylan employees emailing with the subject line "Epipen—Teva/Potential Settlement" and attaching a "Nuvigil Settlement DRAFT");

(5) Mylan signed a covenant not to sue Teva in the EpiPen settlement even though Mylan wasn't the patent holder or a formal party to the litigation; Doc. 2146-3 at 28–29 (Defs.' Ex. 136);

(6) Mylan submitted both settlements to the FTC describing them as "potentially 'related'"; Doc. 2147-13 at 2 (Defs.' Ex. 168);

(7) Mylan's outside counsel emailed Mylan about the FTC letter and referred to the "Nuvigil and EpiPen settlement" using the singular noun "settlement"

instead of referring to two, separate agreements; Doc. 2203-5 at 2 (Pls.' Ex. 294);[56] and

(8) Prof. Elhauge's economic analysis showing that each of the EpiPen and Nuvigil settlements, standing alone, were economically irrational for the generic entrant, and, taken together, the settlements produced greater profits than the parties could have achieved by not linking the settlements; Doc. 2193-4 at 43, 45–46, 51–55 (Pls.' Ex. 85) (Elhauge Expert Report ¶¶ 79, 85–86, 98–104 & Table 1); Doc. 2192-6 at 30–31, 36–37 (Pls.' Ex. 55) (Elhauge Reply Expert Report ¶¶ 44, 57).[57]

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[56] Defendants respond to plaintiffs' citation to this summary judgment fact, arguing that it is a "typo in an email subject line" that is "not evidence." Doc. 2226-3 at 93. Assuming Mylan can adduce evidence to this effect, Mylan can argue that this email's subject line contains a simple typo. And a reasonable juror might accredit that inference. But, on this motion, the court must construe the evidence in plaintiffs' favor, and a reasonable trier of fact also might infer that it wasn't a typo and the author meant to refer to the two as one, single agreement that resolved both cases. The court must leave that determination to the jury. It's not a proper question for the court to resolve on summary judgment.

[57] Defendants assert that Prof. Elhauge's opinion doesn't preclude summary judgment because expert opinion cannot create a triable issue of fact about the existence of a conspiracy. For support, defendants cite a case that prohibited experts from opining on the "ultimate issue" whether a conspiracy existed because experts may not testify about legal conclusions. *See Hyland v. HomeServices of Am., Inc.*, 771 F.3d 310, 322 (6th Cir. 2014) (affirming trial court's decision precluding expert from testifying "to their ultimate opinions that a price-fixing conspiracy existed"). And, they cite another case where the experts' opinions failed to support an inference of conspiracy because the opinions didn't exclude the possibility of independent action. *See Dahl v. Bain Cap. Partners, LLC*, 937 F. Supp. 2d 119, 137 n.17 (D. Mass. 2013) (holding that "experts' ultimate conclusions do not provide a permissible inference under the controlling case law").

Those cases don't apply here. Prof. Elhauge isn't offering an expert opinion on the ultimate legal issue whether a conspiracy existed. Instead, he is offering his opinion, as an expert in antitrust economics, whether the EpiPen and Nuvigil settlements made economic sense for the parties. That kind of evidence is proper expert opinion which the jury can consider and weigh to determine whether it supports the existence of an antitrust conspiracy and excludes the possibility that the two settlements were independent actions.

Also, defendants attack Prof. Elhauge's opinion because, they contend, his analysis shows that the Nuvigil settlement, standing alone, was profitable for Mylan. The court has addressed this argument comprehensively in its Order ruling defendants' Motion to Exclude Prof. Elhauge's expert opinions. As that Order explains, Prof. Elhauge provides a reliable basis for the opinions offered in his original Expert

Defendants, of course, disagree. They repeatedly assert that these facts merely show that the parties negotiated the two settlements around the same time and coincidentally signed the two binding term sheets on the same day, but those facts don't exclude the possibility of independent action. And, they argue, the court should grant summary judgment like the Pennsylvania federal court did in *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, Nos. 2:06-cv-1797, 2:06-cv-1833, 2:06-cv-2768, 2014 WL 2813312, *14 (E.D. Pa. June 23, 2014).

There, plaintiffs alleged that pharmaceutical company "Cephalon entered into four bilateral agreements to settle the then-pending patent infringement litigation against" four competing generic companies. *Id.* Plaintiffs alleged the four agreements were unlawful reverse payment settlements that violated the antitrust laws. *Id.* at *4. The "agreements contained identical entry dates and contingent launch provisions, and also had substantially similar structures." *Id.* at *14. But, the court found that summary judgment was warranted because "the circumstantial evidence" surrounding the four agreements didn't "support an inference of concerted, as opposed to independent, action." *Id.* Among other things, the court found that the summary judgment facts established that "the settlement agreements with the Generics were economically beneficial[,]" and there was "no comparable evidence that the Generic Defendants were dependent on the universal agreement to make the settlements economically attractive." *Id.* at *12. Instead, "the settlements seemed to offer the best of both worlds: an end to costly litigation, combined with lucrative business deals and an assurance that each Generic Defendant would not be disadvantaged regarding the entry of generic Provigil." *Id.*

Defendants assert that this case presents similar summary judgment facts. Defendants argue that this case's summary judgment record lacks any evidence that the agreements were

Report and Reply Report. And, any challenges that defendants assert against them go to the weight that the trier of fact should assign to those opinions.

dependent on one another. And, they contend, the summary judgment facts establish that the settlements made independent economic sense for all parties.

A reasonable trier of fact might agree with defendants' assessment of these facts. But, a reasonable jury also might reach the opposite conclusion, finding that the facts, taken together, "'tend[ ] to exclude the possibility' of independent action." *Llacua*, 930 F.3d at 1179 (quoting *Twombly*, 550 U.S. at 554). A rationale trier of fact could infer as much from the communications among Mylan, Pfizer, and Teva which discussed the two settlements together and produced two binding term sheets signed the very same day—along with the fact that plaintiffs' expert opines that these settlements were not economically rational for the generic entrant (should the jury find this expert opinion credible). Thus, the court finds, the summary judgment facts here support an "inference of conspiracy" that "is reasonable in light of the competing inferences of independent action or collusive action that could not have harmed" plaintiff. *Matsushita*, 475 U.S. at 588; *see also In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 256 (D. Mass. 2014) (denying summary judgment where the summary judgment facts suggested that defendants "possessed strong motives to coordinate the actions they took[,]" and "[i]n conjunction with the interdependence of the agreements themselves, these factors are consistent with the existence of a single agreement, tend to exclude the possibility of independent action, and adequately support a reasonable inference of conspiracy"). And so, the court denies summary judgment based on defendants' argument that the EpiPen and Nuvigil settlements were independent from one another.

c. "Unexplained" Reverse Payment

Third, defendants argue that plaintiffs' antitrust claims can't survive summary judgment because the undisputed summary judgment facts present no triable issue whether defendants

made any "unexplained" reverse payment to settle the EpiPen litigation that violated the antitrust laws. As the Supreme Court has articulated, "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects[.]" *FTC v. Actavis*, 570 U.S. 136, 158 (2013); *see also id.* at 157 (recognizing that a reverse payment "(if otherwise unexplained) likely seeks to prevent the risk of competition"). Defendants make two arguments that plaintiffs can't satisfy *Actavis*'s requirement of proving an "unexplained" reverse payment settlement.

Defendants' first argument asserts that the summary judgment facts establish no "reverse payment" occurred here. Defendants argue that it's undisputed that neither the EpiPen nor Nuvigil settlement agreement contained any monetary payment to Teva. *See generally* Doc. 2146-3 (Defs.' Ex. 136) (EpiPen settlement) & Doc. 2147-11 (Defs.' Ex. 166) (Nuvigil settlement). So, they contend, defendants never made any "reverse payment." For reasons already discussed, *see supra* Part III.A.1.b., the court won't foreclose plaintiffs' generic delay theory simply because the "value" Teva allegedly derived from the settlements didn't include a monetary payment. As explained, plaintiffs have adduced sufficient evidence supporting a triable issue whether defendants made an unlawful reverse payment in the EpiPen settlement in the form of overpaying Teva for its settlement of the Nuvigil litigation.

Also, defendants argue, the summary judgment facts present no triable issue whether the Nuvigil settlement overcompensated Teva. They argue Teva had a strong position in the Nuvigil litigation, demonstrated by the fact that the other defendants in the Nuvigil MDL—in effect, Teva's co-defendants—lost at trial. Memorandum at 1, *In re: Armodafinil Patent Litig.*, No. 1:10-md-02200 (D. Del. Mar. 30, 2013), ECF No. 329 at 1. And, they assert, Mylan benefited from the Nuvigil settlement because it granted Mylan the license to enter the generic Nuvigil market in 2016—eight years before the Nuvigil patents expired. Doc. 2147-11 at 3–4, 6–7

(Defs.' Ex. 166) (Nuvigil settlement); Doc. 2147-16 at 3 (Defs.' Ex. 171) (Nuvigil patents' 2024 expiration dates). Thus, defendants assert, no reasonable factfinder could infer from these facts that the Nuvigil settlement overcompensated Teva and thus constitutes a "reverse payment."

Plaintiffs respond, arguing that this description of the summary judgment evidence is defendants' "preferred resolution of the facts"—but not what the court can consider on summary judgment. Doc. 2190-1 at 91. The court agrees.

Viewing the facts in plaintiffs' favor, a jury could infer from the analysis offered by plaintiffs' experts—should the jury find their opinions credible—that the Nuvigil settlement overcompensated Teva. Prof. Elhauge opines that the Nuvigil settlement produced a $467 million gain for Teva compared to a "but for" settlement and a $547 million gain compared to continued litigation. Doc. 2192-6 at 27–29 (Pls.' Ex. 55) (Elhauge Reply Expert Report ¶ 40 & Table 1). And, Prof. Torrance asserts that Teva had just a 20% (± 10%) chance of winning the Nuvigil case had it gone to final judgment. Doc. 2146-5 at 101 (Defs.' Ex. 138) (Torrance Expert Report ¶ 207) (opining that "a reasonable, competent, and experienced patent attorney would estimate a probability of about 80% ± 10% that Mylan would not have been liable for patent infringement"). Even though the other MDL defendants (effectively, Teva's co-defendants) lost to Teva at trial, Prof. Torrance opines that Teva likely would have lost on appeal to the Federal Circuit. *Id.* at 100 (¶ 204). Plaintiffs assert that a jury could infer that Teva also thought it may lose on appeal based on the fact that Teva settled with the MDL defendants while the Nuvigil lawsuit was on appeal. Doc. 2202-4 (Pls.' Ex. 274); Doc. 2202-5 (Pls.' Ex. 275); Doc. 2202-6 (Pls.' Ex. 276); Doc. 2202-7 (Pls.' Ex. 277). And, in three of the four settlements, Teva agreed to pay the settling defendants millions of dollars in legal fees. *See* Doc. 2202-4 at 6 (Pls.' Ex. 274); Doc. 2202-5 at 5 (Pls.' Ex. 275); Doc. 2202-6 at 6 (Pls.' Ex. 276).

A reasonable jury could infer from the expert opinion evidence that Teva didn't have a strong chance of prevailing in the Nuvigil litigation, and so, Mylan's agreement to delay entry into the generic Nuvigil market until 2016 represented valuable compensation amounting to a reverse payment settlement made in exchange for the EpiPen settlement. Thus, the court finds, a jury could find or infer that defendants made a reverse payment to Teva. Summary judgment isn't warranted on defendants' first argument.

Defendants' second argument asserts that the summary judgment facts present no genuine issue whether the EpiPen and Nuvigil settlements involved an "unexplained" reverse payment. Defendants argue that the EpiPen settlement provided value to Teva because it gave Teva a license to the EpiPen patents and allowed it to enter the generic EAI market by 2015. And, defendants contend, the Nuvigil settlement's value to Teva was avoiding litigation risk and saving millions of dollars in continued litigation costs. Plaintiffs respond, arguing that defendants' version of the facts isolates the two settlements without considering the summary judgment facts that—as already discussed—allow a reasonable jury to infer that the two settlements were dependent on one another. And, plaintiffs argue, a reasonable jury could infer from those facts that the EpiPen settlement involved an "unexplained" reverse payment settlement because, as plaintiffs' expert opines, neither settlement was economically rational for the generic entrant, and, taken together, the settlements produced greater profits than the parties could have achieved by not linking the settlements. Doc. 2193-4 at 43, 45–46, 51–55 (Pls.' Ex. 85) (Elhauge Expert Report ¶¶ 79, 85–86, 98–104 & Table 1); Doc. 2192-6 at 30–31, 36–37 (Pls.' Ex. 55) (Elhauge Reply Expert Report ¶¶ 44, 57). From these summary judgment facts, a jury could infer that the EpiPen settlement involved an "unexplained" reverse payment sufficient to support an antitrust violation based on a pay-for-delay settlement. So, the court denies

summary judgment on defendants' argument that the summary judgment facts present no triable issue whether the EpiPen and Nuvigil settlements involved an "unexplained" reverse payment.

d. Procompetitive Effects of the Settlements

Fourth and *last*, defendants argue that summary judgment is warranted against plaintiffs' antitrust claims premised on a generic delay theory because the summary judgment facts establish that the EpiPen and Nuvigil settlements were procompetitive and thus didn't violate the antitrust laws. Defendants correctly explain that alleged reverse payment settlements are subject to a rule of reason analysis. *FTC v. Actavis*, 570 U.S. 136, 159 (2013). Our Circuit has described the rule of reason as "call[ing] for a holistic assessment of the parties' evidence" to determine "whether a challenged practice restrains trade unreasonably" thus violating the Sherman Act. *Buccaneer Energy (USA) Inc. v. Gunnison Energy Corp.*, 846 F.3d 1297, 1310 (10th Cir. 2017). Defendants assert that plaintiffs fail their summary judgment burden to adduce evidence presenting a triable issue whether the EpiPen and Nuvigil settlements had a "significant anticompetitive effect." *Id.* To the contrary, defendants contend, the EpiPen and Nuvigil settlements were procompetitive because they allowed generic manufacturers to enter the generic EAI and Nuvigil markets many years before the EpiPen and Nuvigil patents expired.

Plaintiffs respond, arguing that the rule of reason applies only to a single reverse-payment patent settlement, like the one at issue in *Actavis.* But here, where defendants and Teva allegedly entered reverse payment settlements agreeing not to compete in each other's markets, plaintiffs assert that defendants entered a horizontal market allocation agreement. This kind of arrangement is a per se violation of the antitrust laws. *See Arizona v. Maricopa Cnty. Med. Soc'y*, 457 U.S 332, 348 (1982) (holding that agreements that "are horizontal and fix maximum prices" don't "escape *per se* condemnation" under the antitrust laws). The court need not decide

which test applies to the alleged reverse payment settlements at issue here because plaintiffs' generic delay claim survives summary judgment whether it's a per se violation or subject to the rule of reason test.

As plaintiffs correctly assert, defendants' argument—*i.e.*, the settlements didn't have an anticompetitive effect—assumes that the procompetitive benefits of allowing generic entrants to enter the market many years earlier than the branded products' patents were set to expire are realized only by the reverse payment settlement. Plaintiffs contend, a no-payment settlement in a "but for" world would have accomplished the same pro-competitive benefits. And, they argue, generic entry would have occurred sooner because the settlements never would have included a "pay for delay." Indeed, the summary judgment facts support a reasonable inference that the parties to the EpiPen and Nuvigil settlements, by negotiating the two settlements together and agreeing to future generic entry dates for both products simultaneously, traded one settlement generic entry date for another. And, a jury could infer that these summary judgment facts "'tend[ ] to exclude the possibility' of independent action." *Llacua*, 930 F.3d at 1179 (quoting *Twombly*, 550 U.S. at 554).

Also, defendants' argument that the settlements had procompetitive effects assumes that the generic entrants had a generic product that infringed the branded product, and thus the generic entrants would have lost their patent infringement lawsuits and thus couldn't have entered the market until the branded products' patents expired. Plaintiffs have adduced evidence from which a jury could infer that the generic entrants had a strong chance of prevailing at trial. Thus, a jury could find that the settlements didn't make economic sense from the perspective of the generic entrants. Like the facts presented in *In re Nameda Direct Purchaser Litigation*, the court cannot conclude on these summary judgment facts, as a matter of law, "[w]hether the

settlement agreements were anticompetitive or procompetitive" because that determination "will depend on several complex factual questions that cannot be decided on summary judgment." No. 15 Civ. 7488 (CM), 2017 WL 4358244, at *19 (S.D.N.Y. May 23, 2017). So, the court declines to grant summary judgment based on the alleged procompetitive effects of the EpiPen and Nuvigil settlements.

e. Conclusion

For reasons discussed, the court declines to enter summary judgment against plaintiffs' antitrust claims premised on their generic delay theory for any of the four arguments defendants assert seeking dismissal. Plaintiffs' generic delay claims thus survive summary judgment and will proceed to trial.

2. Rebate Agreements with Exclusivity Provisions

Next, defendants argue that the summary judgment facts fail to present a genuine issue whether defendants foreclosed branded competition through Mylan's use of exclusive rebate agreements. Defendants' argument here seeks summary judgment against plaintiffs' antitrust claims premised on a theory that defendants engaged in a scheme to block a competing EAI—Sanofi's Auvi-Q—from the market. Doc. 2169 at 17 (Pretrial Order ¶ 3.a.1.c.). Plaintiffs allege that defendants violated the antitrust laws by conditioning rebates paid to PBMs on their agreement to block Auvi-Q (and other competing EAIs) from formulary placement. *Id.* And, they contend, defendants succeeded in their "exclusionary contracting strategy" by excluding Auvi-Q from PBM formulary coverage and by forcing Sanofi to decide not to return Auvi-Q to the market. *Id.* at 18.

Defendants offer two reasons why this antitrust theory fails on summary judgment. *First*, defendants argue, the undisputed facts present no triable issue whether Mylan's rebate

agreements with PBMs were unlawful "exclusive dealing" contracts. *Second*, defendants contend, Mylan always offered prices for the EpiPen that were above cost. And, they say, that practice doesn't violate the antitrust laws because price discounts at above-costs prices are procompetitive. The court takes each argument, in turn.

a. Whether the Rebate Contracts are Unlawful Exclusive Dealing Contracts

Defendants argue that the summary judgment facts present no triable issue whether Mylan's rebate contracts are unlawful exclusive dealing contracts that subject them to liability under the antitrust laws.

An exclusive dealing arrangement is "a contract between a manufacturer and a buyer that forbids the buyer from purchasing the contracted good from any other seller or that requires the buyer to take all of its needs in the contract good from that manufacturer." XI Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 1800a, at 3 (4th ed. 2018); *see also Perington Wholesale, Inc. v. Burger King Corp.*, 631 F.2d 1369, 1374 (10th Cir. 1979) (describing an exclusive dealing arrangement as one that "entails a commitment by a buyer to deal only with a particular seller"). Such an agreement "need not specifically require the buyer to forgo other supply sources if the practical effect [of the agreement] is the same." *Perington Wholesale*, 631 F.2d at 1374; *see also Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 326 (1961) ("[E]ven though a contract does not contain specific agreements not to use the (goods) of a competitor, if the practical effect . . . is to prevent such use, it comes within" the prohibition against exclusivity (citation and internal quotation marks omitted)). "The antitrust vice of these arrangements is the foreclosure of part of the market in which the seller competes by taking away the freedom of the buyer to choose from the products of competing traders in the seller's market." *Perington Wholesale*, 631 F.2d at 1374; *see also ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 270 (3d

Cir. 2012) ("The primary antitrust concern with exclusive dealing arrangements is that they may be used by a monopolist to strengthen its position, which may ultimately harm competition." (citation omitted)).

But, an exclusionary contract doesn't violate the antitrust laws simply because it excludes competitors. Indeed, "[e]xclusive dealing agreements are often entered into for entirely procompetitive reasons, and generally pose little threat to competition." *ZF Meritor*, 696 F.3d at 270 (citation omitted); *see also Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 76 (3d Cir. 2010) ("'[I]t is widely recognized that in many circumstances [exclusive dealing arrangements] may be highly efficient—to assure supply, price stability, outlets, investment, best efforts or the like—and pose no competitive threat at all.'" (quoting *E. Food Servs., Inc. v. Pontifical Cath. Univ. Servs. Ass'n, Inc.*, 357 F.3d 1, 8 (1st Cir. 2004))). On the other hand, "[e]xclusive dealing can have adverse economic consequences by allowing one supplier of goods or services unreasonably to deprive other suppliers of a market for their goods[.]" *ZF Meritor*, 696 F.3d at 270 (citations and internal quotation marks omitted). Also, "[e]xclusive dealing arrangements are of special concern when imposed by a monopolist." *Id.* at 271 (citing *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 187 (3d Cir. 2005) ("Behavior that otherwise might comply with antitrust law may be impermissibly exclusionary when practiced by a monopolist.")).

So, because exclusive dealing arrangements "may actually enhance competition, . . . they are not deemed per se illegal." *Perington Wholesale*, 631 F.2d at 1374 (citing *Tampa Elec.*, 365 U.S. at 333). Instead, courts apply the rule of reason to determine the legality of exclusive dealing arrangements. *ZF Meritor*, 696 F.3d at 271 (citing *Tampa Elec.*, 365 U.S. at 327); *see also McWane, Inc. v. FTC*, 783 F.3d 814, 835 (11th Cir. 2015) (explaining that the Eleventh

Circuit "has joined the consensus that exclusive dealing arrangements are reviewed under the rule of reason" (citation and internal quotation marks omitted)). Thus, to prevail, an exclusive dealing claim plaintiff must prove "it probable that performance of the contract will foreclose competition in a substantial share of the line of commerce affected." *Tampa Elec.*, 365 U.S. at 327;[58] *see also Perington Wholesale*, 631 F.2d at 1374 (explaining that a plaintiff bringing an antitrust claim based on an exclusive dealing contract "must allege and prove that a particular arrangement unreasonably restricts the opportunities of the seller's competitors to market their product").

Here, defendants assert, Mylan's rebate contracts—ones that conditioned rebates to PBMs on excluding Auvi-Q from coverage—don't violate the antitrust laws because they didn't foreclose competition substantially in the EAI market. To decide this question, the Supreme Court has instructed lower courts "[t]o determine substantiality in a given case" by "weigh[ing] the probable effect of the contract on the relevant area of effective competition, taking into account the relative strength of the parties, the proportionate volume of commerce involved in relation to the total volume of commerce in the relevant market area, and the probable immediate and future effects which pre-emption of that share of the market might have on effective competition therein." *Tampa Elec.*, 365 U.S. at 329.

[58] *Tampa Electric* decided a Clayton Act claim and concluded that the contract at issue didn't "tend to foreclose a substantial volume of competition." 365 U.S. at 335. After reaching that conclusion, the Court found it "need not discuss the respondents' further contention that the contract also violates § 1 and § 2 of the Sherman Act, for if it does not fall within the broader proscription of § 3 of the Clayton Act it follows that it is not forbidden by those of the former." *Id.* (citation omitted). Although *Tampa Electric* involved a Clayton Act claim, courts also apply its analysis to exclusive dealing claims asserted under the Sherman Act because each statute "include[s] an anticompetitive conduct element, although each statute articulates that element in a slightly different way." *ZF Meritor*, 696 F.3d at 269 n.9; *see also id.* at 327 n.26 (Greenberg, J., dissenting) ("In substance, the *Tampa Electric* standard for Clayton Act Section 3 claims differs very marginally, if at all, from the fact-intensive rule-of-reason analysis that applies to this case under Section 1 of the Sherman Act."); *Dos Santos v. Columbus-Cuneo-Cabrini Med. Ctr.*, 684 F.2d 1346, 1352 n.11 (7th Cir. 1982) (noting that *Tampa Electric* applies to Sherman Act cases even though it was decided under § 3 of the Clayton Act).

When considering whether the specific contract at issue in *Tampa Electric* tended to foreclose a substantial volume of competition, the Supreme Court considered several factors. *Id.* at 334–35. They included whether the market includes a seller with a dominant position, whether the market has "myriad outlets with substantial sales volume," the prevalence of exclusive contracts in the industry, the duration of the contract, and any pro-competitive justifications for the contract. *Id.* More recently, the Third Circuit recognized that "no set formula" exists "for evaluating the legality of an exclusive dealing agreement," but listed the factors courts consider when making this determination. *ZF Meritor*, 696 F.3d at 271–72. They include: (1) whether the defendant has "significant market power[;]" (2) whether there is substantial market foreclosure; (3) whether the contract's duration is "sufficient . . . to prevent meaningful competition by rivals[;]" (4) "an analysis of likely or actual anticompetitive effects considered in light of any procompetitive effects[;]" (5) whether defendant "engaged in coercive behavior[;]" (6) "the ability of customers to terminate the agreements[;]" and (7) the "use of exclusive dealing by competitors of the defendant[.]" *Id.* (citations omitted).

Other courts also have considered many of these same factors when called to decide if an exclusive dealing arrangement "substantially" forecloses competition and thus violates the antitrust laws. *See Methodist Health Servs. Corp. v. OSF Healthcare Sys.*, 859 F.3d 408, 410–11 (7th Cir. 2017) (affirming summary judgment against exclusive dealing claim based on exclusivity contracts between a hospital and insurers where contracts at issue were only two or three years' duration, plaintiff also had entered exclusive dealing arrangements with insurers, and there was no evidence that the contracts had "a significant exclusionary effect"); *McWane, Inc. v. FTC*, 783 F.3d 814, 837–42 (11th Cir. 2015) (affirming FTC's order prohibiting exclusive dealing contracts after concluding that the evidence supported the FTC's finding that the

contracts foreclosed competition, injured competition, and had no procompetitive justifications); *NicSand, Inc. v. 3M Co.*, 507 F.3d 442, 454 (6th Cir. 2007) (affirming dismissal of exclusive dealing claim where all but one competitor used the same exclusive contracts and the contracts didn't create a barrier to market entry).

Defendants assert that the summary judgment facts here present no triable issue whether Mylan's rebate contracts substantially foreclosed competition. Specifically, they argue that five of the factors articulated by *ZF Meritor*[59] establish—as a matter of law—that Mylan's rebate contracts with PBMs don't violate the antitrust laws. The court considers these five factors,[60] below, in the same order defendants present them in their papers.

i. Factor #5: Coercion

Defendants first argue that the summary judgment facts present no triable issue of coercion. As the Third Circuit has explained, "[e]xclusive dealing will generally only be unlawful where the market is highly concentrated, the defendant possesses significant market

[59] The Tenth Circuit hasn't articulated a set of factors that a court should consider when analyzing an exclusive dealing arrangement, like the Third Circuit provided in *ZF Meritor*. But, the *ZF Meritor* factors include the same factors that the Supreme Court's *Tampa Electric* opinion instructed courts to consider and that other Circuit courts have considered in their analysis of exclusive dealing contracts. The court predicts that the Tenth Circuit, if presented with this question, would apply the *ZF Meritor* factors to Mylan's rebate contracts to determine whether they substantially foreclose competition. Thus, the court applies those factors in its analysis here.

[60] The five factors addressed by defendants' motion are Factors #2, #3, #5, #6, and #7 from *ZF Meritor*. The parties never address the remaining factors (#1 and #4) or how the summary judgment facts support or preclude a finding that the Mylan rebate contracts are unlawful exclusive dealing arrangements under these remaining factors. Several times, plaintiffs call Mylan a "monopolist" but never in the context of *ZF Meritor*'s first factor—*i.e.*, whether the defendant has significant market power. But, even if the summary judgment facts establish that Mylan had significant market power, this factor "is not dispositive." *Eisai, Inc. v. Sanofi-Aventis U.S., LLC*, No. 08-4168 (MLC), 2014 WL 1343254, at *34 (D.N.J. Mar. 28, 2014) (concluding that Sanofi's "significant market power" which was "81% to 92% during the relevant period" was "not dispositive" of the question whether the contracts at issue were unlawful exclusive dealing arrangements). So, the court finds the two remaining factors neutral to its analysis whether a reasonable jury could find or infer an unlawful exclusive dealing arrangement under the summary judgment facts here.

power, *and there is some element of coercion present*." *ZF Meritor*, 696 F.3d at 284 (emphasis added). Defendants assert there is no coercion here because the summary judgment record lacks any evidence that Mylan threatened to cut off its supply of EpiPens if a PBM refused to agree to exclude competing EAIs. The court agrees that the facts here differ markedly from those presented in cases where courts have found evidence of unlawful exclusive dealing based on a defendant's coercive conduct.

In those cases, defendants threatened to stop supplying their products which, in turn, gave customers no choice but to agree to exclusivity provisions because, otherwise, they wouldn't have access to defendants' products. *See, e.g.*, *McWane*, 783 F.3d at 834 (finding that threat to cut off rebates and supply to buyers unless they purchased all pipe fittings was unreasonable because it was "unilaterally imposed by fiat upon all [buyers]" and "resulted in no competition to become the exclusive supplier and no discount, rebate, or other consideration offered in exchange for exclusivity" (citation and internal quotation marks omitted)); *ZF Meritor*, 696 F.3d at 285 (concluding "there was evidence [defendant] leveraged its position as a supplier of necessary products to coerce [buyers] into entering" exclusive contracts because "many of the terms of the [contracts] were unfavorable to the [buyers] and their customers, but [the buyers] agreed to such terms because without [defendant's products], the [buyers] would be unable to satisfy customer demand"); *Dentsply*, 399 F.3d at 190, 196 (finding that defendant's practice of "threaten[ing] to sever access not only to its [artificial teeth], but to other dental products as well" if a tooth supplier offered competing products "impose[d] an 'all-or-nothing' choice on" suppliers and evidence that suppliers "have chosen not to drop [defendant's] teeth in favor of a rival's brand demonstrates that they have acceded to heavy economic pressure").

That's not what happened here. As defendants correctly assert, the summary judgment record contains no evidence of any threats by Mylan to cut off payors' access to EpiPen if they refused to enter exclusive agreements.[61] Instead, the summary judgment facts show that PBMs and payors solicited rebate offers from both Mylan and Sanofi, giving them opportunity to compete through rebates or other discounts, and that some payors suggesting a willingness to exclude or place restrictions on one of the products. *See, e.g.*, Doc. 2159-3 at 3 (Defs.' Ex. 245) (discussing "CVS Caremark's plan to review the [EAI] class and choose an exclusive product"); Doc. 2159-13 at 5 (Defs.' Ex. 255) (explaining that OptumRx "intends to manage the products" in the EAI class "using a combination of tier placement and product exclusion"); Doc. 2159-9 at 2 (Defs.' Ex. 251) (asserting that Cigna was "looking for an offer for exclusive epinephrine positioning"). In response, Mylan often offered PBMs a menu of options from which a PBM's clients could choose and which offered higher rebates in exchange for more fulsome exclusive formulary positioning. *See e.g.*, Doc. 2152-1 at 4–5 (Defs.' Ex. 201); Doc. 2152-2 at 19–21 (Defs.' Ex. 202); Doc. 2152-5 at 4 (Defs.' Ex. 205). And, in the end, PBMs made different decisions about how they would cover EpiPen and Auvi-Q—some covered both EpiPen and Auvi-Q on the preferred brand tier; some covered EpiPen on the preferred tier, and Auvi-Q as non-preferred; some covered Auvi-Q on the preferred tier and EpiPen as non-preferred; some covered EpiPen and restricted Auvi-Q; and some restricted EpiPen in favor of Auvi-Q.

[61] As discussed, *supra* note 44, plaintiffs' citations to two Mylan documents won't support a finding or inference that Mylan ever threatened to cut off EpiPen supply. Instead, the documents showed that Mylan threatened to withdraw discounts if payors restricted or excluded EpiPen—but not if payors refused to exclude Auvi-Q. *See* Doc. 2192-17 at 2–3 (Pls.' Ex. 68) (listing as a "talking point" for a meeting with MedImpact that "Mylan will terminate its current contract if MedImpact implements a step edit *against EpiPen*" (emphasis added)); Doc. 2192-18 at 2 (Pls.' Ex. 69) (informing OptumRx that "[i]f for some reason, [OptumRx/UnitedHealthcare] decides *to exclude EpiPen* in 2014, we will not pay any enhanced rebates in 2013" but never mentioning that Mylan would cut off EpiPen supply (emphasis added)).

Plaintiffs respond that Mylan's increased rebates after Auvi-Q entered the market manifest coercion. Indeed, the summary judgment facts establish that, before 2013, Mylan typically offered rebates below 10 percent. *See* Doc. 2155-9 at 5 (Defs.' Ex. 224); *see also* Doc. 2197-7 at 3–4 (Pls.' Ex. 171) (Foster Dep. 212:17–213:8). But, as Auvi-Q prepared to launch, Mylan implemented a strategy offering PBMs larger rebates but conditioned them on agreements to restrict or exclude Auvi-Q from formulary coverage. Doc. 2197-17 at 4 (Pls.' Ex. 181) (Korczynski Dep. 254:3–10); Doc. 2197-19 at 2 (Pls.' Ex. 183); Doc. 2197-13 at 3 (Pls.' Ex. 177) (Willing Dep. 63:17–25); Doc. 2199-3 at 2–5 (Pls.' Ex. 209) (showing that by June 2015, Mylan's Pricing Committee had approved rebates in the range of 50% to 60% for the largest PBMs and up to 30% for specifically targeted managed care accounts conditioned on exclusive or preferred formulary coverage for EpiPen). As defendants correctly argue, the summary judgment facts establish that Auvi-Q's entry into the market gave PBMs leverage to seek higher rebate offers both from Mylan and Sanofi, and many times they solicited rebate offers conditioned on restrictions or exclusivity. And, when Sanofi responded by offering more aggressive rebates, it often succeeded in securing better formulary placement for Auvi-Q. *See* Doc. 2161-10 at 2 (Defs.' Ex. 283) (reversing exclusion with ESI); Doc. 2162-3 at 2 (Defs.' Ex. 291) (achieving co-preferred status on Aetna's value and premier formularies); Doc. 2162-5 at 2–28 (Defs.' Ex. 293) (improving coverage with CVS); Doc. 2162-6 at 2 (Defs.' Ex. 294) (same).

These undisputed facts suggest that the exclusive offers promoted competition in the EAI market—something the antitrust laws encourage. *See, e.g.*, *NicSand, Inc. v. 3M Co.*, 507 F.3d 442, 454 (6th Cir. 2007) (finding that the court couldn't "ignore the demands of the marketplace in which these [exclusive agreements] arose" because "[i]f *retailers* have made supplier

exclusivity a barrier to entry, one cannot bring an antitrust claim against a *supplier* for acquiescing to that requirement"); *Menasha Corp. v. News Am. Mktg. In-Store, Inc.*, 354 F.3d 661, 663 (7th Cir. 2004) ("That retailers and manufacturers *like* exclusive deals implies that they serve [their] interests" and "[w]hen the consumers favor a product or practice, and only rivals squawk, the most natural inference is that the complained-of practice promotes rather than undermines competition, for what helps consumers often harms other producers[.]"). Thus, plaintiffs present no triable issue of coercion based on Mylan's increasing rebates after Auvi-Q entered the market.[62]

To the contrary, defendants assert that it's not coercion to offer higher discounts in exchange for better formulary placement. To support this argument, they rely on *Eisai, Inc. v. Sanofi Aventis U.S, LLC*, 821 F.3d 394 (3d Cir. 2016). In *Eisai*, the distributor of anticoagulant drug Fragmin sued Sanofi—the seller of Lovenox, a competing anticoagulant drug. *Id.* at 399. During the relevant time frame, Lovenox held the largest share of the anticoagulant drug market with 81.5% to 92.3% market share. *Id.* Fragmin held the second largest market share with 4.3% to 8.2% of the market. *Id.* Plaintiff sued Sanofi for antitrust violations, arguing that its Lovenox contracts with hospitals were unlawful exclusive dealing arrangements. *Id.* at 399–400. Under Sanofi's contracts, hospitals "received price discounts based on the volume of Lovenox they purchased and their market-share calculation tied to their purchases of [other, competing]

[62] Plaintiffs also assert two arguments that PBMs had an incentive to agree to exclusivity restrictions in exchange for higher rebates. They base these arguments on (1) the collective effects that such agreements have on raising market-wide prices, thus producing greater profits for PBMs, and (2) the agreements' bundling of incontestable and contestable demand. Doc. 2190-1 at 98–99. But these arguments don't assert that *defendants* engaged in any coercive behavior by offering rebates conditioned on exclusivity. Instead, they simply assert incentives explaining why a PBM would agree to exclusivity in exchange for higher rebates. The court addresses plaintiffs' incontestable demand theory in greater detail when considering Factor #2 (substantial market foreclosure). But, these two arguments don't present a triable issue on the coercion factor.

anticoagulant drugs." *Id.* at 400. The contracts provided that if the hospital's purchases of Lovenox were below 75% of its total purchases of anticoagulant drugs, then the hospital received a flat 1% discount for its Lovenox purchases. *Id.* But, if the hospital's total purchases of Lovenox increased above the 75% market share threshold, the contract required Sanofi to pay increasingly higher rebates based on a combination of the total volume purchased and the market share. *Id.* These loyalty discounts ranged from 9% to 30% of Lovenox's wholesale price. *Id.* The Sanofi contracts did not obligate the hospitals to purchase any certain quantities of Lovenox. *Id.* They simply provided that a hospital only could receive the flat 1% discount if its total purchases didn't surpass the 75% market share threshold. *Id.* Also, the contract included formulary access clauses. *Id.* These clauses, the Third Circuit held, didn't prevent hospitals from offering other anticoagulant drugs on their formularies. *Id.* But they did prohibit them from favoring other anticoagulant drugs over Lovenox on their formularies. *Id.* And, the penalty for non-compliance was that the hospital's discount dropped to the 1% discount level. *Id.* *Eisai* concluded that Sanofi never limited the hospitals' access to Lovenox. *Id.*

Under these summary judgment facts, the Third Circuit concluded that plaintiff had failed "to demonstrate that hospitals were foreclosed from purchasing competing drugs as a result of Sanofi's conduct." *Id.* at 407. So, it affirmed the district court's decision granting summary judgment against plaintiff's antitrust claims. *Id.* at 399, 410. The Third Circuit noted that hospitals never risked penalties or supply shortages for terminating their rebate contracts or violating their terms. *Id.* at 406. Instead, not meeting the 75% market share threshold or not complying with the formulary access clause had just one consequence: the hospital received the base 1% discount instead of higher rebates. *Id.* The Third Circuit found that "the threat of a lost discount is a far cry from the anticompetitive conduct" that the Circuit had condemned in *ZF*

Meritor and *Dentsply*. *Id.* at 407. And so, plaintiff had failed to identify any summary judgment evidence of harm to competition similar to that at issue in those other Third Circuit cases. *Id.*

Similarly, the rebate contracts here imposed no penalties or supply shortages against a payor who chose to cover Auvi-Q. Instead, like *Eisai*, the only consequence for payors who rejected Mylan's exclusive offers was losing access to greater discounts. Plaintiffs try to distinguish *Eisai*, arguing its discounts differ from Mylan's rebate contracts because the contracts at issue in *Eisai* didn't use rebates to secure exclusivity. That doesn't matter. The result is the same whether rebates are paid based on a high market share discount or exclusivity—*i.e.*, the contracts reward buyers for excluding rivals by giving them the highest discounts. In both instances, however, customers remain "free to switch to a different product in the marketplace" and if they "choose not to do so" because, for example, they want access to a higher discount, then "competition has not been thwarted." *Id.* at 403; *see also Race Tires Am.*, 614 F.3d at 79 (finding that when tire suppliers offered exclusive contracts, "it is no more an act of coercion . . . than it is for such suppliers to offer the lowest tire prices").

The court thus holds that the summary judgment facts present no triable issue whether Mylan's exclusive rebate agreements coerced payors into accepting their terms. Like *Eisai*, Mylan motivated payors to agree to exclusivity by offering them higher discounts but they never "foreclosed [payors] from purchasing competing drugs . . . ." *Eisai*, 821 F.3d at 407.

ii. Factors #3 & #6: Contract Duration and Terminability

Defendants next assert that the summary judgment facts present no triable issue whether the duration and terminability of Mylan's rebate contracts foreclose competition. As courts and commentators have recognized, "short-term" exclusive dealing arrangements "present little threat to competition." *ZF Meritor*, 696 F.3d at 286; *see also Omega Env't, Inc. v. Gilbarco,*

Inc., 127 F.3d 1157, 1163 (9th Cir. 1997) (concluding "the short duration and easy terminability" of exclusivity agreements "negate[s] substantially their potential to foreclose competition"); XI Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 1807b1, at 138 (4th ed. 2018) ("Discounts conditioned on exclusivity in relatively short-term contracts are rarely problematic."). This is so because while "a dominant firm's ongoing policy of offering discounts in exchange for exclusivity gives buyers incentives to stay with the same firm[,] any above-cost discount can be matched by an equally efficient firm." XI Areeda & Hovenkamp, *Antitrust Law* ¶ 1807b1, at 138. And, "[e]ven an exclusive-dealing contract covering a dominant share of a relevant market need have no adverse consequences if the contract is let out for frequent rebidding." XI Areeda & Hovenkamp, *Antitrust Law* ¶ 1802g2, at 101.

Defendants assert that the summary judgment facts here establish that Mylan's rebate contracts were short-term and easily terminable. Thus, defendants argue, the rebate contracts never prevented payors from making formulary changes. The court agrees. The undisputed summary judgment facts show that many of Mylan's rebate agreements had terms of just two or three years. Doc. 2152-8 at 2, 9 (Defs.' Ex. 208) (two years); Doc. 2152-9 at 2 (Defs.' Ex. 209) (two years); Doc. 2152-10 at 2–3 (Defs.' Ex. 211) (two years); Doc. 2192-8 at 11 (Pls.' Ex. 57) (three years). And, PBMs typically renegotiated their rebate agreements at least annually. *See* Doc. 2150-16 at 6 (Defs.' Ex. 189) (Stein (Humana) Dep. 228:1–5); *see also* Doc. 2150-11 at 23–24 (Defs.' Ex. 184) (Kautzner (ESI) Dep. 185:24–186:22).

Also, most of Mylan's rebate agreements with payors allowed either party to terminate the agreement without cause on 90 days' notice or less. *See, e.g.*, Doc. 2152-8 at 9 (Defs.' Ex. 208); Doc. 2152-12 at 5 (Defs.' Ex. 213); Doc. 2155-1 at 3 (Defs.' Ex. 215). And, Mylan's rebate agreements generally reserve to PBMs the right to alter their commercial formularies at

any time. *See* Doc. 2155-2 at 4 (Defs.' Ex. 216); *see also* Doc. 2155-3 at 8 (Defs.' Ex. 217); Doc. 2155-4 at 8 (Defs.' Ex. 218); Doc. 2155-5 at 7 (Defs.' Ex. 219).

The summary judgment record also shows that payors actually invoked these terminability provisions, initiating rebate negotiations mid-contract. Doc. 2150-10 at 34–37 (Defs.' Ex. 183) (Anderson (CVS) Dep. 231:2–234:3) (describing how CVS asked Sanofi and Mylan for better rebate offers mid-contract term); Doc. 2152-11 at 3–4 (Defs.' Ex. 212) (Borneman Dep. 28:9–29:17) (testifying that Sanofi's rebate agreements typically "were annual contracts" and sometimes were renegotiated midterm). Indeed, it's undisputed that Sanofi renegotiated its 2013 and 2014 formulary coverage with payors, and in some cases, achieved better coverage for Auvi-Q when it made stronger rebate offers. As discussed above, Sanofi successfully reversed its exclusion from ESI's national formulary in 2015, achieved co-preferred status with Aetna on its value and premier formularies, and improved its coverage with CVS by securing co-preferred Tier 2 formulary coverage for Auvi-Q on CVS's Preferred Drug List and exclusive coverage on CVS's Value Based and Advanced Control Formularies. Doc. 2161-10 at 2 (Defs.' Ex. 283); Doc. 2162-3 at 2 (Defs.' Ex. 291); Doc. 2162-5 at 2–28 (Defs.' Ex. 293); Doc. 2162-6 at 2 (Defs.' Ex. 294).

Also, the undisputed facts show that Sanofi had the opportunity in 2014 to renegotiate with payors OptumRx/UnitedHealthcare and MedImpact for better coverage on their formularies for 2015. Doc. 2162-14 at 3 (Defs.' Ex. 302); Doc. 2163-2 at 3 (Defs.' Ex. 305). Both payors sought offers with increased discounts, but Sanofi, when it came to OptumRx/UnitedHealthcare, made an offer that was less competitive than Mylan's. Doc. 2162-15 at 5 (Defs.' Ex. 303); Doc. 2163-1 at 10 (Defs.' Ex. 304). And with MedImpact, Sanofi declined to make the offer MedImpact had requested. Doc. 2163-3 at 2 (Defs.' Ex. 306); Doc. 2163-4 at 2 (Defs.' Ex. 307).

Courts have found that exclusionary contracts of similar duration and terminability as the rebate agreements at issue here don't produce "a significant exclusionary effect." *Methodist Health Servs. Corp. v. OSF Healthcare Sys.*, 859 F.3d 408, 409–410 (7th Cir. 2017) (finding no exclusionary effects from contracts that expire "every year or two" thus "giving other [competitors], such as [plaintiff], a shot at obtaining the next contract by outbidding [defendant]"); *see also Omega Env't*, 127 F.3d at 1163–64 (concluding that the "the short duration [*i.e.*, one year terms] and easy terminability of these agreements [*i.e.*, 60 days' written notice] negate substantially their potential to foreclose competition" because "a competing manufacturer need only offer a better product or a better deal to acquire their services"); *Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227, 237–38 (1st Cir. 1983) (affirming summary judgment against Sherman Act § 2 claim for "exclusionary" practices and finding that preclusive agreements that "lasted about two years" were reasonable). In fact, some courts have found that short-term exclusivity agreements "may actually encourage, rather than discourage, competition, because the incumbent and other, competing [sellers] have a strong incentive continually to improve the care and prices they offer in order to secure the exclusive positions." *Balaklaw v. Lovell*, 14 F.3d 793, 799 (2d Cir. 1994).

Plaintiffs disagree, citing several cases for the proposition that even contracts of short duration and easy terminability can restrain competition. Doc. 2190-1 at 100–01. The cited cases differ, though, because their facts presented questions whether the practical effect of the contracts rendered the duration and terminability of the agreement meaningless. For example, in *ZF Meritor*, the court found that the exclusive agreements at issue presented a threat to competition because they lasted for five years, effectively "lock[ing] up over 85% of the market[,]" and the agreements' termination provisions were "essentially meaningless" because

defendant "had assured that there would be no other supplier that could fulfill the [buyers'] needs or offer a lower price." 696 F.3d at 287. Also, the record included evidence that "many of the terms of the [contracts] were unfavorable to the [buyers] and their customers, but that the [buyers] agreed to such terms because without [defendant's] transmissions, the [buyers] would be unable to satisfy customer demand." *Id.* at 285; *see also McWane, Inc. v. FTC*, 783 F.3d 814, 833–34 (11th Cir. 2015) (rejecting argument that short-term agreements were reasonable restraints on competition because the "practical effect" of exclusive dealing arrangement that required buyers to purchase all pipe fittings from defendant or lose rebates and access to defendants' supply "was to make it economically infeasible for distributors to . . . switch" to another competitor (citation and internal quotation marks omitted)); *United States v. Dentsply, Int'l, Inc.*, 399 F.3d 181, 193–94 (3d Cir. 2005) (finding that "in spite of the legal ease with which the relationship can be terminated, the [buyers] have a strong economic incentive to continue" purchasing defendant's product because "the economic elements involved—the large share of the market held by [defendant] and its conduct excluding competing manufacturers—realistically make the arrangements" unlawful exclusionary contracts); *Minn. Mining & Mfg. Co. v. Appleton Papers, Inc.*, 35 F. Supp. 2d 1138, 1144 (D. Minn. 1999) (holding that "genuine issues of fact [existed] whether [defendant's] agreements are actually terminable at will" because plaintiff had "produced evidence that [defendant's] sole-sourcing agreements often include incentives that have the practical effect of tying up [competition] over a period of several years").[63]

[63] Plaintiffs also cite several Supreme Court cases purportedly "condemn[ing] exclusionary agreements even if they are terminable." Doc. 2190-1 at 100–01. But those cases just mention the contract terms in passing without significant analysis whether the terminability provisions produced an exclusionary effect, and the cases turned, instead, on other facts that produced a foreclosure of competition. *See FTC v. Brown Shoe Co.*, 384 U.S. 316, 318–19 & n.2 (1966) (reciting a provision of the agreement that refused to grant certain benefits to shoe retailers who "are dropped or voluntarily

In contrast here, the summary judgment facts present no triable issue whether the practical effects of Mylan's rebate agreements—despite their short duration and termination provisions—threatened competition. Just the opposite, the summary judgment facts establish that payors frequently renegotiated rebate contracts with manufacturers, invoked their early termination provisions, and made changes to formulary coverage and rebate percentages. Also, this summary judgment record includes no facts from which a jury could infer that the practical effects of the rebate agreements made it so payors "were not free to walk away from the agreements and purchase products from the supplier of their choice." *ZF Meritor*, 696 F.3d at 287 (citing *Dentsply*, 399 F.3d at 194). Instead, the summary judgment record provides several examples where payors renegotiated formulary coverage with both Mylan and Sanofi in an effort to secure greater rebates for customers—*i.e.*, as ESI, Aetna, and CVS did with their 2015 formulary coverage decisions.

In sum, the court concludes that the duration and terminability of Mylan's rebate contracts at issue here present no triable issue whether these contract provisions produced significant exclusionary effects.

iii. Factor #7: Use of Exclusive Dealing Contracts by Competitors

Defendants argue that use of exclusive dealing contracts by competitors in the EAI industry precludes a jury from finding or inferring that Mylan's rebate contracts were unlawful exclusive dealing arrangements. Indeed, the undisputed facts overwhelmingly show that

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withdraw from the" program but, in another part of the opinion, discussing the facts that supported the finding "that the franchise program effectively foreclosed Brown's competitors from selling to a substantial number of retail shoe dealers"); *see also Standard Oil Co. v. United States*, 337 U.S. 293, 296, 314 (1949) (concluding that, although a requirements contract lasted only a year and was terminable with 30 days' notice, "the affected proportion of retail sales of petroleum products is substantial" and the contracts presented "a potential clog on competition" that "would impede a substantial amount of competitive activity").

Mylan's competitor in the EAI market—Sanofi—made offers conditioning higher rebates on a payor's agreement to restrict or exclude EpiPen. Doc. 2161-7 at 2 (Defs.' Ex. 280) (Sanofi's CEO suggesting that Sanofi make "an offer that kicks [Mylan] off a formulary"); Doc. 2161-12 at 3 (Defs.' Ex. 285) (showing Sanofi achieved exclusive coverage with ESI formulary); Doc. 2161-13 at 2 (Defs.' Ex. 286) (showing Sanofi offered Aetna a 65% rebate for exclusivity for 2015); Doc. 2162-4 at 19–20 (Defs.' Ex. 292) (showing that Sanofi offered CVS higher rebates conditioned on exclusive formulary placement).

Also, the summary judgment facts establish that use of exclusive dealing contracts is common in the pharmaceutical industry. *See* Doc. 2150-9 at 33–37 (Defs.' Ex. 182) (Navarro Expert Report ¶¶ 58–60) (explaining that PBMs use "Utilization Management" techniques—such as copayments and tiering, step edits, prior authorization, and benefit exclusion—to incentivize the use of one drug over another); Doc. 2150-16 at 3 (Defs.' Ex. 189) (Stein (Humana) Dep. 210:1–8); Doc. 2150-11 at 28 (Defs.' Ex. 184) (Kautzner (ESI) Dep. 197:7–18). And, PBMs use exclusive rebating practices as a way to negotiate lower prices from manufacturers by offering preferred formulary placement in exchange for greater rebates. Doc. 2150-16 at 3 (Defs.' Ex. 189) (Stein (Humana) Dep. 210:1–8); *see also* Doc. 2150-11 at 28 (Defs.' Ex. 184) (Kautzner (ESI) Dep. 197:7–18). Indeed, the summary judgment facts show some PBMs encouraged use of exclusive dealing contracts specifically by soliciting Mylan and Sanofi for exclusive offers. Doc. 2159-3 at 3 (Defs.' Ex. 245) (discussing "CVS Caremark's plan to review the [EAI] class and choose an exclusive product"); Doc. 2159-11 at 2 (Defs.' Ex. 253) (noting in CVS's bid solicitation letter to Mylan the availability of "exclusion opportunities"); Doc. 2159-13 at 5 (Defs.' Ex. 255) (explaining that OptumRx "intends to manage the products" in the EAI class "using a combination of tier placement and product

exclusion"); Doc. 2160-1 at 2 (Defs.' Ex. 257) (explaining MedImpact was "looking for a 1 of 1 offer for the" EAI class); Doc. 2159-9 at 2 (Defs.' Ex. 251) (asserting that Cigna was "looking for an offer for exclusive epinephrine positioning"). Based on these facts, defendants assert that Mylan's use of exclusive rebate contracts isn't "some anticompetitive scheme devised by Mylan; it is the way the entire pharmaceutical industry works." Doc. 2142-1 at 92.

Plaintiffs respond, arguing it's not proper to consider other drug markets, and instead, the court must confine its analysis to the EAI market. *Roxul USA, Inc. v. Armstrong World Indus., Inc.*, No. 17-1258, 2019 WL 1109868, at *11 (D. Del. Mar. 8, 2019) ("We are not similarly persuaded by the parties' reliance on guidance from other markets and involving other competitive strategies."). And, in the proper context of examining just the EAI market, plaintiffs contend, the undisputed facts show that Mylan didn't offer rebate contracts that conditioned higher rebates for EpiPen based on exclusivity until after Sanofi launched Auvi-Q. *Compare* Doc. 2155-9 at 5 (Defs.' Ex. 224) (showing that Mylan was offering up to 8% rebates in 2011), *with* Doc. 2199-3 at 2–5 (Pls.' Ex. 209) (showing that by June 2015, Mylan's Pricing Committee had approved rebates in the range of 50% to 60% for the largest PBMs and up to 30% for specifically targeted managed care accounts conditioned on exclusive or preferred formulary coverage for EpiPen). But, as defendants correctly argue, these facts actually demonstrate increased competition. As competitor Auvi-Q prepared to enter the market, Mylan recognized that it posed a threat to EpiPen; so, Mylan devised a contracting strategy that rewarded PBMs with higher rebates in exchange for their agreement to give EpiPen exclusive formulary placement over Auvi-Q.[64] *See* Doc. 2197-17 at 4 (Pls.' Ex. 181) (Korczynski Dep. 254:3–10); Doc. 2197-19 at 2 (Pls.' Ex. 183); Doc. 2197-13 at 3 (Pls.' Ex. 177) (Willing Dep. 63:17–25).

[64] Plaintiffs assert that Mylan's rebate contracts didn't actually represent price competition because it's undisputed that EpiPen prices rose during the relevant time period. And, plaintiffs contend,

In sum, the summary judgment facts present no question whether competitors in the industry used exclusive contracts. To the contrary, the summary judgment facts show that exclusive contracts are "a normal competitive tool within the [EAI drug] industry." *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1062 (8th Cir. 2000).

iv. Factor #2: Substantial Market Foreclosure

Last, defendants argue that Mylan's exclusive rebate contracts didn't foreclose substantial market share. As already explained, an exclusive contract doesn't violate the antitrust laws unless it is "probable that performance of the contract will foreclose competition in a substantial share of the line of commerce affected." *Tampa Elec.*, 365 U.S. at 327. This type of foreclosure occurs when "'the opportunities for other traders to enter into or remain in [the] market [are] significantly limited'" by the exclusive dealing arrangements. *United States v. Microsoft Corp.*, 253 F.3d 34, 69 (D.C. Cir. 2001) (quoting *Tampa Elec.*, 365 U.S. at 328).

"Traditionally a foreclosure percentage of at least 40% has been a threshold for liability in exclusive dealing cases." *McWane, Inc. v. FTC*, 783 F.3d 814, 837 (11th Cir. 2015); *see also* Jonathan M. Jacobson, *Exclusive Dealing, "Foreclosure," and Consumer Harm*, 70 Antitrust L.J. 311, 362 (2002) ("The recent decisions uniformly favor defendants where foreclosure levels are 40 percent or less, and so it is fair to say that foreclosure in excess of that amount is a threshold requirement where foreclosure is the asserted basis of the antitrust violation."). But

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Mylan's rebating practices caused the price increase because it was the price increases that, in turn, allowed Mylan to offer higher rebates to payors. But this argument ignores summary judgment evidence showing that rebate contract negotiations consisted of more than negotiations over rebate percentages. They also included negotiations over contract terms governing WAC prices and price protection. *See* Doc. 2159-6 at 2 (Defs.' Ex. 248) (reporting that OptumRx asked whether Mylan was "interested in a guaranteed exclusive position for EpiPen in exchange for the addition of 10% price protection"); *see also* Doc. 2159-7 at 3 (Defs.' Ex. 249) (warning to Mylan by OptumRx that "EpiPen is at risk" if it didn't offer price protection because the PBM was "well aware of the price increases Mylan [had] taken"); Doc. 2193-1 at 4 (Defs.' Ex. 82) (showing Sanofi's offer to ESI of a 60.625% rebate with 10% price protection for exclusivity).

"some courts have found that a lesser degree of foreclosure is required when the defendant is a monopolist." *McWane*, 783 F.3d at 837 (citing *Microsoft*, 253 F.3d at 70); *see also Microsoft*, 253 F.3d at 70 (stating in *dicta* that "a monopolist's use of exclusive contracts . . . may give rise to a § 2 violation even though the contracts foreclose less than the roughly 40% or 50% share usually required in order to establish a § 1 violation"); Jacobson, *supra*, 70 Antitrust L.J. at 311–12, 362–63 (recognizing that "[c]ourts have found liability in some cases even when the amount of 'foreclosure' is zero" and "if price, output, quality, choice, or innovation have been harmed, the lack of percentage foreclosure is no defense").

Defendants argue that the summary judgment facts fail to support any triable issue of foreclosure. Defendants cite summary judgment evidence showing that Auvi-Q never was excluded from certain PBMs' formularies, including CVS, Prime, and Cigna, who covered Auvi-Q on Tier 2 or Tier 3 without restriction. Doc. 2150-10 at 9–13 (Defs.' Ex. 183) (Anderson (CVS) Dep. 112:12–116:23); Doc. 2150-15 at 16–17, 23–24 (Defs.' Ex. 188) (Hall (Prime) 110:22–111:9, 129:24–130:7); Doc. 2150-17 at 18–22 (Defs.' Ex. 190) (Kronberg (Cigna) Dep. 79:3–83:8). Also, defendants assert, rebate agreements gave payors the ability to switch their formularies to cover any combination of EpiPen and Auvi-Q at any time. *See, e.g.*, Doc. 2155-2 at 4 (Defs.' Ex. 216) (Mylan/ESI rebate agreement) ("Nothing in this Agreement shall be construed to limit the ability of ESI or any ESI Client to remove a Product from formulary."). And, the terminability provisions allowed competing drug providers to renegotiate their formulary placement at any time. So, defendants argue, these facts show that the exclusionary rebate contracts produced no substantial foreclosure.

Plaintiffs respond, citing their expert's analysis showing the percentage of Auvi-Q foreclosure to consumers—both insured and uninsured. Doc. 2192-6 at 90 (Pls.' Ex. 55)

(Elhauge Reply Expert Report Fig. 104). Prof. Elhauge performed an analysis that shows, in 2013, about 80% of consumers had access to Auvi-Q. *Id.* In 2014, that number fell to around 65%, but it grew again in 2015, to about 69%, meaning that Auvi-Q was foreclosed from about 31% of consumers. *Id.* Plaintiffs argue that Prof. Elhauge's foreclosure percentages support a reasonable inference that Mylan's exclusive rebate contracts produced substantial market foreclosure. The court disagrees. These calculated foreclosure percentages alone don't suffice to create a triable issue of foreclosure when considered alongside the rest of the summary judgment evidence.

As discussed extensively above, the summary judgment facts show that Mylan's rebate contracts were short in duration and easily terminable. It's also undisputed that payors renegotiated contracts with Mylan, Sanofi, and other drug suppliers regularly, typically on an annual basis. As Professors Areeda and Hovenkamp explain,

> The relevant question [when evaluating foreclosure] is always what percentage of the market is effectively "unrestricted" during a specific time period. The unrestricted set includes (a) those dealers who are not bound by exclusive-dealing arrangements at all; plus (b) those dealers whose contracts will expire during that time period in any event; and (c) those dealers whose contracts have termination clauses permitting them to sever existing arrangements during that time period and who realistically can do so.

XI Areeda & Hovenkamp, *Antitrust Law* ¶ 1802g2, at 102.

Here, the summary judgment facts show that payors could invoke the contracts' termination provisions, and they actually renegotiated their rebate percentages often to secure better pricing from drug manufacturers in exchange for better formulary positions. And, the summary judgment facts establish that Sanofi did the same thing. Once Sanofi decided to pursue a more aggressive rebate strategy for 2015, it had success securing better formulary placement for Auvi-Q. This success tracks with Prof. Elhauge's analysis showing that Auvi-Q's

foreclosure percentage steadily decreased in 2015, as Auvi-Q achieved better formulary coverage in response to its more aggressive rebating offers. This trend also shows that Sanofi's more aggressive rebating strategy—one that, like Mylan's, offered higher rebates in exchange for exclusivity—increased competition in the market. And, increased competition is encouraged by the antitrust laws. Indeed, the summary judgment facts show that both Sanofi and Mylan offered higher rebates to payors conditioned on restrictions or exclusivity. And, when Mylan and Sanofi did so, they had success in achieving better formulary placement for their competing EAI products. From these facts, no reasonable factfinder could find or infer that Auvi-Q was foreclosed from a substantial share of the market.

Under similar facts, courts have refused to find a triable issue of substantial foreclosure. *See, e.g.*, *Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 997 (9th Cir. 2010) (affirming summary judgment against Sherman Act claims because evidence showed that "[a]ny customer subject to one of [defendant's] market-share discount agreements could choose at anytime to forego the discount offered by [defendant] and purchase from a generic competitor[,]" so the "agreements at issue here did not fore-close [defendant's] customers from competition because a competing manufacturer needed only offer a better product or a better deal to acquire their business" (citations, internal quotation marks, and internal brackets omitted)); *Eisai Inc. v. Sanofi-Aventis U.S., LLC*, No. 08-4168 (MLC), 2014 WL 1343254, at *34–35 (D.N.J. Mar. 28, 2014) (holding that Sanofi's market share discount contracts didn't foreclose competition in the market because the summary judgment evidence showed that the contracts "were terminable at any time by any party for any reason upon thirty days' written notice" and plaintiff's market share grew during the relevant time period, which

"indicate[d] that customers could walk away from the [Sanofi] discounts when they so desired, and they did").

Plaintiffs also assert that the EAI market's "concentrated channels of distribution and spillover effects" present a triable issue of substantial market foreclosure. Doc. 2190-1 at 96. It is undisputed that Mylan recognized the spillover effects that EpiPen's exclusionary contracts might produce. Doc. 2199-9 at 2 (Pls.' Ex. 215) (showing that Mylan trained its sales force to understand "the 'spill over' effect[,]" meaning that in territories where Mylan was preferred on a majority of plans, the sales force should "emphasize the preferred plans[.]"); *see also* Doc. 2197-7 at 5 (Pls.' Ex. 171) (Foster Dep. 278:1–9) (explaining that the "concept of spillover typically refers to when a doctor is used to writing [a] product" because the manufacturer has "strong formulary positions" and "then it tends to have a spillover effect, where the doctor just gets patterned into" prescribing the product).

Defendants respond to plaintiffs' "spillover" effects argument, asserting that plaintiffs provide no legal support for their theory that the court can consider "spillover" effects in the analysis whether substantial market foreclosure exists. And, defendants contend, evidence that some physicians preferred EpiPen doesn't permit plaintiffs to inflate their foreclosure percentages. That is especially true where, as here, plaintiffs never quantify the degree of this purported spillover into a market foreclosure percentage. And as the antitrust plaintiffs, they shoulder the burden of proof to marshal evidence supporting a genuine issue of foreclosure. Without any evidence showing the quantity of foreclosure attributable to any alleged "spillover" effect, the court can't find that a genuine issue about foreclosure exists on that basis.

In sum, the court holds that the summary judgment facts here present no triable issue whether Mylan's exclusive rebate contracts produced substantial market foreclosure.

v. Conclusion

After considering the *ZF Meritor* factors, the court finds that no reasonable jury could find or infer from the summary judgment facts that: (1) Mylan's exclusive rebate contracts coerced payors into accepting their terms; (2) the contracts' terms governing duration and terminability produced exclusionary effects; (3) competitors in the EAI industry didn't use exclusive rebate contracts, and instead, the use of exclusive rebate contracts was limited just to Mylan; or (4) the contracts produced substantial market foreclosure. Each of these factors favors a finding that the summary judgment facts present no triable issue that Mylan's rebate contracts foreclosed competitors from a substantial share of the market. Applying a rule of reason analysis, the summary judgment facts establish that Mylan's exclusive contracts were relatively short in duration and easily terminable, they were not the product of any unlawful coercion on Mylan's part, and they didn't foreclose Sanofi from competing in the EAI drug market. The court thus concludes under a rule of reason analysis that plaintiffs haven't shouldered their burden to present a triable issue whether Mylan's exclusive rebate contracts violated the Sherman Antitrust Act. So, the court grants summary judgment against plaintiffs' antitrust claims premised on their exclusive dealing theory.

b. Pricing Above Cost

Defendants assert a second argument supporting their summary judgment motion against plaintiffs' exclusive dealing claims. Defendants argue that the summary judgment facts establish that Mylan always offered prices for the EpiPen that were above cost. And, that practice, defendants say, means they didn't violate the antitrust laws because price discounts at above-costs prices are procompetitive.

The Supreme Court expressly has approved competition based on price, recognizing that "[l]ow prices benefit consumers regardless of how those prices are set, and so long as they are above predatory levels, they do not threaten competition[.]" *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 223 (1993) (citation and internal quotation marks omitted). The Supreme Court has noted "the exclusionary effect of prices above a relevant measure of cost . . . reflects the lower cost structure of the alleged predator, and so represents competition on the merits, or is beyond the practical ability of a judicial tribunal to control without courting intolerable risks of chilling legitimate price-cutting." *Id.* The Supreme Court thus has refused to "hold that the antitrust laws protect competitors from the loss of profits due to such price competition" because such a ruling "would, in effect, render illegal any decision by a firm to cut prices in order to increase market share." *Id.* (citation and internal quotation marks omitted). And, the "antitrust laws require no such perverse result." *Id.* (citation and internal quotation marks omitted).

Given this "economic reality," the Supreme Court has "established two prerequisites to recovery on claims of predatory pricing." *Weyerhaeuser Co. v. Ross-Simmons Hardwood Lumber Co., Inc.*, 549 U.S. 312, 318 (2007). "'First, a plaintiff seeking to establish competitive injury resulting from a rival's low prices must prove that the prices complained of are below an appropriate measure of its rival's costs.'" *Id.* (quoting *Brooke Grp.*, 509 U.S. at 222). And second, "a plaintiff must demonstrate that 'the competitor had . . . a dangerous probabilit[y] of recouping its investment in below-cost prices.'" *Id.* at 318–19 (quoting *Brooke Grp.*, 509 U.S. at 224). This two-prong test "is known as the price-cost test." *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 408 (3d Cir. 2016).

The Third Circuit addressed the question whether the price-cost test applies to an alleged anticompetitive rebate program in *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254 (3d Cir. 2012).[65] *ZF Meritor* recognized that "a plaintiff's characterization of its claim as an exclusive dealing claim does not take the price-cost test off the table." *Id.* at 275. Instead, the price-cost test still may apply because "contracts in which discounts are linked to purchase (volume or market share) targets are frequently challenged as *de facto* exclusive dealing arrangements on the grounds that the discounts induce customers to deal exclusively with the firm offering the rebates." *Id.* So, "when price is the clearly predominant mechanism of exclusion, the price-cost test tells us that, so long as the price is above-cost, the procompetitive justifications for, and the benefits of, lowering prices far outweigh any potential anticompetitive effects." *Id.*

But, *ZF Meritor* nonetheless refused to apply the price-cost test in that case because plaintiffs "did not rely solely on the exclusionary effect of [defendant's] prices" to support their exclusive dealing claim. *Id.* at 277. Instead, plaintiffs "highlighted a number of anticompetitive provisions" in the exclusive dealing agreements, including plaintiffs' allegation that defendant "used its position as a supplier of necessary products to persuade [customers] to enter into agreements imposing *de facto* purchase requirements of roughly 90% for at least five years, and that [defendant] worked in concert with [customers] to block customer access to Plaintiffs' products, thereby ensuring that Plaintiffs would be unable to build enough market share to pose any threat to [defendant's] monopoly." *Id.* The Third Circuit thus concluded that "price itself was not the clearly predominant mechanism of exclusion," and so, the price-cost test did not apply to preclude plaintiffs' exclusive dealing claim in that case. *Id.*

[65] The parties do not cite and the court's own research has not located any case where the Tenth Circuit has considered whether the price-cost test applies to an exclusive dealing claim based on a discount or rebate program. The court predicts, if presented with the question, the Tenth Circuit would find *ZF Meritor*'s reasoning persuasive and apply it to the facts presented here.

Applying *ZF Meritor*, other courts also have refused to apply the price-cost test to exclusive dealing claims when price itself was not the clearly predominant mechanism of exclusion. *See, e.g.*, *Dial Corp. v. News Corp.*, 165 F. Supp. 3d 25, 32 (S.D.N.Y. 2016) (denying summary judgment against plaintiffs' exclusive dealing claim and holding that the price-cost test did not apply because price was not the "clearly predominant method of exclusion" but, instead, "the length of the exclusive contracts and their staggered terms may also foreclose competition"); *UniStrip Techs., LLC v. LifeScan, Inc.*, 153 F. Supp. 3d 728, 737–38 (E.D. Pa. 2015) (holding that the price-cost test did not apply to plaintiff's exclusive dealing claim because plaintiff's Complaint never alleged that price was defendants' means of exclusion; instead, plaintiff based its exclusive dealing claim on defendants' allegedly anticompetitive predatory conduct through exclusive dealing arrangements preventing competitors from entering the market).

Here, defendants contend that the price-cost test applies because, unlike the facts at issue in *ZF Meritor*, this case's summary judgment facts establish that price was the clearly predominant mechanism of exclusion. And, defendants argue, the undisputed facts establish that Mylan priced EpiPen above cost. *See* Doc. 2163-5 at 9–10, 39–55 (Defs.' Ex. 308) (Willig Expert Report ¶¶ 14, 89–122) (concluding that "Mylan's prices, taking full account of rebates and price protection, were above an appropriate measure of its cost" in analysis of PBM contracts). Plaintiffs disagree. They assert that the price-cost test applies only when price is the predominant method of exclusion. But here, plaintiffs contend, their unlawful exclusive dealing claims are based on Mylan's rebating practices—not price—so their claims aren't subject to the price-cost test.

In the end, the court need not decide this issue. Confronted with a similar argument by a defendant seeking to apply the price-cost test to market share discount contracts it had offered customers, the Third Circuit declined to consider "when, if ever, the price-cost test applies to this type of claim." *Eisai*, 821 F.3d at 409. It instead considered whether the contracts at issue were unlawful exclusive dealing arrangements under a rule of reason analysis. *Id.* The Third Circuit "concluded that [plaintiff's] claims [were] not substantiated and that they fail[ed] a rule of reason analysis[.]" *Id.* As a consequence, the Third Circuit decided that it need not consider whether the price-cost test applied.[66] *Id.*

Likewise, here, the court already has analyzed plaintiffs' exclusive dealing claims under a rule of reason analysis. That analysis has led the court to conclude that the summary judgment facts present no triable issue whether Mylan's rebate contracts violate the Sherman Antitrust Act. So, the court need not decide whether the price-cost test applies to preclude plaintiffs' antitrust claims. The court thus declines to decide whether summary judgment is warranted for this second reason—*i.e.*, whether the price-cost test applies to plaintiffs' antitrust claims and whether plaintiffs' claims fail under that test because Mylan never priced the EpiPen below its costs.

3. Antitrust Damages

Defendants next argue, if the court doesn't grant summary judgment against plaintiffs' antitrust claims, it should limit plaintiffs' antitrust damages. They provide four reasons.

[66] At the district court level, however, the New Jersey federal court concluded "that price was the predominant mechanism of exclusion" of the market share discount contracts at issue, and "thus, the price-cost" test applied. *Eisai Inc. v. Sanofi-Aventis U.S., LLC*, No. 08-4168 (MLC), 2014 WL 1343254, at *30 (D.N.J. Mar. 28, 2014) (citations and internal quotation marks omitted). The court explained that under the price-cost test, "so long as the price is above-cost, the procompetitive justifications for, and the benefits of, lowering prices far outweigh any potential anticompetitive effects." *Id.* (citations and internal quotation marks omitted). Because it was undisputed that defendant Sanofi never sold its drug below its costs to produce the product, the New Jersey district court held that plaintiff couldn't "recover under the antitrust laws, and summary judgment must be granted in favor of Sanofi." *Id.* The New Jersey court also applied a rule of reason analysis to the plaintiff's exclusive dealing claims and concluded the "result would be the same." *Id.*; *see also id.* at *30–36.

First, defendants argue that certain state antitrust statutes have two or three year statutes of limitations that bar any of plaintiffs' claims premised on conduct falling outside the statute of limitations period. Plaintiffs first filed their state law antitrust claims on January 9, 2017. Amended Class Action Complaint, *Huston v. Mylan, N.V.*, No. 16-2796-JWL (D. Kan. Jan. 9, 2017), ECF No. 6. So, defendants argue, the court must preclude plaintiffs from recovering any damages incurred two years before that date—before January 9, 2015—under Alabama law. *See* Ala. Code § 6-2-38(l) (codifying two year statute of limitations for all "actions for any injury to the person or rights of another not arising in contract"). And, defendants argue, it must preclude plaintiffs from recovering any damages incurred three years before they filed their state law antitrust claims—before January 9, 2014—under Kansas, Mississippi, and Tennessee law.[67] *See Four B Corp. v. Daicel Chem. Indus., Ltd.*, 253 F. Supp. 2d 1147, 1156 (D. Kan. 2003) (applying Kan. Stat. Ann. § 60-512(2)'s three-year limitation period to Kansas Restraint of Trade Act claims); *see also* Miss. Code Ann. § 15-1-49 (providing three year statute of limitations for all "actions for which no other period of limitation is prescribed"); *State ex rel. Leech v. Levi Strauss & Co.*, No. 79-722-III, 1980 WL 4696, at *3 (Tenn. Ch. Sept. 25, 1980) (concluding private antitrust suit for injury or damage "sounds in tort" and "is subject to the three year statute of limitation in" Tenn. Code Ann. § 28-3-105).

Plaintiffs respond, invoking the doctrines of fraudulent concealment, equitable tolling, and the discovery rule. *See Aldrich v. McCulloch Props., Inc.*, 627 F.2d 1036, 1042 (10th Cir. 1980) (explaining that facts supporting a finding or inference of "affirmative conduct to conceal

[67] These statute of limitations arguments are mooted by the courts' other conclusions about antitrust damages. As discussed, plaintiffs don't assert any damages claim based on their generic delay theory before March 14, 2014—the date when (according to plaintiffs' theory) Teva would have launched its generic EAI "but for" the alleged unlawful reverse payment settlement. And, the court dismisses plaintiffs' Tennessee state law claims because there is no properly named plaintiff who asserts claims under that state's laws.

the fraud" invokes "the doctrine of equitable tolling"); *see also Allred v. Chynoweth*, 990 F.2d 527, 530 (10th Cir. 1993) (discussing Utah's application of "the discovery rule to toll the statute of limitations" and explaining that it "estop[s]" defendant "from relying on the statute of limitations as a defense to the action" when defendant "misleads the plaintiff or causes a delay in the bringing of a cause of action" (citation and internal quotation marks omitted)). Plaintiffs argue that these doctrines toll the limitations periods through August 2016—when Congress announced its investigation of EpiPen pricing and thus putting plaintiffs on notice of defendants' alleged unlawful activity.

Defendants disagree that these doctrines save plaintiffs' claims from the statutes of limitations bar. Defendants assert that these doctrines don't apply here because plaintiffs can't show they diligently pursued their causes of action. *See Crowe v. Servin*, 723 F. App'x 595, 597 (10th Cir. 2018) ("A litigant seeking equitable tolling must show (1) that [s]he has been pursuing [her] rights diligently, and (2) that some extraordinary circumstances stood in [her] way." (citation and internal quotation marks omitted)); *In re Urethane Antitrust Litig.*, 913 F. Supp. 2d 1145, 1158 (D. Kan. 2012) (explaining "doctrine of fraudulent concealment" requires showing "(1) the use of fraudulent means by the conspirators; (2) successful concealment from plaintiffs; and (3) that plaintiffs did not know or by the exercise of due diligence could not have known that they might have had a cause of action" (citation omitted)). For example, defendants assert that the April 2012 public announcement by Teva and Pfizer about the EpiPen patent litigation put plaintiffs on notice of their generic delay claims. And thus, they argue, the limitations clock began running in 2012.

Plaintiffs respond, arguing that the summary judgment facts present a triable issue whether they had the means to discover defendants' unlawful actions before 2016 and whether

defendants concealed their actions by entering a reverse payment settlement and issuing misleading press releases. The court agrees with plaintiffs. It can't decide this issue on summary judgment. Whether plaintiffs diligently pursued their claims, thus permitting them to avail themselves of the various tolling doctrines, is a factual issue that the jury must decide at trial. *See Aldrich*, 627 F.2d at 1042 ("The question of whether a plaintiff should have discovered the basis of his suit under the doctrine of equitable tolling does not lend itself to determination as a matter of law."); *In re Urethane Antitrust Litig.*, 913 F. Supp. 2d at 1163 (holding that the "evidence [was] sufficient at least to create a fact question on the issue of fraudulent concealment," so defendant was "not entitled to summary judgment on its statute-of-limitations defense"). Thus, the court declines to limit plaintiffs' antitrust damages on statute of limitations grounds.

Second, defendants argue that the court should limit plaintiffs' generic delay claims to the period between March 14, 2014 to June 22, 2015. The beginning date is the "but for" generic entry date that plaintiffs' expert calculates as the generic entry date produced by an economically rational "but for" settlement in the EpiPen litigation. Plaintiffs respond that defendants' argument is "moot" because plaintiffs' expert doesn't calculate any damages before the March 24, 2014 "but for" generic entry date. Doc. 2190-1 at 106. Because plaintiffs have conceded that they don't offer any evidence of generic delay damages before March 14, 2014, the court grants summary judgment against any claim for generic delay damages before that date.

The end date of the permissible damages period, according to defendants, is June 22, 2015—*i.e.*, the license date that the EpiPen settlement agreement granted Teva. Defendants argue that plaintiffs can't recover any damages after that date because the summary judgment evidence presents no triable issue whether defendants caused Teva's failure to launch by the

settlement's agreed-to generic entry date. The court already addressed this argument in considerable detail when it discussed the causation requirement for plaintiffs' antitrust claims. As the court held, the summary judgment facts, construed in plaintiffs' favor, present a jury question whether defendants caused Teva to delay its efforts to develop its product and whether the delay was a foreseeable consequence of defendants entering a settlement agreement in 2012 that required Teva to wait until 2015 to launch its generic product. So, the court won't grant summary judgment limiting the end date of plaintiffs' damages period to the EpiPen settlement's agreed-to generic entry date.

Third, defendants assert that plaintiffs cannot recover any damages under California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200–17210. Defendants correctly argue that "restitution is the only monetary remedy authorized" by that statute. *Clark v. Superior Ct.*, 235 P.3d 171, 176 (Cal. 2010). But, defendants contend, plaintiffs never assert any claim for restitution in the Pretrial Order. *See generally* Doc. 2169 (Pretrial Order). Instead, plaintiffs assert that they "seek damages (trebled where appropriate), attorneys' fees, and costs;" and they contend they "are entitled to seek statutory damages, treble damages, and attorneys' fees and costs under various state antitrust laws." *Id.* at 52 (Pretrial Order ¶ 5.a.) (citing California's Cartwright Act, Cal. Bus. & Prof. Code § 16750, but omitting reference to California's UCL, Cal. Bus. & Prof. Code § 17200).

Plaintiffs disagree, arguing that the Pretrial Order's assertion that plaintiffs are entitled to damages, generally, suffices to assert a restitution claim and put defendants on notice that plaintiffs are seeking restitution under California law for their claims based on alleged violations of California's UCL. They contend that restitution is a form of damages recoverable by class action plaintiffs. *See Pulaski & Middleman, LLC v. Google, Inc.*, 802 F.3d 979, 986 (9th Cir.

2015) (explaining that "restitution is available on a classwide basis once the class representative makes the threshold showing of liability under the UCL"). But, the case law is clear that restitution under the UCL does not include remedies at law (*i.e.*, actual damages); instead, it only provides for equitable remedies. *See Adir Int'l, LLC v. Starr Indem. & Liab. Co.*, 994 F.3d 1032, 1043 (9th Cir. 2021) ("Equitable remedies (injunctive relief, restitution, and civil penalties) are the only remedies available under" the UCL (citing Cal. Bus. & Prof. Code §§ 17200–17210)); *see also Woo v. Home Loan Grp., L.P.*, No. 07-CV-0202-H(POR), 2007 WL 6624925, at *4 (S.D. Cal. July 27, 2007) (explaining "§ 17200 is an equitable action, and restitution is an equitable remedy" (citing *Cortez v. Purolator Air Filtration Prods. Co.*, 999 P.2d 706, 715 (Cal. 2000)); *Cummings v. Connell*, No. CIVS992176WBS DAD, 1999 WL 1256772, at *5 n.4 (E.D. Cal. Dec. 20, 1999) ("Restitution is ordinarily a substitute for *rather than a form of damages*." (emphasis added)).

Here, the Pretrial Order asserts no claim for restitution or any other form of equitable relief. Instead, it "seek[s] damages (trebled where appropriate), attorneys' fees, and costs;" and it states explicitly that plaintiffs "do not seek any other forms of relief." Doc. 2169 at 52 (Pretrial Order ¶ 5.a.).

Our Circuit has instructed that "a pretrial order should be liberally construed to cover any of the legal or factual theories that might be embraced by [its] language." *Koch v. Koch Indus., Inc.*, 203 F.3d 1202, 1220 (10th Cir. 2000) (citation and internal quotation marks omitted). But, "a district court may more strictly construe a pretrial order when that order has been refined over time, properly drawn, and drafted with substantial specificity." *Id.* (citations omitted). Here, the parties previously asserted that they engaged in "diligent efforts" to prepare the Pretrial Order, "meeting and conferring and exchanging drafts" of it in the days leading up to the court's

deadline for submitting it. Doc. 2072 at 1. The parties asked the court for a four-day extension of time to submit their proposed Pretrial Order, which Judge James granted. *See id.*; *see also* Doc. 2073. The parties then submitted an 80-page proposed Pretrial Order to the court. It contained signature blocks for five lawyers from five different law firms who represent plaintiffs. Then, at the Final Pretrial Conference, six lawyers appeared on plaintiffs' behalf. Doc. 2169 at 1. After that conference, the court filed the 64-page operative Pretrial Order (Doc. 2169) that contains no claim by plaintiffs for restitution under California's UCL, Cal. Bus. & Prof. Code § 17200. Because plaintiffs didn't include a restitution claim in the Pretrial Order—one that was "refined over time, properly drawn, and drafted with substantial specificity"—the court grants summary judgment against any restitution claim under the UCL. *Koch*, 203 F.3d at 1220, 1222 (finding that the district court "did not abuse its discretion when it construed a properly drawn, refined, and specific pretrial order as excluding any accounting claims" not specified in the Pretrial Order); *see also Sunderman v. Westar Energy, Inc.*, 520 F. Supp. 2d 1269, 1278 (D. Kan. 2007) ("The pretrial order is the controlling document for trial. . . . Claims not included in the pretrial order are waived."); *Lewis v. Glickman*, No. 98-4154-SAC, 2000 WL 1863407, at *1 (D. Kan. Nov. 1, 2000) ("The decision to exclude facts or issues as not found in the pretrial order is committed to the trial court's sound discretion." (citation omitted)).

Fourth, defendants argue that plaintiffs' claims asserted under Tennessee law fail for lack of subject matter jurisdiction. The only named plaintiff asserting state antitrust law violations under Tennessee law is April Sumner. Doc. 60 at 21 (Consolidated Class Action Compl. ¶ 54). But, defendants contend, Ms. Sumner is not a named plaintiff in any underlying case transferred to become part of this MDL. And thus, her participation in this case is "an end run around the proper procedural framework that governs MDL proceedings[.]" *In re FCA US LLC Monostable*

Elec. Gearshift Litig., No. 16-md-02744, 2017 WL 6402992, at *4 (E.D. Mich. Mar. 21, 2017), *reconsideration denied*, No. 16-md-02744, 2017 WL 6402991 (E.D. Mich. Mar. 23, 2017). As the Michigan federal court explained, an MDL proceeding isn't "an environment that can spawn fresh actions by new plaintiffs" because that "is at odds with" the framework established by 28 U.S.C. § 1407. *Id.* at *3. In particular, "newly-named plaintiffs who have never filed any lawsuit anywhere, in any court," don't have a case in any "transferor court from which [the transferee court] could inherit its authority over their claims." *Id.* (citation and internal quotation marks omitted). So, defendants argue, the court must dismiss Ms. Sumner's claims for lack of subject matter jurisdiction. *See In re Mortg. Elec. Registration Sys. (MERS) Litig.*, No. MD-09-02119-PHX-JAT, 2016 WL 3931820, at *7 (D. Ariz. July 21, 2016) (holding that the court "must dismiss [newly-added MDL plaintiff's] claims for lack of subject-matter jurisdiction" because they "were not transferred to this court through proper MDL procedures but, rather, were simply added by fiat[,]" and thus, the claims "have no home federal court to which this Court may eventually remand them" (citations and internal quotations omitted)); *In re Packaged Ice Antitrust Litig.*, No. 08-MDL-1952, 2011 WL 6178891, at *9 (E.D. Mich. Dec. 12, 2011) (dismissing newly named plaintiffs to consolidated amended complaint in an MDL proceeding because the amendment "ignored basic Article III principles and . . . bypassed the appropriate MDL process for consolidation of these plaintiffs' claims"); *In re Farmers Ins. Exch. Claims Representatives' Overtime Pay Litig.*, MDL No. 33-1439, 2008 WL 4763029, at *5 (D. Or. Oct. 28, 2008) (dismissing four state law claims because there is "no authority for this court, as an MDL transferee court, to exercise subject matter jurisdiction over state law claims not transferred by the MDL Panel").

Plaintiffs disagree. They argue that defendants waived this argument by conceding subject matter and personal jurisdiction in the Pretrial Order. Doc. 2169 at 2 (Pretrial Order ¶¶ 1.a. & 1.b.). But, "subject-matter jurisdiction, because it involves a court's power to hear a case, can never be forfeited or waived." *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 514 (2006) (citation and internal quotation marks omitted). Instead, the Federal Rules require that the court "must dismiss the action" if it "determines at any time that it lacks subject-matter jurisdiction[.]" Fed. R. Civ. P. 12(h)(3).

Plaintiffs also assert that they have a right to file their RICO claims directly in this court and assert state law antitrust claims as supplemental claims. The court disagrees. The cases plaintiffs cite to support this argument don't address the court's subject matter jurisdiction in an MDL proceeding, but instead address questions about personal jurisdiction. *See Cory v. Aztec Steel Bldg., Inc.*, 468 F.3d 1226, 1231 (10th Cir. 2006) (holding that 18 U.S.C. § 1965 establishes nationwide service of process for RICO claims); *see also United States v. Botefuhr*, 309 F.3d 1263, 1272 (10th Cir. 2002) (discussing the concept of "pendent personal jurisdiction" which "exists when a court possesses personal jurisdiction over a defendant for one claim" but "lacks an independent basis for personal jurisdiction over the defendant for another claim that arises out of the same nucleus of operative fact"). And, as Judge Vance has observed, "[s]upplemental jurisdiction presupposes the existence of a case, already properly before the court, to which the 'other claims' may be attached." *Dorsey v. Mfrs. Life Ins. Co.*, No. Civ. A. 97-2389, 1997 WL 703354, at *3 (E.D. La. Nov. 10, 1997) "In other words, supplemental jurisdiction does not create original jurisdiction, it merely sweeps 'other claims' under the federal court's jurisdictional rug." *Id.* Here, Ms. Sumner's claims don't properly "arise out of supplemental jurisdiction" because she "never filed a suit of [her] own nor had any suit

pending[,]" thus the court can't "consolidate [her] suit with the multidistrict litigation" and "this transferee court 'does not have subject matter jurisdiction to adjudicate an action that is lacking in original federal jurisdiction.'" *In re Mortg. Elec. Registration Sys. (MERS) Litig.*, 2016 WL 3931820, at *8 (quoting *Dorsey*, 1997 WL 703354, at *3).

Because April Sumner is not a named plaintiff in any underlying case transferred to this MDL, the court dismisses Ms. Sumner's claims because the court lacks subject matter jurisdiction over them. For the same reasons, it dismisses the claims asserted by Donna Anne Dvorak, Michael Gill, and Landon Ipson.[68] And, because it dismisses Ms. Sumner's claims and no other plaintiff asserts claims for antitrust violations under Tennessee law, the court dismisses the Tennessee antitrust law claims without prejudice. *See* Doc. 1292 at 3 (dismissing plaintiffs' claims asserted under the West Virginia law because the Class Complaint no longer included any named plaintiff who resides in West Virginia).

4. Conclusion

For reasons explained, the court grants summary judgment against plaintiffs' antitrust claims and denies it in part. The court grants summary judgment against plaintiffs' claims premised on unlawful exclusive dealing. And, the court denies summary judgment against plaintiffs' claims premised on a generic delay claim.

Also, the court grants in part summary judgment against some of plaintiffs' damages claims. Specifically, the court grants summary judgment against: (1) any antitrust damages premised on a generic delay theory occurring before March 14, 2014; (2) any restitution claim under California's Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200–17210; (3) plaintiffs' Tennessee antitrust law claims; and (4) any claims asserted by plaintiffs April Sumner,

[68] The dismissal of these other plaintiffs doesn't require the court to dismiss any pending claims. Other properly named plaintiffs assert the same claims that these plaintiffs have asserted.

Donna Anne Dvorak, Michael Gill, and Landon Ipson. The court denies defendants' arguments seeking summary judgment against plaintiffs' antitrust damages claims in all other respects.

Now, the court turns to consider defendants' arguments against plaintiffs' RICO claims.

B. RICO Claims

Plaintiffs assert RICO claims under 18 U.S.C. § 1962(c) & (d). Doc. 2169 at 42, 44–45 (Pretrial Order ¶¶ 4.a., 4.d.). Subsection 1962(c) of RICO makes it:

> unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt.

18 U.S.C. § 1962(c). Subsection 1962(d) makes it "unlawful for any person to conspire to violate" subsection 1962(c). *Id.* § 1962(d). RICO provides a private civil cause of action for those who are injured by violations of § 1962 and allows recovery of treble damages, costs, and attorney's fees. *Id.* § 1964(c).

To prove a violation of § 1962(c), a plaintiff must establish four elements: "(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." *CGC Holding Co., LLC v. Hutchens*, 974 F.3d 1201, 1210 (10th Cir. 2020). As our Circuit recently has explained:

> The word racketeering tends to evoke images of mobsters and organized criminals, and true enough, RICO—at least initially—"was an aggressive initiative to supplement old remedies and develop new methods for fighting crime." But the plain language of RICO defines racketeering far more broadly in a way that allows the statute to "reach both legitimate and illegitimate" businesses. Indeed, among many other qualifying acts, RICO defines a racketeering activity as "any act which is indictable under" the federal statute outlawing wire fraud—a crime that any modern business could commit.

Id. at 1210–11 (first quoting *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 498 (1985); then quoting *Sedima*, 473 U.S. at 499; then quoting 18 U.S.C. § 1961(1)(B)). Also, the Supreme Court has instructed that "RICO is to be read broadly." *Sedima*, 473 U.S. at 497.

"But proving a RICO violation requires more than racketeering activity alone." *CGC Holding Co.*, 974 F.3d at 1211. To prevail on a RICO claim, a plaintiff must establish: "(1) that the defendant violated § 1962; (2) that the plaintiff's business or property was injured; and (3) that the defendant's violation is the cause of that injury." *Safe Sts. All. v. Hickenlooper*, 859 F.3d 865, 881 (10th Cir. 2017) (citations omitted).

Here, plaintiffs allege that defendants "joined together in an association-in-fact enterprise and used the interstate mails and wires in furtherance of" their scheme to raise EpiPen prices. Doc. 2169 at 9–10 (Pretrial Order ¶ 3.a.1.). Plaintiffs assert that defendants' scheme included: (1) withdrawing the EpiPen single pack from the EAI market and requiring customers to purchase EpiPens exclusively in the 2-Pak based on a false medical rationale; (2) stifling generic competition through pay-for-delay settlements; and (3) foreclosing branded competition from Auvi-Q by entering exclusive rebate contracts with payors. *Id.* at 9.

Plaintiffs allege that defendants made certain fraudulent statements or omissions through the mail and wires to further their pricing scheme including: (1) issuing a fraudulent press release on August 24, 2011, that announced Mylan no longer would sell individual EpiPens in the United States in an effort to align with medical guidelines; (2) issuing a press release in April 2012, announcing the settlement of the EpiPen patent litigation with Teva; and (3) using telephone calls and email to effectuate their exclusive rebate contracts. *Id.* at 13, 16, 18.

Defendants argue that plaintiffs' RICO claims fall short of presenting any genuine issues for trial for several reasons. They argue the court thus should grant summary judgment because the summary judgment facts present no triable issue whether: (1) defendants participated in the conduct of a RICO enterprise; (2) defendants committed any predicate acts sufficient to support a RICO claim; (3) any alleged predicate act caused plaintiffs any harm; (4) defendants conspired to

violate RICO; (5) the statute of limitations bars plaintiffs' RICO claims; and (6) Heather Bresch—individually—is liable for violating RICO.

For reasons explained below, the court concludes that the summary judgment record presents no triable issue whether any of defendants' alleged predicate acts caused plaintiffs to sustain injury. So, plaintiffs' RICO claims fail the causation element. And, the court grants summary judgment against the RICO claims for this reason. The court explains how it reaches this conclusion, below.

1. Causation

Defendants assert that no genuine dispute exists whether any of the alleged RICO predicate acts caused plaintiffs any harm. Thus, defendants argue, plaintiffs cannot show they sustained injury "by reason of a violation of section 1962[,]" as 18 U.S.C. § 1964(c) requires for a plaintiff to prevail on a RICO claim.

The Supreme Court has held that the RICO statute's "'by reason of'" requirement demands that a RICO plaintiff show "the defendant's violation not only was a 'but for' cause of his injury, but was the proximate cause as well." *Holmes v. Sec. Inv. Prot. Corp.*, 503 U.S. 258, 265, 268 (1992) (quoting 18 U.S.C. § 1964(c)); *see also Hemi Grp., LLC v. City of N.Y.C.*, 559 U.S. 1, 9 (2010) (explaining a RICO claim requires plaintiff "to show that a RICO predicate offense 'not only was a "but for" cause of his injury, but was the proximate cause as well'" (quoting *Holmes*, 503 U.S. at 268)). "Sufficiently establishing the element of causation—both actual and proximate—is crucial to proving any violation of RICO." *CGC Holding Co., LLC v. Broad & Cassel*, 773 F.3d 1076, 1088 (10th Cir. 2014) (citing *Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639, 656–60 (2008)).

Defendants assert that plaintiffs can't present a triable issue about either "but for" causation or proximate causation. The court agrees with defendants on "but for" causation. As explained, no reasonable trier of fact could find or infer from the summary judgment facts that, "but for" defendants' alleged misstatements and omissions made in any of the underlying predicate acts, plaintiffs wouldn't have sustained any harm. The court explains why, below.

a. "But For" Causation

Defendants assert two separate and independent arguments supporting summary judgment against plaintiffs' RICO claims for failing to present summary judgment facts supporting a triable issue of "but for" causation. The court addresses the two distinct arguments, separately, below.

i. Plaintiffs' Alleged Harm is the Same Without the Alleged Predicate Acts

Defendants' first argument on the "but for" causation requirement asserts that plaintiffs can't present a triable issue of causation because the summary judgment record shows plaintiffs would have sustained the same harm if defendants never committed any of the alleged RICO predicate acts. For support, they cite the Fourth Circuit's opinion in *Walters v. McMahen*, 684 F.3d 435 (4th Cir. 2012).

This case involved RICO claims asserted by a group of hourly-wage employees who alleged their employers' corporate managers and others had conspired to hire aliens not authorized to work in the United States so that the company could reduce labor costs. *Id.* at 437. When discussing the RICO causation requirement, the Fourth Circuit explained that the "compensable injury resulting from a violation of 18 U.S.C. § 1962(c) necessarily is the harm *caused by the predicate acts*[.]" *Id.* at 444 (emphasis added) (citing *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 457 (2006)). The *Walters* plaintiffs had alleged that defendants committed

RICO predicate acts through "the fraudulent use of identification documents and the false attestations placed on the I-9 forms[.]" *Id.* But, the Fourth Circuit found, it wasn't these alleged RICO violations "that has caused the harm suffered by the plaintiffs" because "such actions [did] not directly impact the plaintiffs' wage levels." *Id.* And, the court explained, the lack of causation "becomes obvious by removing the false attestation acts[.]" *Id.* That is, if the employer "engaged in the hiring of unauthorized aliens without the hiring clerks' fraudulent completion of the I-9 forms, such as by paying the unauthorized employees in cash and not reporting their employment to the United States government, the alleged injury suffered by the plaintiffs *would be the same*[.]" *Id.* (emphasis added). Thus, the Fourth Circuit held, plaintiffs' RICO claims failed as a matter of law because there was "no direct relationship between the injury asserted and the predicate act alleged." *Id.* (citing *Hemi Grp.*, 559 U.S. at 9–10).

Defendants argue the same reasoning applies here. They contend that plaintiffs would have sustained the same harm—*i.e.*, paying higher prices for EpiPen—even if defendants never made the alleged false and misleading statements or omissions in the underlying RICO predicate acts. Thus, defendants argue, the alleged RICO predicate acts can't supply the requisite "but for" cause of plaintiffs' purported injuries. Plaintiffs disagree for two reasons.

First, they assert that RICO doesn't require them to prove that the *predicate acts* caused their injuries. Instead, plaintiffs argue, they only need to present a genuine issue whether defendants' fraudulent EpiPen *pricing scheme* caused their injuries. But plaintiffs' argument isn't faithful to binding precedent. Instead, the Supreme Court has made it clear that "civil RICO" requires a plaintiff "to show that *a RICO predicate offense* not only was a 'but for' cause of his injury, but was the proximate cause as well." *Hemi Grp.*, 559 U.S. at 9 (emphasis added

and citation and internal quotation marks omitted);[69] *Bridge*, 553 U.S. at 658–59 (recognizing if the Cook County, Illinois Treasurer's Office "had not accepted petitioners' false attestations of compliance with the [County's] Single, Simultaneous Bidder Rule," prohibiting simultaneous bidding at public tax lien actions—*i.e.*, the alleged RICO predicate acts—"and as a result had not permitted petitioners to participate in the auction, respondents' injury would never have materialized"); *Anza*, 547 U.S. at 457 ("The Court has indicated the compensable injury flowing from a violation of that [RICO] provision 'necessarily is the harm *caused by predicate acts* sufficiently related to constitute a pattern, *for the essence of the violation is the commission of those acts* in connection with the conduct of an enterprise.'" (emphasis added) (quoting *Sedima*, 473 U.S. at 497); *Holmes*, 503 U.S. at 268 (explaining plaintiff must show "the defendant's [RICO] *violation* not only was a 'but for' cause of his injury, but was the proximate cause as well" (emphasis added)).

Plaintiffs urge the court to ignore these requirements for establishing "but for" causation. Instead, they contend, on summary judgment the court only "considers evidence of the entire 'fraudulent scheme'—not merely the use of the mails or wires, which don't have to be fraudulent and only have to further the scheme in some way." Doc. 2190-1 at 122. But, to support this argument, plaintiffs rely on cases discussing either RICO's predicate act requirement or the proximate cause requirement—not the "but for" causation requirement. *See Sorensen v. Polukoff*, 784 F. App'x 572, 578 (10th Cir. 2019) (explaining that a RICO plaintiff, to allege a plausible predicate act, "need not allege that the mailings or the wire communications themselves

[69] Plaintiffs correctly assert that this language comes from *Hemi Group*'s plurality opinion. But, as the First Circuit has recognized, *Hemi Group* "produced a 4-1-3 decision with no majority on the *proximate cause question*." *In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 21, 38 n.12 (1st Cir. 2013) (emphasis added). The *Hemi Group* plurality opinion's recitation of the "but for" causation standard is consistent with other governing Supreme Court precedent.

were fraudulent[,]" instead, "he needs only allege that they were 'incident to an essential part' of a fraudulent scheme" (quoting *Bridge*, 553 U.S. at 639)); *Safe Sts. All. v. Hickenlooper*, 859 F.3d 865, 890–91 (10th Cir. 2017) (discussing RICO proximate cause requirement and finding no "intermediary breaks the causal chain . . . between the enterprise's" actions and plaintiffs' "injury" because defendants' "criminal cultivation of marijuana"—the RICO predicate act—caused all "alleged injuries"); *Wallace v. Midwest Fin. & Mortg. Servs., Inc.*, 714 F.3d 414, 419–20 (6th Cir. 2013) ("A plaintiff need only show use of the mail in furtherance of a scheme to defraud and an injury *proximately caused* by that scheme. Thus, the appropriate inquiry in this case is not whether [plaintiff] actually relied on the allegedly inflated appraisal, but whether the fraudulent scheme furthered by that appraisal *proximately caused* his financial injuries." (emphasis added)); *In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 21, 37 (1st Cir. 2013) (rejecting defendants' argument that "its supposed misrepresentations went to prescribing doctors, and so the causal link to [plaintiff] must have been broken" because plaintiff satisfied "the proximate cause requirement" by coming forward with evidence that its "injury was a foreseeable and natural consequence of" defendants' actions (citation and internal quotation marks omitted)).[70]

[70] Plaintiffs also cite the court's Order granting in part the class certification motion, asserting that the court held "the plaintiff need not be the victim of the predicate acts" to prevail on a RICO claim. Doc. 2190-1 at 122 n.634. And, elsewhere, plaintiffs' Response asserts that the court's Order ruling the class certification motion explained "how Plaintiffs had demonstrated RICO causation on each of the three schemes to defraud" and made "a number of legal rulings that apply to the legal issues at summary judgment." Doc. 2190-1 at 120. The court disagrees with plaintiffs' application of the certification Order. As the court noted in that Order, the court was required to "'accept the substantive allegations of the complaint as true'" when determining "whether plaintiffs have met their burden of affirmatively demonstrating compliance with Rule 23's requirements[.]" Doc. 2018-1 at 5 n.2 (quoting *Shook v. El Paso Cnty.*, 386 F.3d 963, 968 (10th Cir. 2004)). And, the court's Order never considered the merits of the "but for" causation requirement necessary to support plaintiffs' RICO claims. *See generally id.* But now, because the case has arrived at the summary judgment stop of its progress to trial, the court can't just accept plaintiffs' allegations as true. Instead, plaintiffs bear a summary judgment burden to come forward with admissible proof of a genuine factual question whether plaintiffs would have sustained any injury "but for" defendants' alleged RICO predicate acts. Plaintiffs haven't made that showing.

Here, the alleged RICO predicate offenses are use of the mail and wires to further defendants' EpiPen pricing scheme and corrupting an official proceeding in a pattern of racketeering activity. Doc. 2169 at 42 (Pretrial Order ¶ 4.a.). Under the governing legal standard, plaintiffs must identify a genuine issue for trial whether defendants' use of the mail and wires to further the EpiPen pricing scheme or their corruption of an official proceeding was the "but for" cause of plaintiffs' injuries—*i.e.*, paying inflated prices for EpiPen. They haven't discharged this burden.

Second, plaintiffs assert, even under defendants' standard for proving "but for" RICO causation, the summary judgment facts here present a triable issue whether, "but for" defendants' false representations and omissions, plaintiffs would have sustained harm. They contend the alleged RICO predicate acts were "integral" to defendants' pricing scheme. But, they don't come forward with admissible evidence presenting a triable issue of that assertion. Instead, as the following paragraphs explain, plaintiffs have adduced no evidence capable of supporting a finding that defendants' use of the mail and wires or their alleged corruption of an official proceeding was the "but for" cause of plaintiffs' alleged injuries.

For plaintiffs' first RICO theory—the 2-Pak switch—the alleged predicate acts are defendants' use of the mail and wires to disseminate misleading information about the reasons for the withdrawal of single EpiPens and the switch to selling the EpiPen exclusively in a 2-Pak. Specifically, plaintiffs allege that defendants provided a false rationale for the decision—*i.e.*, citing the medical guidance—when the true reason for the switch was to increase EpiPen profits. But, plaintiffs premise none of their alleged damages on any of defendants' *alleged statements* about the 2-Pak switch. Instead, Prof. Rosenthal calculates plaintiffs' damages based on the increase in the number of EpiPens purchased by consumers. Doc. 2164-4 at 31–32 (Defs.' Ex.

325) (Rosenthal Expert Report ¶ 72) (calculating damages "due to the withdrawal of the single-pen packaging" and not alleged misstatements about the 2-Pak switch). Defendants argue plaintiffs would have sustained these same damages if defendants never had issued any statements about the switch to the 2-Pak—*i.e.*, after the 2-Pak switch, class members still would have purchased the same number of pens because the elimination of the single pack—not defendants' statements—caused the alleged harm.

Plaintiffs respond, arguing that the 2-Pak press release—and the false medical rationale it allegedly provided—was essential to the EpiPen pricing scheme because it provided a "smokescreen" and avoided market "backlash" from the decision to remove single EpiPens from the market. Doc. 2190-1 at 122. Plaintiffs cite various Mylan documents to support this theory, but none of them can support a reasonable finding or inference that, "but for" Mylan's public statements about the 2-Pak, defendants would not have succeeded in implementing the EpiPen pricing scheme that produced plaintiffs' injuries. For instance, plaintiffs cite a statement from an internal Mylan document dated before Mylan's switch to the 2-Pak that referenced a desire to keep EpiPen revenue "'below the radar' for most managed care organizations[,]" but if "managed care organizations do raise concerns" about the 2-Pak switch, Mylan had reserved "1.5% of all revenue . . . as rebates[.]" Doc. 2143-25 at 16 (Defs.' Ex. 58). Also, plaintiffs cite an email sent several weeks after the 2-Pak switch stating that Mylan had implemented the 2-Pak switch without "ANY issues" and received "no backlash" from payors. Doc. 2196-2 at 2 (Pls.' Ex. 144). Neither of these statements connects Mylan's public statements about the 2-Pak switch to Mylan's purported success avoiding scrutiny or objection to the 2-Pak switch. This conclusion is bolstered by the fact—discussed more fully below—that plaintiffs haven't come forward with any evidence showing that *anyone* relied on defendants' alleged misstatements or

omissions about the reasons for the 2-Pak switch and the medical justification that defendants used to support that decision. As defendants correctly argue, none of this evidence can support a reasonable finding or inference that the 2-Pak public statements were "integral" to defendants' pricing scheme. Thus, the undisputed summary judgment facts lead the court to conclude that no reasonable jury could find or infer that plaintiffs wouldn't have sustained their alleged injuries "but for" the public statements made about the reason for the 2-Pak switch.

For plaintiffs' second RICO theory—generic delay—defendants assert a similar argument. They correctly explain that plaintiffs don't seek any damages caused by any purported public misstatements about patent litigation settlements. Instead, Prof. Rosenthal calculates plaintiffs' damages based on the "but for" date that a generic competitor would have entered the market absent the pay-for-delay settlement. Doc. 2164-4 at 27–31 (Defs.' Ex. 325) (Rosenthal Expert Report ¶¶ 61–71). Defendants assert that plaintiffs would have sustained the same purported damages with or without defendants' press release announcing the EpiPen patent litigation settlement.[71] Thus, they contend, the alleged mail and wire fraud can't supply the requisite "but for" causation to support plaintiffs' RICO claims.

Again, plaintiffs disagree. And yet again, they argue the false press release about the EpiPen settlement was "integral" to defendants' fraudulent pricing scheme because it provided the "essential cover for their scheme to stifle competition[.]" Doc. 2190-1 at 123. So, plaintiffs reason, a jury could infer that the press release was necessary to the scheme because Mylan and Pfizer devoted time and resources to crafting and disseminating it over the wires. This characterization stretches the summary judgment facts far too far. The summary judgment record simply doesn't include any facts from which a jury could find or infer that the press

[71] Also, defendants note that no court ever has found a reverse payment settlement allegation sufficient to support a RICO claim.

release provided necessary "cover" for defendants to proceed with their scheme to delay generic competition. This conclusion is supported by the fact—as later discussed—that the summary judgment record is devoid of evidence showing that anyone relied on the press release announcing the EpiPen patent settlement. In short, plaintiffs' "cover" argument is no more than an ipse dixit assertion by counsel that finds no foundation or footing in the facts. The summary judgment facts can't support a reasonable finding or inference that, "but for" the press release announcing the EpiPen patent settlement, plaintiffs wouldn't have sustained the damages incurred because of defendants' purportedly unlawful reverse payment settlement.

Defendants argue that plaintiffs' third RICO theory—the Auvi-Q foreclosure theory—fails for a more basic reason. They contend that plaintiffs have no RICO damages model tied to any alleged brand foreclosure, much less any damages model calculating any damages from defendants' statements about Mylan's rebating practices or other branded competition. *See* Doc. 2164-4 at 3 (Defs.' Ex. 325) (Rosenthal Expert Report ¶ 1) (explaining that Prof. Rosenthal offers a RICO damages model for generic delay and 2-Pak damages but not Auvi-Q foreclosure); *see also* Doc. 2146-4 at 4 (Defs.' Ex. 137) (Elhauge Dep. 38:12–14) (testifying that Prof. Elhauge didn't "evaluate RICO damages"). Plaintiffs respond that Prof. Elhauge's analysis shows a cause-and-effect relationship between Mylan's use of exclusive rebate contracts and plaintiffs' injuries in the form of paying higher EpiPen prices. But, this argument ignores Prof. Elhauge's explicit testimony. He testified that he's not opining about RICO damages. Thus, plaintiffs haven't come forward with any evidence showing that defendants' alleged statements about Mylan's rebating practices caused plaintiffs to sustain RICO damages.[72]

[72] This theory also fails for other reasons the court already has addressed. Simply, the summary judgment facts don't present any triable issues whether Mylan's rebating practices unlawfully restrained competition. Thus, any alleged misrepresentations about Mylan's rebating practices didn't cause plaintiffs to sustain any damages.

In sum, the court holds the summary judgment facts present no triable issue whether defendants' alleged predicate RICO acts were the "but for" cause of plaintiffs' injuries. The court thus grants summary judgment against plaintiffs' RICO claims because plaintiffs haven't presented a triable issue of "but for" causation.

ii. No Triable Issue of Reliance

The court also grants summary judgment against plaintiffs' RICO claims for a second and independent reason. Defendants argue that the summary judgment record fails to support a finding or inference of reliance sufficient to satisfy the RICO causation element. As explained, below, the court agrees with them.

a. No Triable Issue Whether Anyone Relied on the Alleged Predicate Acts

Defendants assert that the summary judgment record is devoid of evidence showing that anyone relied on defendants' alleged misrepresentations in or omissions from the RICO predicate acts. The Supreme Court has explained that a RICO plaintiff need not establish "first-party reliance" to satisfy the causation requirement. *Bridge*, 553 U.S. at 657–58. Nevertheless, "a RICO plaintiff who alleges injury 'by reason of' a pattern of mail fraud" likely can't "prevail without showing that *someone* relied on the defendant's misrepresentations." *Id.* at 658. The Supreme Court has observed that in "most cases, the plaintiff will not be able to establish even but-for causation if no one relied on the misrepresentation." *Id.*; *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharms. Co. Ltd.*, 943 F.3d 1243, 1259 (9th Cir. 2019) (explaining that RICO plaintiffs must prove, at a minimum, indirect reliance "because, logically, a plaintiff cannot even establish but-for causation if *no one* relied on the defendant's alleged misrepresentation").

Plaintiffs respond, arguing that *In re Neutrontin* and *In re Celexa & Lexapro* foreclose defendants' arguments about reliance. They assert both cases permit them to proceed on their RICO claims with evidence supporting an inference of reliance.

The faith plaintiffs attach to these two cases is misplaced. In both cases, plaintiffs came forward with evidence of first-party reliance by *someone*—even if it wasn't plaintiffs who had relied directly on the alleged misrepresentations. *See In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 21, 40–41 (1st Cir. 2013) (holding plaintiff presented "ample evidence" of reliance where summary judgment facts showed plaintiff "received [defendant's] misrepresentations through [defendant's] contacts" with plaintiffs' Drug Information Service ("DIS") "which disseminated information throughout [plaintiff's] organization" and that plaintiffs' "physicians received and acted upon [defendant's] misrepresentations, both through information sent through the DIS and information provided to them at [defendant's] events"); *see also id.* at 31 (noting evidence that plaintiff's "physicians attended conferences where Neurontin was promoted for off-label uses, and after one such conference, in May 1999, new starts of Neurontin increased by 62%"); *see also In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 915 F.3d 1, 13 (1st Cir. 2019) (concluding that plaintiff presented sufficient evidence of RICO causation to survive summary judgment where defendant's off-label marketing to physicians caused, according to plaintiff's experts, "76% and 54% of all pediatric prescriptions of Celexa and Lexapro, respectively" and defendant's "sales representatives called or visited at least two physicians who subsequently ordered pediatric prescriptions of Celexa and Lexapro").

Here, in contrast, plaintiffs present no evidence that anyone—not plaintiffs, not physicians, not third-payor payors, nor anyone else in the supply chain—relied on defendants' alleged misstatements or omissions about the 2-Pak switch, the EpiPen patent litigation

settlement, or Mylan's use of exclusive rebate contracts. Indeed, none of the named plaintiffs testified that he or she had read the August 2011 press release announcing the 2-Pak switch before becoming involved in this litigation. *See* Doc. 2142-1 at 34 & n.110 (Defs.' Mem.) (citing deposition testimony of 34 of the named plaintiffs). And, no named plaintiff testified that he or she had relied on any statements by defendants when purchasing EpiPen devices. *Id.* Thus, the undisputed summary judgment facts here differ materially from those in *In re Neutrontin* and *In re Celexa & Lexapro*. They present no triable issue whether anyone relied on defendants' alleged misstatements or omissions sufficient to support the "but for" causation element of their RICO claims.

b. No Inference of Reliance

Plaintiffs assert that they still can prevail on proving RICO causation by showing an inference of causation with statistical aggregate data from their expert, Prof. Rosenthal. Defendants respond that no court ever has found that an inference of reliance suffices to prove, on the merits, that a defendants' alleged misrepresentations were the "but for" cause of classwide RICO injury. The court also has found no authority supporting plaintiffs' argument that an inference of reliance based on statistical evidence—alone—can prove at the merits stage the "but for" causation element of a RICO claim. Defendants thus assert that the law requires plaintiffs to show that someone in the causal chain relied on the statements asserted in the predicate acts. And, here, plaintiffs have adduced no evidence of any such reliance. So, the court can grant summary judgment for this reason as well.

But, even if plaintiffs could shoulder their burden to prove RICO causation in the form of an inference of reliance, the summary judgment facts here can't support such an inference. As defendants correctly explain, an inference of reliance "does not shift the burden of proof at trial

on the element of RICO causation (or any other elements of the claim)—plaintiffs will still have to *prove* RICO causation by a preponderance of the evidence to win on the merits." *CGC Holding Co., LLC v. Broad & Cassel*, 773 F.3d 1076, 1093 (10th Cir. 2014). Here, defendants assert the summary judgment facts rebut any inference of reliance. Thus, they argue, plaintiffs' RICO claims can't survive summary judgment.

For plaintiffs' 2-Pak theory, defendants assert that Prof. Rosenthal has determined that 62%–68% of patients were not "forced" to buy 2-Paks. Doc. 2166-17 at 15–16 (Defs.' Ex. 96) (Rosenthal Dep. 197:12–198:2). And, they cite the deposition testimony of the named plaintiffs where many testified that they had purchased 2-Paks or multiple single-packs before 2011. Doc. 2144-16 at 2–8 (Defs.' Ex. 102 (citing Defs.' Ex. 102-A)). Also, at least 11 named plaintiffs purchased multiple devices in a single transaction while the single-pack was available. *Id.* And, several named plaintiffs testified that they prefer to have more than one EpiPen device at any given time. *Id.* Defendants assert that this evidence forecloses a reasonable jury from inferring reliance.

Plaintiffs respond, arguing that the court should consider Prof. Rosenthal's analysis of the percentage of consumers injured by defendants' actions when *combining* injury caused by the 2-Pak switch *or* generic delay. Also, plaintiffs argue, the court credited Prof. Rosenthal's analysis at class certification and it should do the same here again. But, plaintiffs' argument misapprehends the difference separating certification proceedings from substantive decisions on the merits. They mistakenly equate the court's consideration of Prof. Rosenthal's opinion on class certification with the court's consideration of her opinion in light of the summary judgment record. The summary judgment facts establish that Prof. Rosenthal opines that 62%–68% of patients were not "forced" to buy 2-Paks. From this evidence and the deposition testimony of

named plaintiffs, no reasonable jury could infer reliance on defendants' alleged misrepresentations about the switch to the 2-Pak.

For plaintiffs' generic delay theory, defendants argue that the summary judgment record can't support an inference of reliance when there is no evidence that plaintiffs sustained any injury from a press release about the EpiPen settlement with Teva. Also, they cite the named plaintiffs' deposition testimony where some plaintiffs testified they continued to purchase EpiPens after filing this lawsuit. Doc. 2144-16 at 11–13 (Defs.' Ex. 102) (citing Defs.' Ex. 102-A). And, some named plaintiffs testified that they purchased EpiPen products even though a generic or other alternative was available for purchase. *Id.* Plaintiffs argue that this individual testimony presents a fact issue that the jury must weigh against common evidence of RICO causation, and the court can't grant summary judgment on this basis. The court disagrees.

The only common evidence of RICO causation for the generic delay theory that plaintiffs identify is Prof. Rosenthal's opinion that consumers sustained a "loss of choice." Prof. Rosenthal opines that each class member sustained classwide injury from defendants' alleged misconduct. Doc. 2191-18 at 52 (Pls.' Ex. 47) (Rosenthal Oct. 31, 2019 Expert Report ¶ 118). And, as part of this opinion, Prof. Rosenthal opines that each allegation 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.* But, she never quantifies how many class members sustained a "loss of choice." Indeed, those class members who chose to purchase branded EpiPen products over a generic sustained no loss of choice. And, plaintiffs concede that Prof. Rosenthal's "loss of choice" opinion is not a measure of damages. Doc. 2183-1 at 20. Thus, no reasonable jury could infer reliance on defendants' statements about the EpiPen patent settlement based simply on Prof. Rosenthal's abstract "loss of choice" opinion.

Instead, viewing the summary judgment facts as a whole and in the light most favorable to plaintiffs, a reasonable jury can't infer reliance where the summary judgment record presents no evidence that any class member sustained damage from the press release about the EpiPen settlement. This is especially true because some class representatives testified that they continued to purchase EpiPens even though a generic product was available.

On the Auvi-Q foreclosure theory, defendants again argue that plaintiffs offer no expert damages analysis of their RICO damages for this foreclosure theory. And thus, they haven't come forward with any evidence supporting an inference of reliance under this RICO theory. For the same reasons discussed in the subsection above, the court finds that plaintiffs have failed to present a triable issue whether they sustained RICO damages based on the alleged Auvi-Q foreclosure theory. The summary judgment record thus lacks evidence permitting an inference of reliance to support plaintiffs' RICO claims under the Auvi-Q foreclosure theory.

In sum, the court concludes that the case law doesn't permit plaintiffs' RICO claims to survive summary judgment simply by coming forward with evidence supporting an inference of reliance when the record is devoid of any evidence showing that at least someone in the causal chain relied on the alleged misrepresentation. But, even if an inference of reliance presented a triable issue of RICO "but for" causation, plaintiffs haven't come forward with summary judgment evidence from which a reasonable fact finder could infer reliance. So, the court grants summary judgment against plaintiffs' RICO claims for this second and independent reason: plaintiffs have failed to present a triable issue of reliance as required to support a finding of RICO "but for" causation.

2. RICO Conspiracy Claim

Defendants argue that plaintiffs' RICO conspiracy theory claim fails as a matter of law because their substantive RICO claim under § 1962(c) fails on summary judgment. They are correct. As our Circuit has explained, "[b]y its terms, § 1962(d) requires that a plaintiff must first allege an independent violation of subsections (a), (b), or (c), in order to plead a conspiracy claim under subsection (d)." *Tal v. Hogan*, 453 F.3d 1244, 1270 (10th Cir. 2006) (citation omitted). And, if "a plaintiff has no viable claim under § 1962(a), (b), or (c), then its subsection (d) conspiracy claim fails as a matter of law." *Id.* (citations omitted). As the court already has concluded, summary judgment is warranted against plaintiffs' § 1962(c) claim. And, because the court has concluded plaintiffs have no viable § 1962(c) RICO claim, plaintiffs' § 1962(d) RICO conspiracy claim also fails as a matter of law. The court thus grants summary judgment against plaintiffs' RICO conspiracy claim.

3. Conclusion

For reasons explained, the court grants summary judgment against plaintiffs' RICO claims.

IV. Conclusion

For the above reasons, the court grants the Mylan defendants' motion for summary judgment in part and denies it in part. The court grants summary judgment against:

- plaintiffs' antitrust claims based on the theory that Mylan's exclusive rebate contracts are unlawful exclusive dealing arrangements because the summary judgment facts present no triable issue whether the contracts foreclose a substantial share of competition to violate the antitrust laws;

- any antitrust damages premised on a generic delay theory occurring before March 14, 2014 because plaintiffs have failed to adduce any summary judgment evidence supporting a triable issue of damages before that date;
- any restitution claim under California's Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200–17210, because plaintiffs have not asserted a restitution claim in the Pretrial Order;
- plaintiffs' Tennessee antitrust law claims because the court lacks subject matter jurisdiction over them, and thus must dismiss them without prejudice;
- any claims asserted by plaintiffs April Sumner, Donna Anne Dvorak, Michael Gill, and Landon Ipson because these plaintiffs are not named plaintiffs in any underlying case transferred to this MDL; and
- plaintiffs' RICO claims.

The court denies the Mylan defendants' summary judgment motion in all other respects.

IT IS THEREFORE ORDERED BY THE COURT THAT the Mylan defendants' Motion for Summary Judgment (Doc. 2141) is granted in part and denied in part.

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