IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

IN RE: EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litigation	**MDL No: 2785**
	Case No. 17-md-2785-DDC-TJJ
(This Document Applies to the *Sanofi* Case)	

MEMORANDUM AND ORDER

Plaintiff Sanofi-Aventis U.S. LLC ("Sanofi") filed a lawsuit against defendants Mylan, Inc. and Mylan Specialty, L.P. (collectively "Mylan") in the District of New Jersey on April 24, 2017. Complaint, *Sanofi-Aventis U.S. LLC v. Mylan Inc., et al.*, Case No. 3:17-cv-02763-FLW-TJB (D.N.J. Apr. 24, 2017), ECF 1 ("the *Sanofi* case"). Sanofi is a pharmaceutical company who alleges that Mylan, distributor of the EpiPen, engaged in a variety of anticompetitive conduct designed to prevent Auvi-Q—a rival product once sold by Sanofi—from gaining access to the epinephrine autoinjector market, and aimed to prevent consumers from acquiring Auvi-Q. Sanofi asserts three claims against Mylan under Section 2 of the Sherman Antitrust Act: (1) monopolization through exclusive dealing; (2) deceptive conduct to further monopolization; and (3) an overall scheme to monopolize. Sanofi brings this action only for itself, and not on behalf of any other plaintiffs or putative class members.

In August 2017, the Judicial Panel on Multidistrict Litigation ("JPML") created MDL 2785, *In re: EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litigation* (the "MDL"). *See* Doc. 1 (JMPL Transfer Order). The JMPL assigned the MDL to

our court, and it transferred several actions filed in other Judicial Districts, including the *Sanofi* case, to our court for "coordinated or consolidated pretrial proceedings." *Id.* at 4.

But for the *Sanofi* case, all the other cases pending in the MDL are brought by individual consumers or third-party payors who allege they purchased EpiPens for use by themselves, their families, or their members, employees, insureds, participants, or beneficiaries. These consumer plaintiffs asserted that defendants—sellers and manufacturers of the EpiPen—violated federal and state antitrust laws, the federal RICO Act, and various state consumer protection laws.[1] And, these consumer plaintiffs successfully sought certification of two classes asserting state antitrust law violations and RICO claims. *See* Doc. 2018-1 at 126–27 (certifying two classes and providing class definitions for those two classes).

Because the *Sanofi* case differs from the MDL's other cases, the court previously concluded that the consumer class cases and the *Sanofi* case warranted separate litigation tracks. Doc. 42 at 3. Thus, the court established two distinct tracks in this MDL—*i.e.*, one for the consumer class cases and one for the *Sanofi* case. *Id.* at 3, 5.

After the *Sanofi* case's transfer to this court, Mylan filed an "Answer, Affirmative Defenses, and Counterclaims." Doc. 112. Mylan Specialty, L.P. ("Mylan Specialty")—as counterclaim plaintiff—asserts two claims against Sanofi, as counterclaim defendant: (1) commercial disparagement and false advertising violating the Lanham Act, 15 U.S.C. § 1125(a), and (2) common law unfair competition. *Id.* at 49, 52.[2]

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[1] These consumer plaintiffs since have abandoned their federal antitrust and state consumer protection law claims. Doc. 2169 at 43 (Pretrial Order ¶ 4.c.).

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

This matter now comes before the court on the parties' cross motions for summary judgment in the *Sanofi* case. Mylan has filed a Motion for Summary Judgment (Doc. 1673 (publicly-filed redaction version), Doc. 1660-1 (version filed under seal)), with a Memorandum in Support (Doc. 1673-1 (publicly-filed redaction version), Doc. 1660-2 (version filed under seal)), seeking summary judgment against all three of Sanofi's Sherman Antitrust Act claims. Sanofi has filed a Memorandum of Law in Opposition to that motion (Doc. 1814 (publicly-filed redacted version), Doc. 1820-1 (version filed under seal)), and Mylan has submitted a Reply (Doc. 1883 (publicly-filed redacted version), Doc. 1882-1 (version filed under seal)).[3]

Sanofi's Motion for Summary Judgment (Doc. 1691), and Memorandum in Support (Doc. 1692 (publicly-filed redaction version), Doc. 1686-1 (version filed under seal)), seeks summary judgment in its favor on one element of its Sherman Antitrust Act claims and against Mylan Specialty's Counterclaim. Specifically, Sanofi asks the court to enter judgment as a matter of law that: (1) the relevant market consists of epinephrine auto-injector devices in the United States, and (2) Mylan possessed and exercised monopoly power in that market. *Id.* at 2. And, Sanofi asks the court to enter summary judgment against Mylan Specialty's Counterclaim asserting (1) violations of the Lanham Act, and (2) unfair competition. *Id.* Mylan has filed a Memorandum of Points and Authorities in Opposition to Sanofi's Motion for Summary Judgment (Doc. 1813 (publicly-filed redacted version), Doc. 1805-1 (version filed under seal)). And Sanofi has submitted a Reply (Doc. 1871 publicly-filed redacted version), Doc. 1872-1 (version filed under seal)).

[3] Sanofi also has submitted four separate filings as supplemental authority for the pending summary judgment motions. Docs. 1951, 1998, 2005, 2235. Mylan has responded to each filing. Docs. 1954, 2000, 2006, 2237. The court also considers these submissions when deciding the parties' summary judgment motions.

The court has considered the parties' thorough and well-presented arguments. And, the court now is prepared to decide their cross motions for summary judgment.

I. Undisputed Facts

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

The Use of EAI Drug Devices to Treat Anaphylaxis

Anaphylaxis is a life-threatening allergic reaction caused by exposure to allergens such as foods, insect stings, pets, latex, or medications. Doc. 1821-2 at 4–5 (Michelis Expert Report ¶¶ 9–10). Between roughly 2% and 5% of the U.S. population is at risk for anaphylaxis. *Id.* at 6 (Michelis Expert Report ¶ 12). Epinephrine is the first-line treatment for anaphylaxis. *Id.* at 9 (Michelis Expert Report ¶ 19); *see also* Doc. 1815-6 at 19 (Blaiss Expert Report ¶ 5.4). Other products, such as antihistamines, are not proper substitutes for epinephrine when treating anaphylaxis. *Id.* (explaining that "treatment with antihistamines does not relieve or prevent all of the pathophysiological symptoms of anaphylaxis, including the more serious complications such as airway obstruction, hypotension, and shock").

An epinephrine auto-injector ("EAI" or "EAI device") is a medical device used to inject a fixed dose of epinephrine through a spring-activated needle. *Id.* at 10–11 (Blaiss Expert Report ¶ 5.1). Physicians prescribe EAI devices to patients at risk for anaphylaxis. *Id.*; *see also* Doc. 1821-2 at 9 (Michelis Expert Report ¶ 19). Over the last 20 years, food-related allergies have increased, increasing the need for access to EAI devices. Doc. 1815-6 at 8 (Blaiss Expert Report ¶ 4.0). Patients or their caregivers should carry an EAI device at all times to provide rapid treatment should an anaphylactic episode occur. Doc. 1821-2 at 7, 9 (Michelis Expert Report ¶¶

13, 19). But, failing to carry an EAI device during an anaphylactic episode is a documented problem. *Id.* at 10–11 (Michelis Expert Report ¶ 22).

It is possible to administer epinephrine without an EAI device through use of pre-filled syringes of epinephrine or vials and syringes. *Id.* at 11 (Michelis Expert Report ¶ 24). But, these methods are not preferred in situations of self-administration because usually the person administrating the epinephrine is a layperson who lacks medical training. *Id.*; *see also* Doc. 1815-6 at 18 (Blaiss Expert Report ¶ 5.2.3) ("While it is not practical or recommended for a patient to self-administer epinephrine using vials and syringes during anaphylaxis, physicians and other medical professionals routinely treat patients for anaphylaxis using vials and syringes in medical offices, hospitals, or other institutional settings."). Also, using vials and syringes to administer epinephrine may cause an incorrect dosage because "syringes do not automatically dispense the medication, and there is a chance that the full dose of medication will not be injected." Doc. 1821-2 at 11 (Michelis Expert Report ¶ 24).

Mylan's Sale and Distribution of the EpiPen

Defendant Mylan, Inc. is a global healthcare company whose affiliates develop and market branded and generic prescription drugs. Defendant Mylan Specialty, L.P. is a subsidiary of Mylan, Inc. Mylan Specialty develops, manufactures, and markets branded specialty prescription drug products.

In 2007, Mylan acquired Dey Pharma L.P.—the predecessor to Mylan Specialty. Dey Pharma L.P. owned the rights to market EpiPen® and EpiPen Jr.® Auto-Injectors (collectively "EpiPen"). Meridian Medical Technologies, Inc. ("Meridian"), a subsidiary of Pfizer, manufactures the EpiPen. Under Dey Pharma L.P.'s Supply Agreement with Meridian, Mylan has the exclusive right to market, distribute, and sell EpiPen in the United States.

Introduced in the 1980s, EpiPen was the first EAI available on the market. An EpiPen is shaped like a pen. A patient administers the EpiPen by removing a cap and swinging it against the thigh, which causes the needle to come out and inject epinephrine. After three seconds, the patient removes the device and a plastic shield covers the needle. After Mylan acquired the rights to the EpiPen, it invested substantially in marketing the product to increase public awareness about the risks and treatment of anaphylaxis. Under the Supply Agreement with Meridian, Mylan's exclusive right to market and sell the EpiPen in the United States will terminate on December 31, 2020.[4]

Sanofi Launches A Rival EAI Device, Auvi-Q

Sanofi is one of the world's largest pharmaceutical companies. It is headquartered in Paris, France. The named plaintiff in this lawsuit—Sanofi-Aventis U.S. LLC—is Sanofi's U.S. subsidiary.[5] In 2009, Sanofi secured a license to market and sell Auvi-Q® ("Auvi-Q"), an EAI device developed by Intellijject. Sanofi agreed to pay Intellijject [redacted] before the product launched and a percentage of royalties based on annual net sales as well as certain "milestone payments" for meeting specific sales volume targets. Doc. 1661-15 at 45–50 (License and Development Agreement § 8). Christopher Viehbacher, Sanofi's former CEO who authorized the Auvi-Q license, testified that the license agreement's royalty percentage payments were on the high end of the range for royalty payments. Doc. 1661-4 at 6 (Viehbacher Dep. 22:16–20);

[4] Sanofi submitted as supplemental authority a public earnings release from Pfizer that, it contends, shows Mylan will continue to market the EpiPen after 2020. Doc. 2005. Mylan disagrees with Sanofi's characterization of the public earnings release. Doc. 2006. But this issue isn't material to the court's resolution of the pending summary judgment motion.

[5] Except for the references in this paragraph, the court's references to "Sanofi" in all other parts of this Order refer to the named plaintiff in this litigation: Sanofi-Aventis U.S. LLC.

Doc. 1823-18 at 3 (Viehbacher Dep. 21:2–12). But he also explained that the milestone payments were pretty low for a product at Auvi-Q's development stage. *Id.*

Like EpiPen, Auvi-Q treats anaphylaxis with the same active ingredient—*i.e.*, epinephrine—using the same delivery mechanism—*i.e.*, an auto-injector device. Twin brothers Eric and Evan Edwards invented Auvi-Q. Doc. 1815-5 at 2 (Katie Thomas, *Brothers Develop New Device to Halt Allergy Attacks*, N.Y. Times, Feb. 1, 2013, https://www.nytimes.com/2013/02/02/business/auvi-q-challenges-epipen-with-a-new-shape-and-size.html). Both brothers have severe allergies, and they were dissatisfied with the EpiPen's design. *Id.* So, they created the Auvi-Q—"a slimmer device shaped like a smartphone"—to better meet their needs and those of patients at risk of anaphylaxis. *Id.*

Auvi-Q differs from the EpiPen in that it is smaller (the thickness of a smart phone and size of a credit card), has a rectangular shape, a needle that retracts (as opposed to one covered before and after injection), and audio instructions. Doc. 1821-2 at 14–15 (Michelis Expert Report ¶¶ 33–34). To administer the Auvi-Q, the patient removes its cover and listens to the audio instructions. *Id.* at 14–15 (Michelis Expert Report ¶ 34). When the patient presses the device against the leg, the needle fires to inject epinephrine into the patient, and then the needle retracts automatically. *Id.* Unlike the EpiPen, Auvi-Q doesn't require a "swing and jab motion." *Id.* Auvi-Q is not AB-rated to EpiPen, meaning it is not a generic pharmaceutical product. No clinical studies show that Auvi-Q is safer or more efficient compared to EpiPen when treating anaphylaxis, Doc. 1661-8 at 25 (Blaiss Expert Report ¶ 6.3), but one preference study found that patients prefer Auvi-Q to EpiPen, Doc. 1823-22 at 4–5 (Michelis Rebuttal Expert Report ¶ 8).

In January 2013, Sanofi launched Auvi-Q in the United States. Sanofi sold Auvi-Q until October 28, 2015, when Sanofi voluntarily recalled all Auvi-Q devices. Sanofi instituted the

voluntary recall after it discovered Auvi-Q's potential for inaccurate dosage delivery of epinephrine—a defect that could include failure to deliver the drug. Sanofi never re-launched Auvi-Q after the recall. Instead, in the fall of 2015, Sanofi elected to return its rights to Auvi-Q to Intellijject (which later changed its corporate name to kaléo, Inc.).

Around the time EpiPen and Auvi-Q both were sold in the United States, the EAI market also included other EAI devices. Adrenaclick® was another EAI, launched both as a branded product and as an authorized generic in 2010. It was discontinued in March 2012, and re-launched in June 2013. Twinject® was another EAI. It contained two doses of epinephrine. Twinject® was launched in 2005, but discontinued in March 2012. Also, in 2016, Mylan released an authorized generic of its EpiPen.

Mylan's Response to Auvi-Q

In 2008, Mylan and Meridian (the Pfizer subsidiary who manufactures EpiPen) jointly considered licensing the product that became known as Auvi-Q. Doc. 1821-5 at 3–4 (Handel Dep. 32:14–33:15). At that time, Meridian described Auvi-Q as a "novel" EAI device and an "innovate product." Doc. 1821-6 at 4 (King Pharmaceuticals presentation). After a joint meeting between Mylan, Meridian, and Intellijject (the inventors of Auvi-Q), one participant from Meridian noted that "there is more that we do not know about the technology than we know," but still, he asserted his belief that Auvi-Q "will be a significant threat to [the] EpiPen business." Doc. 1689-17 at 2 (Meridian email). He noted: "Even if at a higher cost than EpiPen, it seems plausible that [Auvi-Q] will offer patients a solution to one of the most significant problems associated with EpiPen: its size and shape." *Id.* Mylan recognized that Auvi-Q might provide a more attractive option for certain patient populations like teenage boys who "don't carry purses" or "[d]on't always have a backpack." Doc. 1821-5 at 3 (Handel Dep.

31:6–32:11). Auvi-Q was an EAI device that patients "could more easily slide into their pocket and be inconspicuous." *Id.*

In September 2008, Mylan and Meridian submitted a "partnering proposal" to Intellijject to consider. Doc. 1821-8 at 6 (Letter to Intellijject). And with their proposal, Mylan and Meridian expressed their "enthusiasm in pursuing this opportunity further." *Id.* But, ultimately, in December 2009, Intellijject chose to license Auvi-Q exclusively to Sanofi to market in the U.S. and Canada. Doc. 1815-5 at 5 (Thomas, *Brothers Develop New Device to Halt Allergy Attacks*, *supra*).[6]

As Sanofi prepared to launch Auvi-Q, Mylan viewed it as a threat to EpiPen's market share. *See, e.g.*, Doc. 1821-9 at 4 (Meridian presentation) (noting that, before Auvi-Q, "EpiPen has never dealt with a heavyweight competitor—until now"); Doc. 1821-10 at 4 (Foster Dep. 212:10–20) (testifying that "[a]ny time you have a competitor, a brand competitor from a company the size of Sanofi, with a sales force larger than Mylan's, yes, it would be considered a threat, absolutely"); Doc. 1688-19 at 4 (Mylan research findings) (noting Auvi-Q posed "a significant threat to EpiPen market share"). In the years leading to Auvi-Q's launch, EpiPen was the only EAI device that held more than 10% of EAI prescriptions in the U.S. Doc. 1821-12 at 3 (Mylan response to Request for Admission No. 15). But Mylan recognized that "physician research evaluating Auvi-Q and EpiPen perception/messaging [had] indicated strong interest in the new device due to [redacted]" Doc. 1821-13 at 3 (Mylan email). Mylan understood that the research showed "[m]any physicians believe[d] more patients [would] be willing to carry an Auvi-Q auto-injector," and some had "expressed strong interest

[6] In 2014, Mylan again considered buying Auvi-Q but concluded that the FTC likely wouldn't allow it to market both the EpiPen and Auvi-Q. Doc. 1689-18 at 2, 4 (Mylan email) (noting a plan to buy Auvi-Q wasn't "viable near term" and the "FTC will likely force divestiture of [Auvi-Q] anyway"); *see also* Doc. 1808-6 at 2, 28 (Mylan minutes from a "brain storming session").

and intent to prescribe Auvi-Q for a [redacted] percentage of new and repeat patients." *Id.*; *see also* Doc. 1688-19 at 4 (Mylan research findings) (recognizing that "[b]ased solely on device attributes, [redacted] of physicians indicate no reluctance to prescribe Auvi-Q"); Doc. 1821-15 at 2 (Mylan email) (noting "many doctors will think it's a better device for their patients"). In 2012, Mylan's then-President John Thievon recognized that Auvi-Q "is a real competitor with some potential/perceived advantages" and that Mylan "[had its] work cut out." Doc. 1821-15 at 2 (Mylan email).

The Redesigned EpiPen

In August 2011, Mylan and Meridian researched the possibility of redesigning the EpiPen. Doc. 1821-5 at 7–8 (Handel Dep. 95:2–97:9). They considered several new designs, including [redacted] and the "mini EpiPen," which was a "smaller version of the existing design." *Id.* at 8–9 (Handel Dep. 100:20–101:22). Mylan wanted to create a product that was "[s]maller, [t]hinner, [f]latter," used "[v]oice instructions to help in a panic situation," and used "click administration or pressure" instead of the "swing and jab." Doc. 1821-17 at 14 (Mylan presentation); *see also id.* at 20–21 (discussing proposed features of a new design that included a shape like a "smartphone," and "voice instruction [that] walks you through step-by-step"). Mylan CEO Heather Bresch had "stressed the need" to bring the new EpiPen product to the "market before mid-2013." Doc. 1689-19 at 2 (Mylan/Meridian email). But, ultimately, Mylan didn't develop a new EpiPen design because it was too costly and would take too much time to implement. Doc. 1821-5 at 7, 12 (Handel Dep. 94:20–95:9, 114:19–116:5). And, since 2009, Mylan hasn't launched a redesigned EpiPen. Doc. 1821-21 at 3 (Graham Dep. 25:20–22).

How Prescription Drugs are Branded and Priced in the United States

Pharmaceutical manufacturers sell prescription drug products to patients through a commercial distribution chain. Doc. 1661-12 at 28 (Navarro Expert Report ¶ 49); *see also* PhRMA, *Follow the Dollar: Understanding How the Pharmaceutical Distribution and Payment System Shapes the Prices of Brand Medicines*, at 1–4 (Nov. 2017) (hereinafter "*Follow the Dollar* Report"), https://onphr.ma/2MTiXWT. The distribution chain starts with the manufacturer who then sells the product to a wholesaler who then sells to a pharmacy who then sells the product to the patient. Doc. 1661-12 at 28 (Navarro Expert Report ¶ 49). A patient's cost for a drug product is determined by the pharmacy and the patient's insurance coverage. *Id.* An uninsured patient pays the price set by the pharmacy. *Id.* An insured patient pays the price determined by the patient's insurance coverage. *Id.* An insured patient may make a copayment (fixed dollar amount), make a coinsurance payment (a percentage of the drug product's full price), or pay full price, depending on the terms of the patient's insurance. *Id.* For insured patients paying a co-pay or co-insurance, insurance covers the balance. *Id.* Generally, pharmacies negotiate their reimbursement rates with the insurer based on a publicly available Average Wholesale Price ("AWP"). *Follow the Dollar* Report, *supra*, at 4.

Managed care health plans are the most common forms of commercial health insurance in the United States. Doc. 1661-12 at 11 (Navarro Expert Report ¶ 11). These types of plans include health maintenance organizations (HMOs), preferred provider organizations (PPOs), and point-of-service (POS) plans. *Id.* at 17–18 (Navarro Expert Report ¶ 23). "Managed care" means that the health insurance plans control (or manage) patients' access to medicines to reduce costs—this includes controlling access to providers, medical procedures, and prescription drugs. *Id.* at 11–12, 17–18 (Navarro Expert Report ¶¶ 11–12, 23). Patients access commercial health

insurance plans through private insurance companies who sell prescription drug benefits to patients, either directly or indirectly, through employers, unions, or schools that sponsor health benefits for their employees, members, or students. *Follow the Dollar* Report, *supra*, at 1–2.

Some large health insurers develop and manage their own prescription drug benefits, but most retain Pharmacy Benefit Managers ("PBMs") to do so on their behalf. Doc. 1661-12 at 12–14 (Navarro Expert Report ¶¶ 13–16). Full-service PBMs emerged in the 1980s. *Id.* at 12 (Navarro Expert Report ¶ 13). Since that time, the PBM industry has become "highly consolidated," with three PBMs processing about 70% of all prescription claims. *Follow the Dollar* Report, *supra*, at 7. The number of patients enrolled in a particular health insurance plan often is referred to as the number of "covered lives." *See* Doc. 1661-9 at 61 (Scott Morton Expert Report Table 2). Sanofi's expert economist, Fiona M. Scott Morton, Ph.D., estimates that, as of January 2015, seven of the largest PBMs and health insurers managed prescription drug benefits for 86% of covered commercial lives. *Id.* at 58–61 (Scott Morton Expert Report ¶ 87 & n.165 & Table 2). The seven are: Express Scripts ("ESI") (PBM) (38%), CVS Caremark ("CVS") (PBM) (20%), OptumRx (PBM) (10%), Prime Therapeutics ("Prime") (PBM) (7%), MedImpact (PBM) (6%), Cigna (health insurer) (4%), and Aetna (health insurer) (1%). *Id.* Also, Dr. Scott Morton previously estimated that, in May 2017, "just three firms (CVS Caremark, OptumRx, and Express Scripts) control[led] between 80 and 85 percent of the prescription benefit covered lives in the U.S. market." Doc. 1661-18 at 22 (Scott Morton Paper).

The term "formulary" generally refers to the list of prescription drugs covered by a health insurance plan. PBMs and health insurers create a variety of formularies for their health plan clients. *See, e.g.*, Doc. 1661-19 at 4–17 (Sanofi white paper). No requirement mandates payors to cover *all* prescription drugs available in the U.S. Doc. 1661-12 at 21 (Navarro Expert Report

¶ 33). Some payors' formularies offer a wide choice of drugs to treat the same condition but at a higher cost, while other payors choose to restrict the number of covered drugs available on a formulary to save costs. Doc. 1660-4 at 10–11 (Anderson (CVS) Dep. 51:19–52:13).[7] A formulary may be described as "open" or "closed." *Id.* at 23–26 (Anderson (CVS) Dep. 183:14–186:21). An "open" formulary generally covers many, or sometimes all drugs, whether they are listed on the formulary or not. *Id.* And, in general terms, a "closed" formulary only covers drugs listed on the formulary. *Id.* Sanofi's former CEO testified that a pharmaceutical company generally "can control the price [of a pharmaceutical product] by controlling access to the formulary; so the tighter the access to any given formulary, the more you have control over price." Doc. 1661-4 at 7 (Viehbacher Dep. 52:2–9).

Some payors provide "custom formularies," meaning that the clients manage the formulary decisions based on their needs. Doc. 1660-4 at 13–14 (Anderson (CVS) Dep. 67:15–68:7). Some of the largest PBMs maintain hundreds or thousands of formularies. *See, e.g.*, Doc. 1660-28 at 7 (Rogers (OptumRx) Dep. 36:13–21) (describing OptumRx's number of formularies as "[w]ell into the thousands"); Doc. 1660-24 at 35 (Kautzner (ESI) Dep. 178:5–20) (describing ESI as having "likely . . . hundreds of different custom formularies").

Payors typically use what they call utilization management ("UM") techniques to encourage patients to choose more cost-effective products and negotiate better pricing from manufacturers. Doc. 1660-17 at 6–9 (Etemad (UnitedHealthcare) Dep. 24:18–27:25). A drug

[7] Sanofi objects to Mylan's Statements of Fact that describe, generally, how payors use drug formularies. Sanofi asserts that the U.S. EAI market is unique, and Mylan's facts fail to account for how the EAI market differs from other prescription drug markets. The court includes Mylan's facts about how formulary placement works to provide a general overview of how prescription drugs are sold in the U.S. The court recognizes that this general overview is not exact when discussing how the EAI market works. And, where needed, the court explains the unique characteristics present in the EAI market that aren't necessarily reflected in a general industry overview.

class that is subject to various UM techniques commonly is called a "managed class." Doc. 1660-27 at 7 (Minton (Anthem) Dep. 56:6–12). Mylan describes four types of UM techniques commonly used by payors. Doc. 1660-2 at 22–23 (Mylan's Mem. in Supp. of Mot. for Summ. J.).

First, payors use copayments and tiering in their formulas. *See, e.g.*, Doc. 1661-9 at 32–33 (Scott Morton Expert Report ¶ 40). Tiered formularies "are lists of covered drugs that are available to end consumers, typically with different tiers corresponding to different levels of end-consumer co-payments." *Id.* Payors commonly use at least three tiers in a formulary. *Id.* The lowest tier (Tier 1) generally offers generic drugs (generally the lowest cost drugs for the payor). *Id.* The branded counterpart usually is placed on a higher (less preferred) tier. *Id.* With multiple branded drugs, a payor's "preferred" brand product is placed on a lower tier (typically Tier 2), and the less preferred option is placed in a higher tier (typically Tier 3) with a higher patient co-payment. *Id.* When a payor offers coverage for a generic drug, a preferred brand drug, and a second, non-preferred brand drug on the formulary, the patient has the option of paying a relatively low co-pay for the generic drug (or no co-pay at all), a higher co-pay for the preferred brand, and an even higher copay for the non-preferred brand drug. *Id.* Using a tiered formulary, a payor is able to "influence choices among treatments by only including some treatments on the formulary or by putting different treatment options on different tiers." *Id.* And, the tiered formulary's use of different co-pays for different tiers serves as a financial incentive for patients to select the payor's preferred option. *Id.* The use of tiers also creates incentives for manufacturers to offer a lower price so that the payor includes the manufacturer's product on a more favorable, or lower tier. *Id.*

Second, payors may use a UM tool called a "step edit." Doc. 1660-5 at 7 [redacted]; Doc. 1660-20 at 9–10 [redacted]. With a "step edit," the payor requires the patient to fill a prescription for a lower-tiered drug, such as a generic, before it will cover a branded alternative on a higher tier.[8] *Id.*

Third, payors may use a prior authorization requirement as a UM technique. This means that the patient's physician must make a formal request to the payor to approve coverage of a specific drug based on certain criteria developed by the payor. *See, e.g.*, Doc. 1660-5 at 8 [redacted]; Doc. 1660-20 at 15–16 [redacted].

Fourth, payors may exclude drugs from coverage as a UM technique. When a payor excludes a drug from coverage, the patient usually still can purchase the drug but the patient must apply for a medical necessity exception to secure coverage, or the patient must pay out-of-pocket for the drug without any coverage. *See, e.g.*, Doc. 1660-4 at 30–31 (Anderson (CVS) Dep. 221:13–222:20); Doc. 1660-17 at 20 (Etemad (UnitedHealthcare) Dep. 211:9–22); Doc. 1660-25 at 23 (Kronberg (Cigna) Dep. 274:3–15). Payors sometimes refer to excluded drugs as not-covered ("NC") or subject to a "NDC [National Drug Code] block." *See, e.g.*, Doc. 1660-13 at 8–9 (Cunico (Presbyterian) Dep. 146:17–147:22); Doc. 1660-25 at 22 (Kronberg (Cigna) Dep. 209:7–17).

By using these UM techniques, payors are able to create "some degree of price competition between sellers of substitutable treatments by incentivizing pharmaceutical firms to

[8] Sanofi asserts that a "step edit" isn't a UM tool that's relevant to the EAI market because a "step edit" requires a trial of a preferred drug *and failure*. Doc. 1823-29 at 3 (Brodeur Dep. 32:7–13); *see also* Doc. 1823-30 at 2 (noting in an email from Prime Therapeutics that "a clinical program such as step therapy" wouldn't be "consider[ed] appropriate in this class," *i.e.*, the EAI market). But as discussed *infra*, a step edit is a UM tool that some payors discussed in their negotiations with Mylan and Sanofi about EAI coverage, and eventually implemented in certain EAI formularies. The court includes it in its statement of facts for that reason.

offer rebates off their list (or [Wholesale Acquisition Cost ("WAC")]) prices in exchange for better placement on the formulary." Doc. 1661-9 at 34 (Scott Morton Expert Report ¶ 43); *see also* Doc. 1661-12 at 29 (Navarro Expert Report ¶ 51) (describing a rebate as "a retrospective payment, generally a percentage of the WAC, and based upon amount of the drug reimbursed by a health plan or PBM"). A payor's "threat of exclusion, and the resulting loss of sales, may induce a manufacturer to lower its price in order to be retained on the formulary." Doc. 1661-18 at 20 (Scott Morton Paper).

Another way that payors contract for better pricing from manufacturers through rebates is to negotiate price protection. *See, e.g.*, Doc. 1660-20 at 13 [redacted]. With price protection, the manufacturer agrees that if it increases its price above a contracted percentage, then the manufacturer will rebate that amount above the agreed-upon price threshold, thereby negating some or all of the price increase. *See, e.g.*, *id.*; *see also* Doc. 1661-12 at 29–30 (Navarro Expert Report ¶ 55).

As payors negotiate their drug contracts, payors solicit rebate offers from drug manufacturers. Doc. 1661-12 at 36 (Navarro Expert Report ¶ 74). Payors commonly solicit multiple rebate offers from manufacturers, including different rebate offers that correspond to different levels of benefit control and formulary placement. *Id.* Many pharmaceutical companies negotiate their pricing and formulary placement through the use of "bid grids." *Id.* A "bid grid" is a table with "a number of cells, each of which represents a different level of formulary control and number of brands preferred and which correlates with a different rebate percent[age] bid by pharmaceutical manufacturers." *Id.* at 37 (Navarro Expert Report ¶ 76).

Manufacturers of branded pharmaceutical products usually offer higher rebates conditioned on the payor making the drug exclusive on the formulary, or one of only two or three

competing products on the preferred tier of the formulary. *Id.* at 36–37 (Navarro Expert Report ¶ 75). Also, the manufacturer might offer a higher rebate in exchange for the payor agreeing to subject competing products to additional restrictions (like a step edit or prior authorization) or excluding them from the formulary altogether. *Id.*

After a payor and manufacturer reach agreement about rebate offers, the payor enters a rebate agreement with the manufacturer. *Id.* at 40–41 (Navarro Expert Report ¶ 81). Usually, the payor doesn't select a single rebate offer, but, instead, the rebate agreement will include the entire bid grid or a chart of rebate options. *Id.* The rebate agreements typically don't require the payor to make specific drug choices or formulary decisions. *Id.* Instead, the rebate agreement requires the drug manufacturer to pay the rebate for the type of coverage the payor or client selects from the grid or chart. *Id.* The payor submits a claim for rebates to the manufacturer based on the number of prescriptions filled by insured customers whose health plans satisfy the requirements for a particular rebate category. *Id.* Sometimes, a payor may sign rebate agreements with multiple manufacturers for drugs in the same therapeutic class—for example, in 2014, Prime Therapeutics (a PBM) entered rebate agreements with both Mylan and Sanofi, governing the rebate terms for EpiPen and Auvi-Q respectively. *See* Doc. 1662-10 (Prime/Mylan Agreement); Doc. 1662-11 (Prime/Sanofi Agreement).

Several payors have testified that competition in a therapeutic drug class encourages manufacturers to offer more favorable pricing and rebates in exchange for better placement on a payor's formulary. *See, e.g.*, Doc. 1660-5 at 17–18 (Ayers (MedImpact) Dep. 154:18–155:2) ("MedImpact views the entry of competitors as an opportunity to negotiate higher rebates within a therapeutic class, and [the entry of Auvi-Q] would be a case of that."); Doc. 1660-17 at 16 (Etemad (UnitedHealthcare) Dep. 102:1–9) ("With increased competition, we are able to

leverage better pricing."); Doc. 1660-20 at 17 (Hall (Prime) Dep. 98:8–16) ("Prime has a little more leverage[ ] with new products to negotiate . . . cost-saving components that our clients would benefit from."); Doc. 1660-24 at 23 (Kautzner (ESI) Dep. 82:3–16) (testifying ESI could "drive additional discounts" with "competition in the market"); Doc. 1660-25 at 10–12 (Kronberg (Cigna) Dep. 66:9–68:4) (testifying when "manufacturers in the class see that introduction [of a new product] as competition . . . they generally come to the table and offer better financial terms"); Doc. 1660-27 at 17 (Minton (Anthem) Dep. 292:2–13) (testifying that "additional competitor[s]" would "increase[] Anthem's ability to negotiate for higher rebates and greater price protection"); Doc. 1661-3 at 7 (Vargo (Aetna) Dep. 82:10–22) ("[I]f there's more products, that means more competitiveness, and there's potential to reduce cost because [manufacturers are] fighting for . . . better formulary position . . . ."). And, Sanofi's expert has testified before Congress, explaining how payor formulary coverage and manufacturer rebating forces price competition among competing drug companies:

> [T]he way you get low prices in the pharmaceutical industry is by the ability to exclude drugs . . . You identify a few therapeutic substitutes and you essentially hold an auction . . . Whoever gives me the best price is the one I am going to buy from, and everybody else gets none of my business. When you can do that, you force price competition.

Doc. 1661-20 at 18 (Scott Morton Congressional Testimony).

EpiPen Pricing

In the months leading up to Auvi-Q's launch in the EAI market, Mylan implemented various price increases for the EpiPen. *See, e.g.*, Doc. 1821-22 at 15 (Mylan presentation) (recommending an "[i]ncrease in EPIPEN's WAC price [of] 19.9%" because Auvi-Q was "coming to the market" and noting an opportunity to "[g]ain incremental revenue on current volume before competition comes to market"); Doc. 1821-23 at 11 (Mylan presentation)

(proposing an increase to EpiPen's "WAC price [of] 15%" because "[r]evised contract strategy supports a higher price in case a higher price increase % gets noticed by payers"). Between 2009 and 2016, EpiPen's WAC price increased by more than 500%. Doc. 1821-25 at 4 (Mylan/EpiPen Price History); *see also* Doc. 1688-12 at 2 (Aetna email) (commenting that "EpiPen's price has jumped 488 percent in the last four years, despite the fact that epinephrine is not a new drug"). In 2008, EpiPen's WAC price was $98.57, and by 2016, its WAC price was listed at $608.61. Doc. 1821-25 at 4 (Mylan/EpiPen Price History).

In 2012—the year before Sanofi's launch—Mylan implemented three price increases on the EpiPen. *See id.*; *see also* Doc. 1688-8 at 8 (Meridian presentation). EpiPen's net price to PBMs and payors, on average, also increased from 2013 to 2015. *See* Doc. 1687-10 at 58–60 (Scott Morton Expert Report ¶ 87 & Fig. 8) (calculating that EpiPen's net price to PBMs and payors averaged around $111 in early 2013 and increased to more than $150 in late 2015). During this same time, Mylan's EpiPen costs increased between 4.3% to 6.5%, with an average annual price increase of 5.3%. Doc. 1688-8 at 4 (Meridian presentation) (noting "[b]etween 2010-2015 transfer prices [from Meridian] to Mylan increased between 4.3% and 6.5% annually [and average] annual price increase to Mylan was 5.3%").

Meridian (Pfizer's subsidiary who manufactures the EpiPen) raised concerns to Mylan about the EpiPen price increases. Doc. 1688-13 at 2 (noting that Meridian had "raised concerns about EpiPen pricing" to Mylan and expressed a concern "about potential reputational impact to Pfizer/Meridian and impact on patient access"); *see also* Doc. 1688-14 at 9 (Handel Dep. 163:15–164:14) (testifying that Meridian "didn't think that that was an accurate depiction of the cost drivers for the product" for Mylan to say that the "EpiPen auto-injector wholesale price has

changed over time to better reflect the multiple important product features and the value the product provides").

In 2016, Mylan submitted a "U.S. EpiPen Profitability Analysis" to Congress as a supplement to its congressional testimony. Doc. 1694-4 at 2 (U.S. EpiPen Profitability Analysis). It shows that EpiPen's sales increased from 4.5 million pens and $200 million in gross sales in 2009, to 8.3 million pens and $912 million in gross sales in 2015. *Id.* Also, Mylan's analysis shows that Mylan's gross profit margins rose from 56% per pen in 2010, to 72% per pen in 2015. *Id.* Using the data from Mylan's U.S. EpiPen Profitability Analysis, Sanofi's expert concludes that "profits per pen throughout 2013-2015 were far above what Mylan earned in 2012" on EpiPen. Doc. 1690-28 at 24 (Scott Morton Expert Reply Report ¶ 39). And, she has found "[f]rom 2013 to 2015, while Auvi-Q was in the market, Mylan earned $219 million, $313 million, and $312 million respectively, or $30, $40, and $38 on a per-pen basis" and "[a]cross these three years, annual profits increased by 80% relative to 2012, or 67% on a per-pen basis." *Id.*

Mylan attributed a large portion of its profitability to the increase in EpiPen prices. *See, e.g.*, Doc. 1688-17 at 5 (Mylan presentation) (noting that about "60% of revenue growth [is] attributable to price increases"). Sanofi's expert calculates that, in 2013, "EpiPen U.S. operating profits were 34.6% of its global operating profits," and, in 2014, increased to "38.8% of operating profits." Doc. 1687-10 at 20 (Scott Morton Expert Report ¶ 22). Mylan's Director of National Accounts even recognized that Mylan's "[p]rice increases have made a huge difference in Mylan[']s bottom line, but the party won't continue forever without ramifications." Doc. 1688-18 at 2 (Mylan email).

Sanofi Launches Auvi-Q

Around the time when Sanofi was preparing to launch Auvi-Q in 2013, payors increasingly were relying on UM techniques to influence drug prices. Sanofi's market research firm reported that payors, "with the assistance of their health plan and PBM partners, are increasingly influencing physician prescribing decisions and patient use" by "erect[ing] administrative hurdles (*e.g.*, Step-Edits and [prior authorizations])" and "co-pays." Doc. 1662-20 at 5 (PayerSciences Report). Several payors, including CVS, ESI, and UnitedHealthcare, began adding more drugs to their exclusion lists—*i.e.*, the payor's list of products which it excludes from coverage. *See, e.g.*, Doc. 1661-21 at 7, 9 (CVS white paper) (describing how "exclud[ing] certain brand products in categories with ample generic and/or preferred brand options . . . helps drive utilization to lower cost formulary brand and generics" and noting that CVS's "2012 Formulary success shows that plans with a high-control approach to formulary will be able to achieve lower net cost and mitigate brand cost increases"); Doc. 1661-19 at 12 (Sanofi white paper) (noting that "patients and employers welcomed [CVS's] more restrictive formularies" and "[p]atients and payers were willing to give up choice in return for having lower costs[,]" so "ESI responded to their client requests to reduce costs by bringing forward their own exclusion categories effective January 2014"); Doc. 1662-23 at 2 (UnitedHealthcare Oct. 18, 2013 email) (explaining that "when [one does] the apples to apples comparison of exclusions, [UnitedHealthcare] exclude[s] 148 drugs as compared to [ESI's] 56").

Indeed, Sanofi recognized the trend that payors were designing benefit plans that were "becoming more restrictive with tighter controls." Doc. 1661-19 at 11 (Sanofi white paper). Such controls included:

- PBMS are looking to "not covered" products as an answer to co-pay cards
- Migration to exclusion type formularies is increasing at an increasing rate

- Where patients previously wanted choice, they are now more accustomed to switching products to reduce costs
- Patients are looking for tighter formularies if it means out of pocket costs decrease[ ]
- PBMs are utilizing internal capabilities to drive formulary compliance
- PBMs have demonstrated ability to dramatically impact market share with exclusion type formularies

Id. Also, in this time frame, payors increasingly asked for price protection—not just in the EAI market—but generally across all product markets. Doc. 1660-26 at 8–9 (Loreaux Dep. 139:23–140:10).

But—specific to the EAI market—some payors testified that, before Auvi-Q's launch, payors did not manage the EAI device class aggressively. *See, e.g.*, Doc. 1821-27 at 5 (Minton (Anthem) Dep. 279:3–15) (testifying that "from 2007 to 2013" the EAI "type of drug class" was not "historically managed aggressively"); Doc. 1821-29 at 5 (Jan (BCBS Horizon) Dep. 143:23–144:2) (testifying that rebates for the EAI device class weren't "in any way restrictive . . . prior to 2013").

When bringing Auvi-Q into the EAI market, Sanofi's pricing strategy "was to launch at parity [with EpiPen], and then establish the premium afterwards." Doc. 1661-4 at 11 (Viehbacher Dep. 94:1–6). After Auvi-Q's launch in January 2013, Sanofi twice made "large" increases to the WAC price in the first 12 months Auvi-Q was on the market. Doc. 1660-27 at 9–11 (Minton (Anthem) Dep. 90:2–92:10). Sanofi's first WAC increase in August 2013 put Auvi-Q at a 5% WAC premium above the EpiPen, and its second WAC increase in December 2013 put Auvi-Q at a 10% WAC premium above the EpiPen. Doc. 1662-24 at 3 (pricing chart). During the 33 months that Sanofi marketed Auvi-Q, it took six WAC price increases and, for most of those months, it maintained a WAC premium above EpiPen. *Id.* at 3, 6.

When launching Auvi-Q, Sanofi was "not interested in [negotiating] [e]xclusive deals" because it didn't "want to start a bidding war." Doc. 1662-1 at 2 (Sanofi email). As Sanofi's then-CEO testified,

> [W]hen you're marketing a drug . . . the whole point of marketing is that you don't use price, right? Otherwise, you become a commodity. And if you believe your product is better, and Sanofi at that time believed, and probably still does, that Auvi-Q was a better drug, then there shouldn't really be a necessity to have a deep discount. What you may—and also, may not actually want to set off a whole cascade of price discounts.

Doc. 1661-4 at 9–10 (Viehbacher Dep. 74:18–75:13). Indeed, three months before Auvi-Q's launch, Sanofi considered that Mylan might compete with Auvi-Q by "offer[ing] an aggressive discount to all priority accounts in exchange for exclusivity position." Doc. 1663 at 13 (Sanofi presentation). If Mylan pursued that strategy, Sanofi planned to "[c]ontinue to drive the message of unmet need, innovation, ease of use and importance of having unrestricted access" and "[c]losely monitor coverage and uptake." *Id.*

Sanofi's strategy for securing Auvi-Q formulary placement was to seek a "[m]ix of T2 and T3 access (not T2 at all cost)." Doc. 1663-1 at 5 (Sanofi presentation). As Auvi-Q's then-"brand lead" testified, Sanofi was "not planning for a lot of tier two access" for Auvi-Q and was "perfectly fine with tier two or tier three." Doc. 1660-15 at 4–5 (Downey Dep. 8:8–9:7); *see also* Doc. 1660-6 at 4 (Barry Dep. 156:2–12) (testifying that Sanofi was "trying to really negotiate . . . for tier three coverage"); Doc. 1661-5 at 5 (Whitaker Dep. 46:1–3) (testifying 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").

Meanwhile, Mylan also was preparing a strategy for Auvi-Q's launch. In 2011, Mylan's senior leadership recognized the need to prepare for Auvi-Q's launch to protect EpiPen's position in the EAI market. *See, e.g.*, Doc. 1821-34 at 2 (Mylan email) (discussing the need to

"take this time to pre-empt any new market entry and leverage [Mylan's] position/heritage/trust"); Doc. 1821-35 at 3 (Mylan email) (recognizing "the importance of being prepared for competition from Sanofi is critical" and that Mylan's "actions need to be further accelerated," noting that "[t]his sentiment is clearly shared by our Sr Leadership," and stating Mylan "need[s] to act with urgency to defend EpiPen as if [Auvi-Q] were launching on the market today"). In December 2011, Mylan's Director of National Accounts suggested implementing a "proactive" strategy where Mylan "should begin to identify opportunities to restructure our contracts for exclusivity language." Doc. 1821-36 at 2 (Mylan email). He recognized that if Mylan didn't "begin [its] 'war game' scenarios now and begin to restructure contracts now [it] may be too late to do it after [Auvi-Q] gets momentum." *Id.*; *see also* Doc. 1821-37 at 5 (Mylan email) (asking whether Mylan could put some "language in [an Aetna Medicare Rebate Agreement] around exclusivity" because "with [Auvi-Q] potentially coming to market in the next 6–18 months [Mylan] want[s] to secure [its] position as the exclusive product in as many accounts as possible").

Mylan developed a strategy for responding to Auvi-Q's launch that included strengthening or maintaining EpiPen formulary positions by adding, for example, "[e]xclusivity language in 2012 contract renewals" or causing "PBMs [to be] heavily impacted if they work against [Mylan]." Doc. 1821-31 at 3 (Mylan presentation); *see also* Doc. 1821-32 at 2–3 (Mylan presentation) (suggesting in an EpiPen presentation titled "Global Brand Plan 2012–2016" that "[f]or all new contracts and renewals, negotiate, where possible, language requiring plans to put EpiPen in sole preferred position and no restrictions"); Doc. 1821-39 at 8 (Mylan presentation) (listing as one of the "proactive responses" to Auvi-Q's launch as "[r]equiring language in our agreements for Sole Branded Position to better strengthen EpiPen formulary positioning. This

will disincentive Plans from adding in a branded competitor (lost rebate $'s)"). Also, Mylan proposed strategies for responding to Auvi-Q such as "[e]ncourag[ing] payers to require prior authorization" on Auvi-Q. Doc. 1821-38 at 35 (Mylan presentation); *see also* Doc. 1821-40 at 5 (Mylan presentation) (listing the same as a "high" priority and "ongoing").

Before Auvi-Q's launch, Mylan was offering rebates to PBMs and payors that were in the single digits and required that EpiPen have access equal to other EAIs on drug formularies. *See, e.g.*, Doc. 1821-10 at 4–5 (Foster Dep. 212:17–213:8) (testifying that before Auvi-Q, Mylan was offering "3 to 5 percent rebates . . . as mostly goodwill gestures to maintain . . . access"); Doc. 1821-41 at 3 (Jordan Dep. 39:2–8) (testifying that the rebates Mylan offered on his accounts in 2011 were in the single digits); Doc. 1821-43 at 16 (Mylan presentation) (describing "pre-Auvi-Q" strategy as offering "5%–10% access rebates"); Doc. 1821-44 at 4 (2013 Mylan/Aetna Rebate Agreement) (requiring that EpiPen "be listed in equal position of all current and future brand products"). But, Mylan's rebate offers increased significantly after Auvi-Q entered the EAI market. Doc. 1821-42 at 133 (Willig Expert Report Ex. 6) (showing that EpiPen rebates increased from 10% in 2013 to 36% in 2015). And, Mylan required some PBMs to place restrictions on competing products. *See, e.g.*, Doc. 1825-9 at 3 (2014 Mylan/Aetna Rebate Agreement) (requiring that "[a]ll other branded [EAI] products shall be placed on the highest copay tier of such Plan (*i.e.* Tier 3 or higher) and shall be subject to a Step Therapy or Precertification").

Initially, at Auvi-Q's launch, Sanofi adopted contracting guidelines for Auvi-Q that authorized "pretty small" rebates, in the range of 3%–10% for Tier 2 and with no rebate strategy to secure Tier 3 coverage. Doc. 1660-14 at 4 (Denney Dep. 100:1–19); Doc. 1663-2 at 2 (Sanofi email). Also, Sanofi's strategy didn't include price protection. Doc. 1660-14 at 9 (Denney Dep.

114:3–20). Sanofi's account executives reported that payors were rejecting these offers as "inadequate," "not competitive," and even "laughable." Doc. 1663-3 at 2 (Sanofi email about OptumRx); Doc. 1663-4 at 2 (Sanofi email from MedImpact); Doc. 1663-5 at 2 (Sanofi email about Coventry).

But, Sanofi's strategy "quickly" changed because payors were telling Sanofi that "it wasn't enough" and Sanofi "couldn't match the Mylan offer." Doc. 1660-14 at 4 (Denney Dep. 100:1–19). Sanofi learned that Mylan was making offers conditioned on exclusivity that payors "couldn't refuse." Doc. 1824 at 4 (Sanofi email) (internal quotation marks omitted). But, before 2012, no formulary had excluded non-EpiPen EAI devices. Doc. 1821-28 at 5–6 (May Dep. 292:24–293:3). Within a few months after Auvi-Q's launch, Sanofi questioned whether its offers were "being aggressive enough." Doc. 1663-6 at 3 (Sanofi email). But, Sanofi recognized, "[g]iven our [redacted]; we are in bit of a bind and may already be as aggressive as we can be." *Id.* Sanofi believed its initial strategy "made sense based on [its] understanding of the market environment" but it "couldn't have foreseen . . . the unprecedented rebates that were given competitively by Mylan which forced [Sanofi] then into an aggressive rebating strategy to be able to negotiate access, so that put pressure on a P&L, and put pressure on the fact that the royalty rate was 20 percent and it had a higher COGS profile than other pharmaceutical products." Doc. 1823-15 at 5 (Barry Dep. 31:25–32:24). So, "what made sense at launch made less sense after the competitive response to exclude [Auvi-Q] from the marketplace, and what it required for [Sanofi] to claw back appropriate patient access made it challenging from a P&L perspective." *Id.*

Sanofi had concerns that offering aggressive rebates during its first year of launch would "set off a whole cascade of price discounts." Doc. 1661-4 at 9–10 (Viehbacher Dep. 74:18–

75:20). An "Auvi-Q Strategy Discussion" presentation in August 2013 observed: "Newly launched, differentiated products with [] high COGs can not and should not engage in a discounting war," and "[t]here are no winners in a price war." Doc. 1663-7 at 2, 7 (Sanofi presentation). Sanofi's former CEO testified that, by September 2013, the company wasn't yet ready to authorize discounting to match Mylan's offers. Doc. 1661-4 at 12–14 (Viehbacher Dep. 119:5–121:1). He explained why:

> [The] [f]irst objective is really to establish the value proposition of a product with your customer, and pricing moves are very difficult . . . to reverse in the future . . . [I]t's a typical corporate approach where we'd say, you know, well, we know what a price decrease is going to cost us. Are you sure that you have done everything on all of the other levers of marketing really to explain that value proposition and—and avoid that. So it's a judgment call as to when you do that, but six months after launch would be potentially waving the white flag a little bit too early on the ability of the marketing and the sales team to explain that value proposition.

Id.

After Auvi-Q's launch, several payors viewed Auvi-Q to deliver a treatment that was similar to or interchangeable with EpiPen; so, some payors chose to cover just one EAI product. *See, e.g.*, Doc. 1663-8 at 4 (ESI's Pharmacy & Therapeutics ("P&T") committee recommends making Auvi-Q "optional"); Doc. 1663-9 at 22 (CVS document describing EAI products a "[t]herapeutically interchangeable class"); Doc. 1660-28 at 14 (Rogers (OptumRx) Dep. 61:14–19) (testifying that OptumRx's P&T committee "deemed" Auvi-Q "therapeutically equivalent" to EpiPen and other EAI devices); Doc. 1663-10 at 13 (Prime P&T Committee Meeting Minutes noting it would "choose one" EAI product to cover); Doc. 1663-11 at 20 (UnitedHealthcare presentation noting Auvi-Q was "excluded at launch since [it] consists of the same active ingredient as another covered product[,]" *i.e.*, EpiPen); Doc. 1660-5 at 12 (Ayers (MedImpact) Dep. 44:1–8) (testifying that MedImpact's P&T committee determined that Auvi-Q and EpiPen were "therapeutically equivalent"); Doc. 1660-25 at 20–21 (Kronberg (Cigna) Dep. 148:19–

149:14) (testifying that Cigna let the EAI class "compete based on price" because "price is the determinant" when products are "clinically equivalent"); Doc. 1663-12 at 2 (Aetna document describing Auvi-Q and EpiPen as having the same "indication" in that they both are used to treat anaphylaxis); Doc. 1660-27 at 12 (Minton (Anthem) Dep. 129:14–22) (testifying that Anthem's clinical review committee designated Auvi-Q, EpiPen, and Adrenaclick as "comparable" meaning "[t]here's no difference between the products"); Doc. 1663-13 at 2 (Kaiser Permanente document describing Auvi-Q as "a therapeutic alternative" to EpiPen and noting "there is no data to support that Auvi-Q is superior to EpiPen").

Also, some payors viewed Auvi-Q's introduction as an opportunity to manage the EAI class and push for more competitive pricing. *See, e.g.*, Doc. 1663-13 at 6 (Kaiser Permanente document noting: "[s]ince there are two products now available on the market if EpiPen and Auvi-Q are bid out there is potential for more competitive pricing"); Doc. 1660-24 at 23 (Kautzner (ESI) Dep. 82:3–16) (testifying that "Auvi-Q was . . . a new product and had been excluded" so ESI was able "to drive additional discounts because there was now competition in the market"). Indeed, some payors told Sanofi that they intended to cover only one EAI product and encouraged Sanofi to compete based on price. *See, e.g.*, Doc. 1663-14 at 3 (Sanofi email recognizing "CVS Caremark's plan to review the class and choose an exclusive product" and the need to raise the issue with the Auvi-Q brand team); Doc. 1662-1 at 2 (Sanofi email noting that Kaiser Permanente was "very interested in Auvi-Q" and "have suggested that [it] only want[s] one product"); Doc. 1663-16 at 2 (Sanofi email discussing that "MedImpact likes the AuviQ product but wishes to have only one product in the category"); Doc. 1663-17 at 2–3 (Sanofi email explaining that ESI clients "will be looking closely at the financial modeling," and "[w]ithout an access rebate, there is no compelling financial reason for ESI to place AuviQ T3").

Mylan received similar communications from payors about the need to compete on price after Auvi-Q entered the market. *See, e.g.*, Doc. 1663-18 at 2 (Mylan email discussing an offer from OptumRx/UnitedHealthcare for "guaranteed exclusive position for EpiPen in exchange for the addition of 10% price protection at United"); Doc. 1662 at 2 (Cigna email to Mylan requesting "an offer for exclusive epinephrine positioning" and suggesting Cigna can manage the class "us[ing] tier differential and step therapy").

2013 and 2014 Formulary Coverage

At Auvi-Q's 2013 launch, many payors—including ESI, CVS, Prime Therapeutics, Aetna, Cigna—and others treated Auvi-Q as covered on Tier 3 of their formularies before formal review by their P&T committees. Doc. 1663-1 at 17–18 (Sanofi presentation). OptumRx/UnitedHealthcare didn't cover Auvi-Q at launch because it had a policy of "not cover[ing] new products to market with the same active ingredients as other covered products" until the P&T committee reviewed the product. Doc. 1660-17 at 14 (Etemad (UnitedHealthcare) Dep. 84:9–18).

As described in more detail below, four payors—ESI, Aetna, OptumRx/UnitedHealthcare, and MedImpact—excluded or restricted Auvi-Q from coverage in 2014. But, in 2015, two of the four—ESI and Aetna—removed those restrictions. Three payors—CVS, Prime Therapeutics, and Cigna—never restricted or excluded Auvi-Q. These three payors covered Auvi-Q on Tier 2 or Tier 3 without restriction. The following describes the coverage Sanofi negotiated for Auvi-Q from the seven largest payors. It also describes the coverage Mylan negotiated for the EpiPen in these same time frames.

Payor #1: Express Scripts (ESI)

When Sanofi launched Auvi-Q, it initially planned to offer ESI rebates in the 5% range. Doc. 1663-21 at 5 (Sanofi presentation). But, in early 2013, ESI told Sanofi that it would need to offer higher rebate numbers if it wanted to compete with Mylan's offer. Doc. 1663-17 at 2 (Sanofi email). In March 2013, ESI asked both Sanofi and Mylan to complete the ESI "rebate matrix" for the 2014–2015 cycle. Doc. 1662-2 (ESI email soliciting bid from Sanofi); Doc. 1663-22 (Mylan email attaching the ESI bid grids).

Sanofi responded to ESI by submitting a bid grid in May 2013 that included a 15% rebate for Auvi-Q to be co-preferred on Tier 2 with EpiPen, and a 25% rebate to be the exclusive product on Tier 2.[9] Doc. 1663-23 at 4 (Sanofi/ESI bid). Sanofi didn't make an offer for ESI to list Auvi-Q on Tier 3 without restriction. *Id.*; Doc. 1663-24 at 2 (Sanofi email). Sanofi also didn't make an offer for price protection. Doc. 1663-23 at 4. Several months later, Sanofi submitted a revised final offer for Auvi-Q adding a 10% rebate for Tier 3 access, and increasing its prior offers to 20% for co-preferred Tier 2 coverage, and 30% for exclusive Tier 2 coverage. Doc. 1665-1 at 4 (Sanofi/ESI Term Sheet). But Sanofi again didn't offer ESI price protection. *Id.*; *see also* Doc. 1665-2 at 4, 12–13 (Sanofi/ESI Rebate Agreement).

Mylan also responded to ESI's request soliciting rebate offers by offering a range of rebates associated with various formulary restrictions and positions. Doc. 1662-7 at 4 (Mylan/ESI 2014 Rebate Agreement). Mylan's highest rebate offer was 23%, which would apply to plans who chose to make EpiPen the exclusive EAI device on formulary. Doc. 1662-7 at 4 (Mylan/ESI 2014 Rebate Agreement). Mylan also offered ESI price protection. *Id.*

[9] The ESI rebate offers include the offers listed on the bid grid plus ESI's standard 4.375% administrative fee. *See, e.g.*, Doc. 1665-1 at 2 (Sanofi/ESI email).

On August 29, 2013, ESI announced that EpiPen was the exclusive EAI device offered on ESI's 2014 National Preferred and High Performance Formularies. Doc. 1665-4 at 4 (ESI 2014 Commercial Formulary Decisions). ESI's corporate designee testified that ESI chose EpiPen over Auvi-Q because it was "able to get to a lower net cost for our plans" for EpiPen than for Auvi-Q. Doc. 1660-24 at 23 (Kautzner (ESI) Dep. 82:3–21); *see also* Doc. 1816-6 at 2 (Sanofi email) (reporting that "Mylan came back with an exclusive offer [for EpiPen] that 'they couldn't refuse'"). Auvi-Q wasn't the only product that ESI excluded—in 2014, ESI changed its exclusions lists to cover only one product in 19 different therapeutic categories. Doc. 1661-19 at 12 (Sanofi white paper) (noting that ESI's new "exclusion categories result[ed] in 44 drugs immediately becoming not covered on formulary").

Not all of ESI's clients adopted the 2014 exclusion formulary. Doc. 1665-6 at 8 (ESI Auvi-Q Business Update). For employers "not adopting the Exclusion Formulary," non-preferred products, like Auvi-Q, remained covered on Tier 3. *Id.* at 4, 8. Sanofi estimated that Auvi-Q was excluded from about "35% of ESI commercial lives," meaning Auvi-Q remained covered for "2 out of 3 ESI commercial patients." *Id.* at 4.

Payor #2: CVS Caremark

CVS offers clients many formulary options. *See* Doc. 1660-4 at 15–16, 26 (Anderson (CVS) Dep. 99:1–100:24, 186:15–21) (explaining that "managed plans-2T" are CVS's 2-tier plans, where there "generally is not a copayment differential between preferred products and nonpreferred products[;]" "managed plans-3T" are 3-tier plans, which have a $0–$15 "co-payment differential" between the tiers; "highly managed plans" have three or more tiers and a $15 or more copay differential; and "closed plans" cover only "the products that are listed on the formulary"). In late 2012, CVS asked Mylan and Sanofi to complete the CVS "bid document" to

submit bids that would become effective July 1, 2013. Doc. 1662-3 at 2–8 (CVS/Mylan bid request); Doc. 1665-8 at 2–7 (CVS/Sanofi bid request). The bid request instructed the manufacturers: "**Incremental Rebates for Additional Controls (exclusion opportunities) may be used for custom clients in 2013/14, as well as future template exclusions effective January 1, 2014.**" Doc. 1662-3 at 3; Doc. 1665-8 at 2.

Both Mylan and Sanofi offered CVS a variety of rebates, and CVS memorialized the bids in agreements effective July 1, 2013. Doc. 1662-8 (Mylan/CVS Rebate Agreement); Doc. 1665-7 (Sanofi/CVS Rebate Agreement). Mylan offered a 7% rebate for Tier 2 co-preferred coverage, a 9% rebate for 1-of-1 Tier 2 coverage on managed plans, and a 14% rebate for 1-of-1 Tier 2 coverage on closed plans. Doc. 1662-8 at 19.[10] Sanofi offered a 10% rebate for 1-of-1 or 1-of-2 coverage on any tier.[11] Doc. 1665-7 at 22. On its national formulary, CVS covered both products from July 1, 2013, to July 1, 2014, placing EpiPen on Tier 2 and Auvi-Q on Tier 3. *See* Doc. 1660-4 at 17–21 (Anderson (CVS) Dep. 112:14–116:23).

Payor #3: OptumRx/UnitedHealthcare

OptumRx provides PBM services to UnitedHealthcare and other health plans. In February 2013, OptumRx asked Mylan to offer a 30% rebate for EpiPen in exchange for OptumRx making it the exclusive branded EAI product on UnitedHealthcare's formulary for the remainder of 2013 and for 2014. Doc. 1665-10 at 5 (Mylan/OptumRx email). Mylan initially didn't make that offer. Doc. 1665-11 at 2–3 (Mylan/EpiPen proposal for OptumRx). But, in April 2013, Mylan offered a 17% rebate conditioned on EpiPen being the exclusive branded EAI device on UnitedHealthcare's formulary. Doc. 1665-13 at 2 (Mylan/OptumRx Proposal).

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[10] These rebate percentages include a 4% administrative fee. Doc. 1662-8 at 21.

[11] These rebate percentages include a 3% administrative fee. Doc. 1665-7 at 31.

OptumRx rejected that bid, telling Mylan that, "if Mylan did not offer a better rebate for EpiPen, the product would be placed into a benefit exclusion." Doc. 1665-14 at 2 (Mylan email). Mylan understood that UnitedHealthcare would determine at its July formulary meeting "whether Auvi-Q or EpiPen will be the future sole epinephrine auto-injector covered under its benefits" and that, "[i]f Auvi-Q is selected, EpiPen will become excluded." *Id.* OptumRx told Mylan to submit a revised offer "by June 14th to meet deadline of July" formulary meeting. Doc. 1665-15 at 2 (Mylan/OptumRx email). Mylan knew that OptumRx previously had preferred another EAI device—Twinject—over EpiPen in the late 2000s after Twinject made a higher rebate offer. Doc. 1660-17 at 11, 12 (Etemad (UnitedHealthcare) Dep. 61:8–18, 70:4–10). And, previously, Mylan had contracted with OptumRx for "[e]xclusivity language in 2012 contract renewals." Doc. 1824-17 at 24 (Mylan presentation).

In Sanofi's negotiations with OptumRx, it offered rebates ranging from 2% to 7% for co-preferred status with EpiPen, but it didn't offer price protection or any rebate for unrestricted placement on the non-preferred formulary brand tier (Tier 3). Doc. 1665-16 at 2 (Sanofi/OptumRx email); Doc. 1665-17 at 4–5 (Sanofi/OptumRx Term Sheet). After OptumRx rejected Sanofi's earlier offers, it set a deadline of June 28, 2013 for Sanofi to submit a revised proposal. Doc. 1665-18 at 4 (Sanofi/OptumRx email).

Mylan submitted a revised bid to OptumRx on June 13, 2013. Doc. 1665-19 at 2 (Mylan/OptumRx proposal). It presented UnitedHealthcare with seven different rebate options conditioned on various formulary placements, ranging from 2% for co-preferred positioning to 22% for exclusive EAI formulary positioning, with 8% price protection for all formulary positions, and with all proposed rebates effective July 1, 2013. *Id.* at 2–4.

Sanofi submitted its revised bid on June 28, 2013. Doc. 1665-20 at 2 (Sanofi/OptumRx Term Sheet). Sanofi's rebate offer included progressive effective dates. *Id.* at 3. Sanofi offered a 7% rebate for coverage on any tier, effective August 1 through December 31, 2013. *Id.* Then, beginning January 1, 2014, through December 31, 2015, Sanofi offered a 22% rebate plus 9% resetting price protection in exchange for exclusive EAI formulary positions. *Id.* at 3–4.

OptumRx and UnitedHealthcare rejected Sanofi's June 28 offer. Doc. 1660-28 at 16–17 (Rogers (OptumRx) Dep. 330:17–331:15). OptumRx's corporate designee testified: "The Mylan offer [was] better for two reasons." *Id.* First, Mylan's double-digit rebates started earlier, and Sanofi's offer couldn't have started earlier because it wouldn't have been on the formulary. *Id.* Second, Sanofi's price protection offer reset each year, unlike Mylan's cumulative price protection. *Id.* Sanofi's offer also included 9% price protection while Mylan's 8% was a better offer and based on an earlier WAC price. *Id.* at 17 (Rogers (OptumRx) Dep. 331:16–21). OptumRx told Sanofi that its offer "is not close to what is needed." Doc. 1665-21 at 2 (Sanofi/OptumRx email).

On July 12, 2013, Sanofi submitted another revised offer to OptumRx. Doc. 1665-22 at 2, 4–5 (Sanofi/OptumRx email and Term Sheet). The revised offer wasn't as price competitive as Mylan's offer, and so, OptumRx rejected Sanofi's final revised offer. Doc. 1660-28 at 19–22 (Rogers (OptumRx) Dep. 335:20–338:4); Doc. 1665-24 at 2 (OptumRx/UnitedHealthcare email).

OptumRx and UnitedHealthcare memorialized Mylan's offers in a rebate agreement effective July 1, 2013. Doc. 1662-9 (Mylan/OptumRx Rebate Agreement). OptumRx and UnitedHealthcare didn't enter an agreement with Sanofi for Auvi-Q rebates. UnitedHealthcare excluded Auvi-Q from its formularies for about 60% of its commercial lives for the second half of 2013 through the first half of 2015. Doc. 1670-3 at 2 (Auvi-Q Business Update). And,

OptumRx restricted Auvi-Q with a step edit or prior authorization on its 2014 standard national formularies for external health plan clients. Doc. 1667 at 2 (Mylan email).

Payor #4: Prime Therapeutics ("Prime")

From 2013 to 2015, Prime recommended to its members—primarily Blue Cross Blue Shield plans—a national formulary they could use to base their own formulary decisions. Doc. 1660-20 at 6–8 (Hall (Prime) Dep. 21:10–23:11). When Auvi-Q launched into the EAI market, Mylan offered Prime two rebate options memorialized in a rebate agreement effective April 1, 2013, through December 31, 2015: 8% for Tier 2 co-preferred coverage, and 12% for placement as the exclusive branded product on Tier 2. Doc. 1662-5 at 8 (Mylan/Prime Rebate Agreement).

In early 2013, Prime asked Sanofi to submit rebate proposals for Auvi-Q, and repeatedly told Sanofi that certain Prime clients would consider placing a new product on Tier 2 only if a rebate proposal contained price protection. Doc. 1667-1 at 2 (Sanofi/Prime email); Doc. 1667-2 at 2–3 (Sanofi/Prime email); Doc. 1667-3 at 2 (Sanofi/Prime email). Sanofi's account executive told Prime that his internal request for price protection was "denied nationally due to the reduction of price for AuviQ, prior to launch, to be equal with EpiPen." Doc. 1667-1 at 2 (Sanofi/Prime email). Prime kept EpiPen on Tier 2 on its national commercial formulary in 2013, and it placed Auvi-Q on Tier 3. Doc. 1660-20 at 19–20 (Hall (Prime) Dep. 110:1–111:9).

In early 2014, Prime renegotiated its EpiPen rebate agreement with Mylan. Doc. 1667-5 (Mylan/Prime bid). Prime had been "push[ing] [Mylan] very hard for price protection." Doc. 1667-4 at 3 (Mylan email). So, Mylan offered Prime the same 8% rebate for Tier 2 co-preferred coverage and the same 12% rebate for Tier 2 exclusive coverage described above. Doc. 1667-5 at 2 (Mylan/Prime bid). But, it also offered a 17% rebate plus price protection if EpiPen was the

exclusive EAI device on Tier 2 with "[a]ll other auto-injectors listed tier 3 or higher with step therapy restriction." *Id.*

When negotiating with Prime, Mylan "encourage[ed]" Prime to restrict Auvi-Q's coverage on its formulary. *See* Doc. 1821-11 at 4 (Willing Dep. 73:4–75:3) (testifying that Mylan was "encouraging" Prime to restrict Auvi-Q though a step edit); *see also* Doc. 1821-45 at 2 (Mylan email) (discussing if Mylan could "work with" Prime and "encourage them to take on the [step edit] that was offered"). But ultimately, Prime chose not to recommend that its clients place a step edit on Auvi-Q. Instead, Prime asked Mylan to increase its rebate for exclusive Tier 2 placement. Doc. 1667-6 at 2–3 (Mylan email). Mylan responded by increasing its offer for exclusive Tier 2 coverage from 12% to 14%. Doc. 1667-7 at 7 (Mylan/Prime bid). The 8%, 14%, and 17% rebate options were memorialized in an amendment to Prime's rebate agreement with Mylan, effective April 1, 2014, through December 31, 2015. Doc. 1662-10 (Mylan/Prime Rebate Agreement).

Sanofi offered Prime a 17% rebate plus price protection for Tier 2 equal access. Doc. 1667-8 at 3 (Sanofi/Prime Term Sheet). Sanofi memorialized its offers to Prime in an agreement effective April 1, 2014, through December 31, 2015. Doc. 1662-11 (Sanofi/Prime Rebate Agreement). Sanofi didn't offer rebates for exclusive Tier 2 coverage. *Id.* Prime continued to list EpiPen as the exclusive EAI device on Tier 2 of its national formulary in 2014, with Auvi-Q on Tier 3 without restrictions. Doc. 1660-20 at 22–23 (Hall (Prime) Dep. 129:4–130:14); *see also* 1821-46 at 3 (Mylan email) (noting that Mylan "bumped up" its rebate offers and was "able to keep Auvi-Q non preferred"). But, during that time, Prime's clients continued to make independent determinations for their formularies—*e.g.*, from 2013 to 2015, Horizon Blue Cross Blue Shield of New Jersey covered both Auvi-Q and EpiPen on Tier 2 (co-preferred). *See* Doc.

1661-9 at 121 (Scott Morton Expert Report ¶ 204); Doc. 1660-23 at 6 (Jan (Horizon) Dep. 62:3–8).

Payor #5: MedImpact

With Auvi-Q's launch, MedImpact used the entry of a new EAI product as a "negotiation technique" designed to "create a perception" with both Mylan and Sanofi that "there is a very good possibility that [the other] product would be a formidable challenger to their product on our formularies" to induce them "to offer as large a rebate as possible" to MedImpact. Doc. 1660-5 at 15–16 (Ayers (MedImpact) Dep. 150:2–151:14). Before Auvi-Q's launch, Mylan was paying MedImpact a 5% rebate on EpiPen conditioned on Tier 2 formulary coverage. Doc. 1667-9 at 5 (Mylan/MedImpact Rebate Agreement). In early 2013, Mylan offered MedImpact a 10% rebate conditioned on EpiPen being the only branded EAI device on Tier 2 with all other branded EAI devices on the highest copay tier. Doc. 1667-10 at 3 (Mylan email). MedImpact responded by asking Mylan to submit a better offer, and specifically, asked for a rebate offer conditioned on MedImpact putting a step edit on Auvi-Q. *Id.* Mylan's account representative reported that MedImpact "wanted to know if [Mylan] would raise [its] rebate level if [MedImpact] decided to do a step edit in the class." *Id.* In a list of talking points for an upcoming meeting with MedImpact, Mylan's Director of National Accounts noted that "Mylan will terminate its current contract if Medimpact implements a step edit against EpiPen" and expressed that Mylan didn't "intend to allow Medimpact to cherry pick [its] contract and get access rebate only in the membership that is not controlled." Doc. 1822-6 at 3 (Mylan email).

MedImpact also solicited a "1 of 1 offer" from Sanofi. Doc. 1667-12 at 2 (Sanofi/MedImpact email). MedImpact told Sanofi that it "wishes to have only one product in the category" and that "[a]ll other products" would be "Not Covered or T3 PA/Step Edit" on

MedImpact's controlled and closed plans. Doc. 1667-11 at 3 (Sanofi email). Sanofi responded by offering MedImpact several rebate options, including 4% for exclusive preferred coverage on the closed formulary. Doc. 1667-13 (Sanofi/MedImpact Term Sheet). MedImpact rejected Sanofi's offer as "not competitive" and invited Sanofi to submit a revised offer. Doc. 1667-14 at 3 (Sanofi/MedImpact email).

Both Mylan and Sanofi submitted revised bids in March 2013. They included a menu of rebates, including higher rebates conditioned on step edits against competing EAI devices. Doc. 1667-15 at 2 (Sanofi/MedImpact email); Doc. 1667-16 at 2–3 (Mylan/MedImpact bid). Among other offers, Sanofi offered MedImpact a 15% rebate for 1-of-1 coverage on a closed formulary. Doc. 1667-15 at 2 (Sanofi/MedImpact email). Mylan offered MedImpact a 13% rebate for exclusive formulary position for EpiPen on Tier 2 (or better) and, for all other EAI devices, placement on the highest copay tier (Tier 3 or higher) and with a step edit. Doc. 1667-16 at 3 (Mylan/MedImpact bid).

In late April 2013, MedImpact informed Mylan that it was going to "go with Auvi-Q." Doc. 1667-17 at 2 (MedImpact email). In response, Mylan responded with a final offer that included: a 5% rebate for unrestricted placement on Tier 2; a 10% rebate for exclusive preferred brand placement; a 20% rebate for exclusive preferred brand placement, with all other branded EAI products "placed on the highest copay tier" and subject to step edit; and a 22% rebate to be the exclusive product in the lowest preferred branded tier, with all other EAI products (branded or generic) "placed on the highest copay tier" and subject to step edit. Doc. 1667-18 at 4–6 (Mylan/MedImpact Proposal). Mylan and MedImpact memorialized this final offer, with four EpiPen rebate options, in a rebate agreement effective July 1, 2013, through December 31, 2015.

Doc. 1662-6 (Mylan/MedImpact Rebate Agreement); *see also* Doc. 1667-19 (Mylan/MedImpact Rebate Agreement) (entered Jan. 1, 2014 with the same terms).

In May 2013, MedImpact told Mylan and Sanofi that it had selected EpiPen as the exclusive EAI device on the preferred tier, and Auvi-Q would be "in a [Non-Formulary] position with a [step edit]." Doc. 1667-21 at 3 (Sanofi/MedImpact email); Doc. 1667-20 at 3 (Mylan/MedImpact email). MedImpact concluded that EpiPen had "a better price, net of rebate," with EpiPen costing $113/device compared to Auvi-Q's $145/device. Doc. 1667-22 at 19 (May 10, 2013 MedImpact Formulary Committee Minutes). MedImpact also reported to Sanofi that it had reached "the decision to stick with EpiPen" "[b]ased on the analysis of the offers from both companies, the potential for disruption, [and] observation of market adoption rates . . . ." Doc. 1667-21 at 2 (Sanofi/MedImpact email). Sanofi asked if it could submit another offer. Doc. 1667-23 at 2 (Sanofi/MedImpact email). MedImpact initially declined. *Id.* But between mid-September and early October 2013, Sanofi negotiated with MedImpact to provide higher rebates for MedImpact's custom clients who covered Auvi-Q. Doc. 1667-24 at 2 (Sanofi email); Doc. 1668 at 2–3 (Sanofi/MedImpact email); Doc. 1668-1 (Sanofi/MedImpact email). Sanofi offered MedImpact rebates ranging from 5% to 20% for various unrestricted coverage options. Doc. 1668-2 at 6 (Sanofi/MedImpact Rebate Agreement). MedImpact agreed to the offer which the parties memorialized in an agreement effective December 31, 2013, running through December 31, 2015. *Id.* at 2.

Although EpiPen retained an exclusive Tier 2 position with a step edit placed on Auvi-Q on MedImpact's three standard commercial formularies, custom clients remained eligible for rebates from Sanofi if they covered Auvi-Q. Doc. 1668-3 at 2–4 (Sanofi email). For example, MedImpact's client, the University of Michigan, added Auvi-Q to its formulary in a Tier 2

position. Doc. 1668-4 at 2 (Sanofi email). Also, on open plans—about 15% of MedImpact's clients—Auvi-Q had equal preferred positioning with EpiPen. Doc. 1668-3 at 2–4 (Sanofi email).

Payor #6: Aetna

On May 21, 2013, Aetna created an "Initiative Feasibility Summary" that addressed a "[r]evenue opportunity by placing [prior authorization or step edit] on Auvi-Q." Doc. 1663-12 at 2 (Aetna Initiative Feasibility Summary). The "Initiative Feasibility Summary also recognized a "[c]hallenge[ ]" of the initiative was that "[p]atients will need to try and fail preferred products before stepping to non-preferred" and a "[r]isk[ ]" was "[m]ember and provider dissatisfaction[.]" *Id.* at 3. Later that month, Mylan offered Aetna a 15% rebate plus price protection conditioned on Tier 2 formulary placement for EpiPen on Aetna's national formulary in 2014 and Tier 3 formulary placement for Auvi-Q with a step edit. Doc. 1668-5 at 2 (Mylan email). Mylan and Aetna memorialized Mylan's rebate offers in an amendment to Mylan's rebate agreement with Aetna, effective January 1, 2014, through December 31, 2015. Doc. 1662-17 at 2–4 (Mylan/Aetna Rebate Agreement).

Aetna also negotiated with Sanofi, but Aetna only agreed to Sanofi's offer for a 25% rebate for exclusive Tier 2 coverage on Aetna's Qualified Health Plans in 2014. Doc. 1668-7 at 8 (Sanofi/Aetna Rebate Agreement). In August 2013, Aetna announced that it would place a step edit on Auvi-Q on its national formulary in 2014. Doc. 1668-8 at 2 (Sanofi email). In March 2014, Aetna offered to remove the restriction on Auvi-Q beginning June 1, 2014, in exchange for Sanofi offering a 30% to 40% rebate for unrestricted Tier 3 access. Doc. 1668-9 at 2 (Sanofi email). Sanofi's corporate representative designated to testify on the topic of Auvi-Q rebates explained that Sanofi was "not willing to" offer Aetna's proposed rebates, and so,

Aetna's restriction on Auvi-Q stayed in place for the rest of 2014. Doc. 1660-14 at 11–12 (Denney Dep. 125:15–126:17).

Payor #7: Cigna

Before Auvi-Q's launch, Cigna asked Mylan to provide a rebate offer for "exclusive epinephrine positioning." Doc. 1662 at 2 (Mylan/Cigna email). Mylan responded with a 10% rebate offer conditioned on EpiPen being the sole preferred brand. Doc. 1668-10 at 8 (Mylan/Cigna email). Cigna responded by asking whether there was any "further opportunity (above 10%) for any lines of business where we are able to implement NDC [b]locks and/or Step therapy on competing products?" *Id.* In June 2013, Mylan offered Cigna a 13% rebate for placement as the sole preferred EAI with all other EAIs "branded or generic . . . placed on the highest copay tier of such Plan (i.e. Tier 3 or higher) and subject to a step therapy edit." Doc. 1668-10 at 18–19 (Mylan/Cigna Proposal). Cigna didn't accept Mylan's offer for sole preferred placement, but instead, Cigna signed a contract with Mylan for a 7% rebate for EpiPen, conditioned only on co-preferred coverage. Doc. 1668-11 at 4 (Mylan/Cigna Rebate Agreement).

At the same time, Sanofi offered Cigna a 12% rebate for placement as a co-preferred EAI through December 2013, and a 15% rebate for placement as a co-preferred EAI from January 2014 through December 2015. Doc. 1668-12 at 3 (Sanofi/Cigna Term Sheet). Cigna didn't accept the proposal, and Auvi-Q remained on the formulary as non-preferred, without a rebate agreement. Doc. 1668-14 (Auvi-Q presentation). Sanofi then offered Cigna a 35% rebate for co-preferred formulary placement or a 20% rebate for Tier 3 access. Doc. 1668-15 at 2 (Sanofi email). Cigna again declined the offer, and Auvi-Q remained on Tier 3 with no rebate agreement through 2014. Doc. 1668-16 at 20 (Sanofi presentation) (noting that "rebates not required at

some key accounts (Cigna, Catamaran)"). In 2015, though, Sanofi and Cigna entered a Rebate Agreement that included a 20% rebate for Auvi-Q as a non-preferred brand. Doc. 1824-28 at 32 (Sanofi/Cigna Rebate Agreement).

Other PBMs and Health Plans

Like the payors described above, other payors made decisions about their formulary coverage for Auvi-Q in 2014. In negotiations with these other payors, Mylan asked some of them to exclude Auvi-Q. *See, e.g.*, Doc. 1822 at 2 (Mylan email) (offering to give Humana a higher rebate for blocking competitors); Doc. 1822-1 at 4 (Mylan email) (asking Humana for an exclusive agreement for EpiPen); Doc. 1822-5 at 2 (Mylan email) (explaining that Kaiser Permanente contract terms "were carefully negotiated to ensure Auvi-Q was non-formulary").

In the end, some payors covered both Auvi-Q and EpiPen on the preferred brand tier. *See* Doc. 1668-17 at 2 (Sanofi email) (noting that Blue Shield of California covered EpiPen and Auvi-Q as co-preferred). Some payors covered EpiPen on the preferred tier, and Auvi-Q as non-preferred. *See* Doc. 1668-18 at 2–3 (Sanofi email) (noting that Humana had placed Auvi-Q on Tier 3 without restrictions). Other payors covered Auvi-Q on the preferred tier and EpiPen as non-preferred. *See* Doc. 1668-20 at 2 (Sanofi email noting that, as of March 1, 2014, Auvi-Q was the exclusive EAI on the Presbyterian Health Plan formulary).[12] And other payors covered EpiPen as the preferred brand and placed a restriction on Auvi-Q. *See, e.g.*, Doc. 1668-23 at 2 (Auvi-Q Business Update) (noting that WellPoint/Anthem had placed EpiPen at Tier 2 and Auvi-Q at Tier 3 with prior authorization); Doc. 1663-1 at 18 (Sanofi presentation) (noting Coventry had placed Auvi-Q on Tier 3 with a prior authorization). Some payors chose to cover only one

[12] Sanofi offered more competitive rebates to Presbyterian than Mylan. *Compare* Doc. 1668-21 at 2 (Sanofi/Presbyterian Term Sheet showing that Sanofi offered a 25% rebate for preferred formulary placement) *with* Doc. 1668-22 at 2 (Mylan/Presbyterian Proposal showing Mylan offered a 15.5% rebate for preferred formulary placement).

device and selected EpiPen. Doc. 1661-1 at 10–12 (Shia (Kaiser Permanente) Dep. 106:11–108:12) (testifying that Kaiser Permanente chose Mylan's offer for EpiPen because it had the "better price"). And, at least one payor restricted EpiPen in favor of Auvi-Q. Doc. 1670-4 at 2–3 (Sanofi email) (announcing that Geisinger Health Plan was making Auvi-Q its sole, preferred EAI on its commercial formularies with EpiPen either at Tier 3 or subject to a prior authorization).

Effects of Formulary Coverage

Often, prescribers consider the cost of an EAI device when prescribing treatment to a patient. *See* Doc. 1815-6 at 22 (Blaiss Expert Report ¶ 6.3) (explaining that when prescribing an EAI device to a patient "much of the discussion is on cost and if one device is substantially different in coverage and out of pocket cost, that tends to be the device that is prescribed"). Generally, prescribers will write prescriptions based on the products they know that are available to all of their patients. Doc. 1821-18 at 86 (Scott Morton Expert Report ¶ 135). But, patients usually are insured by many different plans, which poses a "challenge" for prescribers when determining which formulary options are available for each patient when prescribing an EAI device. *Id.* Often, prescribers tend to default to the product that they know is most widely available in the region. *Id.* So, for example, if one or more large plans in a region has excluded Auvi-Q, the prescribers tend to prescribe EpiPen to patients in the region, even if the health plans for those patients provide equal or even preferred access to Auvi-Q or other EAI devices. *Id.* Sanofi's expert refers to this consequence as a "spillover effect." *Id.*

Mylan recognized that EpiPen would enjoy this "spillover effect" from its exclusive offers to payors who blocked access to Auvi-Q. *See, e.g.*, Doc. 1822-7 at 2 (Mylan email) (noting that Mylan's offer to OptumRx making EpiPen the exclusive EAI "will have a really

strong benefit for us at United as well as spillover"); Doc. 1822-8 at 2 (Mylan email) (recognizing that "both the United and ESI advantages for EpiPen as the exclusive product on formulary will have positive impact and spillover effect on the perception of coverage for other and all plans" (internal parenthesis omitted)); Doc. 1822-9 at 2 (Mylan email) (listing points to discuss with sales representatives including "[u]nderstanding the 'spill over' effect. If territories have [five] plans where we are preferred and [one] where we are equal, [the sales people] need to emphasize the preferred plans and let customers know").

Also, Mylan encouraged its sales people to leverage EpiPen's exclusive formulary coverage by discussing formulary access with health care providers and suggesting that they should prescribe EpiPen because patients' health care plans are more likely to cover that EAI device. *See, e.g.*, Doc. 1822-12 at 3 (Mylan email) ("The direction I've been giving to my area has been to leverage these positions and speak to those physicians who are heavy EpiPen writers to try to drive home the message that AuviQ will be a difficult product for their patients to obtain. While these opportunities may be short lived I agree that they can have a great impact in affecting a physician[']s prescribing habits especially if they start to see a few denials initially."); Doc. 1822-14 at 2 (Mylan email) (encouraging sales people to "leverage EpiPen's superior formulary coverage, and put Sanofi out of business!"); Doc. 1822-15 at 15 (Mylan presentation) (noting it was "[c]ritical" for sales representatives to "highlight the gap in [EpiPen vs. Auvi-Q] coverage & **quantify** what it means to the physician and their staff" when their "patients will experience an issue with Auvi-Q's formulary coverage"); Doc. 1822-18 at 2 (Mylan email) (emphasizing to "make sure" to communicate to sales teams "the importance of leveraging [EpiPen's] preferred coverage compared to Auvi-Q" and noting that the author's team "will continue to communicate the formulary status with the field" and "will continue to make

formulary sell sheets to emphasize [Mylan's] positioning"); Doc. 1822-19 at 2 (Mylan email) (attaching "physician list for the states that have a large amount of" patients covered by plans that exclude Auvi-Q and noting, "[t]his is just another opportunity to sell [the EpiPen] product, and show that patients will not be able to access our competitor like they can EpiPen").

Mylan marketed to physicians that EpiPen was "preferred" on many health plans while Auvi-Q was restricted. Doc. 1822-27 at 3 (EpiPen marketing material). 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 with their customers." Doc. 1822-9 at 2 (Mylan email). 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. 1822-28 at 3 (Graham Dep. 178:13–179:21).

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. 1822-30 (Study and Mylan presentation) (emphasis added). But, the FDA concluded that the epinephrine in Auvi-Q—itself—"demonstrated bioequivalence" with the epinephrine in EpiPen. Doc. 1816-32 at 6 ("The [pharmacokinetics] trial . . . demonstrated bioequivalence . . . ."). And, Mylan's experts agree that the two products are bioequivalent. Doc. 1821-4 at 4 (Blaiss Dep. 197:14–25) (testifying that he prescribed both Auvi-Q and EpiPen to patients and that he didn't "think that one was superior to the other"); *id.* at 5 (Blaiss Dep. 214:1–10) (testifying that EpiPen and Auvi-Q "have equal clinical effectiveness" and "equal

safety"); Doc. 1821-3 at 3 (Zieziula Dep. 26:13–20) (testifying that "both products have the same amount of epinephrine and [are] deemed bioequivalent by the FDA").

Sanofi's 2015 Formulary Coverage

In 2015, Sanofi "changed [its] contracting strategy" and "made deeper offers" to payors to gain formulary access. Doc. 1660-14 at 5–7 (Denney Dep. 107:12–109:9). Sanofi's former CEO Chris Viehbacher testified that, after seeing the "very aggressive approach on pricing to try to exclude Auvi-Q[,]" "it became clear [to Sanofi] that there was no choice but to try to gain an access to the marketplace by significantly discounting." Doc. 1661-4 at 14–15 (Viehbacher Dep. 121:18–122:10). So, in early 2014, Mr. Viehbacher proposed "mak[ing] an offer that kicks [Mylan] off a formulary. If Mylan knows we can be aggressive it may help." Doc. 1670-6 at 2 (Sanofi email). Sanofi's change in "contracting strategy" had an "impact[ ] [on its] profitability" but it helped Sanofi to "resecure the ESI business starting in [20]15" and secured a "tier two parity agreement for 2015" with Aetna. Doc. 1660-14 at 6–7 (Denney Dep. 108:14–109:1). "So those deeper offers started to pull [Sanofi's] access back." *Id.*

First, Sanofi was able to reverse its exclusion from ESI's national formulary. Doc. 1670-12 at 2–3 (Sanofi email). It did so by giving approval to its Auvi-Q team to make more enhanced offers to secure Auvi-Q's formulary status with ESI. Doc. 1670-9 at 3 (Sanofi US Business Review). For the first time, Sanofi offered ESI price protection. Doc. 1670-10 at 3 (Sanofi/ESI Rebate Matrix). Also, Sanofi made a "portfolio contract" offer for Auvi-Q that provided for a 2% rebate on Lantus—in addition to the contracted-for Lantus rebate—if Auvi-Q was removed from the exclusion list. Doc. 1670-7 at 2 (Sanofi email); Doc. 1670-11 at 2 (ESI email). Lantus is Sanofi's market-leading insulin drug which, in 2013–2014, had "[s]omewhere around $4 billion in sales" in the U.S.—a "formidable" volume unmatched by any Mylan

product. Doc. 1661-4 at 18–21 (Viehbacher Dep. 130:18–133:4). Initially, ESI decided to "[r]everse exclusion and exclude EpiPen and prefer Auvi-Q." Doc. 1670-11 at 2 (ESI email). But after more analysis, ESI concluded that it could "decrease the cost per rx significantly" for both EpiPen and Auvi-Q "without excluding." Doc. 1665-3 at 2 (ESI email). So, ESI decided to cover both products on its national formularies but exclude EpiPen on its High Performance formulary in favor of Auvi-Q. Doc. 1670-11 at 2 (ESI email) ("No exclusion for the category results in gain of 400k per quarter (1.6 million per year) over reversing exclusion"); Doc. 1670-12 at 3 (Sanofi email) ("Auvi-Q will be the exclusive Epinephrine AI on the High Performance formulary."). About these negotiations and new coverage decisions, ESI's corporate designee testified that ESI "did our job there" and "lowered the overall net cost for [its] plans, and in many cases, for members, depending on what their specific benefit design would have been." Doc. 1660-24 at 23–24 (Kautzner (ESI) Dep. 82:3–83:10).

Next, Sanofi offered Aetna a 65% rebate, with price protection, conditioned on Aetna listing Auvi-Q as the exclusive EAI on its formulary for 2015. Doc. 1670-13 at 2 (Sanofi Recommendation for Aetna Contract Offer). In response, Aetna developed a 2015 formulary design that would (1) make Auvi-Q the exclusive preferred product on its value formularies and (2) make Auvi-Q and EpiPen co-preferred on its premier formularies. Doc. 1670-14 at 6 (Aetna P&T Committee Minutes). Aetna then used the Sanofi offer as leverage to threaten Mylan with EpiPen exclusion. Doc. 1670-15 at 2 (Mylan email). By doing so, Aetna was able to convince Mylan to pay a 45% rebate plus 10% price protection for EpiPen to be co-preferred on T2. *Id.* at 5 (Mylan emails); Doc. 1670-16 at 3 (Mylan/Aetna Rebate Agreement). Sanofi ultimately agreed to pay Aetna a 30% rebate plus 12% price protection for Auvi-Q to be co-preferred on Tier 2 (*i.e.*, a lower rebate than Mylan for the same access). Doc. 1670-17 at 7 (Sanofi/Aetna

Rebate Agreement). Effective January 1, 2015, Aetna made EpiPen and Auvi-Q co-preferred on its value and premier formularies. Doc. 1670-19 at 2 (Mylan email).

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, plus 10% price protection.[13] Doc. 1670-20 at 19–20 (Sanofi/CVS Rebate Matrix). Sanofi and CVS memorialized these offers in a rebate agreement effective July 1, 2014, through December 31, 2015. Doc. 1670-21 at 10, 23 (Sanofi/CVS Rebate Agreement). With this offer, Sanofi secured co-preferred Tier 2 formulary coverage for Auvi-Q on CVS's Preferred Drug List, and also Auvi-Q 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. 1670-22 at 2 (Mylan/CVS email). CVS also leveraged Sanofi's offer to encourage Mylan to offer increased rebates to avoid exclusion of EpiPen on its Preferred Drug List. Doc. 1670-23 at 3 (Mylan email); Doc. 1670-24 at 8 (Mylan presentation); Doc. 1671 (Mylan/CVS Rebate Agreement). After CVS already had excluded EpiPen from its smaller formularies in 2014, CVS used the threat of excluding EpiPen from its Preferred Drug List to extract further price concessions from Mylan for EpiPen in 2015. Doc. 1661-7 at 8, 10–11 (Willing Dep. 317:10–20, 322:11–323:8). Mylan agreed to a 34% rebate for 1 of 1 status on closed plans as well as an additional 5% incremental base rebate "on all Plan types[,]" "if Auvi-Q is excluded."[14] Doc. 1822-4 at 22 (Mylan/CVS Rebate Agreement). And, even though Mylan tried to reverse CVS's exclusion of EpiPen from CVS's Value and Advanced Control formularies, *see, e.g.*, Doc. 1671-2 at 2–3 (Mylan emails), Doc. 1671-3 at 3–4

[13] These rebate percentages include a 4% administrative fee. Doc. 1670-20 at 20.

[14] As explained above, CVS never excluded Auvi-Q, despite Mylan's offer to pay a 5% incremental rebate for excluding Auvi-Q.

(Mylan/CVS Proposal), CVS continued to exclude EpiPen from those formularies until early November 2015—after Auvi-Q was recalled from the market, *see* Doc. 1671-4 at 2 (Mylan/CVS email).

Finally, in 2015, Sanofi maintained the coverage it previously had secured at Prime and Cigna, among others. Doc. 1671-5 at 7 (Sanofi presentation) (listing "Great Recent Auvi-Q Decisions" and exclaiming: "Thanks for Your Tremendous Efforts to Recapture and Secure Access!!").

But, Sanofi didn't succeed in securing coverage with all payors in 2015. For example, UnitedHealthcare sought to renegotiate with Sanofi, expressly requesting an offer for exclusive formulary coverage and telling Sanofi its target rebate was 60% plus 6% cumulative price protection with a base date of December 1, 2014. Doc. 1671-6 at 3 (UnitedHealthcare email). Sanofi declined to make an exclusive offer, offering instead a lower rebate—35% rebate plus 8% price protection with a WAC price base date of January 1, 2015—for coverage on any tier. Doc. 1671-7 at 5 (Sanofi/OptumRx (UnitedHealthcare) Term Sheet). In contrast, Mylan offered a higher rebate (37% plus 8% price protection) for exclusive coverage, and maintained its position as the exclusive EAI on the formulary. Doc. 1671-8 at 10 (Mylan/OptumRx (UnitedHealthcare) Rebate Agreement).

As another example, in March 2014, Sanofi asked MedImpact what rebate it should offer to secure removal of the step-edit on Auvi-Q. Doc. 1671-9 at 3 (Sanofi/MedImpact email). In response, MedImpact told Sanofi that it "would need to offer a discount in the upper 30s to low 40s with Price Protection to even open the conversation." *Id.* at 2. MedImpact also recognized "[i]t would be very difficult for Sanofi to neutralize th[e] savings advantage [from Mylan's exclusive rebate offer] given the current share [of Auvi-Q]." *Id.* After internal discussion,

Sanofi declined to offer MedImpact's requested discount. Doc. 1671-10 at 2 (Sanofi emails); Doc. 1671-11 at 2 (MedImpact email).

Payors also approached Mylan with requests for deeper discounts, using competition in the EAI market as a leverage. For example, after Sanofi had increased its rebate offer to Prime in late 2014, *see* Doc. 1671-12 at 5 (Sanofi/Prime Rebate Agreement), Prime told Mylan in July 2015 that "Sanofi is aggressively selling in the market," "that we are starting to see some share shift in certain areas," and that "there has been some discussions around a possible move to an equal status due to this shift and the possible upcoming generic entry[,]" Doc. 1671-13 at 2 (Prime/Mylan email). Prime reminded Mylan that it was seeking "overall enhancements on terms and on price protection" because "Mylan [had] taken several increases from 2008 forward (over 350% in [the author's] time at Prime) and Prime's expectation is to see incremental in the rebate and more competitive price protection to provide some cost sharing with our plans rather than resetting price protection which is essentially a delayed price increase." *Id.* Prime asked that Mylan "take the items discussed into consideration and please provide your most competitive offer to Prime." *Id.* at 3. In response, Mylan offered better price protection to Prime. Doc. 1671-14 at 5–7 (Mylan/Prime Proposal); Doc. 1671-15 at 5 (Mylan/Prime Rebate Agreement).

In April 2015, after seeing that Auvi-Q had regained "80% commercial market access overall," *see* Doc. 1671-16 at 17 (Sanofi presentation), Sanofi's newly appointed CEO, Dr. Olivier Brandicourt, asked the U.S. team to prepare an "upside proposal for Auvi-Q, to drive profitable growth[,]" Doc. 1671-17 at 2 (Sanofi email). Sanofi "increased [its] investment in [the] brand," Doc. 1660-22 at 9 (Harr Dep. 314:11–21), including by developing and approving a plan providing for substantial increases to the Auvi-Q budget, Doc. 1671-18 at 2–3 (Sanofi

email). With the changes in its contracting strategy, Sanofi began to see Auvi-Q's market share increase starting in 2015. Doc. 1671-19 at 7 (Sanofi presentation).

Market Share

Several payors testified that they could have excluded EpiPen in favor of Auvi-Q because they could shift product use from EpiPen to Auvi-Q. *See, e.g.*, Doc. 1660-25 at 21 (Kronberg (Cigna) Dep. 149:10–14) (agreeing that Cigna "could have moved market share from EpiPen to Auvi-Q"); Doc. 1660-17 at 18 (Etemad (UnitedHealthcare) Dep. 115:21–23) (testifying that it "was [ ] a possibility to exclude EpiPen"); Doc. 1671-20 at 2 (MedImpact email) (estimating that, if MedImpact applied step therapy to either EpiPen or Auvi-Q, the preferred product "should" achieve 75 percent market share "right away"); Doc. 1670-13 at 3 (Sanofi/Aetna Contract Offer) (noting that "Aetna believes Auvi-Q would see an 80% shift of utilization from Epi-Pen in Yr 1"); Doc. 1661-1 at 13–14 (Shia (Kaiser Permanente) Dep. 260:6–261:13) (testifying that Kaiser Permanente is "known for moving [market share from] product A to B" "in a very short time frame" "when everything is equivalent" and that "it would not be difficult" to move from one branded EAI device to another).

ESI has used its drug exclusions list to exclude many popular products with high market shares, including GlaxoSmithKline's leading asthma medication (Advair) and Gilead's leading Hepatitis C treatment (Sovaldi). Doc. 1660-24 at 40–42 (Kautzner (ESI) Dep. 191:21–193:13). Sanofi even recognized that ESI had "commented that they are not concerned about including a market leader as an excluded product." Doc. 1661-19 at 12 (Sanofi white paper). And, Sanofi's market access and payor research consultant agreed that PBMs are "able to transition market share from the product that has been excluded to the new product" and that payors were "willing

to remove market leaders . . . in certain circumstances." Doc. 1660-12 at 4–6 (Byrne Dep. 67:19–68:3, 267:7–10).

With the EAI drugs at issue in this case, patients shifted to Auvi-Q when two payors excluded EpiPen. *First*, CVS excluded EpiPen in 2014 from its Advanced Control Formulary ("ACF") and told Mylan in 2015 that its market share on that formulary was "all but gone." Doc. 1671-1 at 3 (Mylan/CVS email). But, CVS also had excluded EpiPen from its Value Based Formulary ("VBF") beginning July 1, 2014, and reported that the VBF was "still holding share[.]" *Id.* Still, CVS also told Mylan it "view[ed] the ACF as a trial balloon of sorts" and that there had "been no noise or complaints or issues with ACF . . . which would indicate not a big deal excluding [E]pipen." *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." Doc. 1671-21 at 11 (Mylan presentation). So, Mylan developed an enhanced rebate offer to "[r]everse the [e]xclusion." *Id.* at 12. CVS projected that if it excluded EpiPen in favor of Auvi-Q on its national template formulary, EpiPen's share would drop from 66% to 7%, with Auvi-Q's share increasing from 10% to 75%. Doc. 1671-22 at 3 (CVS analysis).

Second, ESI's corporate representative testified that market share "is one of the factors that [ESI] would evaluate" in making the decision whether to exclude a drug, but explained "that manufacturers have to know sometimes that you're actually going to go through with exclusions, and so this was an instance where the value [offered by Auvi-Q for exclusion on ESI's High Performance Formulary] was large enough that we were prepared to do that." Doc. 1660-24 at 48–49 (Kautzner (ESI) Dep. 237:20–238:14). When ESI eventually excluded EpiPen from its High Performance Formulary, EpiPen's share for plans that adopted the exclusion list (*i.e.*, plans

with a closed formulary structure) "dropped from an average of 94% in the end of 2014, to about 12% by June 2015." Doc. 1661-13 at 83 (Willig Expert Report ¶ 204). When Sanofi crafted its 2015 commercial bid for ESI, it also assumed this shift in market share would occur. Doc. 1671-23 at 10 (Sanofi white paper) (analyzing data when "Auvi-Q Preferred on Exclusions List @ 65%" and estimating an 89% market share for Auvi-Q). Sanofi predicted that excluding EpiPen in favor of Auvi-Q would achieve 89% market share for Auvi-Q on plans adopting the exclusion list. *Id.* (Sanofi white paper) (estimating an 89% market share for Auvi-Q).

Effect of Rebate Negotiations

From 2008 through 2015, the total output of EAI devices increased in the U.S. Doc. 1661-10 at 24–25 (Scott Morton Expert Reply Report ¶ 40). EpiPen's average net price rose from 2013 through 2014. Doc. 1661-9 at 60 (Scott Morton Expert Report Fig. 8). Then, at the beginning of 2015, EpiPen's average net price fell somewhat. *Id.* But, through the remainder of 2015, EpiPen's average net price again increased. *Id.* At least one PBM testified that its rebate negotiations in the EAI market were "highly effective in making this a very competitive class" which brought "the rates down, lowering that cost, both for [its] plans and ultimately for many members." Doc. 1660-24 at 30–31 [redacted].

EpiPen4Schools® Program

In 2012, Mylan launched its EpiPen4Schools® program. Doc. 1660-18 at 10–11 (Graham Dep. 128:1–129:9). This program has donated more than 1,000,000 free EpiPens to schools. *Id.* Mylan's program offered four free EpiPens to schools, and also offered a discount for schools who wanted more than the four free EpiPens. Doc. 1672-1 at 3–6 (EpiPen4Schools® program Certification Forms). Mylan recognized that this program allowed it to "hav[e] EpiPens in schools prior to a competitive launch [which] would be a huge advantage for [Mylan] because

many parents would prefer to send their kids to school with an epinephrine injector that the teachers are trained on." Doc. 1822-32 at 3 (Mylan email). And, Mylan viewed the EpiPen4Schools® program "as pivotal in support of EpiPen access, visibility, brand equity and market-share retention." Doc. 1822-33 at 22 (Mylan presentation); *see id.* (also recognizing "significant down-side risk to program discontinuation, e.g. substitution opportunity for Auvi-Q . . . .").

Mylan's EpiPen4Schools® program offered two discount levels: (1) a discount with no conditions on purchasing competing products, and (2) a greater discount if the school certified it would purchase only EpiPen products and purchase no competing products for twelve months. Doc. 1672-1 at 5–6; *see also* Doc. 1822-36 at 5 (requiring school to certify that "[i]t will not in the next twelve (12) months purchase any products that are competitive products" to EpiPen). So, if any school purchased Auvi-Q or a competing EAI device other than the EpiPen, it would not qualify for the discounted price under the EpiPen4Schools® program. Doc. 1821-21 at 4 (Graham Dep. 119:12–120:21).

Around June 2016, Mylan eliminated the certification requirement for the deeper discounts. Doc. 1660-18 at 15 (Graham Dep. 339:11–19). As of September 2016, Mylan had sold about 45,000 EpiPens to schools through the discount program (both levels combined). Doc. 1672-2 at 2 (Mylan email). Sanofi never implemented a program to donate Auvi-Q devices to schools. Doc. 1660-18 at 10 (Graham Dep. 128:17–21). Mylan's market research showed that the EpiPen4Schools® program successfully prevented Auvi-Q from gaining market share. *See* Doc. 1822-38 at 3 (Mylan/Meridian Joint Commercial Committee Minutes) (noting a "[s]tatistically significant impact on Auvi-Q share (lower Auvi-Q market share in Zip3's that opted in to the program[)]").

Auvi-Q's Predicted Performance in the EAI Market

Before Auvi-Q's launch, both Mylan and Sanofi forecasted that Auvi-Q would gain market share of 30% or more. *See, e.g.*, Doc. 1823-4 at 3 (2010 Mylan document predicting 30% market share for Auvi-Q two years after launch and 40% market share four years after launch); Doc. 1821-32 at 4 (2011 Mylan presentation predicting that Auvi-Q would have a 30% market share by 2015); Doc. 1823-5 at 8 (2012 Sanofi forecast predicting 34.9% market share by 2015 and 40.2% by 2016). Sanofi's expert opines that, in Canada, where Auvi-Q had equal access to EpiPen, Auvi-Q achieved at least a 30% market share three years after launch. Doc. 1821-18 at 119–124 (Scott Morton Expert Report ¶¶ 202–206). Sanofi expected that Auvi-Q would prove to be a "long-term growth driver" for the company. *See* Doc. 1823-10 at 5 (Sanofi presentation) ("Long term: Demonstrate continued strong YoY growth to solidify Auvi-Q as a long-term growth driver with 2029 LoE"); *see also* Doc. 1823-9 at 3 (2009 Sanofi summary of Auvi-Q license project) (listing one of the benefits of Auvi-Q as "[n]ear-term product opportunity with sustainable, long-term growth").

In 2014, Sanofi noted that when it agreed to license Auvi-Q in 2009, neither Sanofi nor kaléo "anticipated the managed care response or the aggressive tactics that Mylan would employ." Doc. 1823-17 at 6 (Nov. 2014 Sanofi presentation); *see also* Doc. 1823-9 at 3 (2009 Sanofi summary of Auvi-Q license project) (assuming Auvi-Q would have "Strong Formulary access"). But, by 2014, Sanofi was proposing several options for improving the profitability of Auvi-Q, including an early return of rights of the product to kaléo. Doc. 1823-17 at 4 (discussing several "tactics" and "alternatives" including a "Walk-Away in 2015").

Sanofi's Promotion of Auvi-Q

Before Auvi-Q's launch, Sanofi conducted market research on its product. Doc. 1689-25 at 2 (Mylan email summarizing research). The market research revealed that physicians were

interested in an EAI device that was smaller in size, easy for patients and caregivers to use, and didn't have a needle. *Id.* at 4 (Sanofi research). Some physicians also reacted positively to the audio instruction feature that Auvi-Q offered. Doc. 1689-26 at 2 (Mylan email summarizing research).

Sanofi's advertisements for Auvi-Q highlighted the features that, according to its market research, were favorably received by physicians. *See, e.g.*, Doc. 1689-27 at 2 (Auvi-Q "I talk" advertisement noting "step-by-step voice instructions guide . . . through the injection process[,]" "[c]ompact size[,]" and "'Press-and-hold' injection method"); Doc. 1690 at 2 (Auvi-Q "The Word is Out" advertisement describing "Audio & visual cues" and "Unique compact size and shape"); Doc. 1690-1 at 2 ("Meet Auvi-Q" advertisement describing the "first and only compact epinephrine auto-injector with voice instructions for adults and children at risk for life-threatening allergic reactions"); Doc. 1690-2 at 2 (Auvi-Q "Have You Heard" advertisement describing "the world's only talking epinephrine auto-injector"); Doc. 1690-3 at 2 (Auvi-Q "Let me introduce myself" advertisement highlighting "voice instructions" and "compact design").

Sanofi had an internal Review Committee that reviewed advertising to "ensure . . . compliance with FDA and company regulations and policies" governing "promotion of prescription drug products[.]" Doc. 1690-11 at 3, 5 (Parker Dep. 8:23–9:15, 14:18–15:4). Sanofi's internal policies required advertisements to have "appropriate characterization of claims and support" for those claims. *Id.* at 5 (Parker Dep. 14:25–15:4). Also, the Review Committee reviewed advertising proposals to "give [an] opinion on the concepts and [the] likelihood that they would be approved[.]" *Id.* at 4–5 (Parker Dep. 13:17–14:5). And, the Review Committee approved sales force training materials. Doc. 1805-15 at 4–5 (Parker Dep. 29:2–30:15). But it

didn't monitor the sales force to ensure that sale representatives were complying with their training. *Id.*

The Review Committee included representatives from Sanofi's regulatory, medical, legal, and marketing departments. Doc. 1690-11 at 3 (Parker Dep. 9:16–22). While Auvi-Q was available on the market, Sanofi's Review Committee met weekly to review promotional materials and advertisements. *Id.* at 4 (Parker Dep. 13:1–3).

Preference Study

In 2011, Sanofi sponsored a study titled "Auvi-Q Versus EpiPen: Preferences of Adults, Caregivers, and Children." Doc. 1695-19. The purpose of the study was "evaluat[ing] whether adults, caregivers, and children in the United States, with and without experience of using an EAI device, have a preference for the current design of Auvi-Q compared with the current design of EpiPen." *Id.* at 3. The results of this study showed that participants preferred Auvi-Q for its "method of instruction," "device size," and "device shape" as compared with EpiPen. *Id.* at 2. A peer-reviewed medical journal published the study. *See* Carlos A. Camargo, Jr., *et al.*, *Auvi-Q Versus EpiPen: Preferences of Adults, Caregivers, and Children*, 1 J. of Allergy & Clinical Immunology: In Practice 266 (May–June 2013), at http://dx.doi.org/10.1016/j.jaip.2013.02.004.

Before conducting the study, Sanofi sent its research proposal to the FDA for feedback on the study's design. Doc. 1690-4 (Government Agency Contact Report). Sanofi specifically asked for guidance about "the level of evidence needed to make comparative patient preference claims . . . ." *Id.* at 2. Initially, the study's design used EAI trainer devices that were similar to the actual products, but did not contain needles or drug product. Doc. 1690-5 at 12 (Sanofi study protocol). In response, the FDA informed Sanofi that the results of the study wouldn't provide

adequate evidence that Auvi-Q was "easier to use" or "eas[ier] to carry" because the study didn't call for participants actually to administer the EAI. Doc. 1690-6 at 2 (Government Agency Contact Report); Doc. 1690-7 at 3 (Minutes of Meeting discussing study). But, Sanofi determined that it could pursue promotional claims based on patient preference for Auvi-Q's size, shape, and preferred method of instruction. Doc. 1690-7 at 3 (Minutes of Meeting discussing study); *see also* Doc. 1808-14 at 15, 21–22 (Sanofi presentation) (acknowledging that Sanofi could make "[n]on-comparative claims" that "focus on device features" but "[c]omparative claims" require "generation of additional data" and the study couldn't support claims that Auvi-Q was easier to use, easier to carry, instructions were easier to follow, or that patients had a "[g]eneral overall preference" for Auvi-Q over EpiPen).

Sanofi developed marketing and training materials that promoted Auvi-Q based on the study's results. Doc. 1690-9 (Auvi-Q presentation). The study showed that 77% of participants preferred Auvi-Q's method of instruction, 85% preferred the size of the device, and 65% preferred the shape of Auvi-Q over EpiPen. *Id.* at 10.

To sell Auvi-Q to patients, Sanofi relied on its pharmaceutical sales force to visit healthcare providers and provide marketing information about Auvi-Q. *See, e.g.*, Doc. 1807-24 at 64–67 (Sanofi presentation); Doc. 1806-10 at 57–59 (Sanofi presentation discussing strategies for marketing Auvi-Q with allergists, pediatricians, and other health care providers). Sanofi's training materials used to train sales representatives about the preference study's results recite that preference claims "can only be made on the preference results shown" by the study. Doc. 1690-10 at 11 (Auvi-Q presentation). The training materials also warned that the study doesn't allow sales representatives "to make an overall preference claim of Auvi-Q vs. EpiPen." *Id.* Sanofi's policies and training prohibited sales representatives from creating "homemade

promotional materials, including messages on post-it notes or any other product communications, outside of Sanofi's formal approval process" or altering "existing [Sanofi] approved promotional materials in any way." Doc. 1690-12 at 2 (Sanofi letter). Sanofi employees who didn't follow company policy governing the dissemination of promotional materials are subject to discipline. *Id.* at 3 (Sanofi letter).

Before Auvi-Q's launch, Sanofi prepared a "Launch Readiness Review." Doc. 1808 (Auvi-Q presentation). It described Auvi-Q as the "smart solution" to managing anaphylaxis because it is "easy to carry anywhere" and "has audio-visual cues" to guide the user. *Id.* at 10. Also, it referred to two patient surveys that "suggest[ed] that most patients do not carry their epinephrine auto-injectors as recommended." *Id.* at 11. And, it described how "63% of caregivers of children at risk worry that others will not know how to use their child's epinephrine auto-injectors[.]" *Id.* Sanofi's "Launch Readiness Review" proposed "[e]stablish[ing] the need" for Auvi-Q by "driv[ing] awareness of patient noncompliance and patient uncertainty [about] EAI usage." *Id.* at 29.

In a January 2013 press release announcing Auvi-Q's launch, Sanofi referenced two surveys showing "that two-thirds of patients and caregivers do not carry their epinephrine auto-injectors as recommended, and nearly half worry that others will not know how to use their or their child's epinephrine auto-injector correctly during an emergency." Doc. 1809-14 at 2 (Sanofi press release). It noted that "[m]ultiple studies have found an association between delay in epinephrine administration and death from anaphylaxis." *Id.*

Also, Sanofi prepared a "Brand Plan" for Auvi-Q. Doc. 1807-24 at 3 (Sanofi presentation). It listed the following as one of the "strengths" of Auvi-Q: "1st EAI with head to

head preference data versus market leader." Doc. 1807-24 at 37. Also, it included a chart showing results of the study comparing Auvi-Q to EpiPen. *Id.* at 84.

EAI Market Research

A few months after Auvi-Q's launch, Sanofi commissioned a "Wave 1" message recall study used to "[d]etermine the messages that physicians are recalling post detail." Doc. 1809-21 at 8 (Sanofi presentation); *see also* Doc. 1809-19 ("Auvi-Q Message Recall Tracker Integrated Report W1 2013"). This Wave 1 Study reported that "47% of physicians recall Sanofi sales reps comparing Auvi-Q with another epinephrine auto-injector[.]" Doc. 1809-19 at 31. Physicians listed "[e]asy to carry" and "[e]ase of use" as two of the five top comparison points. *Id.*

In October 2013, Auvi-Q conducted a "Wave 2" message recall study. Doc. 1809-22 ("Auvi-Q HCP Message Recall Tracker Wave 2 2013"). It found that 17% of allergists and 52% of pediatricians had aided recall of Sanofi sales representatives comparing Auvi-Q with another EAI device. *Id.* at 29. Also, the Wave 2 study found that 31% of allergists and 19% of pediatricians recalled "increased compliance as one of the most important messages provided by Auvi-Q sales reps." *Id.* at 18.

Sanofi tracked Auvi-Q's performance after launch using a weekly "Launch Tracker." Doc. 1810 (Sanofi email attaching "Auvi-Q Launch Tracker"). The "Launch Tracker" incorporated summaries of the message recall study. *See id.* at 46–54 (discussing the "Wave 1" message recall study results); *see also* Doc. 1810-1 at 6 (Auvi-Q presentation discussing results of "Wave 2" study).

Also, Sanofi conducted several waves of Awareness Trial and Usage (ATU) market research. *See, e.g.*, Doc. 1810-2 ("Physician ATU Research—Wave 1" dated June 2013); Doc. 1810-3 (ATU Tracking Report dated Nov. 20, 2013); Doc. 1810-4 (ATU Tracking Report dated

June 18, 2014); Doc. 1810-5 (ATU Tracking Report dated Aug. 15, 2014); Doc. 1810-6 (ATU Tracking Report dated Oct. 2015). Mylan's expert has described ATU studies as "the standard industry practice of how pharmaceutical companies track awareness, trial and usage of launch brands, and message recall from physicians." Doc. 1806-6 at 9 (Zieziula Export Report). Sanofi provided input about the ATU studies' design. Doc. 1810-7 at 2 (Sanofi meeting description). And, Sanofi incorporated findings from the ATU studies in its weekly tracking reports for Auvi-Q that it circulated to Sanofi leadership. *See, e.g.*, Doc. 1810-8 at 2, 47–57 (Sanofi email attaching June 18, 2013 Auvi-Q Launch Tracker); Doc. 1810-9 at 83–98 (June 20, 2013 Auvi-Q Launch Update); Doc. 1810-10 at 2, 6 (Sanofi email attaching Nov. 26, 2013 Auvi-Q Launch Tracker).

Sanofi's Wave 1 Physician ATU Research Report found that physicians recalled messaging that Auvi-Q was "[e]asy to use/[l]ess chance of confusion." Doc. 1810-2 at 9 (Auvi-Q Physician ATU Research Wave 1). The study collected information about Sanofi's messaging for Auvi-Q, as well as Mylan's messaging for EpiPen. *Id.* The ATU study found that 8% of physicians recalled messaging that *EpiPen* was "better/[r]eliable." *Id.* Also, the ATU study showed that pediatricians were "most influenced by Auvi-Q's ease of use." *Id.* at 13. Sanofi incorporated the ATU study results into its Auvi-Q Launch Tracker. Doc. 1810-8 at 47–57 (Auvi-Q Launch Tracker dated June 18, 2013). Also, the Auvi-Q Launch Tracker noted that "EpiPen prescriptions have started to decline since the introduction of Auvi-Q." *Id.* at 53.

In 2014, Sanofi's ATU market research showed physicians recalled sales representative making comparisons between EpiPen and Auvi-Q, including "[e]ase of use" as a point of comparison for Auvi-Q. Doc. 1810-4 at 41–42, 46, 68–69, 73 (ATU Tracking Report dated June 18, 2014); Doc. 1810-5 at 15, 17 (ATU Tracking Report dated Aug. 15, 2014); Doc. 1810-6 at

108–109, 113 (ATU Tracking Report dated Oct. 2015). In response to a 2014 ATU study, Sanofi's Senior Manager for Auvi-Q Business Intelligence suggested that Sanofi "[f]ocus messaging to Allergists on Patient Preference and Ease of Use." Doc. 1810-11 at 3 (Sanofi email). And, in 2015, Sanofi's ATU studies again showed that physicians recalled messaging that Auvi-Q was "easy to use," "easy to carry," and "[i]s preferred" by patients. Doc. 1810-12 at 65 (ATU Tracking Report dated Aug. 28, 2015).

In November 2014, Sanofi commissioned Brand Impact Reports for Auvi-Q "to ensure that their brand strategy and field force performance is operating at competitively high levels." Doc. 1810-14 at 4 (Brand Impact Proposal). The December 2014 report showed that physicians had messaging recall that participants in a "comparative survey . . . significantly preferred Auvi-Q." Doc. 1810-15 at 17 (Auvi-Q Brand Impact Analysis dated Dec. 2014). And, in 2015, the Brand Impact Reports found that some of the most prevalent messaging recalled by physicians was that Auvi-Q was "[e]asy to use," "[e]asy to follow instructions," "[c]onvenient to carry," and "[p]referred by" patients. *See, e.g.*, Doc. 1810-16 at 17–19 (Auvi-Q Brand Impact Analysis dated Mar. 2015); Doc. 1810-17 at 17–18 (Auvi-Q Brand Impact Analysis dated May 2015); Doc. 1810-18 at 15–17 (Auvi-Q Brand Impact Analysis dated June 2015); Doc. 1810-19 at 6, 30 (Auvi-Q Brand Impact Analysis dated Aug. 2015).

Sanofi wasn't alone in conducting ATU research. Mylan also conducted its own ATU research "to track, among prescribers, the key metrics for EpiPen in the wake of the Auvi-Q launch," including "detailing activities" and "message recall." Doc. 1809-12 at 6 (EpiPen "Awareness, Attitude, & Usage Tracking Study" dated 2013). In 2013, Mylan's ATU research concluded that 14% to 27% of physicians recalled messaging that Auvi-Q was a "better device." *Id.* at 14. In 2015, Mylan's ATU research found that 28% of 364 health care providers surveyed

recalled messaging that Auvi-Q was preferred over EpiPen in a comparative survey. Doc. 1810-22 at 4, 8 (EpiPen "Awareness, Attitude, & Usage Tracking" dated Aug. 2015).

Sanofi's Communications about Auvi-Q with Physicians and Payors

On one occasion, a Sanofi sales representative wrote a note to a physician that read: "The overwhelming majority of patients given the choice by their clinician prefer . . . Auvi-Q as evidenced by clinical experience & peer reviewed surveys." Doc. 1690-18 at 31 (Attachment to Mar. 23, 2015 letter). After the FDA brought this note to Sanofi's attention, Sanofi "sent out a communication to all Sanofi field personnel reminding them that Sanofi employees, consistent with [Sanofi's] policies and training, may not under any circumstances create homemade promotional materials, including messages on post-it notes or any other product communications, outside of Sanofi's formal approval process, or alter existing [Sanofi] approved promotional materials in any way." Doc. 1690-12 at 3 (Sanofi letter). Other Sanofi documents or communications included references that patients "overwhelmingly prefer" Auvi-Q over EpiPen. *See, e.g.*, Doc. 1809-18 at 2 (Sanofi/UnitedHealthcare email) ("Patients overwhelming[ly] Prefer Auvi-Q"); Doc. 1811 at 10 (workbook reciting that patients "overwhelmingly prefer" Auvi-Q); Doc. 1811-1 at 11 (same); Doc. 1811-2 at 2 (Sanofi email) (suggesting changes to a Wellpoint presentation to include "Patients overwhelmingly prefer Auvi-Q over other EAIs").

When deciding whether to cover Auvi-Q, Horizon Blue Cross Blue Shield of New Jersey's P&T Committee noted in its "Overall Conclusion" that, among other things, Auvi-Q's "preference over EpiPen [was] statistically significant due to its ease of use, ease to carry, ease of following instructions provided, and preference to use overall[.]" Doc. 1811-3 at 4 (Horizon BCBS of New Jersey P&T Committee Formulary Review Summary). But, Horizon's corporate

representative testified that the decision to cover Auvi-Q was based on several "pieces of information," including "clinical data . . . and even . . . anecdotal experience from physicians." Doc. 1805-12 at 17–18 (Jan (Horizon) Dep. 113:17–114:24).

Sanofi Promotes Retractable Needle

One of Sanofi's advertisements for Auvi-Q—the "I talk" advertisement—referred to Auvi-Q as the "first and only" EAI device with a "[r]etractable needle mechanism designed to help prevent accidental needle sticks." Doc. 1811-5 at 2 (Auvi-Q advertisement). Sanofi widely disseminated this advertisement to physicians and payors. Doc. 1811-6 at 2, 6 (Sanofi email); Doc. 1811-7 at 2, 3 (Sanofi email). EpiPen doesn't have a retractable needle, like Auvi-Q. Doc. 1872-10 at 3–4 (Willig Dep. 16:19–17:21). But, since 2009, the EpiPen has included a needle cover that extends over the needle after the user has administered the EpiPen. *Id.*

References to a "New EpiPen"

Sanofi's pre-launch research recognized that the EpiPen brand had "become eponymous of the [EAI] category." Doc. 1811-8 at 14 (Sanofi presentation) (comparing EpiPen to "'Kleenex' for tissues or 'Band-Aid' for bandages"). After Auvi-Q's launch, Mylan's market research showed that some physicians recalled messaging that Auvi-Q was a "new EpiPen." *See, e.g.*, Doc. 1811-11 at 6 (Mylan email attaching verbatims); Doc. 1811-13 at 16–19 (Mylan Competitive Intelligence Update).

Two employees of an allergy clinic in Arizona recall that a pharmaceutical sales representative visited the clinic in January 2013, to tell them about Auvi-Q. Doc. 1811-9 at 6 (Hartneck Decl. ¶¶ 2–3); Doc. 1811-9 at 8 (Alcorn Decl. ¶¶ 2–5). Bryanna Hartneck, a receptionist and administrative assistant at the clinic, remembered the sales representative telling her that "Auvi-Q was replacing the EpiPen, that the EpiPen was no more, and that the Auvi-Q

was the new up-and-coming EpiPen." Doc. 1811-9 at 6 (Hartneck Decl. ¶ 3). Jhade Alcorn, a medical assistant, recalled the sales representative telling her that "Auvi-Q was going to replace the EpiPen and that it was going to be like the new EpiPen." Doc. 1811-9 at 8 (Alcorn Decl. ¶ 3). After this meeting, Ms. Alcorn "believed that the EpiPen was being phased out and that [the clinic] would have to switch to the Auvi-Q" until "the Mylan representative on a sales call . . . informed [her] that the EpiPen was still going to be available." *Id.* at 8–9 (Alcorn Decl. ¶ 5).

Sanofi launched an advertising campaign on YouTube that showed Auvi-Q advertisements when a user typed in certain search terms. Doc. 1811-17 at 2 (Sanofi email). Sanofi identified the terms "new EpiPen" and "talking EpiPen" as "keywords" that are "top conversation drivers and bring engaged traffic to the site." Doc. 1811-18 at 6 (Sanofi presentation).

When Sanofi launched Auvi-Q, its website stated that Auvi-Q's epinephrine was bioequivalent to EpiPen's. Doc. 1811-21 at 2 (Auvi-Q website). The website never mentioned whether the products were therapeutically equivalent. *Id.* Mylan contacted the FDA to complain about the bioequivalence statement on the Auvi-Q website. Doc. 1811-22 at 3–4 (Mylan letter). Mylan also contacted Sanofi to complain that Sanofi sales representatives allegedly were describing Auvi-Q as the "new EpiPen." Doc. 1811-24 at 2 (Mylan letter).

Physician Prescribing Behavior

Sanofi tracked whether the physicians it had "targeted" for sales representative calls were writing Auvi-Q prescriptions. *See* Doc. 1812 at 2 (Sanofi email); Doc. 1812-1 at 2 (Sanofi email). Between April 2013 and July 2013, the percentage of targeted physicians writing Auvi-Q prescriptions increased from 10.3% to 22.6%. *Id.* The percentage of targeted allergists

writing Auvi-Q prescriptions increased from 39.2% to 61.6%, and for pediatricians, from 4.3% to 15.2%. *Id.*

At the end of July 2013, Sanofi estimated that the "reach" of its Auvi-Q sales force had improved, with "[a]bout 700 new targets reached in the last 2 weeks." Doc. 1812-2 at 2, 5 (Sanofi email attaching Auvi-Q Launch Tracker). Also, Sanofi reported that "[a]bout 1000 new targets wrote Auvi-Q [prescriptions] in [the] last 2 weeks." *Id.* at 5. About two weeks later, in August 2013, Sanofi reported that "more than three in four [allergists]" and "one in four [pediatricians]" who were called on by Sanofi's sales force "conver[ted]" to prescribe Auvi-Q. Doc. 1812-3 at 29 (Auvi-Q Launch Tracker dated Aug. 12, 2013). In that same "Launch Tracker" report, Sanofi reported, based on the May 2013 Physician ATU research, that pediatricians were "most influenced" by Auvi-Q being "[e]asy to carry" and "[e]asier to [u]se," and that "[e]asier to [u]se" was the third-highest influence on physicians' prescribing behavior. *Id.* at 50.

In September 2013, Sanofi's weekly "Launch Tracker" estimated more improvement in the "reach" of its Auvi-Q sales force, with "[a]bout 50 new targets reached in last week." Doc. 1812-4 at 2, 4–5 (Sanofi email attaching Auvi-Q Launch Tracker). Also, Sanofi reported that "[a]bout 437 new targets wrote Auvi-Q in [the] last week." *Id.* at 5. In November 2013, Auvi-Q's brand lead, Bryan Downey, sent the head of Sanofi's allergy division a "Multi-Purpose Slide Deck" to use for Auvi-Q presentations. Doc. 1810-1 at 2 (Sanofi email attaching presentation). One slide in the presentation recited: "[Health Care Providers] buy the story. Auvi-Q messages are viewed as highly relevant, believable, unique and important." *Id.* at 56.

In early 2014, Sanofi's physician ATU research reported that "the more satisfied [pediatricians were] with the quality of the detail," the "more likely they are to prescribe and

recommend Auvi-Q." Doc. 1810-4 at 21 (ATU Tracking Report dated June 18, 2014). In 2014, when Sanofi's overall share of EAI prescriptions declined, Sanofi concluded that "[p]rescribers who have been detailed show a smaller drop in Auvi-Q share compared to those not called on." Doc. 1812-5 at 31 (Auvi-Q Share Drop Analysis); *see also id.* at 32–33. In August 2014, Sanofi's physician ATU research showed that the sales force "continue[d] to be the primary source of EAI information" for allergists and pediatricians. Doc. 1810-5 at 31, 46 (ATU Tracking Report dated Aug. 15, 2014). It also found that "65% of [a]llergists believe they have INCREASED Auvi-Q prescri[ptions] in the past 6 months and expect to continue INCREASING for their next 100 patients." *Id.* at 33. It drew a similar conclusion that pediatricians had increased Auvi-Q prescriptions and expected to continue increasing for their next 100 patients. *Id.* at 48. Also, the report listed "[e]ase of use" as one of the reasons allergists were more likely to recommend Auvi-Q. *Id.* at 88.

Sanofi's study of 24 months of data—from August 2013 to July 2015—concluded that Sanofi's "sale force generated 15% of all" Auvi-Q prescriptions. Doc. 1812-6 at 5 (Auvi-Q Marketing Mix Model).

Auvi-Q Recall and Return of Rights

On October 22, 2015, the FDA arrived at Sanofi's facility in Bridgewater, New Jersey, for an unannounced inspection. Doc. 1672-15 at 5 (Sanofi email). The FDA previously had received a report in July 2015 about an issue that could cause Auvi-Q to fail to inject epinephrine. Doc. 1672-11 at 4–5 (Final NDA-Field Alert Report). About a week before the Bridgewater inspection, the FDA had completed an inspection of the Auvi-Q manufacturing process at Sanofi's contract manufacturer, Medivative. *Id.* at 4–15.

On the first day of the Bridgewater inspection, the FDA informed Sanofi that "[a]n internal consultation with [FDA's Center for Drug Evaluation & Research] has been performed with the apparent assessment that [a] Class I recall was appropriate." Doc. 1672-15 at 4 (Sanofi email). A Class I recall is "a situation in which there is a reasonable probability that the use of . . . a violative product will cause serious adverse health consequences or death." U.S. Food & Drug Admin., *Recalls Background and Definitions* (July 31, 2014), https://www.fda.gov/safety/industry-guidance-recalls/recalls-background-and-definitions.

On October 26, 2015, Sanofi decided to effect a voluntary Class I recall of all Auvi-Q devices in U.S. and Canada. Doc. 1672-24 at 4 (Sanofi letter to FDA). Also, Sanofi discontinued Auvi-Q manufacturing operations. *Id.* In a letter to the FDA, Sanofi explained that this 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." *Id.* Sanofi publicly announced the recall on October 28, 2015. *Auvi-Q (epinephrine injection, USP) Recall* (Oct. 28, 2015), https://www.sanofi.us/en/products-and-resources/Auvi-Q-epinephrine-injection-USP-Recall/.

On December 5, 2015, the head of the Auvi-Q brand at Sanofi, Patrick Barry, received an updated slide deck discussing sales scenarios for Auvi-Q. Doc. 1672-17 at 2 (Sanofi email attaching presentation). It projected a relaunch of Auvi-Q occurring 18 months later—in June 2017. *Id.* at 6. But, in another forecast, Sanofi had predicted that it could relaunch Auvi-Q within nine to 12 months. Doc. 1824-43 at 5–6 (Sanofi presentation); *see also* Doc. 1824-41 at 21–22 (Stevens Rebuttal Expert Report ¶¶ 62–64) (opining that Sanofi had the ability and capacity to relaunch Auvi-Q more quickly than the 16 months it took kaléo to relaunch the product). The presentation sent to Patrick Barry also showed the prescription volume for other

drugs that were recalled and later reintroduced to the market. Doc. 1672-17 at 6, 23–26. When reintroduced to the market, each product had experienced more than a 90% drop in sales volume compared to pre-recall sales levels. *Id.*

Sanofi's Patrick Barry testified that Sanofi eventually decided to return the rights for Auvi-Q to kaléo after considering "the market environment" and "the behaviors of the competitor," *i.e.*, Mylan. Doc. 1823-15 at 6–7 (Barry Dep. 37:24–38:14). Sanofi had "assum[ed] that there was a likelihood that [Mylan] would continue to try to blunt [Auvi-Q's] launch in terms of using their lion's share of the market inappropriately" and recognized "the level of investment that would be required to achieve a relaunch." *Id.*; *see also id.* at 8 (Barry Dep. 43:24–44:7) (testifying that Sanofi "felt like . . . Mylan would continue to use a very large dominant market share to try to make it very difficult for payers to put Auvi-Q on formulary"); Doc. 1823-14 at 4 (Guenter Dep. 326:9–327:22) (testifying that Sanofi chose not to relaunch Auvi-Q because it involved "restarting from scratch, with a market share of zero, re[-]contracting for access, anticipating that Mylan with EpiPen would be probably more aggressive than ever to try to avoid that [Auvi-Q] would regain access"). And so, Sanofi "determined that . . . it would be best to put those investments somewhere else and then to then transition the product back" to kaléo. Doc. 1832-15 at 6–7 (Barry Dep. 37:24–38:14).

On December 7, 2015, Sanofi advised kaléo it would return the rights to Auvi-Q and terminate the license agreement. Doc. 1660-7 at 6–8 (Barry Dep. 21:8–23:17). On February 24, 2016, Sanofi and kaléo signed the Termination Agreement. Doc. 1672-18 (Termination Agreement).

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. 1816-42 at 2 (press release). "The claims settled by [the] agreement [were] allegations only, and there [was] no determination of liability." *Id.* at 3.

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. 1822-39 at 3 (Magellan Health email) (noting that "[e]very data point we have suggest 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"). Also, Mylan recognized that—with its Medicaid rebates for OptumRx—if EpiPen "had been treated as a brand for Best Price purposes, then [Mylan] could not have rebated the product to OptumRx over the past 4 or 5 years" as it had done "because it would have been unprofitable" for Mylan. Doc. 1822-40 at 2 (Mylan email).

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 that it is "entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). When it applies this standard, the court 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 the 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)); *Conoshenti v. Pub. Serv. Elec. & Gas Co.*, 364 F.3d 135, 140 (3d Cir. 2004) (explaining the "initial burden is on the summary judgment movant to show the absence of a genuine issue of material fact" (citation and internal quotation marks omitted)). A summary judgment movant can satisfy this burden by demonstrating "that 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, to meet its summary judgment burden, the moving party "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)); *Conoshenti*, 364 F.3d at 140 (explaining that the moving party may discharge its summary judgment burden by "'showing'—that is, pointing out to the district court—that there is an absence of evidence to support the nonmoving party's case' when the nonmoving party bears the ultimate burden of proof" (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)); *Childers v. Joseph*, 842 F.2d 689, 695–96 (3d Cir. 1988) ("Where a party opposing a motion for summary judgment has the burden of persuasion, and the moving party has identified sufficient facts of record to demonstrate that no genuine issue of material fact remains, the nonmoving party is obliged to identify those facts of record which would contradict the facts identified by the movant.". 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 himself 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.

The court applies this same standard to cross motions for summary judgment, like the ones the parties have filed here. With cross motions for summary judgment, each party bears the burden of establishing that no genuine issue of material fact exists and that it is entitled, as a matter of law, to the judgment sought by its motion. *Atl. Richfield Co. v. Farm Credit Bank of Wichita*, 226 F.3d 1138, 1148 (10th Cir. 2000); *see also Appelmans v. City of Phila.*, 826 F.2d 214, 216 (3d Cir. 1987) (explaining that the summary judgment "standard does not change when the issue is presented in the context of cross-motions for summary judgment"). Cross motions for summary judgment "are to be treated separately; the denial of one does not require the grant of another." *Buell Cabinet Co., Inc. v. Sudduth*, 608 F.2d 431, 433 (10th Cir. 1979); *see also*

Lawrence v. City of Phila., Pa., 527 F.3d 299, 310 (3d Cir. 2008) (explaining that cross motions for summary judgment are "no more than a claim by each side that it alone is entitled to summary judgment, and the making of such inherently contradictory claims does not constitute an agreement that if one is rejected the other is necessarily justified or that the losing party waives judicial consideration and determination whether genuine issues of material fact exist" (citation and internal quotation marks omitted)). But, where the cross motions overlap, the court may address the legal arguments together. *Berges v. Standard Ins. Co.*, 704 F. Supp. 2d 1149, 1155 (D. Kan. 2010) (citation omitted).

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). And, summary judgment has "particular importance in the area of antitrust law, because it helps to avoid wasteful trials and prevent lengthy litigation that may have a chilling effect on pro-competitive market forces." *Major League Baseball Props., Inc. v. Salvino, Inc.*, 542 F.3d 290, 309 (2d Cir. 2008) (citations, internal quotation marks, and alterations omitted); *see also Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 73 (3d Cir. 2010) (stating that "[t]he entry of summary judgment in favor of an antitrust defendant may actually be required in order to prevent lengthy and drawn-out litigation, which may have a chilling effect on competitive market forces" (citation omitted)). Indeed, the Supreme Court has recognized that "[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 Corp.*, 372 U.S. at 259)).

III. Analysis

The court first addresses Mylan's Motion for Summary Judgment against Sanofi's Sherman Antitrust Act § 2 claims alleging (1) monopolization through exclusive dealing; (2) deceptive conduct to further monopolization; and (3) an overall scheme to monopolize. For reasons explained, the court grants summary judgment against Sanofi's Sherman Antitrust Act claims.

The court next addresses Sanofi's Motion for Summary Judgment that seeks summary judgment in its favor on one element of its Sherman Antitrust Act § 2 claims and against Mylan Specialty's Counterclaim asserting (1) violations of the Lanham Act, and (2) unfair competition. As explained below, the court denies as moot Sanofi's Motion for Summary Judgment in its favor on a portion of Mylan's Sherman Antitrust Act § 2 claims. Specifically, Sanofi asks the court to enter judgment as a matter of law that the relevant market consists of EAI devices in the United States and that Mylan possessed and exercised monopoly power in this market. The court need not decide this issue because it concludes—when ruling Mylan's Motion for Summary Judgment—that the summary judgment facts present no triable issue whether Mylan engaged in anticompetitive conduct or whether Sanofi sustained an antitrust injury sufficient to support a Sherman Act claim. Thus, Sanofi's Sherman Act claims fail as a matter of law. So, the court need not decide Sanofi's Motion for Summary Judgment seeking judgment in its favor on a different element of this claim. But, for Sanofi's remaining summary judgment arguments, the

court grants summary judgment against Mylan's Counterclaim alleging Lanham Act and unfair competition claims.

A. Mylan's Motion for Summary Judgment

Mylan argues that it deserves summary judgment against Sanofi's Sherman Act § 2 claims. Section 2 of the Sherman Act makes it illegal to "monopolize, or attempt to monopolize . . . any part of the trade or commerce among the several states . . . . " 15 U.S.C. § 2. A Sherman Act § 2 monopolization claim "has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966); *see also Christy Sports, LLC v. Deer Valley Resort Co., Ltd.*, 555 F.3d 1188, 1192 (10th Cir. 2009) (quoting *Grinnell Corp.*, 384 U.S. at 570–71).[15]

Mylan moves for summary judgment against the second element of Sanofi's Sherman Act § 2 claims. Mylan asserts three reasons why—it contends—the undisputed summary judgment facts present no triable issue whether Mylan willfully acquired or maintained monopoly power in violation of federal antitrust law. *First*, Mylan argues the summary judgment facts fail to create a genuine issue whether Mylan engaged in anticompetitive acts. *Second*, Mylan asserts no reasonable jury could find from the undisputed summary judgment facts that Sanofi sustained an antitrust injury. *Finally*, Mylan contends Sanofi's claim for antitrust damages fails as a matter of law.

[15] More recently, the Tenth Circuit has recited the elements of a § 2 monopolization claim as requiring plaintiff "to prove three items: (1) monopoly power in the relevant market; (2) willful acquisition or maintenance of this power through exclusionary conduct; and (3) harm to competition." *Lenox MacLaren Surgical Corp. v. Medtronic, Inc.*, 762 F.3d 1114, 1119 (10th Cir. 2014) (citing *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966) (further citations omitted)).

As explained below, the court agrees with Mylan's first two arguments. It concludes that the summary judgment facts fail to present a factual dispute whether Mylan engaged in anticompetitive conduct or whether Sanofi sustained an antitrust injury. Thus, the court grants summary judgment against Sanofi's Sherman Act § 2 claims for these two, independent reasons. Having reached those two conclusions, the court declines to consider Mylan's third argument, that Sanofi hasn't presented evidence sufficient to support its damages claim.

1. Anticompetitive Conduct

Mylan argues that the summary judgment facts present no genuine issue whether Mylan acted anticompetitively, thus violating Sherman Act § 2. Mylan asserts four arguments why its conduct wasn't anticompetitive: (1) Mylan contends that its rebate agreements with payors don't violate the antitrust laws because they pass the price-cost test; (2) Mylan argues its rebate agreements aren't unlawful exclusionary contracts under a rule of reason analysis; (3) Mylan asserts that the court shouldn't accept Sanofi's theory of antitrust liability, which argues that Mylan unlawfully leveraged non-contestable demand for EpiPen against its contestable demand; and (4) Mylan contends that none of its other conduct—either its marketing of EpiPen or its administration of the EpiPen4Schools® program—violates the antitrust laws. The court addresses each argument, in turn.

a. Price-Cost Test

Mylan first argues that Sanofi's Sherman Act § 2 claim based on Mylan's rebate agreements with payors fail as a matter of law because, the summary judgment facts establish, Mylan never priced EpiPen below its costs to produce it. Mylan argues that its rebate agreements were nothing more than competition based on price—something that the antitrust laws don't prohibit. To the contrary, 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 "[t]o 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.* And, "[t]he antitrust laws require no such perverse result." *Id.*

Considering 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 "[s]econd, 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).

But, Sanofi responds, its antitrust claims here are not ones for predatory pricing. Instead, Sanofi asserts, it brings unlawful exclusive dealing claims based on Mylan's rebating practices

that aren't subject to the price-cost test. Thus, Sanofi argues, the price-cost test doesn't apply and doesn't foreclose Sanofi's antitrust claims here.

As the court explained when deciding Mylan's Motion to Dismiss Sanofi's Complaint, *see* Doc. 98 at 11–12, 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).[16] *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.*

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[16] The parties do not cite, and the court has not found any case where the Tenth Circuit specified when the price-cost test applies to an exclusive dealing claim based on a discount or rebate program. 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). Also, this court has explained that "[t]his 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 Prod. 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."). And, although the transferor court's law is not binding precedent, it "merits close consideration" by the transferee court. *In re Korean Air Lines Disaster of Sept. 1, 1983*, 829 F.2d 1171, 1176 (D.C. Cir. 1987). The court thus considers closely the law of the Third Circuit (where the *Sanofi* case originated) when deciding the parties' cross motions for summary judgment.

But, *ZF Meritor* refused to apply the price-cost test 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. *Id.*

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 defendant's means of exclusion; instead, plaintiff based its exclusive dealing claim on defendant's allegedly anticompetitive predatory conduct through use of exclusive dealing arrangements preventing competitors from entering the market).

Here, Mylan contends 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. Doc. 1660-2 at 67–71. And, Mylan argues, the undisputed facts establish that Mylan priced EpiPen above cost. *Id.* at 71–72. Sanofi responds that it hasn't alleged a predatory pricing case but, instead, an exclusive dealing claim premised on Mylan's unlawful rebating practices. Doc. 1820-1 at 90–91. Thus, Sanofi contends, the price-cost test doesn't apply.

In the end, the court need not decide this issue. When confronted with a similar argument where Sanofi—who was the defendant in that case—sought to apply the price-cost test to the market share discount contracts Sanofi had offered to 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. The court 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.[17] *Id.*

[17] 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 Sanofi never sold its drug product below its costs to produce it, the 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.

Similarly, here, the court proceeds to analyze Sanofi's exclusive dealing claims under a rule of reason analysis in the next section. After applying that analysis, the court concludes that the summary judgment facts present no triable issue whether Mylan's rebate agreements violate the Sherman Antitrust Act. So, the court need not decide whether the price-cost test applies to preclude Sanofi's antitrust claims. The court now turns to that rule of reason analysis, below.

b. Exclusionary Contracts Under a Rule of Reason Analysis

Mylan next argues that, even if the price-cost test doesn't apply, it deserves summary judgment because no reasonable jury could find from the summary judgment facts that its rebate agreements are unlawful under the Sherman Act using a rule of reason analysis.

Sanofi asserts that Mylan's rebating practices with payors constitute unlawful exclusive dealing contracts that violate federal antitrust law. 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). "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)).

Mylan never argues that its rebate contracts aren't exclusionary contracts. And indeed, the summary judgment facts establish that Mylan entered rebate contracts with some payors that required those payors to exclude Auvi-Q. But, Mylan contends that its rebate agreements don't violate the antitrust laws because they don't impose an unreasonable restriction on competition.

As courts repeatedly have explained, 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 Catholic 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 on an exclusive dealing claim, a 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;[18] *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").

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

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[18] *Tampa Electric* analyzed 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 prescriptions of § 3 of the Clayton Act it follows that it is not forbidden by those of the former." *Id.* 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).

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. When considering whether the 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 a seller with a dominant position exists in the market, whether the market has "myriad outlets with substantial sales volume," the prevalence in the industry of using exclusive contracts, the duration of the contract, and the existence of 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.*

Naturally, the parties to the current dispute take conflicting positions about how the court should apply these factors for a rule of reason analysis examining the exclusionary contracts at issue. Mylan contends that evaluating its rebate contracts under these factors presents no triable issue whether Mylan's rebating practices foreclosed competition, and thus the court must enter summary judgment against Sanofi's Sherman Act § 2 claims. Just the opposite, Sanofi contends

that the summary judgment records contains "overwhelming evidence for a jury to find that Mylan's exclusive dealing substantially foreclosed Auvi-Q from the market." Doc. 1820-1 at 62.

Sanofi also contends that exclusive dealing cases generally present fact-intensive inquiries and so, it says, courts typically conclude that a jury should make the factual determination whether an exclusionary contract imposes an unreasonable restriction on competition. Doc. 1820-1 at 63 (first citing *Roxul USA, Inc. v. Armstrong World Indus., Inc.*, No. 17-1258, 2019 WL 1109868, at *18 (D. Del. Mar. 8, 2019); then citing *Complete Ent. Res. LLC v. Live Nation Ent., Inc.*, No. CV 15-9814 DSF (AGRx), 2017 WL 6512223, at *3 (C.D. Cal. Oct. 16, 2017); then citing *Meredith Corp. v. SESAC LLC*, 1 F. Supp. 3d 180, 196 (S.D.N.Y. 2014)). But, Sanofi's argument ignores that the discrete facts at issue in the particular cases it cited created a triable issue precluding summary judgment. *See, e.g.*, *Roxul USA, Inc.*, 2019 WL 1109868, at *18 (concluding that the summary judgment record presented "genuine issues of material fact [about] the duration of the exclusivity agreements" and "[c]ombined with evidence of [defendant's] share of the market, a reasonable jury could credit [plaintiff's] evidence and decide [defendant's] exclusivity agreements prevent meaningful competition by its rivals"); *Complete Ent. Res. LLC*, 2017 WL 6512223, at *2–3 (concluding that Sherman Act exclusive dealing claims involved "a number of material factual disputes" and thus "cannot be resolved by way of summary judgment" because, among other things, plaintiff had "presented expert testimony" that the agreements at issue "may harm competition" and, although defendants disagreed with the expert's theory, the court held it must "let the finder of fact decide who is right and who is wrong"); *Meredith Corp.*, 1 F. Supp. 3d at 223 (denying summary judgment against Sherman Act § 2 claim because "plaintiffs have adduced sufficient evidence upon which

a jury could find that the anti-competitive effects of [defendant's] licensing practices outweigh their pro-competitive virtues").

Also, Sanofi ignores other cases where courts have had no difficulty entering summary judgment against exclusive dealing claims when the summary judgment facts presented no genuine factual issue permitting a jury to find that defendant had foreclosed a substantial volume of competition. *See, e.g.*, *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 407–08 (3d Cir. 2016) (affirming summary judgment against an exclusive dealing claim "under a rule of reason analysis" because "[w]ithout evidence of substantial foreclosure or anticompetitive effects, [plaintiff] has failed to demonstrate that the probable effect of [defendant's] conduct was to substantially lessen competition in the relevant market, rather than to merely disadvantage rivals"); *Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 73, 82–83 (3d Cir. 2010) (noting "summary judgment is not disfavored in the antitrust context" and "may actually be required in order to prevent lengthy and drawn-out litigation, which may have a chilling effect on competitive market forces" and affirming summary judgment against an exclusive dealing claim because the summary judgment record provided "more than ample justifications" for the exclusionary conduct, and "in the absence of any coercion or improper interference[,]" the practice was lawful and should continue "without undue and costly interference on the part of courts and juries").

The court thus proceeds to examine the various factors used to evaluate the legality of exclusive dealing arrangements under this cases' summary judgment facts. The court considers these factors to determine if they present any jury questions whether Mylan's rebate contracts substantially foreclosed competition. It discusses the relevant factors in sections i–vi, following.

i. *ZF Meritor* Factor #1: Did Defendant Possess Significant Market Power?

Mylan doesn't concede the issue of market power for purposes of summary judgment. Doc. 1660-2 at 73 n.346. But Mylan doesn't dispute that, between January 2007 and December 2012, EpiPen was the only EAI device holding more than 10% of the EAI prescriptions in the U.S. Doc. 1821-12 at 3 (Mylan Resp. to Req. for Admis. No. 15). And, it never controverts the conclusion reached by Sanofi's expert that EpiPen market share in the U.S. EAI market ranged from around 80% to 98% between 2011 and 2017. Doc. 1687-10 at 49–50 (Scott Morton Expert Report ¶ 73 & Fig. 7).[19] Also, Mylan's own documents and testimony show that Mylan occupied the most significant share of the number of EAI prescriptions written in the United States both before and after Auvi-Q entered the market. *See* Doc. 1687-23 at 4 (2013 Mylan presentation) (reciting that "EpiPen currently owns the dominant share of the market"); *see also* Doc. 1686-11 at 6 (Bresch Dep. 268:1–269:4) (testifying that EpiPen had "significant market share" from 2012 to 2015); Doc. 1687-26 at 5 (Graham Dep. 55:18–56:9) (testifying that 80% to 90% of total EAI prescriptions were for EpiPen).

So, the summary judgment record here establishes that Mylan had significant—one even could say, dominant—market share of the total number of EAI prescriptions in the United States. And, as *ZF Meritor* recognized, "if the defendant occupies a dominant position in the market, its exclusive dealing arrangements invariably have the power to exclude rivals." 696 F.3d at 284. This is so because "a monopolist may use its power to break the competitive mechanism and deprive customers of the ability to make a meaningful choice." *Id.* at 285. The court thus

[19] Sanofi makes this factual statement in its Memorandum of Law in Support of its Motion for Summary Judgment. Doc. 1686-1 at 21 (Statement of Undisputed Material Facts ¶ 29). Mylan doesn't controvert this specific fact in its Opposition, though it repeatedly objects to how Sanofi has defined the relevant antitrust market. *See generally* Doc. 1805-1.

concludes this factor favors a finding of foreclosure to competition, but 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). The court thus proceeds to consider the other rule of reason factors to determine whether Mylan used its dominate market share of EAI prescriptions in a way that unlawfully excluded rivals.

ii. *ZF Meritor* Factors #3 & #6: Was the Contract's Duration Sufficient to Prevent Meaningful Competition? And Does the Customer Have the Ability to Terminate the Contract?

Next, the court examines whether the duration and terminability of Mylan's rebate contracts at issue 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 Envtl., 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.

Here, Mylan asserts that its rebate contracts were short-term and easily terminable. Thus, Mylan argues, its contracts never prevented payors from making formulary changes. The court

agrees. The undisputed summary judgment facts show that several of Mylan's rebate agreements imposed terms of 2.5 years or less. *See, e.g.*, Doc. 1662-6 at 9 (Mylan/MedImpact Rebate Agreement) (2.5 years); Doc. 1662-17 at 2 (Mylan/Aetna Rebate Agreement) (two years); Doc. 1662-9 at 2–3 (Mylan/OptumRx Rebate Agreement) (two years). And, many rebate agreements included termination provisions allowing either party to terminate the agreement without cause on 90 days' written notice or less. *See, e.g.*, Doc. 1662-6 at 9 (Mylan/MedImpact Rebate Agreement) (90 days' written notice termination provision); Doc. 1660-20 at 11 (Hall (Prime) Dep. 50:20–25) (testifying that Prime contract includes 90 days' advance written notice termination provision); Doc. 1661-3 at 9 (Vargo (Aetna) Dep. 116:3–8) (testifying that contracts include termination provisions); Doc. 1662-15 at 3 (Mylan/Cigna Rebate Agreement) (requiring 60 days' written notice of termination).

Also, the summary judgment record establishes that payors invoked these termination provisions and renegotiated rebate agreements annually and, sometimes, even more frequently. *See, e.g.*, Doc. 1660-24 at 38–39 (Kautzner (ESI) Dep. 185:24–186:22) (testifying that ESI is "in constant negotiation with manufacturers" but "normally" contracting decisions are made annually); Doc. 1661-2 at 8 (Stein (Humana) Dep. 226:20–24) (testifying that Humana has the right to renegotiate and solicit bids from manufacturers at any time). 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, in 2015, Sanofi successfully reversed its exclusion from ESI's national formulary, 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. 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 in 2015. Both payors sought offers with increased discounts, but with OptumRx/UnitedHealthcare, Sanofi made an offer that was less competitive than Mylan's; and with MedImpact, Sanofi declined to make the offer MedImpact had requested.

Courts have found that exclusionary contracts of similar duration and terminability as the rebate agreements at issue here don't produce "significant exclusionary effects." *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 Envtl.*, 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).

But, Sanofi cites several cases for the proposition that even contracts of short duration can restrain competition. Doc. 1820-1 at 84–86. Those cases differ, though, because the facts in

them 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 286–87. 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 agreements" 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").

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 case 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. 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.

Next, Sanofi argues that even short-term rebate agreements had a cumulative, practical effect of locking competition out of the market because it was difficult for payors to switch products. The summary judgment record won't abide Sanofi's argument. Again, as discussed, the summary judgment facts establish that payors gave Sanofi repeated opportunities to renegotiate formulary coverage. And, when Sanofi made better rebate offers that were competitive to Mylan's bids, Sanofi successfully gained more formulary coverage for Auvi-Q. Also, the summary judgment record includes testimony by several payors who asserted that they could have excluded EpiPen in favor of Auvi-Q because they could shift product use from EpiPen to Auvi-Q. And, the record includes two examples of payors—CVS and ESI—who did just that. When these two payors excluded EpiPen from specific formularies (CVS in its

Advanced Control Formulary, and ESI in its High Performance Formulary), EpiPen's market share dropped significantly while Auvi-Q's increased, thus capturing that market share.

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. *ZF Meritor* Factor #5: Did Defendant Engage in Coercive Behavior?

The court next considers whether Mylan engaged in coercive behavior such that it substantially foreclosed competition in the market. 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 power, *and there is some element of coercion present*." *ZF Meritor*, 696 F.3d at 284 (emphasis added). Mylan argues that the summary judgment record here presents no evidence of coercion. Instead, Mylan contends the summary judgment facts show that the only exclusionary conduct in which Mylan offered payors discounts for excluding Auvi-Q—sometimes making these offers in response to requests by the payors themselves. And, Mylan argues, simply offering price discounts is not coercion.

The undisputed facts here show that many payors considered Auvi-Q interchangeable with EpiPen. So, some payors chose to cover just one EAI product, and they communicated that preference both to Sanofi and Mylan.[20] *See, e.g.*, Doc. 1663-14 at 3 (CVS); Doc. 1662-1 at 2

[20] Sanofi argues that the unique characteristics of EAIs made this drug class inappropriate for formulary management through the use of exclusive contracts that limit drug treatment options just to one EAI device "given the life-threatening nature of anaphylaxis and the need for an EAI in an emergency." Doc. 1820-1 at 79–80. But, this argument ignores that payors overwhelmingly concluded that EpiPen and Auvi-Q were therapeutically equivalent products, and thus interchangeable treatments for anaphylaxis. *See, e.g.*, Doc. 1663-8 at 4 (ESI); Doc. 1663-9 at 22 (CVS); Doc. 1660-28 at 14 (OptumRx); Doc. 1663-10 at 13 (Prime); Doc. 1663-11 at 20 (UnitedHealthcare); Doc. 1660-5 at 12 (MedImpact); Doc. 1660-25 at 20–21 (Cigna); Doc. 1663-12 at 2 (Aetna); Doc. 1660-27 at 12 (Anthem); Doc. 1663-13 at 2 (Kaiser Permanente).

(Kaiser Permanente); Doc. 1663-16 at 2 (MedImpact); Doc. 1663-17 at 2–3 (ESI); Doc. 1663-18 at 2 (OptumRx/UnitedHealthcare); Doc. 1662 at 2 (Cigna). Also, some payors sent bid requests both to Sanofi and Mylan on forms that asked for exclusive offers. *See, e.g.*, Doc. 1662-2 (ESI bid grids provided to Sanofi); Doc. 1663-22 (ESI bid grids provided to Mylan); Doc. 1662-3 (CVS/Sanofi bid request); Doc. 1665-8 (CVS/Mylan bid request).

Mylan responded to those payor communications by offering enhanced rebates and price protection conditioned on excluding Auvi-Q from coverage. Sanofi characterizes Mylan's conduct as "push[ing]" contingent rebates and price protection that thereby coerced payors into exclusive rebate contracts. Doc. 1820-1 at 79–83. Although the court must construe the summary judgment facts in Sanofi's favor as the non-movant, it cannot construe the facts as far as Sanofi tries to stretch them here. Instead, the court finds, the summary judgment record simply is devoid of evidence that would allow a trier of fact to infer coercion.

Sanofi is right about one thing: Mylan offered payors rebates conditioned on exclusivity. But, as Mylan argues, "[t]here is nothing wrong with" this kind of market conduct. Doc. 1882-1 at 36 (italics omitted). The court agrees. Mylan's exclusive offers providing payors greater discounts for excluding rivals—without more—don't amount to unlawful anticompetitive conduct. *See, e.g.*, *Race Tires Am.*, 614 F.3d at 76 ("[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." (citation and internal quotation marks omitted)). Also, Sanofi's argument ignores the outcome of Mylan's rebate negotiations. In many instances, payors *rejected* Mylan's exclusive offers and chose to cover Auvi-Q. For example, Sanofi's brief provides 11 examples where Mylan asked payors for exclusivity. Doc. 1820-1 at 80–83. But of those 11 payors, only three (ESI, Aetna,

and Anthem) restricted or excluded Auvi-Q from coverage. And, as discussed, both ESI and Aetna removed the restrictions on Auvi-Q in 2015 after Sanofi presented these payors with stronger rebate offers. These facts simply can't support a reasonable inference of coercion by Mylan. To the contrary, the facts show that payors could, and often did, walk away from Mylan's exclusive rebate offers.[21]

As Mylan correctly argues, the summary judgment 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

[21] Sanofi also argues that Mylan used its "ill-gotten gains" from misclassifying the EpiPen on Medicaid formularies to offer significant rebates conditioned on excluding Auvi-Q that it otherwise could not have offered if it had classified the EpiPen properly with Medicaid. Doc. 1820-1 at 79. It is undisputed that, 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. 1816-42 at 2 (press release). But, the evidence that Sanofi cites to argue that Mylan couldn't have offered significant rebates unless it had misclassified the EpiPen is one email from Mylan to OptumRx where the discussion specifically centered around Mylan's *Medicaid* rebates for OptumRx (not commercial rebates). Doc. 1822-40 at 2 (Mylan email) (recognizing that if EpiPen "had been treated as a brand for Best Price purposes, then [Mylan] could not have rebated the product to OptumRx over the past 4 or 5 years" as it had done "because it would have been unprofitable" for Mylan). Sanofi also has submitted, as supplemental authority on this issue, an SEC Complaint against Mylan alleging that Mylan failed to disclose timely to investors that the DOJ was investigating whether Mylan overcharged Medicaid by misclassifying the EpiPen. Doc. 1951. But, as Mylan notes in its response, this Complaint only asserts unproven allegations against Mylan and qualifies as inadmissible hearsay. Doc. 1954 at 1 (citing *United States v. Klein*, No. 16-cr-442(JMA), 2017 WL 1316999, at *2 (E.D.N.Y. Feb. 10, 2017)); *see also Klein*, 2017 WL 1316999, at *2–8 (excluding an SEC Complaint from evidence as inadmissible hearsay and finding that it didn't qualify for any exception to the hearsay rule including that: (1) it wasn't a public record under Fed. R. Evid. 803(8) because it didn't contain "factual findings" but instead just mere allegations; (2) it didn't qualify as an admission by a party opponent under Rule 801(d)(2); and (3) it didn't fall within Fed. R. Evid. 807's residual hearsay exception). Sanofi identifies no other evidence in the record to support its theory that Mylan's misclassification of EpiPen with Medicaid allowed it to offer significant rebates to all other payors on their commercial formularies. Without such evidence, Sanofi's theory is pure speculation. And, this unsupported theory can't preclude the court from entering summary judgment against Sanofi's antitrust claims.

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").

But that's not what happened here. 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. Sanofi cites two documents that, it contends, support coercion. But, in one, Mylan threatened to withdraw discounts if payors *excluded EpiPen*—not if payors refused to exclude Auvi-Q. *See* Doc. 1822-6 at 2–3 (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. 1824-8 at 2 (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" (emphasis added)).

Again, Sanofi presents no evidence that Mylan threatened to cut off discounts to EpiPen *entirely* if payors refused to exclude Auvi-Q. The summary judgment facts show just the opposite. It is undisputed Mylan offered payors a range of rebates conditioned on various formulary placement for EpiPen. In some instances, Mylan offered payors greater rebates if they agreed to exclusivity. But, Mylan also offered smaller rebates for payors who chose to cover other EAI devices on the formularies. Under these facts, Mylan's rebate offers didn't amount to an "all-or-nothing" discount, as Sanofi argues. Doc. 1820-1 at 83–84 (citing *LePage's Inc. v. 3M*, 324 F.3d 141, 159 (3d Cir. 2003)). In *LePage's*, defendant refused to offer any discounts unless the customer agreed to exclude rivals. 324 F.3d at 158–59. The only purported evidence that Sanofi cites to argue Mylan made "all-or-nothing" offers is a stray remark in an *internal* Mylan email discussing negotiations with ESI's client WellPoint for 2015 formulary coverage. Doc. 1819-39 at 2 ("We will only pay rebates if a client is willing to exclude Auvi-Q."). But, in 2015, Mylan actually offered ESI a range of rebates including a 40.625% rebate for co-preferred coverage not conditioned on Auvi-Q's exclusion. Doc. 1882-27 at 4. In sum, Sanofi has adduced no evidence that Mylan refused to pay rebates on EpiPen altogether unless payors excluded Auvi-Q from their formularies.

Also, the summary judgment facts show that when payors agreed to exclude Auvi-Q, Mylan had offered a lower price on EpiPen. As Mylan argues, it's not coercion for a payor to agree to accept a lower price. Mylan likens the facts here to those presented in *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] 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 with the clause 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, plaintiff had failed to identify any summary judgment evidence of harm to competition similar to that at issue in these other Third Circuit cases. *Id.*

Likewise, here, Mylan's rebate contracts 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.

Sanofi tries to distinguish *Eisai*, arguing it differs from the facts presented by Mylan's rebate contracts because the contracts at issue in *Eisai* didn't exclude rivals, but instead only offered market share discounts. Mylan responds that this is a distinction without a difference because 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 highest discounts. In both instances, 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, "[i]t 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. Similar to *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.

Finally, the payors' conduct here refutes any finding of coercion. The undisputed summary judgment facts establish that some payors solicited exclusive offers from both Mylan and Sanofi. And, other payors testified that they viewed Auvi-Q's entry to the EAI market as an opportunity for payors to manage the EAI drug class and seek discounts for their customers. 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[.]").

In sum, Mylan has it right. The summary judgment facts here fail to present a triable issue of coercion.

iv. *ZF Meritor* Factor #7: Did Competitors of Defendant Use Exclusive Dealing Contracts?

Next, the court considers whether competitors used exclusive dealing contracts when selling EAI devices to payors. On this issue, the undisputed facts establish that they did. Indeed, Sanofi's expert testified before Congress that "[t]he way you get low prices in the pharmaceutical industry is by the ability to exclude drugs." Doc. 1661-20 at 18 (Scott Morton

Congressional Testimony). And, she explained that use of exclusive contracts "force[s] price competition." *Id.* Also, it is undisputed that Sanofi, like Mylan, used exclusive offers—both for Auvi-Q and its insulin drug Lantus.[22] Sanofi argues that the court shouldn't compare the EAI drug market with other pharmaceutical products because of its unique differences. Also, the court recognizes, this *ZF Meritor* factor requires the court to consider the "use of exclusive dealing by competitors of the defendant." *ZF Meritor*, 696 F.3d at 272. Sanofi is a competitor of Mylan in the EAI market. But the record doesn't explain whether Sanofi and Mylan also compete in the insulin drug market. So, the court questions whether it properly can consider Sanofi's contracts for Lantus under this factor.

In the end, it doesn't matter. If the court limits its review of the evidence just to the EAI market, the undisputed facts in the summary judgment record establish that Sanofi made exclusive offers for Auvi-Q, just as Mylan did. *See, e.g.*, Doc. 1665-20 at 3–4 (Sanofi's offer to OptumRx for a 22% rebate plus 9% resetting price protection on Auvi-Q in exchange for exclusive EAI formulary positions); Doc. 1667-15 at 2 (Sanofi's offer to MedImpact for a 15% rebate for 1-of-1 coverage of Auvi-Q on a closed formulary). And, some payors accepted Sanofi's exclusive offers—selecting Auvi-Q as the exclusive EAI device on a formulary and excluding EpiPen. *See, e.g.*, Doc. 1670-12 at 3 (discussing that ESI had selected Auvi-Q to be

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[22] Sanofi complains that it was "forced to offer rebates on Lantus" just to secure formulary access for Auvi-Q. Doc. 1820-1 at 78. In its 2015 contract with ESI—one where Sanofi successfully reversed ESI's exclusion of Auvi-Q—Sanofi asserts that it paid "nearly $34 million in discounts alone" on Lantus. *Id.* (emphasis omitted). But, Sanofi's complaints ring hollow in the context of its antitrust claims.

The purpose of the antitrust laws is "the protection of competition, not competitors." *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962). Here, the parties' rebating practices provided consumers greater discounts on pharmaceutical products—something that benefited consumers. *See Atl. Richfield Co. v. USA Petroleum, Co.*, 495 U.S. 328, 340 (1990) ("Low prices benefit consumers regardless of how those prices are set, and so long as they are above predatory levels, they do not threaten competition."). Sanofi's increased rebate offers for Lantus certainly didn't harm competition. Just the opposite, they promoted it.

"the exclusive Epinephrine AI on the High Performance formulary"); Doc. 1671-1 at 3 (discussing that CVS had excluded EpiPen in 2014 from its Advanced Control Formulary in favor of Auvi-Q). 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).

v. *ZF Meritor* Factor #4: What are the Anticompetitive Effects vs. Procompetitive Effects of the Contracts?

The next factor the court considers is the anticompetitive effects of the exclusive dealing contracts compared to their procompetitive effects. Mylan asserts that its rebate agreements were procompetitive because they provided incentives for payors to choose exclusivity in the form of discounts. Doc. 1660-2 at 82. Sanofi disagrees. Sanofi argues that the summary judgment record contains "overwhelming evidence" that Mylan's rebate contracts were anticompetitive. Doc. 1820-1 at 64. To support this argument, Sanofi relies on documents that—Sanofi contends—show Mylan intended to use its exclusive contracts to exclude rivals and that Mylan had no legitimate business purpose for offering large rebates. *Id.* at 64–71. Instead, Sanofi argues, Mylan's only purpose was blocking Auvi-Q from entering the market.

But, as our Circuit has explained, "intent to harm a rival, protect and maximize profits, or do all the business if they can, is neither actionable nor sanctioned by the antitrust laws." *SCFC ILC, Inc. v. Visa USA, Inc.*, 36 F.3d 958, 969 (10th Cir. 1994) (citation and internal quotation marks omitted); *see also A.A. Poultry Farms, Inc. v. Rose Acre Farms, Inc.*, 881 F.2d 1396, 1401 (7th Cir. 1989) ("Firms 'intend' to do all the business they can, to crush their rivals if they can. . . . . Rivalry is harsh, and consumers gain the most when firms slash costs to the bone and pare

price down to cost, all in pursuit of more business. Few firms cut price unaware of what they are doing; price reductions are carried out in pursuit of sales, at others' expense."); *see also id.* at 1402 ("Intent does not help to separate competition from attempted monopolization and invites juries to penalize hard competition.").

The court recognizes, though, that "knowledge of intent may help the court to interpret facts and to predict consequences." *Bd. of Trade of City of Chi. v. United States*, 246 U.S. 231, 238 (1918). But intent is not dispositive. *Hahn v. Or. Physicians' Serv.*, 868 F.2d 1022, 1026 (9th Cir. 1988). Intent or "[m]otive can, of course, be a guide to expected effects, but effects are still the central concern of the antitrust laws[.]" *U.S. Healthcare, Inc. v. Healthsource, Inc.*, 986 F.2d 589, 596 (1st Cir. 1993). "[M]otive is mainly a clue," but "the ultimate issue in exclusivity cases remains the issue of foreclosure and its consequences." *Id.* (concluding that "[a]bsent a compelling showing of foreclosure of substantial dimensions . . . there is no need . . . to pursue any inquiry into [defendant's] precise motives for the clause, the existence and measure of any claimed benefits from exclusivity, the balance between harms and benefits, or the possible existence and relevance of any less restrictive means of achieving the benefits").

Thus, subsection vi, below, proceeds to examine this "ultimate issue"—*i.e.*, whether Mylan's rebate contracts substantially foreclosed competition. *U.S. Healthcare*, 986 F.3d at 596. As discussed, Sanofi hasn't made the kind of "compelling showing of foreclosure," so the court declines to inquire "into [Mylan's] precise motives for" the exclusive contracts. *Id.*

vi. *ZF Meritor* Factor #2: Is There Substantial Market Foreclosure?

As previously discussed, 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 "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").

Mylan argues that Sanofi hasn't come forward with substantial evidence of foreclosure because the highest foreclosure percentage calculated by Sanofi's expert was 31% of the U.S. population in December 2013 and March 2014. Doc. 1661-10 at 50–51 (Scott Morton Expert Reply Report ¶ 104 (citing Mylan presentations calculating foreclosure)); *see also* Doc. 1822-35 at 5 (Mylan December 2013 presentation stating "[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) of

the US population"). Mylan asserts that this calculation is flawed because it simply reports Mylan's internal calculation of the share of the U.S. population for which Auvi-Q was not covered. But, Mylan contends, this calculation never defines the amount of foreclosure based on Mylan's alleged anticompetitive conduct. Nevertheless, Mylan argues that the 31% foreclosure calculation can't suffice to create a triable issue of substantial foreclosure.

Also, Mylan argues that the 31% calculation overstates the foreclosure percentage because the rebate contracts at issue here had a short duration and were easily terminable. Indeed, 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.

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. Payors regularly invoked the contracts' termination provisions, and they frequently renegotiated their rebate percentages to secure better pricing from drug manufacturers in exchange for better formulary positions. 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 foreclose [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").

Sanofi disputes the proposition that its foreclosure percentages are inflated because they don't account for payors' ability to walk away from their contracts and purchase from a competitor.[23] Just the opposite, Sanofi contends that its foreclosure percentage is underestimated because it doesn't account for the "spillover" effects that Mylan enjoyed from securing exclusionary contracts for EpiPen. But Sanofi never quantifies the amount of this purported spillover into a market foreclosure percentage. And, as the antitrust plaintiff, Sanofi bears the burden of proof to marshal evidence supporting a genuine issue of foreclosure. Here, 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.

[23] Sanofi also argues that it has presented evidence of substantial foreclosure through the percentage of Mylan's non-contestable or entrenched demand and Dr. Scott Morton's Effective Entrant Burden ("EEB") test. As discussed in the following section, Sanofi cannot survive Mylan's summary judgment motion though its non-contestable market share theory. And, as discussed in the court's contemporaneously-filed Order ruling the parties' *Daubert* motions, the court excludes Dr. Scott Morton's EEB theory for two reasons: (1) it's unreliable, and (2) it's not supported by the factual record in this case.

Even more, Sanofi's argument about "spillover" effects doesn't translate to a showing of market foreclosure. Sanofi's expert, Dr. Scott Morton, opines that any "spillover" effects "increase[d] Mylan's *entrenched share* throughout the market" by "leverag[ing] exclusionary restrictions it secured at some of the largest PBMs" to prevent physicians from prescribing Auvi-Q to patients who used other PBMs. Doc. 1821-18 at 86 (Scott Morton Expert Report ¶ 134) (emphasis added); *see also id.* (Scott Morton Expert Report ¶ 135) (explaining that the "most important" factor that contributes to the "spillover" effect is that physicians "write prescriptions based in part on what products they know are available to all of their patients" so "if one or more large plans in a region have excluded Auvi-Q and only make EpiPen available, [physicians] will tend to prescribe EpiPen to other patients in the region, even if the health plans for those patients provide equal or even preferred access to Auvi-Q (or other competing EAIs)."). The court can't make the leap to infer foreclosure from Dr. Scott Morton's opinion. In any instances where a "spillover" effect occurred, a patient whose PBM or payor covered Auvi-Q wasn't prevented from accessing Auvi-Q. With her opinion, Dr. Scott Morton simply asserts that spillover effects increased Mylan's entrenched market share—but not that any market *foreclosure* occurred.

But, importantly, and to the extent one can infer from the facts that any spillover had a market foreclosure effect, that effect is negated by payors' ability to renegotiate rebate contracts on a regular basis or walk away from rebate contracts in favor of better discount offers from competitors. Indeed, Sanofi never disputes that by 2015, when it had to recall Auvi-Q, it had regained "80% commercial market access overall." Doc. 1671-16 at 17 (Sanofi presentation); *see also* Doc. 1820-1 at 34 (responding that Mylan's Statement of Fact ¶ 124 is undisputed). When presented with similar facts, at least one court has held that level of foreclosure insufficient to support an antitrust claim. *See, e.g.*, *TCA Bldg. Co. v. Nw. Res. Co.*, 873 F. Supp.

29, 38–39 (S.D. Tex. 1995) (granting summary judgment against an exclusive dealing claim where plaintiff had "almost 70% of the . . . market open to it"). Similarly, here, the summary judgment facts don't present a triable issue of foreclosure when it is undisputed that Auvi-Q had access to 80% of the commercial market within two years of its coming to the EAI market.

vii. Conclusion

The court has considered all of the *ZF Meritor* factors to determine whether Mylan's exclusive rebate contracts substantially foreclosed competition. After analyzing those factors, the court agrees with Mylan. Under these summary judgment facts, Sanofi has failed to present a triable issue that Mylan's rebate contracts foreclosed Sanofi from a substantial share of the market. Applying a rule of reason analysis to the summary judgment facts here, the record shows 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 Sanofi hasn't shouldered its burden to present a triable issue whether Mylan's exclusive rebate contracts violated the Sherman Antitrust Act under a rule of reason analysis.

c. Contestable and Non-contestable Demand

Next, Mylan argues that the court should grant summary judgment against Sanofi's Sherman Act claims to the extent they are based on a theory that Mylan leveraged its non-contestable demand for EpiPen to force payors to agree to cover EpiPen and exclude Auvi-Q from their EAI formularies. Sanofi's expert, Dr. Scott Morton, explains that "non-contestable demand" is "the portion of the market that—even in the face of entry of an alternative—will not switch away from the incumbent's product, at least in the shorter term." Doc. 1821-18 at 52 (Scott Morton Expert Report ¶ 76). Dr. Scott Morton opines that EpiPen "benefited" from non-

contestable demand because it had a "committed customer base that would not easily switch away from the EpiPen." *Id.* She explains, "Even when faced with competition from an innovative product, and even were there not significant barriers to entry . . . Mylan would still be able to keep a significant portion of the market, at least in the shorter term." *Id.* Dr. Scott Morton further concludes that EpiPen's "non-contestable demand" gave Mylan "entrenched market power." *Id.* She opines that Mylan used its entrenched market share to offer exclusionary rebates that it knew Sanofi couldn't match "because switching all or nearly all customers from EpiPen to Auvi-Q was not possible." *Id.* at 75–76 (Scott Morton Expert Report ¶ 118). And, she calculates Mylan's entrenched market share as falling "in the range of 50–70% of the EAI market." *Id.* at 96 (Scott Morton Expert Report ¶ 151).

The Third Circuit considered in *Eisai* whether a dominant supplier unlawfully had restricted a competitor's sales by using its non-contestable demand. There, plaintiff's expert opined that the market share discount contracts at issue "restricted rival sales by bundling each customer's contestable demand for" Sanofi's drug, Lovenox "with the customer's incontestable demand for Lovenox[.]" *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 401 (3d Cir. 2016). "The incontestable demand for Lovenox was based, at least partially, on its unique cardiology indication, which no other anticoagulant in the market possessed and which hospitals needed to treat certain of their patients." *Id.*

When considering the expert's bundling theory, the Circuit noted that "a bundling arrangement generally involves discounted rebates or prices for the purchase of multiple products." *Id.* at 405. But, in *Eisai*, the plaintiff didn't assert that "Sanofi conditioned discounts on purchases across various product lines," instead, plaintiff alleged that Sanofi bundled "different types of demand for the same product." *Id.* The Circuit found that "[s]uch conduct

does not present the same antitrust concerns" as traditional bundling arrangements for multiple products and the Circuit was "aware of no court that has credited this novel theory." *Id.* at 405–06. So, the Circuit refused "to extend the rationale of [an unlawful bundling case] based on the facts presented" in *Eisai*. *Id.* at 406.

Mylan asserts that this court, like the Third Circuit, should reject Sanofi's attempt to assert a novel antitrust theory premised on Mylan leveraging its non-contestable demand to force payors into agreeing to exclusive contracts. Sanofi responds by citing two fairly recent district court cases that have denied motions to dismiss exclusive dealing claims that included allegations that a defendant's bundling of contestable and non-contestable demand produced anticompetitive effects. *See In re Remicade Antitrust Litig.*, 345 F. Supp. 3d 566, 578–80 (E.D. Pa. 2018); *Pfizer Inc. v. Johnson & Johnson*, 333 F. Supp. 3d 494, 504 (E.D. Pa. 2018).

Mylan responds to Sanofi's use of these two, related cases, arguing that they differ from the summary judgment facts here. Defendants in those cases offered multi-product bundles—something not at issue in this case. *See In re Remicade Antitrust Litig.*, 345 F. Supp. 3d at 575, 578 (concluding that plaintiffs plausibly alleged defendant's "exclusive contracts and rebate bundles make it impossible for competitors" to compete because they "could never effectively offset [defendant's] rebates because the rebates are linked to such a wide proportion of the patient market (the incontestable demand for [the drug product] Remicade, comprised of patients unlikely to switch treatment), *and also linked, through [defendant's] rebate bundles, to other [defendant] products that [competitors] cannot offer*" (emphasis added)); *see also Pfizer Inc.*, 333 F. Supp. 3d at 504 (concluding that defendant's "multi-product bundles, on their own . . . do not present antitrust concern" because plaintiff still could compete by offering its own multi-product bundle). But, while these cases had multi-product bundle components, plaintiffs also

had alleged a theory of bundling contestable and non-contestable demand for the same product. *See In re Remicade Antitrust Litig.*, 345 F. Supp. 3d at 575; *Pfizer Inc.*, 333 F. Supp. 3d at 498–99. And, in both cases, the Pennsylvania federal court found that the bundling allegations asserted under this theory plausibly alleged anticompetitive conduct. *See In re Remicade Antitrust Litig.*, 345 F. Supp. 3d at 578 (concluding that plaintiff stated a plausible antitrust claim where it alleged it "could never effectively offset [defendant's] rebates because the rebates are linked to such a wide proportion of the patient market (the incontestable demand for Remicade, comprised of patients unlikely to switch treatment)" as well as multi-product bundled rebates and finding that these allegations sufficiently "pled facts that make it plausible that the 'probable effect'" of defendant's conduct "is to substantially lessen competition"); *Pfizer Inc.*, 333 F. Supp. 3d at 504 (explaining that *Eisai* "did not completely shut the door" on a theory based on "bundling contestable and incontestable demand, for the same product," and refusing to dismiss plaintiff's antitrust claim based on this bundling theory because "[b]undling Remicade's incontestable demand could create anticompetitive consequences by foreclosing competition for new . . . patients—thereby posing antitrust concern").

But, even if the court were to accept Sanofi's non-contestable demand theory, the summary judgment facts here present no triable issue whether "an equally efficient competitor was unable to compete with" Mylan. *Eisai*, 821 F.3d at 406. Instead, the summary judgment facts show that payors viewed EpiPen and Auvi-Q as therapeutically equivalent and interchangeable.[24] Several payors testified that they could have excluded EpiPen in favor of

[24] In contrast, in *Eisai*, Sanofi's drug Lovenox had an FDA-approved use "for treating certain more severe forms of heart attack, an indication that [plaintiff's drug] Fragmin does not have." 821 F.3d at 399. Yet, the Third Circuit still found no evidence to support plaintiff's incontestable demand theory because, while "obtaining an FDA indication requires investing a significant amount of time and resources in clinical trials[,]" plaintiff did not "offer evidence demonstrating that fixed costs were so high that competitors entering the market were unable to obtain a cardiology indication." *Id.* at 406.

Auvi-Q because they could shift product use from EpiPen to Auvi-Q. And, the summary judgment evidence includes several examples where Sanofi successfully took market share from EpiPen and converted it to Auvi-Q's by securing exclusive or preferred formulary status. *See, e.g.*, Doc. 1671-1 at 3 (Mylan/CVS email) (discussing that, after EpiPen's exclusion from CVS's Advanced Control Formulary, EpiPen's market share was "all but gone"); Doc. 1671-21 at 11 (Mylan presentation) (noting EpiPen use on plans that adopted CVS Value Formulary "completely disappeared in Q4 2014"); Doc. 1661-13 at 83 (Willig Expert Report ¶ 204) (finding that when ESI excluded EpiPen from its High Performance Formulary, EpiPen's share for plans that adopted the exclusion list (*i.e.*, plans with a closed formulary structure) "dropped from an average of 94% in the end of 2014, to about 12% by June 2015"). [25]

Attempting to dispute these facts, Sanofi relies on Dr. Scott Morton's calculation of EpiPen's entrenched market share as falling "in the range of 50% and 70% of the EAI market." Doc. 1821-18 at 96 (Scott Morton Expert Report ¶ 151). But, as Mylan's expert explains, Dr. Scott Morton calculated this percentage using data from plans that had and had not excluded EpiPen. Doc. 1661-13 at 82–86 (Willig Expert Report ¶¶ 203–208). So, Mylan contends, Dr. Scott Morton's calculation isn't an accurate measurement of foreclosure. The court agrees. And, as shown by the concrete examples discussed in the previous paragraph, the actual data for

[25] Importantly, these facts differ from the ones alleged in *Pfizer*. The *Pfizer* case noted that plaintiff had alleged that it "offered more competitive pricing for [its product][,]" and if plaintiff could "prove true" that allegation "then the pricing data may indicate that [defendant's] conduct has prevented [plaintiff] from competing in violation of the antitrust laws." *Pfizer*, 333 F. Supp. 3d at 505. In contrast here, a case that has reached the summary judgment stage, the undisputed facts reveal Sanofi never was excluded or restricted from payors' formularies when it offered lower prices than Mylan offered on the EpiPen. And the summary judgment facts show that Sanofi was able to reverse payors' exclusions when it offered more competitive rebates for Auvi-Q.

plans where EpiPen was excluded reveals EpiPen lost significant market share when it was excluded in favor of Auvi-Q.

Sanofi also relies on testimony from payors recognizing EpiPen as a market leader and discussing the ability to switch customers to Auvi-Q. Doc. 1820-1 at 73–75. But none of this evidence quantifies any amount of non-contestable market share enjoyed by EpiPen. Also, Sanofi points to a document that Dr. Scott Morton cited in her Expert Report. Doc. 1821-18 at 54–55 (Scott Morton Expert Report ¶ 80). It refers to an internal Mylan email discussing "talking points" for an upcoming meeting with MedImpact that included a discussion of EpiPen's ability to maintain 40 to 70% market share on Medicaid plans when blocked with a step edit preferring Adrenaclick. *See id.* Mylan argues that this one reference to another EAI product's performance (which one payor testified had supply problems) on a Medicaid formulary doesn't present a triable issue whether EpiPen had significant non-contestable share in commercial formularies such that Auvi-Q couldn't compete with EpiPen. Doc. 1882-1 at 43–44. The court agrees with Mylan's point, especially when the evidence shows that Auvi-Q successfully captured EpiPen market share on formularies where EpiPen was excluded.

Finally, Sanofi points to testimony by Mylan's expert where he was asked about Mylan's ability to keep a majority market share on UnitedHealthcare's formulary when UnitedHealthcare excluded EpiPen for Twinject. Doc. 1824-9 at 5 (Willig Dep. 161:5–164:11). But, none of this testimony references any evidence showing EpiPen's ability to retain significant market share even when excluded from formularies. Instead, the testimony consists of defendant's expert responding to hypothetical questions about what EpiPen's performance in that hypothetical scenario could have shown. In short, the evidence Sanofi relies on doesn't present a triable issue

whether EpiPen's non-contestable demand prevented Auvi-Q from competing as an equally efficient competitor in the market.[26]

For these reasons, the court grants summary judgment against Sanofi's antitrust claims to the extent they are premised on a theory that Mylan unlawfully leveraged its non-contestable demand for EpiPen to exclude rivals.

d. Mylan's Other Conduct

Last, the court considers whether Sanofi has adduced evidence of any anticompetitive conduct (other than Mylan's rebating practices) from which a reasonable jury could find that Mylan engaged unlawfully in an overall scheme to restrict competition in the EAI market. Sanofi points to two other types of allegedly anticompetitive conduct on Mylan's part: (1) deceptive speech, and (2) the EpiPen4Schools® program. The court discusses each, in turn, below. And, the court concludes that the summary judgment facts don't present a triable issue whether Mylan's speech or the EpiPen4Schools® program amount to anticompetitive conduct sufficient to contribute to an overall scheme to monopolize violating the Sherman Antitrust Act.

i. Deceptive Speech

Deceptive speech about a rival "without more, rarely interferes with competition enough to violate the antitrust laws[;]" but "some cases, such defamation, which plainly is not competition on the merits, can give rise to antitrust liability, especially when it is combined with other anticompetitive acts." *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 109 n.14 (3d Cir. 2010); *see also Caldera, Inc. v. Microsoft Corp.*, 87 F. Supp. 2d 1244, 1249 (D.

[26] Sanofi also urges the court to apply Dr. Scott Morton's Effect Entrant Burden ("EEB") test to calculate the amount of Mylan's non-contestable share that foreclosed competition in the market. But, as discussed, the court excludes Dr. Scott Morton's EEB theory because it is unreliable and unsupported by the factual record. So, Sanofi's reliance on the EEB test doesn't save Sanofi's antitrust claims from summary judgment.

Utah 1999) (holding that "misleading statements may not amount to a finding of Section 2 liability standing alone" but "[t]he statements viewed with other behavior may, however, support a Section 2 violation").

The Tenth Circuit has explained that a defendant's "deceptive actions—usually aimed at third parties in the marketplace" can give rise to antitrust liability when the deceptive acts are "so widespread and longstanding and practically incapable of refutation that they are capable of injuring both consumers and competitors." *Novell, Inc. v. Microsoft Corp.*, 731 F.3d 1064, 1079–80 (10th Cir. 2013). The Circuit has applied a test that presumes that allegedly false speech "bears only a *de minimis* effect on competition." *Lenox MacLaren Surgical Corp. v. Medtronic, Inc.*, 762 F.3d 1114, 1127 (10th Cir. 2014); *see also Nat'l Ass'n of Pharm. Mfrs., Inc. v. Ayerst Labs.*, 850 F.2d 904, 916 (2d Cir. 1988) ("[A] plaintiff asserting a monopolization claim based on misleading advertising must overcome a presumption that the effect on competition of such a practice was de minimis." (citation and internal quotation marks omitted)).

An antitrust plaintiff "may rebut this presumption by satisfying a six-factor test, showing that the disparagement was: (1) clearly false, (2) clearly material, (3) clearly likely to induce reasonable reliance, (4) made to buyers without knowledge of the subject matter, (5) continued for prolonged periods, and (6) not readily susceptible to neutralization or other offset by rivals." *Lenox*, 762 F.3d at 1127 (citing *Am. Prof'l Testing Serv., Inc. v. Harcourt Brace Jovanovich Legal & Prof'l Publ'ns, Inc.*, 108 F.3d 1147, 1152 (9th Cir. 1997)); *see also Ayerst Labs.*, 850 F.2d at 916 (quoting III P. Areeda & D. Turner, *Antitrust Law* ¶ 738a, at 278–79 (1978)).

The Tenth Circuit has not decided whether a plaintiff must establish all six factors to overcome the *de minimis* presumption. *Lenox*, 762 F.3d at 1128 & n.9 (declining to decide whether a plaintiff needs to satisfy all six factors when the summary judgment record presented

"sufficient evidence to create a question of material fact on each prong of the trade-disparagement test"); *see also Duty Free Ams., Inc. v. Estee Lauder Cos.*, 797 F.3d 1248, 1269 (11th Cir. 2015) (holding that the court need not determine whether a plaintiff must allege all six factors because the complaint failed to allege falsity).

Sanofi argues that the court shouldn't apply this test and, instead, consider Mylan's anticompetitive conduct as a whole, as the Utah federal district court did in *Caldera.* Doc. 1820-1 at 94 (citing *Caldera*, 87 F. Supp. 2d at 1251). As discussed in this Order, though, the court finds that Mylan's other conduct doesn't raise any triable issues of anticompetitive conduct. So, this argument doesn't help Sanofi.

But, Sanofi also argues that, even if *Lenox*'s six-factor test applies, genuine issues exist on all six factors. The court disagrees. Instead, it finds that the summary judgment facts present no triable issue about the first factor—*i.e.*, the falsity of Mylan's statements. Also, the record fails to show a fact issue on the fifth and sixth factors—*i.e.*, that the statements "continued for prolonged periods" and were "not readily susceptible to neutralization or other offset by rivals." *Lenox*, 762 F.3d at 1127.

Sanofi argues that Mylan made just two allegedly deceptive statements about Auvi-Q.[27] Doc. 1820-1 at 93. *First*, Sanofi identifies a study that Mylan funded and presented. It's titled: "Auvi-Q Versus EpiPen Auto-Injectors: Failure to Demonstrate Bioequivalence of Epinephrine Delivery Based on Partial Area Under the Curve." Doc. 1822-30 (Study and Mylan

[27] Sanofi also alleges that Mylan shared competitively sensitive rebate information among payors to encourage them to exclude Auvi-Q and improperly acquired and used confidential information about Sanofi's marketing. Doc. 1820-1 at 99. The summary judgment evidence that Sanofi cites to support these assertions simply doesn't substantiate the claims—and the inferences Sanofi asks the court to draw from that evidence are patently unreasonable. *See, e.g.*, Doc. 1820-1 at 29–31, 91, 99. The court thus finds no triable issue that Mylan either shared competitive rebate information or improperly obtained and used Sanofi's sensitive confidential information.

presentation). Sanofi argues that the title of this study is false and misleading because the FDA concluded that the epinephrine in Auvi-Q "demonstrated bioequivalence" with the epinephrine in EpiPen. *See* Doc. 1816-32 at 6 ("The [pharmacokinetics] trial . . . demonstrated bioequivalence . . . ."). But, as Mylan correctly argues, the study doesn't assert falsely that Auvi-Q's epinephrine—itself—isn't bioequivalent to EpiPen's epinephrine. Instead, the study found a "Failure to Demonstrate Bioequivalence of Epinephrine *Delivery*." Doc. 1822-30 at 3 (emphasis added). The study suggests that Auvi-Q's delivery of epinephrine wasn't bioequivalent because, it concluded, the EpiPen epinephrine was absorbed more quickly upon delivery. *See id.* (concluding that bioequivalence "could not be concluded for comparison of Auvi-Q with EpiPen following a single epinephrine 0.3-mg dose, primarily attributed to lower epinephrine exposure from Auvi-Q relative to EpiPen during the early phase of epinephrine absorption"). Sanofi directs the court to no evidence creating a triable issue whether this study's conclusion was clearly false.

Second, Sanofi argues that Mylan engaged in deceptive speech by suggesting in marketing materials that payors' decisions to exclude Auvi-Q from their formularies was based on clinical recommendations and not Mylan's large rebates conditioned on Auvi-Q exclusion. Doc. 1820-1 at 93. But, in each of the cited statements, Mylan truthfully recited that payors made their coverage decisions based on financial and clinical recommendations. The summary judgment facts establish that payors conducted a clinical review of Auvi-Q and determined that Auvi-Q was a treatment similar to or interchangeable with EpiPen. So, some of these payors chose to cover just one EAI product. Sanofi contends that Mylan—by making the statements about Auvi-Q's formulary coverage—was implying that payors decided to exclude Auvi-Q for safety reasons. But, that inference isn't a reasonable one. Nothing in these materials refer to

Auvi-Q's safety or effectiveness. They simply recite—truthfully—payors' coverage decisions. So, the summary judgment record doesn't present a jury question whether the statements about Auvi-Q's formulary coverage were "clearly false." *Lenox*, 762 F.3d at 1127.

Also, the summary judgment record doesn't present a fact issue about the fifth or sixth *Lenox* factors. Sanofi presents no evidence that the allegedly deceptive statements "continued for prolonged periods." *Id.* Sanofi argues that the court already decided that Mylan's statements continued for a legally sufficient prolonged period when it denied Mylan's Motion to Dismiss. Doc. 1820-1 at 97. But, that's not right. On the Motion to Dismiss, the court recognized that Sanofi's Complaint failed to "allege facts capable of supporting all of the factors required to overtake the *de minimis* presumption" but it found that the "factors require[d] factual development through the discovery process," so the court "refuse[d] to dismiss Sanofi's claim at the pleading stage." Doc. 98 at 27–28. Now, at summary judgment, Sanofi must come forward with evidence showing when and how long Mylan made these allegedly deceptive statements so that there is a fact issue whether Mylan made the statements for prolonged periods. Sanofi hasn't shouldered that burden here. Simply, it hasn't presented a triable issue whether the statements "continued for prolonged periods," as the fifth *Lenox* factor requires. *Lenox*, 762 F.3d at 1127.

Sanofi also can't point to a factual dispute whether the allegedly deceptive statements were "not readily susceptible to neutralization or other offset by rivals." *Lenox*, 762 F.3d at 1127. *Lenox* held that a plaintiff had shown a triable issue on this factor when it presented evidence from which a jury could find that defendant helped initiate an FDA recall of plaintiff's product. *Id.* The court relied on testimony from plaintiff's expert and company president, who explained that hospitals were unwilling to purchase products that the FDA had recalled because

it could expose them to malpractice claims. *Id.* So, the court concluded "a fact-finder could reasonably infer that [plaintiff] could not have neutralized the effects of the recall" once its product appeared on the FDA's recall list. *Id.*

In contrast here, the allegedly deceptive statements weren't made as part of a scheme to recall a competitor's product. Instead, Mylan made the statements at issue in its marketing of EpiPen. Sanofi's only evidence about its inability to neutralize Mylan's statements comes from statements that *Mylan* executives made in a lawsuit Mylan brought in West Virginia state court seeking a preliminary injunction against the West Virginia Department of Health And Human Resources' decision to remove EpiPen from its Medicaid Preferred Drug List. Doc. 1820-1 at 97 (citing Doc. 1817-28). But, Mylan's assertions in an unrelated lawsuit about EpiPen's formulary status on a state Medicaid formulary don't have any bearing on Sanofi's ability to neutralize Mylan's marketing statements about Auvi-Q.

As Mylan argues, Sanofi is one of the world's largest pharmaceutical companies. The summary judgment record establishes, as uncontroverted, that Sanofi has teams of sales representatives around the county. And it is undisputed that this sales force engaged in various marketing efforts for Auvi-Q. No reasonable jury could infer from these summary judgment facts that Sanofi's Auvi-Q marketing efforts were incapable of responding to Mylan's marketing of EpiPen. *See Am. Council of Certified Podiatric Physicians & Surgeons v. Am. Bd. of Podiatric Surgery, Inc.*, 323 F.3d 366, 372 (6th Cir. 2003) (affirming summary judgment against antitrust claim premised on false advertising because "the record clearly establishes that any negative effects of the statements could be cured with relative ease by plaintiff[,]" plaintiff "clearly did so in a number of instances[,]" and plaintiff "could directly contact the individuals targeted by defendant and did not have to engage in a series of expensive media campaigns").

The final *Lenox* factor doesn't require a showing that plaintiff succeeded in its effort to neutralize the alleged false statements—it just requires a showing that the statements aren't "readily susceptible to neutralization or other offset." *Lenox*, 762 F.3d at 1127; *see also Am. Prof'l Testing Serv., Inc. v. Harcourt Brace Jovanovich Legal & Prof'l Publ'ns, Inc.*, 108 F.3d 1147, 1152 (9th Cir. 1997) (affirming judgment against Sherman Act claims where plaintiff "presented little evidence" that defendant's "false advertising was not readily susceptible to neutralization or other offset by" plaintiff and rejecting plaintiff's "argument that its neutralization efforts were not completely successful" because "the test refers to 'susceptible to neutralization' not 'successful in neutralization'"). The summary judgment facts here simply don't present a triable issue for that final *Lenox* factor.

The court thus finds that Sanofi has failed to adduce evidence permitting a reasonable jury to conclude that Mylan's allegedly deceptive speech qualifies as anticompetitive conduct prohibited by the Sherman Act.

ii. EpiPen4Schools® program

Last, Mylan asserts that the summary judgment facts raise no genuine dispute whether the EpiPen4Schools® program was unlawful anticompetitive conduct. Sanofi argues that Mylan used this program to entrench demand for EpiPen and block access to Auvi-Q. But the undisputed summary judgment facts establish that the program offered four free EpiPens to schools, and also offered a discount for schools who wanted more than the four free EpiPens. Doc. 1672-1 at 3–6 (EpiPen4Schools® program Certification Forms). The program had two discount levels. *See, e.g.*, Doc. 1822-36 at 5 (certification form). A school could receive (1) a discount on EpiPen purchases with no conditions on purchasing competing products, or it could receive (2) a greater discount if the school certified that it would purchase only EpiPen products

and not competing products for 12 months. *Id.* Through this program, Mylan has donated more than 1,000,000 free EpiPens to schools. And, as of September 2016, Mylan had sold about 45,000 EpiPens through the program.

Sanofi never implemented a similar plan to provide free Auvi-Q devices to schools. And the summary judgment record contains no evidence suggesting that anything prevented Sanofi from doing so. Like the exclusive offers that EpiPen made to commercial payors, the EpiPen4Schools® program didn't block Auvi-Q from access completely. Schools still could purchase competing EAI devices and receive Mylan's four free EpiPens. The only penalty that schools faced for purchasing other EAI devices was losing access to deeper discounts for the EpiPen.

No reasonable factfinder could infer from these undisputed facts that Mylan engaged in anticompetitive activity by offering free EpiPens to schools. To be sure, Mylan recognized the advantages of this program—*i.e.*, supplying free EpiPens to schools increased the product's visibility and familiarity among parents and patients. But nothing in the antitrust laws prohibits that kind of reputation building. Mylan chose to devote its capital to this effort. Sanofi didn't. The court thus finds that the summary judgment facts don't present a triable issue whether Mylan engaged in unlawful anticompetitive conduct by implementing its EpiPen4Schools® program.

e. Conclusion

The Ninth Circuit recently observed: "Anticompetitive behavior is illegal under federal antitrust law," but "[h]ypercompetitive behavior is not." *FTC v. Qualcomm Inc.*, 969 F.3d 974, 1005 (9th Cir. 2020). So long as a competitor doesn't engage in anticompetitive conduct, it's not unlawful for a competitor to "exercise[ ] market dominance[,]" or "play[ ] a powerful and disruptive role" in the market. *Id.* In the same vein, it's perfectly lawful for a competitor to flex

"its economic muscle 'with vigor, imagination, devotion, and ingenuity,'" and "'act[ ] with sharp elbows—as businesses often do.'" *Id.* (first quoting *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 610 (1972); then quoting *Tension Envelope Corp. v. JBM Envelope Co.*, 876 F.3d 1112, 1122 (8th Cir. 2017)). In the end, "[t]he antitrust laws are concerned with 'the protection of competition, not competitors.'" *Eisai*, 821 F.3d at 398–99 (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962)). Thus, conduct that causes damage to a competitor "is not a harm for which Congress has prescribed a remedy." *Id.* at 399.

Here, the court carefully has considered the summary judgment evidence presented by the parties. And, it concludes that the record presents no triable jury issue whether Mylan engaged in anticompetitive conduct sufficient to support Sanofi's Sherman Act claims. The court's job here is "not to condone or punish [Mylan] for its success, but rather to assess whether [Sanofi] has met its burden under the rule of reason to show that [Mylan's] practices have crossed the line to 'conduct which unfairly tends to destroy competition itself.'" *Qualcomm Inc.*, 969 F.3d at 1005 (quoting *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993)). Sanofi simply hasn't met that burden under the summary judgment facts.

The court notes that it has analyzed each type of conduct to which Sanofi raises objection—*i.e.*, Mylan's rebate contracts, its alleged use of non-contestable demand to force payors to agree to exclusive contracts, its allegedly deceptive speech, and its EpiPen4Schools® program. As our court has explained, "where claims of anticompetitive conduct are individually shown 'in numerous critical respects [to be] utterly lacking' the plaintiff's claims then 'collectively cannot have any synergistic effect' rescuing their validity." *United States v. AMR Corp.*, 140 F. Supp. 2d 1141, 1218 n.28 (D. Kan. 2001) (quoting *Ne. Tel. Co. v. Am. Tel. & Tel. Co.*, 651 F.2d 76, 94–95 n.28 (2d Cir. 1981)) (rejecting plaintiff's attempt to "rescue [its]

unfounded [antitrust] claims based upon a general allegation of a 'scheme'"). The court thus concludes that Sanofi's Sherman Act claim alleging an overall scheme to monopolize can't survive summary judgment. None of the acts Sanofi claims to have formed a part of that scheme are supported by sufficient summary judgment evidence from which a trier of fact could find or infer that Mylan engaged in anticompetitive conduct violating Sherman Act § 2.

In sum, the court grants summary judgment against Sanofi's Sherman Act § 2 claims because the undisputed summary judgment facts present no triable issue whether Mylan engaged in anticompetitive conduct.

2. Antitrust Injury

The court also grants summary judgment against Sanofi's Sherman Act claims for a second and independent reason: The summary judgment facts fail to present a triable issue whether Sanofi sustained an antitrust injury.

Sanofi's Sherman Act claims require proof that Sanofi sustained "'an antitrust injury, as defined by the Sherman Act.'" *Cohlmia v. St. John Med. Ctr.*, 693 F.3d 1269, 1280 (10th Cir. 2012) (quoting *Tal v. Hogan*, 453 F.3d 1244, 1257–58 (10th Cir. 2006)); *see also W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 101 (3d Cir. 2010) (explaining that an antitrust "plaintiff must establish that it suffered an antitrust injury"). "'The primary concern of the antitrust laws is the corruption of the competitive process, not the success or failure of a particular firm' or individual." *Cohlmia*, 693 F.3d at 1280 (quoting *Tal*, 453 F.3d at 1258); *see also Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977) (stating that the "antitrust laws . . . were enacted for the protection of competition not competitors" (citation and internal quotation marks omitted)). The antitrust laws thus require a plaintiff to prove an "injury of the type the antitrust laws were intended to prevent and that flows from that which makes

defendants' acts unlawful." *Brunswick Corp.*, 429 U.S. at 489; *see also W. Penn Allegheny*, 627 F.3d at 101 ("The antitrust-injury requirement helps ensure that the harm claimed by the plaintiff corresponds to the rationale for finding a violation of the antitrust laws in the first place, and it prevents losses that stem from competition from supporting suits by private plaintiffs for . . . damages." (citation and internal quotation marks omitted)).

So, to survive summary judgment against its Sherman Act claims, Sanofi must come forward with facts showing a genuine issue of harm to competition, not just harm to Sanofi's business. *Cohlmia*, 693 F.3d at 1281; *see also SCFC ILC, Inc. v. Visa USA, Inc.*, 36 F.3d 958, 965 (10th Cir. 1994) (requiring that an antitrust violation "must actually or potentially harm consumers"). Sanofi can satisfy this antitrust injury requirement by showing that the "'challenged conduct affected the prices, quantity or quality of goods or services, not just [Sanofi's] own welfare.'" *Cohlmia*, 693 F.3d at 1281 (quoting *Mathews v. Lancaster Gen. Hosp.*, 87 F.3d 624, 641 (3d Cir. 1996)); *see also Nahas v. Shore Med. Ctr.*, 828 F. App'x 89, 91 (3d Cir. 2020) (affirming summary judgment against a Sherman Act claim because plaintiff failed to present evidence of "an injury that 'affected the prices, quantity or quality of goods or services' available to consumers or that had an anticompetitive effect beyond [plaintiff's] 'own welfare'" (quoting *Mathews*, 87 F.3d at 641)).

Mylan argues that the summary judgment facts here present no triable issues of harm to EAI prices or the quantity or quality of those devices. So, Mylan argues, the court should grant summary judgment against Sanofi's Sherman Act claims because no trier of fact could find or infer that Sanofi sustained any antitrust injury.

On price, Sanofi directs the court to the fact that EpiPen's WAC price increased by more than 500% between 2009 and 2016. Doc. 1821-25 at 4. But, "[s]etting a high price . . . is not in

itself anticompetitive." *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 294 (2d Cir. 1979); *see also In re Indep. Serv. Orgs. Antitrust Litig.*, 85 F. Supp. 2d 1130, 1149–50 (D. Kan. 2000) ("High prices alone, however, are insufficient to show that [defendant] unlawfully acquired or maintained monopoly power."). Instead, "high prices, far from damaging competition, invite new competitors into [a] monopolized market." *Berkey Photo*, 603 F.2d at 274 n.12.

Also, the summary judgment facts show that EpiPen prices fell when Auvi-Q competed for formulary position based on price. Sanofi's expert, Dr. Scott Morton, calculated EpiPen's average net price. She concluded that the average net price rose from 2013 through 2014. Doc. 1661-9 at 60 (Scott Morton Expert Report Fig. 8). But, toward the end of 2014 and beginning of 2015, both EpiPen and Auvi-Q's net prices dropped sharply. *Id.* The timing of this price drop corresponds to the period when Sanofi started to make more aggressive rebate offers to payors to achieve better formulary positioning. And Mylan's expert, Dr. Willig, calculates that, "but-for" Mylan's exclusive rebate offers, EpiPen prices would have been *higher* than they actually were in 2013, 2014, and 2015. Doc. 1661-13 at 57–58, 136 (Willig Expert Report ¶¶ 127, 129 & Ex. 5).

Sanofi asserts that Dr. Willig's calculation is a "gimmick," Doc. 1820-1 at 100, but never explains what that pejorative label means and never presents any conflicting evidence or opinion. Sanofi contends that Dr. Scott Morton's calculation showing that EpiPen's net price would have been lower "but-for" Auvi-Q's entry in the market creates a fact issue about anticompetitive injury. Doc. 1821-26 at 22–24 (Scott Morton Expert Reply Report ¶¶ 36–37 & Fig. 2). But, the calculation Dr. Scott Morton cites as support for her proposition doesn't quantify what the price of EpiPen would have been *but-for Mylan's anti-competitive conduct—i.e.*, its exclusionary

rebate contracts. *Id.* Instead, it calculates, Dr. Scott Morton contends, what Mylan would have charged for EpiPen *absent any competition from Auvi-Q*. *Id.*; *see also* Doc. 1661 at 17–18 (Scott Morton Dep. 474:17–475:24). As Mylan correctly argues, "[t]hose are very different concepts." Doc. 1883 at 49. And, although Dr. Scott Morton calculates—most of the time—the EpiPen's "but-for" net price was lower than its actual net price, her calculation shows that EpiPen's net price dropped sharply—and *below* her calculated "but-for" price—in late 2014 and early 2015, when Sanofi began competing more aggressively against Mylan by offering greater rebates on Auvi-Q in exchange for better formulary placement. From these facts, no reasonable jury could conclude that Mylan's exclusive rebate agreements increased EpiPen prices. To the contrary, the record shows just the opposite: Mylan's rebate offers caused EpiPen prices to *drop* when Sanofi competed against Mylan based on price.

On output, Sanofi's expert concedes that "total output did increase in the U.S. EAI market from 2008 through 2015." Doc. 1821-26 at 24–25 (Scott Morton Expert Reply Report ¶ 40); *see also* Doc. 1661-9 at 26 (Scott Morton Expert Report Fig. 2) (calculating that total output from 2013 to 2015 increased by about 20%). But, Dr. Scott Morton nonetheless opines that "output would have been higher" had Mylan not engaged in exclusionary conduct. Doc. 1821-26 at 24–25 (Scott Morton Expert Reply Report ¶ 40). But, to reach that conclusion, Dr. Scott Morton performed no calculation quantifying the purported higher output. Doc. 1661 at 12 (Scott Morton Dep. 244:7–24). Instead, she testified that she determined the level of output "directionally" based on the *assumption* that "[o]utput would be higher in a competitive world." *Id.* Dr. Scott Morton's conclusory and unsupported assumption doesn't create a fact issue about output. Instead, the undisputed facts show that output increased during the relevant time period. And, according to Dr. Scott Morton's chart, output increased most significantly between 2013

and 2015, when Auvi-Q was in the market competing against EpiPen. *See* Doc. 1661-9 at 26 (Scott Morton Expert Report Fig. 2).

On quality, Sanofi cites evidence showing that Auvi-Q was a novel and innovative product because its small size and shape made it easier for patients to carry. Sanofi argues that Mylan harmed consumers by preventing them from accessing Auvi-Q and also by depriving them of the benefits of improvements it made to the EpiPen. But, as discussed, the uncontroverted evidence shows that actual payors in the actual market viewed the two products as interchangeable because they both delivered epinephrine to treat anaphylaxis. And, while the record contains evidence that some patients liked Auvi-Q's features that EpiPen didn't offer, this evidence doesn't establish that one product was superior in quality to the other. Also, Sanofi ignores the undisputed fact that it eventually recalled Auvi-Q from the market after it discovered Auvi-Q's potential for inaccurate dosage delivery of epinephrine—a defect that could cause the device to fail to deliver the drug. No reasonable jury could conclude from these undisputed facts that Mylan prevented consumers from accessing a higher quality product when Auvi-Q contained a defect that led to Sanofi voluntarily recalling the product from the market.

Finally, Sanofi argues that Mylan's conduct deprived consumers of *choice*. For support, Mylan cites deposition testimony from the corresponding consumer class cases where consumers testified that they lacked access to Auvi-Q. But this testimony merely presents a consumer's perspective about that particular consumer's options. It doesn't establish that Mylan's exclusive contracts wholly prohibited consumers from accessing Auvi-Q. Instead, the summary judgment record establishes that patients always could purchase Auvi-Q if a doctor prescribed it for them. But, the price the patient would pay for Auvi-Q depended on the patient's health insurance plan and that plan's coverage of Auvi-Q. Otherwise, as Mylan notes, the only time that patients were

prevented from purchasing Auvi-Q was after October 28, 2015—when Sanofi voluntarily recalled Auvi-Q from the market.

From these facts, and drawing all reasonable inferences in Sanofi's favor, the court concludes that no reasonable jury could find that Mylan's conduct produced an antitrust injury. Importantly, the Third Circuit has found that exclusive contracts produce no antitrust injury when a competitor "had the clear opportunity to compete and did compete, sometimes successfully, for the exclusive . . . contracts." *Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 84 (3d Cir. 2010) (granting summary judgment against plaintiff's antitrust claims because it "never suffered the kind of injury that gives rise to an antitrust claim" and thus "fail[ed] to meet the antitrust injury requirement"). That's precisely what the summary judgment facts show here. Sanofi had the opportunity to compete for better placement on payors' formularies by offering bigger discounts in exchange for exclusivity for Auvi-Q. And, in some instances, Sanofi succeeded, securing exclusive or preferred treatment when it offered more competitive pricing than Mylan offered for EpiPen. Under these summary judgment facts, Sanofi's Sherman Act claims fail as a matter of law. The court thus grants summary judgment against those claims for this second and independent reason: The summary judgment record presents no triable issue of antitrust injury.

3. Conclusion

For reasons explained, the court grants summary judgment against Sanofi's Sherman Act § 2 claims against Mylan for two reasons. The summary judgment facts present no triable issue (1) whether Mylan engaged in anticompetitive conduct violating the Sherman Act, or (2) whether Sanofi sustained an antitrust injury sufficient to support its Sherman Act claims. Sanofi's Sherman Act claims thus fail as a matter of law.

The court now turns to address Sanofi's Motion for Summary Judgment.

B. Sanofi's Motion for Summary Judgment

Sanofi asks the court to grant summary judgment against Mylan's Counterclaim alleging (1) Lanham Act violations, and (2) an unfair competition claim.[28] The court addresses the two claims, separately, below.

1. Lanham Act

The Lanham Act imposes liability when a person "in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities[.]" 15 U.S.C. § 1125(a)(1)(B); *see also Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 122 (2014) (explaining that the Lanham Act, 15 U.S.C. § 1125(a)(1)(B), prohibits false advertising); *Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 941 (3d Cir. 1993) ("Because honesty and fair play are prominent arrows in America's quiver of commercial and personal ideals, Congress enacted section 43(a) of the Lanham Act to stop the kind of unfair competition that consists of lying about goods or services." (citation and internal quotation marks omitted)).

To prevail on a claim for false or misleading representations under the Lanham Act, a plaintiff must establish that: "(1) that defendant made material false or misleading representations of fact in connection with the commercial advertising or promotion of its product; (2) in commerce; (3) that are either likely to cause confusion or mistake as to (a) the

[28] As discussed, *supra*, Sanofi also seeks summary judgment in its favor on the first element of its Sherman Antitrust Act claims—that Mylan possessed monopoly power in the EAI market. But, the court has found that the summary judgment facts present no triable issue on other elements those claims—*i.e.*, (1) whether Mylan engaged in anticompetitive conduct violating the Sherman Act, or (2) whether Sanofi sustained an antitrust injury sufficient to support Sanofi's Sherman Antitrust Act claims. So, Sanofi's Sherman Antitrust Act claims fails as a matter of law. The court thus denies as moot the portion of Sanofi's Motion for Summary Judgment seeking judgment in its favor on the first element of its Sherman Act claims.

origin, association or approval of the product with or by another, or (b) the characteristics of the goods or services; and (4) injur[y] [to] the plaintiff." *Cottrell, Ltd. v. Biotrol Int'l, Inc.*, 191 F.3d 1248, 1252 (10th Cir. 1999) (citations omitted). Other Circuits express the formula in slightly different terms. *See Pernod Ricard USA, LLC v. Bacardi U.S.A., Inc.*, 653 F.3d 241, 248 (3d Cir. 2011) ("To establish a false advertising claim under the Lanham Act, a plaintiff must prove: 1) that the defendant has made false or misleading statements as to his own product [or another's]; 2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience; 3) that the deception is material in that it is likely to influence purchasing decisions; 4) that the advertised goods traveled in interstate commerce; and 5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc." (citation omitted)).

Sanofi argues the court should grant summary judgment against Mylan's Lanham Act claim for four reasons. *First*, Sanofi contends that Mylan has failed to come forward with admissible evidence showing that Sanofi actually made any of the false or misleading statements alleged by the Counterclaim. *Second*, Sanofi asserts, no reasonable jury could conclude that any of the challenged statements—even if made by Sanofi—were false or misleading. *Third*, Sanofi contends that the summary judgment record presents no triable issue whether the challenged promotional statements qualify as commercial advertising or promotion. That is, Sanofi contends that the summary judgment facts, even viewed in Mylan's favor, preclude a finding that Sanofi made promotional statements that qualify as commercial advertising or promotion. *Last*, Sanofi asserts that Mylan cannot show any triable issue whether Mylan sustained an injury caused by any of Sanofi's actionable statements.

The court addresses each of Sanofi's arguments in the next four subsections. Because the court agrees with Sanofi's second, third, and fourth arguments, it grants summary judgment against Mylan's Lanham Act claim.

a. Sanofi's Assertion of the Challenged Statements

First, Sanofi argues that Mylan has adduced no admissible evidence capable of supporting a finding that Sanofi made any of the false or misleading statements alleged by Mylan. Sanofi contends that Mylan bases its claims on statements allegedly made to physicians' offices about Auvi-Q—including that (1) Auvi-Q is the "new EpiPen" or the "talking EpiPen," and (2) Auvi-Q is preferred by physicians and patients over EpiPen.[29] Sanofi argues that none of its advertisements or promotional materials made any of these assertions. And, it contends,

[29] Mylan's Counterclaim includes other allegations. They allege that Sanofi falsely stated that Auvi-Q can withstand higher temperatures than EpiPen and that Sanofi offered kick-backs to increase Auvi-Q sales. *See* Doc. 112 at 47–48 (Mylan Counterclaim ¶¶ 55–56, 59–61). Mylan concedes that discovery hasn't revealed sufficient evidence to support these claims. Doc. 1805-1 at 89 n.320. Although Mylan doesn't say so explicitly, the court finds that Mylan has abandoned these allegations. *See Hinsdale v. City of Liberal, Kan.*, 19 F. App'x 749, 768–69 (10th Cir. 2001) (affirming district court's dismissal of plaintiff's equal protection claim after it concluded that plaintiff had abandoned the claim because he had not addressed it in his memorandum opposing summary judgment); *see also C.T. v. Liberal Sch. Dist.*, 562 F. Supp. 2d 1324, 1337 (D. Kan. 2008) (concluding that plaintiff had abandoned his retaliation claim by not responding to defendant's motion for summary judgment against the claim).

Also, Mylan's Counterclaim alleges that Sanofi falsely represented that Auvi-Q was bioequivalent to and therapeutically interchangeable with the EpiPen. Doc. 112 at 41 (Mylan Counterclaim ¶¶ 32, 35). But its Opposition to Sanofi's summary judgment motion doesn't come forward with evidence to support this allegation. Indeed, the Opposition only mentions this alleged misrepresentation one time, but it doesn't identify any record evidence where Sanofi made such a misrepresentation. Doc. 1805-1 at 96. The Counterclaim asserts that Sanofi used its website to make this alleged misrepresentation. Doc. 112 at 41 (Mylan Counterclaim ¶ 35). But, the summary judgment record shows that Sanofi's website recited that Auvi-Q's epinephrine was bioequivalent to EpiPen's. Doc. 1811-21 at 2 (Auvi-Q website). And, the FDA had concluded that the epinephrine in Auvi-Q "demonstrated bioequivalence" with the epinephrine in EpiPen. Doc. 1816-32 at 6 ("The [pharmacokinetics] trial . . . demonstrated bioequivalence . . . ."). So, the website's statements appear consistent with the FDA's finding. Mylan doesn't offer any other evidence explaining why the website's statement was false or misleading. Thus, the court doesn't include Mylan's allegation that Sanofi falsely misrepresented that Auvi-Q was bioequivalent and thus interchangeable with the EpiPen in its analysis above because no evidence in the summary judgment record supports it.

Mylan can't support its Lanham Act claim by citing Sanofi's internal documents reporting Sanofi market research because it is inadmissible evidence.

Mylan responds that Sanofi's market research is admissible evidence because it qualifies as a business record under Fed. R. Evid. 803(6), a party admission under Fed. R. Evid. 801(d)(2), and falls within Fed. R. Evid. 807's residual hearsay exception. *See, e.g.*, *Schering Corp. v. Pfizer, Inc.*, 189 F.3d 218, 238 (2d Cir. 1999) (holding that a survey commissioned by Pfizer and its internal analysis of that survey was admissible as a party admission under Rule 801(d)(2)); *BoDeans Cone Co., L.L.C. v. Norse Dairy Sys., L.L.C.*, 678 F. Supp. 2d 883, 903–06 (N.D. Iowa 2009) (holding that survey results were admissible under Rule 807's residual exception and as "'business records' evidence" under Rule 803(6)). Mylan has the better of the argument. Sanofi's internal documents qualify as admissible evidence because they qualify both as business records under Fed. R. Evid. 803(6) and party admissions under Fed. R. Evid. 801(d)(2). Given these conclusions, the court does not need to reach the residual exception in Rule 807.

While the market research qualifies as admissible evidence, the court holds substantial reservations about the evidence's capacity to establish a critical component of this first element, *i.e.*, that Sanofi actually made the allegedly false or misleading statements. *See Cottrell, Ltd.*, 191 F.3d at 1252 (reciting first element of Lanham Act claim as requiring that "*defendant made* material false or misleading representations of fact in connection with the commercial advertising or promotion of its product" (emphasis added)); *see also Pernod Ricard USA*, 653 F.3d at 248 (3d Cir. 2011) (listing first element of Lanham Act claim as "*defendant has made* false or misleading statements as to his own product [or another's]" (emphasis added)). For one thing, the court questions whether Sanofi's internal documents can qualify as "commercial advertising or promotion" because nothing in the summary judgment record suggests that Sanofi

distributed those materials to consumers. Some cases view this omission to preclude satisfaction of the first element of a Lanham Act claim. *See Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 459 (D.N.J. 2009) ("[I]nternal documents such as marketing plans and medical bulletins do not constitute 'commercial advertising or promotion' because they are not disseminated to consumers, much less disseminated to a sufficient portion of the relevant purchasing public so as to constitute 'advertising' or 'promotion' within the industry[.]").

But more fundamentally yet, Mylan hasn't adduced admissible evidence to support a finding that the market research materials capture evidence of statements that Sanofi's sales representatives actually made to physicians. Instead, the research captures what physicians reported they recalled about their interactions with sales representatives. As Mylan's own expert concedes, the purpose of market research is "track[ing] awareness, trial and usage of launch brands, and message recall from physicians." Doc. 1806-6 at 9 (Zieziula Export Report). Neither Mylan's use of the internal reports nor any other evidence in the summary judgment record can support a finding that Sanofi's market research captured actual statements made by Sanofi's representatives.

These reservations aside, the court's analysis considers the market research evidence because it is admissible evidence at the summary judgment stage. And as explained below, even if the court assumes the market research captures actual statements made by Sanofi's representatives, Mylan's Lanham Act claim can't withstand summary judgment.

Mylan also cites other summary judgment evidence that contains statements by Sanofi that, according to Mylan, violate the Lanham Act. This evidence includes Sanofi's communication with the FDA about a handwritten note allegedly left by a Sanofi sales person, two declarations by employees of an allergy practice in Arizona about statements that a Sanofi

sales representative made to them, and a news article about Sanofi's launch of Auvi-Q. The court considers this evidence in the analysis of Mylan's Lanham Act claim, below. But for now, the court concludes that Sanofi's first argument does not entitle it to summary judgment against Mylan's Lanham Act claim.

b. False or Misleading Statements

Next, Sanofi argues that the summary judgment record presents no triable issue whether any of the challenged statements were false or misleading. This argument warrants a brief overview of the kind of statements actionable under the Lanham Act.

The Lanham Act prohibits two types of representations: "(1) those that are literally false, and (2) those that, while literally true, are likely to mislead and confuse consumers." *Intermountain Stroke Ctr., Inc. v. Intermountain Health Care, Inc.*, 638 F. App'x 778, 785 (10th Cir. 2016) (citations omitted); *see also Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 586 (3d Cir. 2002) ("Liability arises if the commercial message or statement is either (1) literally false or (2) literally true or ambiguous, but has the tendency to deceive consumers."). Sanofi contends that Mylan hasn't come forward with admissible evidence sufficient to present a jury question whether Sanofi made either type of representation.

i. Literally False Statements

Mylan asserts that Sanofi made three types of statements that were literally false.

First, Mylan argues Sanofi's statements that Auvi-Q was the "new EpiPen" or a "talking EpiPen" were literally false. These statements were literally false, Mylan contends, because they convey that Auvi-Q was a new model of the EpiPen—something that is not true. The governing legal principles provide that the factfinder must evaluate a statement's literal falsity based "'upon

the explicit claims made by an advertisement,'" but it also may conclude a statement is literally false from "'any claims the advertisement conveys by "necessary implication."'" *Zoller Labs., LLC v. NBTY, Inc.*, 111 F. App'x 978, 982 (10th Cir. 2004) (quoting *Clorox Co. P.R. v. Proctor & Gamble Com. Co.*, 228 F.3d 24, 34–35 (1st Cir. 2000)). "A literally false 'claim is conveyed by necessary implication when, considering the advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated.'" *Id.* at 982–83 (quoting *Clorox*, 228 F.3d at 35); *see also Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 586–87 (3d Cir. 2002). But, "'[c]ommercial claims that are implicit, attenuated, or merely suggestive usually cannot fairly be characterized as literally false.'" *Zoller Labs.*, 111 F. App'x at 983 (quoting *United Indus. Corp. v. Clorox Co.*, 140 F.3d 1175, 1181 (8th Cir. 1998)). Thus, "only an *unambiguous* message can be literally false." *Novartis*, 290 F.3d at 587; *see also Zoller Labs.*, 111 F. App'x at 984 (quoting *Novartis*, 290 F.3d at 586–87); *Hill's Pet Nutrition, Inc. v. Nutro Prods., Inc.*, 258 F. Supp. 2d 1197, 1209 (D. Kan. 2003) (noting that "ambiguity precludes a finding of literal falsity" and "[o]nly an unambiguous message can be literally false" (citations and internal quotation marks omitted)). "The greater the degree to which a message relies upon the viewer or consumer to integrate its components and draw the apparent conclusion, however, the less likely it is that a finding of literal falsity will be supported." *Novartis*, 290 F.3d at 587 (quoting *United Indus. Corp.*, 140 F.3d at 1181).

Sanofi argues that the "new EpiPen" statements at issue here are not "unambiguous" messages that were literally false. The court agrees. The only evidence in the summary judgment record about the "new EpiPen" statements are found in market research reports where some physicians recalled messaging that Auvi-Q was a "new EpiPen," *see, e.g.*, Doc. 1811-11 at

6 (Mylan email attaching verbatims), Doc. 1811-13 at 16–19 (Mylan Competitive Intelligence Update), and the declarations from two allergy clinic employees in Arizona who recalled a pharmaceutical sales representative telling them that "Auvi-Q was the new up-and-coming EpiPen," Doc. 1811-9 at 6 (Hartneck Decl. ¶ 3), and that Auvi-Q "was going to be like the new EpiPen," Doc. 1811-9 at 8 (Alcorn Decl. ¶ 3). But, the summary judgment record also includes undisputed facts showing that the term—EpiPen—was used to describe the entire category of EAI devices. *See, e.g.*, Doc. 1811-8 at 14 (Sanofi presentation) (recognizing that the EpiPen brand had "become eponymous of the [EAI] category" and comparing EpiPen to "'Kleenex' for tissues or 'Band-Aid' for bandages"); Doc. 1872-12 at 6 (Michelis Rebuttal Expert Report ¶ 15) ("EpiPen has been virtually the only EAI device since its inception in 1987, 'epipen' is sometimes colloquially used as a synonym for the category of EAI devices, similar to using the term 'Kleenex' to refer to tissues."). Thus, Sanofi argues, a statement referring to a "new EpiPen" is ambiguous because the statement is subject to varying interpretations. And, thus, the statement is not literally false as a matter of law.

Mylan argues that the facts presented here resemble those the Tenth Circuit considered in *General Steel Domestic Sales, LLC v. Chumley*, 627 F. App'x 682 (10th Cir. 2015). There, the competitor of a company named "General Steel" advertised that "it offered 'general steel' buildings for sale." *Id.* at 684. The competitor, the Lanham Act defendant, argued that its references to "general steel" were ambiguous because they didn't necessarily refer to General Steel—meaning the plaintiff—but instead to general, *i.e.*, all-purpose, steel buildings. *Id.* The Tenth Circuit rejected defendant's argument because the record included "no credible evidence . . . that the term 'general steel' is used in the industry to describe steel buildings sold by anyone else." *Id.* The competitor/defendant also had "included side-by-side comparisons between its

products and those offered by the General Steel company" in its ads, and it "used General Steel's logo and sometimes capitalized 'General Steel.'" *Id.* The Circuit held "[i]n this light, there's just no doubt what [the competitor defendant's] ads were talking about—or that they were literally false." *Id.*

General Steel's facts differ markedly from the summary judgment facts presented here. *General Steel* concluded that the use of the term "general steel" was unambiguous because the record included no evidence that the term had any other meanings in the industry. In contrast, here, the record includes evidence that the term "new EpiPen" is subject to more than one interpretation. In sum, the summary judgment facts preclude a reasonable finding that the purportedly literally false statements—references to Auvi-Q as the "new EpiPen" and similar statements—qualify as unambiguous messages capable of supporting a literally false theory. *Novartis*, 290 F.3d at 587.

Second, Mylan argues that Sanofi's statements about Auvi-Q's ease of use, ease of carry, and patient preference were literally false because they were unsubstantiated and not supported by Sanofi's preference study. *See, e.g.*, *Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 464 (D.N.J. 2009) ("The focus of a Lanham Act inquiry is whether statements are false or misleading at the time they are made." (citation and internal quotation marks omitted)). The evidence Mylan uses to support its attack on these statements comes from Sanofi's physician marketing research. This research reported that physicians recalled messaging that Auvi-Q was "easy to use," "easy to carry," and "easy to follow instructions." *See, e.g.*, Doc. 1810-2 at 9 (Auvi-Q Physician ATU Research Wave 1); Doc. 1810-12 at 65 (ATU Tracking Report dated Aug. 28, 2015); Doc. 1810-16 at 17–19 (Auvi-Q Brand Impact Analysis dated Mar. 2015). It also reported messaging that Auvi-Q was preferred by patients.

Doc. 1810-12 at 65 (ATU Tracking report dated Aug. 25, 2015); Doc. 1810-16 at 17–19 (Auvi-Q Brand Impact Analysis dated Mar. 2015).

To the extent Mylan argues that the messaging about "patient preference" is literally false, the summary judgment record doesn't support that allegation. Instead, a statement that patients preferred Auvi-Q is supported by Sanofi's preference study which found that patients preferred Auvi-Q's size, shape, and method of instruction. *See* Doc. 1690-9 at 10 (Auvi-Q presentation) (showing that Sanofi's preference study found that 77% of participants preferred Auvi-Q's method of instruction, 85% preferred the size of the Auvi-Q device, and 65% preferred the shape of Auvi-Q over EpiPen). As Mylan correctly asserts, the FDA told Sanofi that it couldn't use this study to make comparison claims that Auvi-Q was easier to use and easier to carry because patients weren't actually administrating the EAI devices in the study. Doc. 1690-6 at 2 (Government Agency Contact Report). But nothing in the summary judgment record presents a triable issue whether Sanofi made any such *comparison statements about Auvi-Q versus EpiPen.* Instead, as discussed, the physician market research just refers to messaging about a patient "preference" for Auvi-Q but doesn't include any messaging about specific comparisons that Auvi-Q is easier to use or easier to carry than EpiPen. Thus, Mylan has failed to adduce facts presenting a triable issue whether Sanofi made literally false statements about patient's preference for Auvi-Q.

Also, the summary judgment facts don't present any jury question whether messaging that Auvi-Q was "easy to use," "easy to carry," and had "easy to follow instructions" was literally false. Mylan tries to argue that these statements were improper comparison claims, but, again, the summary judgment record doesn't support that assertion. The physician market research doesn't contain messaging that Auvi-Q was *easier to use* or *easier to carry* compared to

the EpiPen. Instead, the physician market research reflects just generalized messaging about Auvi-Q being easy to carry, easy to use, and easy to follow its instructions.

And, as Sanofi correctly argues, these types of statements qualify as ones of "general opinion" that are "not actionable" under the Lanham Act. *Pizza Hut, Inc. v. Papa John's Int'l, Inc.*, 227 F.3d 489, 495–96 (5th Cir. 2000); *see also id.* at 498–99 (holding that the advertising slogan "Better Ingredients. Better Pizza" was a "general statement of opinion regarding the superiority of [Papa John's] product over all others" and "not actionable under the Lanham Act"); *Intermountain Stroke Ctr., Inc. v. Intermountain Health Care, Inc.*, 638 F. App'x 778, 788–89 (10th Cir. 2016) (holding "that advertising declarations about 'best medical practices, exceeding the standard of care, delivering the best possible care and . . . delivering high quality care in all services,'—all of which speak generically to the caliber of [defendant's] brand—are classic puffery" that are "incapable of objective verification" and "cannot form the basis of a Lanham Act claim"). Statements that Auvi-Q was easy to carry, easy to use, and had easy to follow instructions are subjective opinions about Auvi-Q's superiority as an EAI device. And, they can't support a Lanham Act claim. *See United Indus. Corp. v. Clorox Co.*, 140 F.3d 1175, 1180 (8th Cir. 1998) (explaining that "representations of product superiority that are vague or highly subjective" are "[n]onactionable puffery" that don't violate the Lanham Act).

Mylan disagrees with classifying these statements as opinions. It argues that these statements are specific and objectively measurable—as Sanofi tried to measure in its own study. But, this argument doesn't describe the Sanofi study accurately. The summary judgment facts establish the study was a preference study. It sought to determine whether participants *preferred* Auvi-Q over EpiPen based on certain metrics. And, as discussed, the FDA told Sanofi that its study couldn't quantify the easier to carry and easier to use metrics because patients weren't

administering the EAI devices in the study. So, the participants couldn't say whether they *preferred* Auvi-Q over EpiPen because they found it easier to use or easier to carry. As discussed, the summary judgment record doesn't contain evidence explicitly showing that Sanofi made comparison statements about Auvi-Q and EpiPen on these specific metrics. Instead, the physician market research referred to messaging that Auvi-Q generally was "easy to use," "easy to carry," and "easy to follow instructions." These kinds of statements are subjective, based on an opinion, and can't form the basis for a Lanham Act violation. Thus, the court concludes these statements about Auvi-Q don't present a triable issue whether Sanofi made any literally false statements that could support Mylan's Lanham Act claim.

Last, Mylan argues that Sanofi made false statements by necessary implication when it made statements that patients didn't carry their EAI devices and that Auvi-Q was the first EAI device with a retractable needle. Sanofi rightly asserts that both statements—even when the facts are viewed in the light most favorable to Mylan—are literally true. *See* Doc. 1821-2 at 10–11 (Michelis Expert Report ¶ 22) (Sanofi's expert explaining that patients failing to carry an EAI device during an anaphylactic episode is a documented problem); *see also* Doc. 1872-10 at 3–4 (Willig Dep. 16:19–17:21) (Mylan's expert conceding that EpiPen doesn't have a retractable needle like Auvi-Q does). But Mylan nonetheless persists, claiming that these statements are literally false because the advertisements convey false claims by "necessary implication." *Zoller Labs.*, 111 F. App'x at 982 (citation and internal quotation marks omitted).

As discussed, "[a] literally false claim is conveyed by necessary implication when, considering the advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated." *Id.* at 982–83 (citation and internal quotation marks omitted). A literally false message "is necessarily implied" if it "will necessarily and unavoidably be

received by the consumer" from the promotional statement. *Novartis*, 290 F.3d at 588. And, where "'a plaintiff's theory of recovery is premised upon a claim of implied falsehood, a plaintiff must demonstrate, by extrinsic evidence, that the challenged [advertisements] tend to mislead or confuse consumers.'" *Zoller Labs.*, 111 F. App'x at 982 (quoting *Scotts Co. v. United Indus. Corp.*, 315 F.3d 264, 273 (4th Cir. 2002)). Here, Sanofi argues that Mylan has presented no extrinsic evidence of consumer confusion. Thus, Sanofi contends, Mylan's claims that Sanofi made literally false claims by necessary implication fail as a matter of law. For reasons explained in the next subsection, the court agrees. Mylan's failure to present extrinsic evidence of confusion dooms its Lanham Act claim based on an implied falsity. But, even if Mylan had presented such extrinsic evidence, the court concludes that no reasonable jury could find from the summary judgment facts that either statement necessarily and unavoidably conveys a false statement to the recipient.

Mylan argues that Sanofi's advertisement referring to Auvi-Q as the "first and only" EAI device with a "[r]etractable needle mechanism designed to help prevent accidental needle sticks" implies falsely that EpiPen doesn't have needlestick protection. Doc. 1811-5 at 2 (Auvi-Q advertisement). Mylan argues that's untrue because EpiPen has a needle cover that extends over the needle after the EpiPen is administered. The court rejects Mylan's argument. Sanofi's advertising statement doesn't "necessarily and unavoidably" convey that EpiPen lacks needlestick protection. It just conveys that EpiPen doesn't have a *retractable* needle like Auvi-Q. And that's indisputably true. There is nothing false about Sanofi stating that Auvi-Q was the first and only EAI device with a retractable needle designed to prevent accidental needlesticks. That statement doesn't falsely imply anything about EpiPen's needlestick protection.

Also, Mylan argues that Sanofi's statement that patients didn't carry their EAI devices falsely implies that patients are more likely to carry Auvi-Q than other EAI devices. Mylan argues that this necessary implication arises when one juxtaposes the truthful statement about carry rates with a claim that Auvi-Q is easy to carry. Doc. 1805-1 at 95. But, Mylan never cites any admissible evidence that Sanofi ever made these two statements in the juxtaposition Mylan's argument assumes. Instead, Mylan merely cites a hypothetical question presented to a deponent. *Id.* (citing Doc. 1805-15 at 14–17 (Parker Dep. 62:2–65:23)). Lawyers' questions—whether asked at a trial or in a deposition—aren't evidence. *See, e.g.*, 10th Cir. Crim. Pattern Jury Instruction No. 1.06 (2011 ed. Updated Feb. 2018) ("The lawyers' statements and arguments are not evidence. Their questions and objections are not evidence."); *Burke v. Regalado*, 935 F.3d 960, 1033 (10th Cir. 2019) (approving curative action by the court that included an instruction that "[a]rguments and statements by lawyers are not evidence").

Mylan also relies on a Sanofi press release issued at Auvi-Q's launch. Doc. 1809-14 at 2 (press release). That press release noted two surveys showing that some patients don't carry their EAI devices as recommended. *Id.* Also, it touted the availability of Auvi-Q as a new EAI device to treat anaphylaxis. *Id.* The press release highlights Auvi-Q's size, shape, and audio instructions. *Id.* But it never claims that Auvi-Q is easy to carry. *Id.* In short, this press release doesn't provide any evidence that Sanofi juxtaposed statements about carry rates with a claim that Auvi-Q is easy to carry in a way that conveyed a false implication. In sum, Mylan hasn't come forward with any evidence capable of supporting a finding that Sanofi made literally false claims by necessary implication. And, along with the other conclusions in this subsection, it means that the summary judgment facts present no jury question whether Sanofi made literally false statements that could support Mylan's Lanham Act claim.

ii. Misleading Statements

Next, Sanofi asserts that Mylan hasn't presented a triable issue whether Sanofi made any misleading statements that violate the Lanham Act. To prevail on a Lanham Act claim based on a misleading statement, a plaintiff "must show 'actual consumer deception.'" *Vincent v. Utah Plastic Surgery Soc'y*, 621 F. App'x 546, 550 (10th Cir. 2015) (quoting *Abbott Labs. v. Mead Johnson & Co.*, 971 F.2d 6, 14 (7th Cir. 1992)); *see also Zoller Labs.*, 111 F. App'x at 982 (explaining that if "a plaintiff's theory of recovery is premised upon a claim of implied falsehood, a plaintiff must demonstrate, by extrinsic evidence, that the challenged [advertisements] tend to mislead or confuse consumers" (citation and internal quotation marks omitted)).

A plaintiff "can make this showing by presenting extrinsic evidence that demonstrates 'a statistically significant part of the commercial audience holds the false belief allegedly communicated by the challenged advertisement.'" *Vincent*, 621 F. App'x at 550 (quoting *Johnson & Johnson * Merck Consumer Pharms. Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 297–98 (2d Cir. 1992)). "Consumer surveys are normally used to satisfy this additional requirement." *Hill's Pet Nutrition, Inc. v. Nutro Prods., Inc.*, 258 F. Supp. 2d 1197, 1211 (D. Kan. 2003); *see also Novartis*, 290 F.3d at 588 (holding that the district court erred "in finding that a message of superior efficacy is necessarily implied" by defendant's advertising and "[i]nstead, [plaintiff] should have been required to prove through a consumer survey that the name and advertising actually misled or had a tendency to mislead consumers"); *Johnson & Johnson*, 960 F.2d at 298 ("[T]he success of a plaintiff's implied falsity claim usually turns on the persuasiveness of a consumer survey."); *Am. Home Prods. Corp. v. Proctor & Gamble Co.*,

871 F. Supp. 739, 756 (D.N.J. 1994) ("[A] case of implied falsity cannot be made out here as there is no consumer survey establishing that the public has been misled by this claim.").

Here, Sanofi argues, Mylan has adduced no evidence of customer confusion. It hasn't conducted any consumer surveys showing actual deception or confusion. And thus, Sanofi contends, Mylan's Lanham Act claim fails as a matter of law. Mylan responds, relying on the various physician market research which it characterizes as "abundant survey evidence in the record [that] would permit a jury to find confusion." Doc. 1805-1 at 98. But, this market research is insufficient as a matter of law. Sanofi's physician market research doesn't qualify as a customer survey capable of satisfying Mylan's burden to demonstrate actual confusion. The evidence Mylan cites consists of internal Sanofi presentations summarizing physician marketing research that was designed to track brand awareness and message recall from physicians. None of this evidence shows that a "statistically significant part of the commercial audience holds the false belief allegedly communicated by the challenged advertisement." *Vincent*, 621 F. App'x at 550 (citation and internal quotation marks omitted); *see also Hill's Pet Nutrition*, 258 F. Supp. 2d at 1211 (holding that plaintiff's survey was "insufficient to show actual consumer confusion" because of "the lack of scientific validity of the survey" and because "the survey, even if valid, does not speak to any causal connection"). The court thus rejects Mylan's attempts to offer Sanofi's physician market research as a legally sanctioned substitute for evidence of actual customer confusion.

This conclusion leaves Mylan with just two examples of customer confusion. First, Mylan cites the declarations from two Arizona allergy clinic employees. Next, it cites one sentence from the minutes of Horizon Blue Cross Blue Shield of New Jersey's P&T Committee about its decision to cover Auvi-Q. These two examples of purported confusion among the

entire customer base for EAI devices fail to demonstrate "*a statistically significant part* of the commercial audience" was actually confused or deceived by any alleged misleading statement by Sanofi. *Vincent*, 621 F. App'x at 550 (emphasis added).

Last, Mylan argues that it is entitled to a presumption of consumer confusion because "'where a plaintiff adequately demonstrates that a defendant has intentionally set out to deceive the public,' and the defendant's 'deliberate conduct' in this regard is of an 'egregious nature,' a presumption arises 'that consumers are, in fact, being deceived.'" *Johnson & Johnson*, 960 F.2d at 298–99 (quoting *Res. Devs., Inc. v. Statue of Liberty-Ellis Island Found., Inc.*, 926 F.2d 134, 140 (2d Cir. 1991)). As the Second Circuit has explained, "[t]his presumption which may be engendered by the expenditure 'of substantial funds in an effort to deceive consumers and influence their purchasing decisions' relieves a plaintiff of the burden of producing consumer survey evidence that supports its claim." *Id.* at 299 (quoting *Statue of Liberty-Ellis Island Found.*, 926 F.2d at 140). "In such a case, once a plaintiff establishes deceptive intent, 'the burden shifts to the defendant to demonstrate the absence of consumer confusion.'" *Id.* (quoting *Statue of Liberty-Ellis Island Found.*, 926 F.2d at 140).

Mylan asserts that the summary judgment record presents evidence creating a triable issue about Sanofi's intent to deceive the public. It alleges that Sanofi knew from its physician market surveys and communications with the FDA that its sales force was making false statements, but it was indifferent to their conduct. Although the court must construe the facts in Mylan's favor—as the non-moving party—the summary judgment record won't permit Mylan to stretch the evidence as far as Mylan's argument does. The summary judgment facts, even when construed in Mylan's favor, simply don't support Mylan's allegations of Sanofi's indifference. Instead, the record shows that Sanofi had an internal Review Committee that reviewed Sanofi's

advertising and training material to ensure it complied with the company's policies for promoting drug products. Sanofi's training materials recited the kinds of comparative claims sales representatives could make about Auvi-Q based on the preference study. Doc. 1690-10 at 11 (Auvi-Q presentation). It also warned that preference claims "can only be made [based] on the preference results shown" by the study. *Id.* Also, Sanofi warned its sales representatives that the study didn't allow them "to make an overall preference claim of Auvi-Q vs. EpiPen." *Id.* Sanofi's policies and training prohibited sales representatives from creating their own promotional materials or altering Sanofi's promotional materials in any way. Doc. 1690-12 at 2 (Sanofi letter). And, Sanofi employees who don't follow company policy governing dissemination of promotional materials are subject to discipline. *Id.* at 3 (Sanofi letter). These undisputed facts preclude an inference that Sanofi was indifferent to false statements allegedly made by its sales force so as to support a triable issue of deceptive intent. Also, the summary judgment record contains no evidence that Sanofi engaged in an "expenditure 'of substantial funds in an effort to deceive consumers and influence their purchasing decisions'" to support a presumption of actual confusion. *Johnson & Johnson*, 960 F.2d at 299 (quoting *Statue of Liberty-Ellis Island Found.*, 926 F.2d at 140); *see also id.* (refusing to "extend the presumption of consumer confusion to this case" based on "the indirect and controverted nature of the evidence regarding the intent" that was presented at trial).

Mylan has failed to come forward with evidence presenting a triable issue about actual customer confusion, as required to support its Lanham Act claim based on misleading statements.

In sum, no reasonable jury could find or infer from the summary judgment facts that Sanofi made false or misleading statements violating the Lanham Act. Mylan's Lanham Act

claim fails as a matter of law because it hasn't presented a triable issue on this required element of a Lanham Act claim. The court thus grants summary judgment against Mylan's Lanham Act claim for this reason.

c. Commercial Advertising or Promotion

Sanofi also argues that Mylan's Lanham Act claim fails to survive summary judgment for a second and independent reason: Mylan hasn't presented evidence that Sanofi widely disseminated the allegedly false or misleading statements such that it constituted commercial advertising or promotion violating the Lanham Act. *See, e.g.*, *Cottrell, Ltd. v. Biotrol Int'l, Inc.*, 191 F.3d 1248, 1252 (10th Cir. 1999) (reciting as one of the required elements of a Lanham Act claim that "defendant made material false or misleading representations of fact *in connection with the commercial advertising or promotion of its product*" (emphasis added)).

To qualify as "commercial advertising or promotion" for Lanham Act purposes, a representation "must be disseminated sufficiently to the relevant purchasing public to constitute 'advertising' or 'promotion' within that industry." *Proctor & Gamble Co. v. Haugen*, 222 F.3d 1262, 1273–74 (10th Cir. 2000) (citation omitted); *see also Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 460–461 (D.N.J. 2009); *Garland Co. Inc. v. Ecology Roof Sys. Corp.*, 895 F. Supp. 274, 277 (D. Kan. 1995) (Lungstrum, J.). "The analysis required to determine whether something has been sufficiently disseminated consists of comparing the infringing behavior to the market as a whole." *Vivint, Inc. v. NorthStar Alarm Servs., LLC*, No. 2:16-cv-00106-JNP-EJF, 2019 WL 1098986, at *7 (D. Utah Mar. 8, 2019).

Our Circuit has recognized "that the extent of distribution necessary to constitute commercial advertising or promotion in a particular case may be an elastic factor, so that a relatively modest amount of activity may be sufficient in the context of a particular case." *Sports*

Unlimited, Inc. v. Lankford Enters., Inc., 275 F.3d 996, 1005 (10th Cir. 2002) (citation omitted). But still, the Circuit has held, "these terms by their plain, everyday meaning connote *some* level of *public* dissemination of information." *Id.* (citation omitted) (holding that "distribution to two persons associated with the same project . . . simply does not . . . amount to commercial advertising or promotion and is not sufficient in the context of this case to establish a Lanham Act claim"). This showing is required because "Lanham Act coverage" doesn't extend "to every isolated alleged misrepresentation made to a potential customer by a business competitor." *Garland*, 895 F. Supp. at 279; *see also Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc.*, 314 F.3d 48, 57 (2d Cir. 2002) ("[B]usinesses harmed by isolated disparaging statements do not have redress under the Lanham Act[.]").

Trying to supports its argument that there is a triable issue on this element of the Lanham Act claim, Mylan again relies on Sanofi's own internal presentation documenting physician market research. Mylan argues that a reasonable jury could infer from these documents widespread dissemination of false statements. But, Mylan doesn't identify evidence showing that these surveys quantify the prevalence of the challenged statements among the customer base. For example, Mylan argues that Sanofi targeted allergists and pediatricians with comparative messages, and it contends those physicians accounted for more than 40% of EAI prescriptions. Doc. 1805-1 at 102 (citing Doc. 1806-10 at 57 (Sanofi Business Review)). But, the evidence Mylan cites doesn't contain any evidence showing the scope of dissemination for the allegedly false messages. Instead, the presentation merely recites the fact that allergists and pediatricians account for more than 40% of EAI prescriptions. It never shows that 40% of EAI prescribers were recipients of the allegedly false or misleading statements.

Also, Mylan points the court to its own market research noting that "28% of 364 physicians surveyed recalled that Sanofi [sales representatives had] said 'Auvi-Q preferred over EpiPen in comparative survey.'" Doc. 1805-1 at 102 (citing Doc. 1810-22 at 4, 8). Yet again, however, Mylan provides no other information about this message to quantify the number of physicians—if any—who received a false or misleading comparative claim. Indeed, the preference study found that certain numbers of patients preferred Auvi-Q over EpiPen for its size, shape, and method of instruction. So, that comparative statement is true. Although other comparative statements might qualify as a false or misleading statement capable of violating the Lanham Act, Mylan hasn't identified any summary judgment evidence quantifying the dissemination of such false or misleading messaging. And Mylan's summary judgment burden requires evidence sufficient for a reasonable trier of fact to conclude it was disseminated widely enough to support a Lanham Act claim. *See Sports Unlimited*, 275 F.3d at 1004–05 (affirming summary judgment against a Lanham Act claim where distribution of allegedly false statements to two persons didn't "amount to commercial advertising or promotion and [was] not sufficient in the context of this case to establish a Lanham Act claim"); *see also Fashion Boutique*, 314 F.3d at 58 (concluding that "a total of twenty-seven oral statements regarding plaintiff's products in a marketplace of thousands of customers" was "insufficient to satisfy the requirement that representations be disseminated widely in order to constitute 'commercial advertising or promotion' under the Lanham Act.").

Finally, Mylan relies on its expert who says he reviewed "several examples of Sanofi sales representatives" making the challenged statements to customers in Arizona, Alabama, California, and Massachusetts, as well as "Mylan field intelligence reports and message recall studies" showing that the challenged statements were "widespread." Doc. 1806-6 at 14 (Zieziula

Expert Report). Mylan's expert asserts that, in his experience, he "would have relied on reports from sales representatives of frequent occurrences of confusing messaging, combined with documented evidence of those messages, to determine whether a competitor's messaging campaign was widespread." *Id.*

But, once again, none of this evidence ever quantifies how "widespread" the allegedly false statements were disseminated among the customer base. Instead, Mr. Zieziula relies merely on a handful of examples and non-descript intelligence reports from Mylan to conclude the messaging was widespread. But, as the Colorado federal district court has explained: "[D]issemination of information must reach some numerically-significant quantity of actual or potential customers of the parties' products" to "constitute an actionable advertising or promotional campaign[.]" *Gen. Steel Domestic Sales, LLC v. Chumley*, 129 F. Supp. 3d 1158, 1175 (D. Colo. 2015). In *General Steel*, the summary judgment "record [was] vague as to how many human beings might have encountered" the allegedly false statement, and "thus, any conclusions the Court could reach about those matters would be sheer speculation." *Id.* So, the Colorado court granted summary judgment against the false advertising claim under the Lanham Act because plaintiff had "not come forward with evidence that shows that the material posted by [defendant] reached sufficient numbers of customers . . . to permit the conclusion that it was 'advertising[.]'" *Id.*

Similarly, Utah's federal district court granted summary judgment against a false advertising Lanham Act claim were plaintiff identified 216 customers who were subject to false statements which "average[ed] 43 customers per year, compris[ing] less than 0.5% of" defendant's sales. *Vivint, Inc. v. NorthStar Alarm Servs., LLC*, No. 2:16-cv-00106-JNP-EJF, 2019 WL 1098986, at *8 (D. Utah Mar. 8, 2019) (internal quotation marks omitted). Plaintiff

argued that the 216 number represented "only a sample of the total number of customers that [defendant] has targeted and will continue to target over the years, establishing a pattern of dissemination of false representations." *Id.* Also, *Vivant*'s plaintiff argued "that the total market size is irrelevant because the Tenth Circuit does not require a statistical threshold to constitute public dissemination." *Id.* The Utah court disagreed. *Id.* at *9. It explained: "While the Tenth Circuit has not established a strict statistical threshold, it is clear . . . that there must be *some* statistical analysis of the number of alleged incidents in comparison to the relevant market." *Id.* (citing *Sports Unlimited*, 275 F.3d at 1004–05). Because plaintiff hadn't provided that analysis, and instead, relied "on mere speculation," the court concluded plaintiff's evidence didn't suffice to establish actionable "commercial advertising or promotion" to survive summary judgment. *Id.* (internal quotation marks omitted).

The same is true here. Mylan hasn't presented a triable issue of the widespread dissemination needed to support an actionable Lanham Act claim. Mylan simply hasn't come forward with any statistical analysis or any other evidence to quantify dissemination of alleged false statements. Like the Utah and Colorado courts, the court can't find a genuine issue of dissemination based simply on speculation. *See Vivint, Inc.*, 2019 WL 1098986, at *9; *Gen. Steel Domestic Sales*, 129 F. Supp. 3d at 1175. Thus, the court concludes, the undisputed summary judgment facts fail to present a jury question whether the alleged representations were "disseminated sufficiently to the relevant purchasing public to constitute 'advertising' or 'promotion' within that industry." *Proctor & Gamble*, 222 F.3d at 1273–74. The court thus grants summary judgment against Mylan's Lanham Act claim for this second, independent reason.

d. Harm from Sanofi's Statements

Last, Sanofi argues that Mylan's Lanham Act claim fails for a third reason. Sanofi asserts that the summary judgment facts present no jury question whether Mylan sustained injury caused by any alleged statement by Sanofi.

The Supreme Court requires that "[t]o invoke the Lanham Act's cause of action for false advertising, a plaintiff must plead (and ultimately prove) an injury to a commercial interest in sales or business reputation proximately caused by the defendant's misrepresentations." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 140 (2014); *see also In re Syngenta AG MIR 162 Corn Litig.*, 249 F. Supp. 3d 1224, 1230 (D. Kan. 2017) (explaining "[i]t is clear" that to prevail on a Lanham Act claim "plaintiffs must prove that their injuries were caused by the alleged misrepresentations"). Here, Sanofi argues, Mylan has come forward with no summary judgment evidence showing that Sanofi's statements caused Mylan any harm.

Indeed, both of Mylan's experts testified that they didn't undertake any analysis to determine the harm allegedly caused by Sanofi's false or misleading conduct. *See* Doc. 1686-13 at 9 (Zieziula Dep. 403:22–404:14) (testifying that Mylan's expert didn't "undertake any analysis to parse out the portion of [Auvi-Q] sales that were supposedly attributable to the promotional claims that [he] thought were false or misleading," and that he wasn't "offering any opinions about the percentage of [Auvi-Q] sales that were affected by the promotional claims"); *see also* Doc. 1692-37 at 4 (Varner Dep. 89:11–14) (testifying that the expert didn't "do any economic analysis to determine that all sales were related to the alleged false and misleading conduct"). Also, Mylan's Rule 30(b)(6) witness testified that Mylan didn't know whether "any [Auvi-Q] sales were a result of the alleged misleading claims by Sanofi"). Doc. 1690-15 at 3

(York Dep. 11: 9–14). Thus, Sanofi argues, the summary judgment record includes no evidence showing that Mylan sustained any harm from Sanofi's alleged conduct.

Mylan responds that it is entitled a presumption of injury because Sanofi made false comparative claims about Auvi-Q and EpiPen. *See Sunlight Saunas, Inc. v. Sundance Sauna, Inc.*, 427 F. Supp. 2d 1032, 1061 (D. Kan. 2006) (explaining that a "presumption" of injury is "'properly limited to circumstances . . . when the defendant has explicitly compared its product to the plaintiff's or the plaintiff is an obvious competitor with respect to the misrepresented product'" (quoting *Hutchinson v. Pfeil*, 211 F.3d 515, 522 (10th Cir. 2000)); *see also Gen. Steel Domestic Sales, LLC v. Chumley*, No. 10-cv-01398-PAB-KLM, 2013 WL 1900562, at *14 (D. Colo. May 7, 2013) ("Injury may be presumed when . . . the defendant has explicitly compared its product to the plaintiff's or the plaintiff is an obvious competitor with respect to the misrepresented product"). But, as Sanofi correctly argues, the summary judgment record here includes just two specific instances where a Sanofi representative compared Auvi-Q to EpiPen by name—*i.e.*, a handwritten note purportedly left by a Sanofi sales representative and statements made by a sales representative to two allergy clinic employees in Arizona. Otherwise, the advertising at issue here "is not explicitly comparative," and so, "a presumption of injury is inappropriate because each competitor's injury may be only a small fraction of the defendant's sales, profits, or advertising expenses." *Gen. Steel Domestic Sales*, 2013 WL 1900562, at *15. Also, Mylan argues that evidence of "intent or willful deception" can "trigger a presumption of injury." *Id.* But, as already discussed, the summary judgment facts here can't support a reasonable finding or inference of an intent to deceive by Sanofi.

Finally, Mylan argues that even without these presumptions, the summary judgment record here contains sufficient evidence for a rational trier of fact to find or infer that Sanofi's

statements caused Mylan harm. To support this argument, Mylan relies on the physician market research and other summary judgment evidence that Mylan characterizes as showing Sanofi's "widespread" use of false or misleading advertising among customers. Doc. 1805-1 at 108. It also cites the analysis conducted by Sanofi's damages expert showing that Auvi-Q's actual market share exceeded its forecasted share in 2013. *Id.* at 109. But importantly, none of this evidence *ties* Sanofi's conduct to specific harm sustained by Mylan sufficient to create a triable issue of causation. *See, e.g.*, *Verisign, Inc. v. XYZ.COM LLC*, 848 F.3d 292, 299 (4th Cir. 2017) (holding that plaintiff "failed to establish yet another Lanham Act element—that it suffered an injury *flowing directly from* the challenged statements" (emphasis added)).

In *Verisign*, the Fourth Circuit affirmed summary judgment against a Lanham Act claim because plaintiff hadn't presented evidence of Lanham Act damages. *Id.* at 300–301. The Fourth Circuit affirmed the trial court's exclusion of an expert's damages opinion because it suffered "a 'fatal flaw'" in calculating Lanham Act damages: It assume[d] rather than demonstrate[d] that every [sale of plaintiff's product] during the relevant time period was the result of [plaintiff's] allegedly false statements." *Id.* Thus, the court concluded, the trial court properly found that plaintiff had adduced no evidence that the allegedly false or misleading statements were "causally linked to damages[.]" *Id.* at 301. And, "[f]or that reason alone," plaintiff could not "prevail on its Lanham Act claim[.]" *Id.*

The summary judgment record here parallels *Verisign*'s. Mylan has failed to come forward with any evidence of a triable issue whether any harm sustained by Mylan "flow[ed] directly from the challenged statements." *Id.* at 299; *see also In re Syngenta AG MIR 162 Corn Litig.*, 249 F. Supp. 3d at 1231 (granting summary judgment against plaintiffs' Lanham Act claims because the record lacked "evidence that the alleged misrepresentations caused any

increase in sales" which "means that plaintiffs have failed to provide the necessary evidence of causation"). The court thus grants summary judgment against Mylan's Lanham Act claim for this third and independent reason—*i.e.*, the summary judgment record presents no jury question whether Mylan sustained any harm caused by Sanofi's statements.

e. Conclusion

For all the reasons explained above, the court finds that Mylan's Lanham Act claim fails as a matter of law based on three and independent reasons. The court has concluded that the summary judgment facts, even when viewed in Mylan's favor, present no triable issue (1) whether Sanofi made any false or misleading statements violating the Lanham Act, (2) whether Sanofi widely disseminated the statements such that they constituted commercial advertising or promotion under the Lanham Act, and (3) whether Sanofi's statements caused Mylan to sustain any injury. For each of these reasons, the court grants summary judgment against Mylan's Lanham Act claim.

2. Unfair Competition

Mylan also asserts an unfair competition claim under New Jersey common law based on Sanofi's allegedly false or misleading advertising statements. Doc. 112 at 52–53 (Answer, Affirmative Defenses, and Counterclaims ¶¶ 76–83); Doc. 1805-1 at 110 (clarifying that Mylan asserts its unfair competition claim under New Jersey law).

The parties' briefs devote little space to Mylan's unfair competition claim. Mylan simply argues that a reasonable jury could find that Sanofi "unfairly competed" with Mylan by promoting Auvi-Q as the "new EpiPen," thereby misappropriating the EpiPen name and injuring Mylan. Doc. 1805-1 at 111. But, Mylan's Counterclaim never alleges a misappropriation claim. *See generally* Doc. 112. Instead, Mylan bases its unfair competition claim solely on Sanofi's

allegedly false and misleading statements about Auvi-Q and EpiPen.[30] *Id.* at 52–53 (Answer, Affirmative Defenses, and Counterclaims ¶¶ 76–83).

Sanofi argues that New Jersey common law doesn't recognize false advertising claims. Doc. 1686-1 at 85–86 (citing *Tris Pharma, Inc. v. UCB Mfg., Inc.*, No. A-5808-13T3, 2016 WL 4506129, at *5 (N.J. Super. Ct. App. Div. Aug. 29, 2016)). Indeed, the New Jersey Superior Court has recognized that "no New Jersey precedent . . . supports [an] assertion that the common law tort of unfair competition encompasses . . . false advertising." *Tris Pharma*, 2016 WL 4506129, at *5; *see also Smart Vent, Inc. v. Crawl Space Door Sys. Inc.*, No. 13-5691 (JBS/KMW), 2017 WL 4948063, at *2 n.3 (D.N.J. Nov. 1, 2017) (refusing "to extend a Lanham Act analysis to [plaintiff's New Jersey] state-law unfair competition claims" because "'no New Jersey precedent'" supports a false advertising claim (quoting *Tris Pharma*, 2016 WL 4506129, at *5)).

Mylan makes no response to Sanofi's cited cases. It fails to direct the court to any New Jersey authority recognizing a common law tort claim based on false advertising. Thus, Mylan's unfair competition claim fails as a matter of law. But, even if New Jersey common law recognizes a claim for false advertising, Mylan's claim would fail for the same reasons the court concluded its Lanham Act claim fails. *See Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 454 (D.N.J. 2009) (recognizing that trademark infringement claims brought as "unfair competition claims under New Jersey statutory and common law generally parallel those under § 43(a) of the Lanham Act."). The summary judgment record presents no jury

[30] The Counterclaim also alleges that Sanofi competed unfairly by offering illicit cash payments to physicians that were intended to influence prescribing and purchasing decisions by health care customers. Doc. 112 at 53 (Answer, Affirmative Defenses, and Counterclaims ¶ 82). As already discussed, Mylan concedes that discovery hasn't revealed sufficient evidence to support these claims. Doc. 1805-1 at 89 n.320. So, the court concludes that Mylan abandons this allegation. *See supra* note 29. As a consequence, this unsubstantiated allegation can't support Mylan's unfair competition claim.

question whether Sanofi made false or misleading statements in its advertising or promotion of Auvi-Q. Thus, the court grants summary judgment against Mylan's unfair competition claim.

3. Conclusion

For these reasons, the court grants Sanofi's Motion for Summary Judgment against Mylan's Counterclaim asserting Lanham Act violations and a New Jersey common law unfair competition claim.

IV. Conclusion

For reasons explained, the court grants Mylan's Motion for Summary Judgment against Sanofi's Sherman Antitrust Act claims. The court grants Sanofi's Motion for Summary Judgment in part and denies it in part. Specifically, it grants Sanofi's Motion for Summary Judgment against Mylan's Counterclaim. But the court denies the portion of Sanofi's summary judgment motion asking the court to grant summary judgment in its favor on one element of its Sherman Antitrust Act claims. That aspect of the motion is moot in light of the court's ruling on Mylan's motion.

IT IS THEREFORE ORDERED BY THE COURT THAT Mylan's Motion for Summary Judgment (Doc. 1673) is granted.

IT IS FURTHER ORDERED THAT Sanofi's Motion for Summary Judgment (Doc. 1691) is granted in part and denied in part, as set forth in this Order.

IT IS SO ORDERED.

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

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