

**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**

On September 14, 2017, the court ordered that this MDL proceed on two separate tracks. [Doc. 42](#). This Order affects just one of those tracks—the *Sanofi* case.

Plaintiff Sanofi-Aventis U.S. LLC (“Sanofi”) is a pharmaceutical company who purportedly competes with defendant Mylan, Inc. 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. *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](#) (“*Sanofi* Complaint”). The *Sanofi* Complaint alleges that Mylan engaged in a variety of anticompetitive conduct designed to prevent Auvi-Q<sup>®</sup>—a rival product once sold by Sanofi—from gaining access to the epinephrine autoinjector market, and designed to prevent consumers from acquiring Auvi-Q<sup>®</sup>. Sanofi asserts three claims against Mylan under Section 2 of the Sherman Antitrust Act. These claims assert: (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.

On August 3, 2017, the Judicial Panel on Multidistrict Litigation transferred the *Sanofi* case and five others to our court for coordinated and consolidated proceedings. [Doc. 1](#). Before transfer, while the case still was pending in New Jersey, Mylan had filed a Motion to Dismiss the *Sanofi* Complaint. [Doc. 43](#). The motion seeks dismissal under [Federal Rule of Civil Procedure 12\(b\)\(6\)](#) for failing to state a claim. *Id.* After transfer, Sanofi filed in our court its Memorandum in Opposition to the Motion to Dismiss. [Doc. 44](#). And, at the court's Initial Scheduling Conference on September 7, 2017, Sanofi asked the court to place its case on a separate track and decide the pending Motion to Dismiss the *Sanofi* Complaint. The court granted that request, designating the *Sanofi* case on a separate track and ordering Mylan to file any Reply to the pending Motion to Dismiss by October 6, 2017. *See* [Doc. 42](#). Mylan filed its Reply consistent with the court's order. [Doc. 57](#). Thus, the Motion to Dismiss is now fully briefed, and after carefully considering the arguments presented by the parties' filings, the court is prepared to rule. For the reasons explained below, the court grants Mylan's Motion to Dismiss the *Sanofi* Complaint in part and denies it in part.

### **I. Factual Background**

The following facts are taken from the *Sanofi* Complaint. The court accepts the facts asserted in the *Sanofi* Complaint as true and views them in the light most favorable to plaintiff. *Burnett v. Mortg. Elec. Registration Sys., Inc.*, [706 F.3d 1231, 1235](#) (10th Cir. 2013) (citing *Smith v. United States*, [561 F.3d 1090, 1098](#) (10th Cir. 2009)).

Anaphylaxis is a serious allergic reaction that has a rapid onset and may cause death. Anaphylaxis can result from allergic reactions to foods, pets, insects, or exposure to other allergens. Epinephrine is the recognized first-line treatment for anaphylaxis. One can administer a controlled dose of epinephrine during an anaphylactic episode using an epinephrine

auto-injector (“EAI”) drug device. Doctors thus recommend that patients at risk for anaphylaxis always carry a portable EAI drug device and have training about its use.

Since 2007, Mylan has marketed and distributed in the United States an EAI drug device known as the EpiPen<sup>®</sup>. The EpiPen<sup>®</sup> has been the number-one prescribed EAI drug device in the United States for over 25 years. Indeed, in December 2012, Mylan touted that EpiPen<sup>®</sup> “has been the number one prescribed epinephrine auto-injector for more than 20 years and constitutes more than 99% of the epinephrine auto-injector market.” *Sanofi* Complaint ¶ 3. And, on August 1, 2013, Mylan reported to investors that the EpiPen<sup>®</sup> had a “93.3% market share.” *Id.* ¶ 39.

An EAI drug device gains access to the market almost entirely through contracts with third-party payors—such as commercial insurance companies, pharmaceutical benefit managers, and state-based Medicaid agencies—because a significant majority of patients with prescription drug insurance coverage receive their benefits through third-party payors. From 2013 to 2015, commercial third-party payors accounted for about 71% of the EAI drug device market in the United States. During this same period, state-based Medicaid plans made up another 16% of the EAI drug market. So, from 2013 to 2015, almost 90% of the EAI drug device market in the United States consisted of commercial third-party payors and Medicaid plans.

For a competitor to enter and compete vigorously in the EAI drug device market, it is crucial that it have access to these third-party payors’ drug formularies. Third-party payors use formularies to govern a drug’s coverage. Commercial third-party payors commonly use tiered formularies, placing drugs on different tiers that establish the enrollee patient’s co-pay and create incentives for the enrollee to prefer the lowest cost yet clinically effective drug. Most state-based Medicaid plans use a formulary that distinguishes only between drugs that are covered or not covered. If a drug is not covered under a third-party payor’s formulary, the patient probably

cannot access the product. Historically, third-party payors covered all available EAI drug devices at difference coverage tiers but, typically, they never excluded EAI drug devices from coverage altogether.

Also, it is common for pharmaceutical companies to provide rebates to third-party payors. In some circumstances, rebates can create a form of price competition that ultimately helps lower prices for end consumers, both for the costs that they pay for prescription drugs and what they pay for health insurance premiums. In some cases, a pharmaceutical company may offer rebates for exclusive coverage on a given third-party payor's drug formulary.

In 2013, Sanofi launched a competing EAI drug device in the United States known as Auvi-Q<sup>®</sup>. Auvi-Q<sup>®</sup>'s creators developed the product for patients who were not satisfied with the EpiPen<sup>®</sup>'s design and wanted something better. After its launch, Auvi-Q<sup>®</sup> garnered praise for its smaller size and shape that made it more likely that at-risk children and adults would carry their EAI drug device and have it available to treat anaphylaxis. As a result, Auvi-Q<sup>®</sup> gained traction quickly in the marketplace in the first few months after its launch.

Sanofi launched Auvi-Q<sup>®</sup> at price parity with EpiPen<sup>®</sup>. One of the reasons Sanofi chose this pricing point was to ensure that patients would have equal access to Auvi-Q<sup>®</sup> as they had for EpiPen<sup>®</sup>. Sanofi wanted to avoid giving formularies an incentive to provide preferential treatment to a lower-priced drug. Thus, Sanofi chose to offer Auvi-Q<sup>®</sup> at a price competitive with EpiPen<sup>®</sup>. In response to the competitive threat posed by Auvi-Q<sup>®</sup>, Mylan began erecting artificial barriers to consumers' access to and use of Auvi-Q<sup>®</sup> in the United States. Mylan did so in several ways.

*First*, shortly after Sanofi launched Auvi-Q<sup>®</sup>, Mylan began to offer large rebates (30% or higher) to third-party payors. But, Mylan expressly conditioned the rebates on exclusivity. That

is, Mylan required the third-party payors to exclude Auvi-Q<sup>®</sup> from the formularies and only offer EpiPen<sup>®</sup> to their enrollees.<sup>1</sup> Using its monopoly market share and these large rebates, Mylan successfully coerced third-party payors to accept huge rebates in exchange for offering EpiPen<sup>®</sup> exclusively instead of foregoing those rebates and allowing Auvi-Q<sup>®</sup> to compete in the market.

According to Sanofi, Mylan subsidized its large exclusionary rebates by misclassifying the EpiPen<sup>®</sup> to the federal and state governments. By misclassifying the EpiPen<sup>®</sup>, Mylan paid substantially less in required rebates for patients covered by Medicaid. And, with those savings, Mylan, in turn, was able to offer the large rebates to third-party payors conditioned on their excluding Auvi-Q<sup>®</sup>. Mylan also drove up EpiPen<sup>®</sup>'s price in the years leading up to Sanofi's launch of Auvi-Q<sup>®</sup>. Since 2007, EpiPen<sup>®</sup>'s price has increased by more than 500%. According to Sanofi, one purpose for the price increase was to help Mylan absorb the large conditional discounts it offered to third-party payors who excluded Auvi-Q<sup>®</sup>.

Sanofi could not match Mylan's large rebates unless it offered rebates in excess of its revenues from Auvi-Q<sup>®</sup>. That is, Sanofi would lose money on its sales of Auvi-Q<sup>®</sup> if it tried to compete against EpiPen<sup>®</sup> in the market. With its rebate program, Mylan successfully blocked Auvi-Q<sup>®</sup> from accessing almost 50% of the United States EAI drug device market. In some states, where the number of third-party payors who did not cover Auvi-Q<sup>®</sup> was over-represented, Auvi-Q<sup>®</sup> was blocked from an even higher percentage of the market.

*Second*, Mylan imposed contractual exclusivity provisions in its schools programs. Both Mylan and Sanofi had programs designed to provide free or discounted EAI drug devices to schools. But, unlike Sanofi, Mylan required schools taking part in its discounted EpiPen<sup>®</sup> program to certify in writing that the school would not purchase any products that compete with

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<sup>1</sup> Sanofi alleges that Mylan blocked Auvi-Q<sup>®</sup> from all third-party payor formularies. But on at least some formularies, Mylan allowed other EAI drug devices to remain, just not Auvi-Q<sup>®</sup>.

the EpiPen<sup>®</sup> within the next year. According to Sanofi, Mylan's contractual exclusivity term had one purpose: to prevent schools from having access to Auvi-Q<sup>®</sup>. Mylan later eliminated its school programs' exclusivity policy after the New York Attorney General and other legal commentators questioned whether it violated the antitrust laws.

*Third*, after the Auvi-Q<sup>®</sup> launch, Mylan started offering consumers \$0 co-pay coupons for the EpiPen<sup>®</sup>. Sanofi also offered \$0 co-pay coupons for Auvi-Q<sup>®</sup>. But, because of Mylan's rebate offers to third-party payors, most of Auvi-Q<sup>®</sup>'s coverage—even when it was on the same drug formulary with the EpiPen<sup>®</sup>—was at a less preferential tier. This typically meant the co-pay for an EpiPen<sup>®</sup> was \$25 and the co-pay for Auvi-Q<sup>®</sup> was \$50 to \$75. As a result, Sanofi was forced to absorb two to three times the cost Mylan absorbed when offering the \$0 co-pay to consumers. In this way, Mylan drove up Sanofi's costs to cover patients' co-pays.

*Finally*, Mylan created and spread misinformation about Auvi-Q<sup>®</sup> and its bioequivalence to EpiPen<sup>®</sup>, even though the United States Food & Drug Administration had determined that the epinephrine used in Auvi-Q<sup>®</sup> was bioequivalent to the EpiPen<sup>®</sup>'s epinephrine. Mylan also marketed physicians, contending that Auvi-Q<sup>®</sup> was not covered under third-party payors' formularies and suggesting that the decision to exclude Auvi-Q<sup>®</sup> from the formularies was based on clinical recommendation—and not Mylan's huge, conditional rebate offers.

In the first six months after Sanofi launched Auvi-Q<sup>®</sup>, Sanofi's market shares tracked its projected market shares. And, Auvi-Q<sup>®</sup>'s market share was poised to continue to grow. But, as a result of Mylan's conduct, Auvi-Q<sup>®</sup>'s market share decreased dramatically. By the end of 2013 and into 2014, Auvi-Q<sup>®</sup>'s market share was about half of its projected market share. And, by October 2015, Auvi-Q<sup>®</sup>'s national market share was less than half of what Sanofi had projected. But, in Canada, Auvi-Q<sup>®</sup> (known there as Allerject<sup>®</sup>) had a stronger performance,

even though EpiPen<sup>®</sup> similarly dominated the Canadian EAI drug device market before Sanofi had launched the Allerject<sup>®</sup> there. In Canada, provincial authorities control drug formularies, the Allerject<sup>®</sup> was treated at parity with the EpiPen<sup>®</sup>, and the two devices were equally available for physicians to prescribe to consumers. By the end of 2013—its first year on the Canadian market—Allerject<sup>®</sup> exceeded its projections, growing to 21% market share. In 2014 and 2015, Allerject<sup>®</sup> continued to gain market share. It reached 25% market share by the end of 2014, and it peaked at 32% market share in 2015.

In October 2015, Sanofi undertook a voluntary recall of Auvi-Q<sup>®</sup> following reports of manufacturing issues with some devices. Sanofi never relaunched Auvi-Q<sup>®</sup>. Instead, in February 2016, Sanofi returned the rights in the drug to kaléo, inc. Sanofi asserts, though, that Mylan's conduct contributed to Sanofi's decision to forego its investment in Auvi-Q<sup>®</sup> and return its rights to kaléo, inc. Sanofi also alleges that Mylan's conduct cost it hundreds of millions of dollars in lost sales within the United States EAI drug device market.

## II. Legal Standard

Fed. R. Civ. P. 8(a)(2) provides that a complaint must contain “a short and plain statement of the claim showing that the pleader is entitled to relief.” Although this Rule “does not require ‘detailed factual allegations,’” it demands more than “[a] pleading that offers ‘labels and conclusions’ or ‘a formulaic recitation of the elements of a cause of action’” which, as the Supreme Court explained, “will not do.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)).

When considering a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), the court must assume that the factual allegations in the complaint are true. *Id.* (citing *Twombly*, 550 U.S. at 555). But, the court is “‘not bound to accept as true a legal conclusion couched as a

factual allegation.” *Id.* (quoting *Twombly*, [550 U.S. at 555](#)). “Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice” to state a claim for relief. *Bixler v. Foster*, [596 F.3d 751, 756](#) (10th Cir. 2010) (quoting *Iqbal*, [556 U.S. at 678](#)). Also, the complaint’s “[f]actual allegations must be enough to raise a right to relief above the speculative level.” *Twombly*, [550 U.S. at 555](#) (citations omitted).

For a complaint to survive a motion to dismiss under Rule 12(b)(6), the pleading “must contain sufficient factual matter, accepted as true, to ‘state a claim for relief that is plausible on its face.’” *Iqbal*, [556 U.S. at 679](#) (quoting *Twombly*, [550 U.S. at 570](#)). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* at 678 (citing *Twombly*, [550 U.S. at 556](#)). “The plausibility standard is not akin to a ‘probability requirement,’ but it asks for more than a sheer possibility that a defendant has acted unlawfully.” *Id.* (quoting *Twombly*, [550 U.S. at 556](#)); *see also Christy Sports, LLC v. Deer Valley Resort Co., Ltd.*, [555 F.3d 1188, 1192](#) (10th Cir. 2009) (“The question is whether, if the allegations are true, it is plausible and not merely possible that the plaintiff is entitled to relief under the relevant law.” (citation omitted)).

In the antitrust context, the Supreme Court observed in *Twombly* that “proceeding to antitrust discovery can be expensive.” *Twombly*, [550 U.S. at 558](#) (applying the plausibility pleading standard to Sherman Act claims). So, courts must “‘insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed.’” *Id.* (quoting *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, [459 U.S. 519, 528 n.17](#) (1983)). But, still, antitrust cases are not subject to a standard requiring “heightened fact pleading of specifics.” *Id.* at 570. Instead, an antitrust Complaint must allege “only enough facts to state a claim to relief that is plausible on its face” sufficient to “nudge[ ] the[ ] claims across



the line from conceivable to plausible.” *Id.*; see also *In re Urethane Antitrust Litig.*, 663 F. Supp. 2d 1067, 1074 (D. Kan. 2009) (explaining on a Rule 12(b)(6) motion to dismiss antitrust claims that “the Court must ensure that plaintiffs have alleged facts to support those elements sufficient to provide the ‘heft’ to show an entitlement to relief and to ‘nudge’ plaintiffs’ claims over the line from mere[ ] possibility or speculation to plausibility” (quoting *Twombly*, 550 U.S. at 557, 570)).

The court’s analysis, below, applies this governing standard to Mylan’s Rule 12(b)(6) dismissal arguments.

### **III. Analysis**

Mylan asserts that Sanofi’s three claims under Section 2 of the Sherman Antitrust Act fail to state plausible claims for relief. “Section 2 of the Sherman Act prohibits actions by ‘person[s] who shall monopolize, [or] attempt to monopolize . . . any part of the trade or commerce.’” *Cohlma v. St. John Med. Ctr.*, 693 F.3d 1269, 1280 (10th Cir. 2012) (quoting 15 U.S.C. § 2). To state a claim under Section 2, a plaintiff must plead facts that, if true, make two elements plausible. They are: “(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).

Mylan’s papers never assert that Sanofi has failed to allege the first element of a Sherman § 2 claim—*i.e.*, monopoly power in the relevant market. Indeed, the *Sanofi* Complaint alleges that the relevant product market is EAI drug devices, that this market has high barriers to entry, and that Mylan has monopoly power in that market with a share market exceeding 90%. *Sanofi* Complaint ¶¶ 39, 116, 123, 126–34. So, Sanofi has alleged facts sufficient to establish that

Mylan possessed monopoly power in the relevant market, thus satisfying the first element of its Sherman § 2 claims.

Instead, Mylan asserts that Sanofi has not satisfied the second element of a Sherman § 2 claim. Specifically, Mylan argues that the Complaint fails to allege facts sufficient to make a plausible showing of Mylan's willful acquisition or maintenance of its monopoly power. Mylan thus asks the court to dismiss the *Sanofi* Complaint under Federal Rule of Civil Procedure 12(b)(6) for failing to state a claim. Mylan asserts five principal arguments in support of its request. The court addresses each argument, in turn, in subsections A through E, below.

**A. Does the *Sanofi* Complaint State a Claim for Unlawful Exclusive Dealing Based on Mylan's Rebate Offers?**

First, Mylan contends that the *Sanofi* Complaint fails to state a plausible Sherman Act claim based on Mylan's rebate offers. Mylan asserts two arguments to support its contention. First, Mylan contends that Sanofi's exclusive dealing claim fails as a matter of law because the Complaint never alleges that Mylan's rebates priced the EpiPen<sup>®</sup> below its costs to produce it. Second, Mylan argues that the *Noerr-Pennington* doctrine bars Sanofi's exclusive dealing claim to the extent Sanofi bases it on discounts or rebates offered to state or state agencies. The court addresses each argument separately. As explained below, the court finds Mylan's first argument unpersuasive. But the court agrees with Mylan's second argument.

**1. The *Sanofi* Complaint alleges facts about Mylan's rebate offers to non-governmental third-party payors that plausibly state a claim for exclusive dealing in violation of the Sherman Antitrust Act.**

Mylan asserts that Sanofi fails to state a claim for relief based on Mylan's rebate offers because the Complaint never alleges that Mylan's offers resulted in prices below the cost of production. Indeed, the Supreme Court has recognized 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 explained that “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 . . . .” *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.*

So, the Supreme Court requires a plaintiff in a predatory pricing case to allege two things: (1) that “the prices complained of are below an appropriate measure of its rival’s costs;” and (2) that “the competitor had a reasonable prospect, or, under § 2 of the Sherman Act, a dangerous probability, of recouping its investment in below-cost prices.” *Id.* at 222, 224 (citations omitted). Mylan argues that Sanofi’s claim here fails as a matter of law because the Complaint never alleges facts capable of supporting the first requirement of this test—that Mylan’s rebate offers resulted in prices that were below its costs to produce the EpiPen<sup>®</sup>.

Sanofi responds to Mylan’s argument, asserting that this is not a predatory pricing case. Instead, Sanofi explains that its rebate claim is based on Mylan’s allegedly unlawful exclusive dealing arrangements that, Sanofi contends, violate the Sherman Antitrust Act. Thus, Sanofi argues, the price-cost test does not apply here.

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).<sup>2</sup> *ZF Meritor* recognized that “a plaintiff’s characterization of its claim as an exclusive

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<sup>2</sup> The parties do not cite, and the court has not found, any Tenth Circuit case law addressing when the price-cost test applies to an exclusive dealing claim based on a discount or rebate program. Our court

dealing claim does not take the price-cost test off the table.” *Id.* at 275. Instead, the price-cost test still may apply because “contracts in which discounts are linked to purchase (volume or market share) targets are frequently challenged as *de facto* exclusive dealing arrangements on the grounds that the discounts induce customers to deal exclusively with the firm offering the rebates.” *Id.* So, “when price is the clearly predominant mechanism of exclusion, the price-cost test tells us that, so long as the price is above-cost, the procompetitive justifications for, and the benefits of, lowering prices far outweigh any potential anticompetitive effects.” *Id.*

But the Third Circuit refused to apply the price-cost test in *ZF Meritor* 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.*

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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) (first citing *Murphy v. FDIC*, 208 F.3d 959, 965–66 (11th Cir. 2000) (citing cases from the D.C., Second, Eighth, and Ninth Circuits); then citing *In re United States Dep’t of Defense and United States EPA Final Rule*, 817 F.3d 261, 272 (6th Cir. 2016) (citing *Murphy* and following the other circuits)). 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 closely considers the law of the Third Circuit (where the *Sanofi* case originated) when deciding this Motion to Dismiss.

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"); *see also UniStrip Techs., LLC v. LifeScan, Inc.*, [153 F. Supp. 3d 728, 737](#) (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, viewing its allegations in the light most favorable to Sanofi, the court concludes that the Complaint does not rely "solely on the exclusionary effect of [Mylan's] prices" to support its exclusive dealing claim based on Mylan's rebate program. *ZF Meritor*, [696 F.3d at 277](#). The *Sanofi* Complaint alleges that Mylan leveraged its greater than 90% market share by offering unprecedented rebates to third-party payors (30% or higher) but expressly conditioned those rebates on excluding Auvi-Q<sup>®</sup>. *Sanofi* Complaint ¶¶ 6, 57. That is, in exchange for the large rebates, Mylan required the third-party payors to exclude Auvi-Q<sup>®</sup> from the drug formularies and offer only EpiPen<sup>®</sup> to enrollees. *Id.* ¶¶ 6, 59. The Complaint also alleges that Mylan specifically targeted Auvi-Q<sup>®</sup>, allowing some other EAI drug devices to remain on at least some third-party payors' formularies but requiring exclusion of Auvi-Q<sup>®</sup>. *Id.* ¶ 59. Sanofi

alleges that no legitimate business reason existed for Mylan’s deep conditional rebates other than its desire to block Auvi-Q<sup>®</sup> from the market. *Id.*

Sanofi alleges that Mylan’s exclusive dealing agreements effectively blocked Auvi-Q<sup>®</sup> from nearly 50% of the EAI drug device market nationwide. *Id.* ¶¶ 6, 68. This percentage was even greater in some larger states. *Id.* ¶¶ 6, 68. Sanofi also alleges that Mylan’s rebate program unlawfully raised Sanofi’s costs of entry into the market. *Id.* ¶¶ 108–09. And, after Mylan successfully used its rebate program to block Auvi-Q<sup>®</sup> from the market, Sanofi contends Mylan “poisoned the well” with physicians by sending them misleading marketing materials that described EpiPen<sup>®</sup> as the “preferred” EAI device for 99% of patients while Auvi-Q<sup>®</sup> was “preferred” for just 2%. *Id.* ¶¶ 7, 98–99. But, in reality, these percentages were driven by Mylan’s exclusionary rebates—not patient preferences. *Id.* ¶ 98.

The court thus concludes that the *Sanofi* Complaint alleges that Mylan’s rebate program involved anticompetitive conduct—beyond pricing itself—that was designed to block customer access to Auvi-Q<sup>®</sup> and protect Mylan’s monopoly in the EAI drug market. The price-cost test thus does not apply to Sanofi’s exclusive dealing claim. *See Eisai, Inc. v. Sanofi-Aventis U.S., LLC*, No. 08-4168(MLC), [2014 WL 1343254](#), at \*23 (D.N.J. Mar. 28, 2014) (explaining that *ZF Meritor* held that above-cost pricing does not preclude antitrust liability when the defendant “engaged in an otherwise unlawful exclusive dealing arrangement” because while “[p]rices are unlikely to exclude equally efficient rivals unless they are below cost, . . . exclusive-dealing arrangements can exclude equally efficient rivals because those rivals are never given the opportunity to compete” (citing *ZF Meritor*, [696 F.3d at 278, 281](#)));<sup>3</sup> *see also UniStrip Techs.*,

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<sup>3</sup> Mylan contends that Sanofi has taken positions that are inconsistent with the ones it asserted in *Eisai*—a case where Sanofi was accused of violating the antitrust laws through its own use of loyalty-discount contracts. But, *Eisai* involved different facts and a different procedural posture than the ones presented here. Thus, Sanofi’s arguments in *Eisai* are of no moment to the motion to dismiss in this case.

153 F. Supp. 3d at 737 (holding that the price-cost test does not apply when plaintiff's Complaint pleads "anticompetitive behavior rather than merely competitive pricing").

The court thus turns to consider a second question, *i.e.*, whether Sanofi has alleged a plausible Sherman Act claim based on Mylan's exclusive dealing arrangements. 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 (3d ed. 2011); *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 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).

Our Circuit has explained that "[t]he antitrust vice of these arrangements is the foreclosure part of the market in which the seller competes by taking away the freedom of the buyer to choose from the products of competing traders in the seller's market." *Perington Wholesale*, 631 F.2d at 1374; *see also ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 270 (3d Cir. 2012) ("The primary antitrust concern with exclusive dealing arrangements is that they may be used by a monopolist to strengthen its position, which may ultimately harm competition." (citation omitted)).

But, “[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 (citing *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[.]” *Id.* (quoting *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 45 (1984) (O’Connor, J., concurring), *abrogated on other grounds by Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006) (further citation omitted)). Also, “[e]xclusive dealing arrangements are of special concern when imposed by a monopolist.” *Id.* at 271 (quoting *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. F.T.C.*, 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 assert an exclusive dealing claim, a plaintiff must plead facts capable of supporting a finding or inference that the “probable effect” of “performance of the contract will foreclose competition in a substantial share of the line of commerce affected.” *Tampa Elec.*, 365 U.S. at 327, 329;<sup>4</sup> *see also Perington Wholesale*, 631 F.2d at 1374 (“Thus, a complaining trader 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 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.*

Here, Mylan argues that Sanofi cannot proceed with an exclusive dealing claim based on a single product rebate (that is priced above cost) without alleging other exclusionary conduct

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<sup>4</sup> Although *Tampa Electric* involved a Clayton Act claim, courts also apply its analysis to exclusive dealing claims asserted under the Sherman Act. *See ZF Meritor*, 696 F.3d at 327 n.26 (“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.”); *see also Tampa Elec.*, 365 U.S. at 335 (“We 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.”).

that would impede a customer’s ability to decline the rebate if a competitor—such as Sanofi—made a better offer. To state a viable exclusive dealing claim based on a rebate program, Mylan asserts, courts require a plaintiff to allege other exclusionary conduct that produces a substantial foreclosure of competition such as bundling or tying the rebates to the sale of other products,<sup>5</sup> or threatening to terminate supply,<sup>6</sup> or imposing long-term exclusivity agreements.<sup>7</sup> Mylan contends that Sanofi never asserts any such exclusionary conduct here. Thus, Mylan argues, Sanofi fails to state a plausible exclusive dealing claim.

The court disagrees. As the court already has concluded above, the *Sanofi* Complaint sufficiently alleges exclusionary conduct in addition to Mylan’s pricing to state a plausible exclusive dealing claim. Sanofi has alleged that Mylan leveraged its greater than 90% market

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<sup>5</sup> See, e.g., *United States v. Microsoft, Corp.*, 253 F.3d 34, 60, 70 (D.C. Cir. 2001) (affirming district court’s decision holding that Microsoft’s exclusive dealing contracts violated § 2 of the Sherman Act where the government alleged “that Microsoft attempted to monopolize the browser market and unlawfully tied its browser to its operating system so as to foreclose competition in the browser market”); *UniStrip Techs., LLC v. LifeScan, Inc.*, 153 F. Supp. 3d 728, 740–41 (E.D. Pa. 2015) (denying motion to dismiss where plaintiff alleged that defendant “engaged in exclusive dealing, in violation of several antitrust laws, and that this exclusive dealing consists of bundling schemes by which rebates are offered on the condition that multiple products from [defendant] are purchased”); *Suture Express, Inc. v. Cardinal Health 200, LLC*, 963 F. Supp. 2d 1212, 1217, 1227–29 (D. Kan. 2013) (denying motion to dismiss plaintiff’s exclusive dealing claim based on contracts “which unlawfully tied the sale of sutures and endo products to the sale of other products in the med-surg basket”).

<sup>6</sup> See, e.g., *McWane, Inc. v. FTC*, 783 F.3d 814, 819, 834–38 (11th Cir. 2015) (finding a dominant producer of domestic pipe fittings engaged in unlawful exclusive dealing arrangements when it threatened to take away rebates and cut off supply for 12 weeks unless customers purchased all domestic pipe fittings exclusively from the producer); *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 277, 289 (3d Cir. 2012) (concluding that sufficient evidence existed for a jury to find that defendant engaged in unlawful exclusive dealing when its contracts conditioned rebates, as well as continued product supply, on the customer’s purchase of a specific percentage of defendant’s product).

<sup>7</sup> See, e.g., *E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc.*, 637 F.3d 435, 452–53 (4th Cir. 2011) (reversing a district court’s dismissal of a Sherman Act § 2 claim because plaintiff sufficiently alleged that defendant’s use of multi-year exclusive contracts constituted anticompetitive conduct and foreclosed competition in the market); *Dial Corp. v. News Corp.*, 165 F. Supp. 3d 25, 31–32 (S.D.N.Y. 2016) (denying summary judgment against plaintiffs’ exclusive dealing claim because “the length of the exclusive contracts and their staggered terms may also foreclose competition” and the evidence showed that defendant “intentionally staggered the end dates of key contracts to prevent competitors from acquiring a ‘critical mass’ of retail distribution”).

share by offering unprecedented rebates to third-party payors (30% or higher) and specifically targeted Auvi-Q<sup>®</sup> for exclusion from the market by expressly conditioning the large rebates on excluding Auvi-Q<sup>®</sup> from third-party payors' drug formularies. Also, Sanofi alleges that Mylan had no legitimate business purpose for offering these large rebates but used the program, instead, to block a new entrant—Auvi-Q<sup>®</sup>—from the market and to protect its 90%-plus market share.

In *Dial Corp. v. News Corp.*, the Southern District of New York denied summary judgment against an exclusive dealing claim because the evidence showed that the length of the defendant's exclusive dealing contracts and their staggered terms may have foreclosed competition in the relevant market. [165 F. Supp. 3d 25, 32](#) (S.D.N.Y. 2016). The court also found that the defendant had “intentionally staggered the end dates of key contracts to prevent competitors from acquiring a ‘critical mass’ of retail distribution.” *Id.* at 31. The court recognizes that *Dial Corp.*'s facts differ from the ones asserted by the *Sanofi* Complaint. Here, the Complaint alleges that third-party payors' coverage decisions “typically” last for only “one or two years.” *Sanofi* Complaint ¶ 67. Also, the Complaint makes no allegations that Mylan staggered the terms of its rebate program in a way to foreclose competition. But, like *Dial Corp.*, Sanofi alleges that Mylan's rebate program blocked a competitor from entering and getting traction in the market. Here, Sanofi alleges that Mylan specifically targeted Auvi-Q<sup>®</sup>, blocking it from nearly 50% of the EAI drug device market nationwide and an even higher percentage in some larger states. One plausibly could infer from the facts alleged that Mylan intentionally and successfully prevented Auvi-Q<sup>®</sup> from developing a “critical mass” of customers that would allow them to compete against Mylan—the dominant player in the market with a market share that exceeded 90%.

Also, recognizing that *Tampa Electric* provides a “number of other factors which may be relevant to a rule of reason analysis in an exclusive dealing claim,” our court has refused to “decide at the pleading stage that plaintiff had failed to plead adequate foreclosure levels” to state an exclusive dealing claim. *Suture Express, Inc. v. Cardinal Health 200, LLC*, 963 F. Supp. 2d 1212, 1229 (D. Kan. 2013). The court reaches the same conclusion here. The question whether the alleged exclusive dealing arrangements foreclosed a substantial share of the market requires the court to weigh various factors, and that is not a proper function for the pleading stage. Instead, the court views the Complaint’s allegations in the light most favorable to Sanofi. And, it concludes that Sanofi has alleged that Mylan’s rebate program involved exclusionary conduct capable of supporting a finding or inference that the probable effect of Mylan’s rebate program—conditioned on exclusivity—substantially foreclosed competition. Sanofi thus states a plausible exclusive dealing claim under the Sherman Act.

**2. The *Noerr-Pennington* doctrine bars Sanofi’s exclusive dealing claim premised on rebates offered to states or state agencies.**

Mylan also asserts that Sanofi cannot allege an exclusive dealing claim based on discounts or rebates offered to state-based Medicaid agencies because the *Noerr-Pennington* doctrine bars those claims. “The *Noerr-Pennington* doctrine is drawn from the Supreme Court’s opinions in *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961) and *United Mine Workers of America v. Pennington*, 381 U.S. 657 (1965).” *Tal v. Hogan*, 453 F.3d 1244, 1257 n.13 (10th Cir. 2006). The *Noerr-Pennington* doctrine ““exempts from antitrust liability any legitimate use of the political process by private individuals, even if their intent is to eliminate competition.”” *Id.* at 1259 (quoting *Zimomra v. Alamo Rent-A-Car, Inc.*, 111 F.3d 1495, 1503 (10th Cir. 1997)). “The doctrine arises from the [Supreme] Court’s conclusion that the Sherman Act was not intended to derogate the First Amendment right of

citizens to petition the government for a redress of grievances.” *GF Gaming Corp. v. City of Black Hawk*, 405 F.3d 876, 883 (10th Cir. 2005) (citing *Noerr*, 365 U.S. at 136–39).

The scope of the *Noerr-Pennington* doctrine depends “on the source, context, and nature of the anticompetitive restraint at issue.” *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 499 (1988). “*Noerr-Pennington* immunity does not apply if the purported effort to influence or obtain government action is in fact only an attempt to interfere with the business relationships of a competitor.” *Classic Commc’ns, Inc. v. Rural Tel. Serv. Co., Inc.*, 956 F. Supp. 910, 917 (D. Kan. 1997) (first citing *Noerr*, 365 U.S. at 144; then citing *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 511 (1972)). “This is the so-called ‘sham’ exception to the *Noerr-Pennington* doctrine.” *Id.* The sham exception applies “when ‘persons use the governmental *process*—as opposed to the *outcome* of that process—as an anticompetitive weapon.’” *GF Gaming Corp.*, 405 F.3d at 884 (quoting *City of Columbia v. Omni Outdoor Advertising, Inc.*, 499 U.S. 365, 380 (1991)). “The exception thus ‘involves a defendant whose activities are not genuinely aimed at procuring favorable government action at all,’ such as a defendant who files ‘frivolous objections to the license application of a competitor, with no expectation of achieving denial of the license but simply in order to impose expense and delay.’” *Id.* (quoting *City of Columbia*, 499 U.S. at 380).

In *GF Gaming*, the Tenth Circuit held that plaintiff had failed to state Sherman Antitrust Act claims because it alleged antitrust injuries based on the outcome of defendants’ lobbying activities—and not on the process of that lobbying activity. *Id.* Thus, the Tenth Circuit held, the *Noerr-Pennington* doctrine immunized the non-governmental defendants from liability based on their lobbying activities. *Id.*

The same reasoning applies here. Sanofi asserts that it has stated a plausible antitrust claim based on rebates offered to government agencies because Mylan—a private actor with no legislative or quasi-legislative authority—engaged in “anticompetitive efforts . . . to unlawfully maintain its EpiPen<sup>®</sup> monopoly.” [Doc. 41 at 26](#) (citing the *Sanofi* Complaint ¶¶ 7–8); *see also Sanofi* Complaint ¶ 67 (asserting that Mylan’s “illegal conditional rebate scheme to exclude Auvi-Q<sup>®</sup> was successful” because “in most of [the states that manage their Medicaid drug formularies] Auvi-Q<sup>®</sup> was excluded.”). These allegations accuse Mylan of using the *outcome* of a government process—*i.e.*, exclusion of Auvi-Q<sup>®</sup> from the drug formularies—*not the process itself* to harm a competitor. The *Noerr-Pennington* doctrine shields this very type of conduct from antitrust liability, even if Mylan, as a private actor, intended to eliminate competition. *See GF Gaming*, [405 F.3d at 884](#) (holding that conduct that “amounts to nothing more than lobbying of government officials . . . is immune from Sherman Act liability under the *Noerr-Pennington* doctrine” and “[e]ven if defendants’ sole motive for petitioning the [government] officials was to injure competition, the conduct would still be protected by the *Noerr-Pennington* doctrine”); *see also Tal*, [453 F.3d at 1260](#) (holding that *Noerr-Pennington* immunity applied to preclude antitrust claims based on defendant’s vigorous petitioning of government officials and rejecting plaintiff’s argument that the doctrine does not apply to private entities as “clearly wrong” because “that is precisely for whom the immunity was created”).

Sanofi argues, alternatively, that Mylan cannot invoke *Noerr-Pennington* immunity because Sanofi asserts that Mylan provided false and misleading information to federal and state governments misclassifying the EpiPen<sup>®</sup> as a non-innovator drug under Medicaid, allowing Mylan to pay substantially less in required rebates to Medicaid and enjoy savings that it then used to provide additional rebates conditioned on exclusivity. Sanofi contends that *Noerr-*

*Pennington* does not provide immunity for these types of misrepresentations. Doc. 41 at 27 (first quoting *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 513 (1986) (“Misrepresentations, condoned in the political arena, are not immunized when used in the adjudicatory process.”); then quoting *Allied Tube*, 486 U.S. at 499–500 (“unethical and deceptive practices can constitute abuses of administrative or judicial processes that may result in antitrust violations”)).

But Sanofi’s antitrust claims are not based on Mylan’s alleged misrepresentations about the EpiPen<sup>®</sup>’s drug classification. Instead, Sanofi premises its rebate claims on Mylan’s conduct offering rebates to federal and state governments in exchange for exclusivity. Sanofi never asserts that Mylan’s alleged misclassification of the EpiPen<sup>®</sup> influenced a government agency’s decision to agree to exclude Auvi-Q<sup>®</sup> in exchange for the rebates, or that the alleged misclassification otherwise affected a governmental agency’s decision to participate in the exclusive rebate program. Instead, the conduct that Sanofi alleges to have violated the antitrust laws was Mylan’s petitioning of federal and state governments to exclude Auvi-Q<sup>®</sup> from the drug formularies in exchange for rebates. As already noted, the *Noerr-Pennington* doctrine immunizes such conduct. The court thus dismisses Sanofi’s exclusive dealing claims based on discounts or rebates provided to state-based Medicaid agencies because they are barred by the *Noerr-Pennington* doctrine. These claims fail to state a plausible claim for relief.

**B. Does the *Sanofi* Complaint State a Claim for Relief Based on Mylan’s Supposedly Deceptive Speech?**

Mylan next asserts that Sanofi fails to state a plausible Sherman Act claim based on Mylan’s allegedly deceptive speech. Mylan asserts that our Circuit has explained that the Sherman Act is concerned only with “‘protection of competition or prevention of monopoly,’” but “‘not the vindication of general ‘notions of fair dealing,’ which are the subject of many other

laws at both the federal and state level.” *Four Corners Nephrology Assoc., P.C. v. Mercy Med. Ctr.*, [582 F.3d 1216, 1225](#) (10th Cir. 2009) (quoting IIB Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 770, at 190 (3d ed. 2008)). Thus, Mylan asserts, the antitrust laws afford no protection to Sanofi’s claims based on purportedly deceptive speech.

But, *Four Corners* was a case involving a refusal to deal—not deceptive speech, like Sanofi’s allegations here. *See Four Corners*, [582 F.3d at 1222–25](#) (affirming summary judgment against plaintiffs’ antitrust claims based on a hospital’s refusal to deal with a physician). In contrast, other courts have recognized that deceptive speech can support Sherman Act claims because “in 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 Caribbean Broad. Sys., Ltd. v. Cable & Wireless PLC*, [148 F.3d 1080, 1087](#) (D.C. Cir. 1998) (holding that plaintiff’s allegations, “namely, that the defendants made fraudulent misrepresentations to advertisers and sham objections to a government licensing agency in order to protect their monopoly” constituted sufficiently anticompetitive conduct to support a Sherman Act claim); *Nat’l Ass’n of Pharm. Mfrs., Inc. v. Ayerst Labs*, [850 F.2d 904, 916](#) (2d Cir. 1988) (reversing a district court’s dismissal of a Sherman Act § 2 claim based on defendant’s publication of an allegedly false and misleading letter touting its product’s superiority and told pharmacists never to dispense a generic drug because plaintiff’s allegations were sufficient “to go forward with the discovery process to substantiate its claim”); *Caldera, Inc. v. Microsoft Corp.*, [87 F. Supp. 2d 1244, 1249](#) (D. Utah 1999) (holding that alleged misleading statements about the plaintiff’s product viewed with other anticompetitive behavior supported a Sherman Act § 2 claim sufficient to survive summary judgment).



In *West Penn Allegheny*, the Third Circuit recognized that “[a]nticompetitive conduct can come in too many different forms, and is too dependent upon context, for any court or commentator ever to have enumerated all the varieties.” 627 F.3d at 109 (citations and internal quotation marks omitted). And, “[f]or present purposes,” the court held “anticompetitive conduct can include . . . making false statements about a rival to potential investors and customers.” *Id.* (first citing *LePage’s Inc. v. 3M*, 324 F.3d 141, 153 (3d Cir. 2003); then citing *Caribbean Broad. Sys., Ltd. v. Cable & Wireless PLC*, 148 F.3d 1080, 1087 (D.C. Cir. 1998) (further citations omitted)). The Third Circuit listed several types of anticompetitive conduct that the *West Penn Allegheny* Complaint alleged, including that “on several occasions, [defendant] made false statements about [plaintiff’s] financial health to potential investors, which caused [plaintiff] to pay artificially inflated financing costs on its debt.” *Id.* at 110. Viewing the Complaint’s allegations as a whole, the Third Circuit held that plaintiff plausibly had alleged anticompetitive conduct sufficient to state a Sherman Act § 2 claim. *Id.*

Likewise, the *Sanofi* Complaint alleges that Mylan engaged in various anticompetitive conduct designed to block Auvi-Q<sup>®</sup> from the market, including making allegedly false and deceptive statements. These allegations include: (1) Mylan funded and promoted a misleading study entitled “Auvi-Q<sup>®</sup> versus EpiPen<sup>®</sup> Auto-Injectors: Failure to Demonstrate Bioequivalence of Epinephrine Delivery Based on Partial Area Under the Curve” intended to undermine the FDA’s conclusion that Auvi-Q<sup>®</sup> demonstrated bioequivalence to the epinephrine in the EpiPen<sup>®</sup>; and (2) Mylan made misleading statements to physicians about Auvi-Q<sup>®</sup>’s exclusion from the marketplace and touted EpiPen<sup>®</sup> as the “preferred” brand, promoted Auvi-Q<sup>®</sup>’s status as “Not Covered” or “Excluded from Benefit” from third-party payors’ drug formularies, and suggested that the decision to exclude Auvi-Q<sup>®</sup> from the formularies was based on clinical

recommendation and not Mylan’s huge, conditional rebate offers. *Sanofi* Complaint ¶¶ 93–98, 139. Sanofi alleges that it sustained harm from this allegedly deceptive speech. Sanofi asserts that Mylan’s deceptive speech successfully blocked Auvi-Q<sup>®</sup> from the market. *Id.* ¶ 99. Sanofi also asserts that it incurred increased marketing costs to correct Mylan’s misleading statements. *Id.* ¶ 140. And, Sanofi alleges that Mylan engaged in this deceptive conduct unlawfully to maintain its monopoly power in the EAI drug device market. *Id.* ¶ 139.

Mylan contends that these allegations fall short of pleading a plausible claim because 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*.”” *Ayerst Labs.*, [850 F.2d at 916](#) (quoting *Berkey Photo, Inc. v. Eastman Kodak Co.*, [603 F.2d 263, 288 n.41](#) (2d Cir. 1979)). *Cf. Eisai Inc. v. Sanofi-Aventis U.S., LLC*, No. 08-4168(MLC), [2014 WL 1343254](#), at \*36 (D.N.J. Mar. 28, 2014) (describing defendant’s argument as one asserting that a plaintiff generally cannot state a claim for deceptive sales practices under the antitrust laws because “such advertising is believed to have a *de minimis* effect on competition.”). And, Mylan contends, Sanofi’s allegations fail to overcome this presumption here. The court disagrees.

The *de minimis* presumption “is based on the perception that, while “[t]here is no redeeming virtue in deception, . . . there is a social cost in litigation over it,” because ““the likelihood of a significant impact upon the opportunities of rivals is so small in most observed instances—and because the prevalence of arguably improper utterance is so great . . . .”” *Ayerst Labs.*, [850 F.2d at 916](#) (quoting III P. Areeda & D. Turner, *Antitrust Law* ¶ 738a, at 278–79 (1978)). A plaintiff may overcome the *de minimis* presumption ““by cumulative proof that the representations were (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 of neutralization or other offset by rivals.” *Id.* (quoting Areeda & Turner, *Antitrust Law* ¶ 738a, at 279).

In *Ayerst*, the Second Circuit held that a district court had erred by dismissing a Sherman Act § 2 claim. Plaintiff based its claim on an allegedly false and deceptive letter that defendant had sent to customers. The court found that plaintiff’s Complaint alleged several of the factors required to overtake the *de minimis* presumption—including that the letter was clearly false, clearly material, and clearly likely to induce reasonable reliance. *Id.* But the court also agreed with defendant that plaintiff had not alleged other certain factors because the Complaint asserted that defendant sent the letter to pharmacists—persons likely to have knowledge about the subject matter—and that defendant only could have made the misrepresentations for a short time period. *Id.* at 917. Nevertheless, the court concluded that “several factors . . . cannot be adequately evaluated until the discovery process has moved forward to a greater extent than it has thus far.” *Id.* The court thus held that the Complaint pleaded a Sherman Act § 2 claim sufficient to survive Rule 12(b)(6) dismissal.

Viewing the facts alleged here in the light most favorable to Sanofi, the Complaint alleges several of the factors required to overcome the presumption that deceptive statements have a *de minimis* effect on competition. Sanofi alleges that Mylan circulated marketing materials containing false and misleading statements that caused customers to refrain from purchasing Auvi-Q<sup>®</sup>, produced hundreds of millions of dollars in lost sales for Sanofi, and erected artificial barriers preventing Auvi-Q<sup>®</sup> from entering the market. *Sanofi Complaint* ¶¶ 139–40. Like the *Ayerst* plaintiff, the court finds that Sanofi “should be allowed to go forward with the discovery process to substantiate its claim” that Mylan’s allegedly deceptive speech violated § 2 of the Sherman Act. The court recognizes that, like *Ayerst*, the Complaint does not

allege facts capable of supporting all of the factors required to overtake the *de minimis* presumption. But, the court finds persuasive *Ayerst*'s conclusion that these factors require factual development through the discovery process. And, because the court cannot evaluate several of the factors adequately without the facts that discovery will manifest—or not—the court refuses to dismiss Sanofi's claim at the pleading stage. *See Ayerst Labs.*, [850 F.2d at 917](#).

Mylan also asserts that Sanofi alleges that it “was able to successfully combat” Mylan's allegedly deceptive conduct in two ways. [Doc. 57 at 27](#). First, Sanofi spoke with key thought leaders and key allergy advocacy groups to dispel any doubts about Auvi-Q<sup>®</sup>. *Id.* (citing *Sanofi* Complaint ¶ 94). Second, Sanofi secured support from physicians who preferred Auvi-Q<sup>®</sup> to the EpiPen<sup>®</sup> and wrote articles or letters to third-party payors supporting Auvi-Q<sup>®</sup>'s coverage on the drug formularies. *Id.* (citing *Sanofi* Complaint ¶ 100). Thus, Mylan contends, Sanofi's allegations differ from ones asserted by “nascent firm[s]” that have “no established customer base and typically lack[ ] the resources to answer the dominant firm's deception effectively.” IIB Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 782b, at 353 (4th ed. 2015).

Mylan's interpretation of the *Sanofi* Complaint stretches it beyond the point of reason. Sanofi never alleges that it “successfully” responded to Mylan's deceptive conduct with its outreach efforts. To the contrary, Sanofi alleges that Mylan's conduct blocked it from the market and resulted in significant sales losses. Sanofi also alleges that Mylan—a monopolist with a market share exceeding 90%—engaged in this deceptive conduct to block a new entrant to the market (Auvi-Q<sup>®</sup>) and thereby preserve its monopoly power. Considering these allegations along with the other anticompetitive conduct alleged in the Complaint as a whole, the court concludes that Sanofi has stated a plausible Sherman Act § 2 claim based on Mylan's alleged deceptive speech.

**C. Does the *Sanofi* Complaint State a Claim for an “Overall Scheme” to Monopolize Violating Section 2 of the Sherman Antitrust Act?**

Next, Mylan asserts that the *Sanofi* Complaint fails to allege facts sufficient to state a claim for an overall scheme to monopolize violating Sherman Act § 2.

A plaintiff may assert a plausible Sherman Act claim based on “one overarching claim of a § 2 violation.” *Caldera, Inc. v. Microsoft Corp.*, 72 F. Supp. 2d 1295, 1309 (D. Utah 1999). *See also In re: Lipitor Antitrust Litig.*, 868 F.3d 231, 274 (3d Cir. 2017), *petition for cert. filed* (U.S. Nov. 20, 2017) (Nos. 17-752, 17-771) (holding the district court erred by dismissing plaintiffs’ allegations that defendant “participated in an overall scheme of monopolistic conduct” because plaintiff had asserted plausible allegations of various anticompetitive conduct); *Kobe, Inc. v. Dempsey Pump Co.*, 198 F.2d 416, 425 (10th Cir. 1952) (affirming judgment against a patent holder for violating the Sherman Act because the patent holder’s “infringement action and the related activities, of course, in themselves were not unlawful, and standing alone would not be sufficient to sustain a claim for damages which they may have caused, but when considered with the entire monopolistic scheme which preceded them . . . they may be considered as having been done to give effect to the unlawful scheme.”); *In re Neurontin Antitrust Litig.*, MDL No. 1479, 2009 WL 2751029, at \*15–17 (D.N.J. Aug. 28, 2009) (explaining that “[i]f an antitrust plaintiff can allege that a series of actions, when viewed together, were taken in furtherance and as an integral part of a plan to violate the antitrust laws, that series of actions may trigger antitrust liability as an overall scheme,” and holding that plaintiffs “adequately stated a claim for monopolization and attempted monopolization on the basis of allegations that defendant [had] engaged in an overall scheme to monopolize”).

Our Circuit instructs courts to view purported conduct supporting a Sherman Act § 2 violation based on an intent to create or maintain a monopoly “as a whole.” *Aspen Highlands*

*Skiing Corp. v. Aspen Skiing Co.*, [738 F.2d 1509, 1522 n.18](#) (10th Cir. 1984), *aff'd* [472 U.S. 585](#) (1985). The Circuit reasoned that each type of alleged anticompetitive conduct “need not be supported by sufficient evidence to amount to a § 2 violation. It is enough that taken together they are sufficient to prove the monopolization claim.” *Id.* See also *LePage’s Inc. v. 3M*, [324 F.3d 141, 162](#) (3d Cir. 2003) (explaining that “courts must look to the monopolist’s conduct taken as a whole rather than considering each aspect in isolation” when determining whether a Sherman Act § 2 violation has occurred); *Nobody in Particular Presents, Inc. v. Clear Channel Commc’ns, Inc.*, [311 F. Supp. 2d 1048, 1109](#) (D. Colo. 2004) (explaining that “the individual aspects or events of a defendant’s conduct viewed in isolation need not be supported by sufficient evidence to amount to a section 2 violation for liability to exist. Rather, it is enough that the incidents taken together as a whole create sufficient evidence of attempted monopolization.” (first citing *Aspen Highlands*, [738 F.2d at 1522 n.18](#); then citing II Phillip E. Areeda, Roger D. Blair, & Herbert Hovenkamp, *Antitrust Law* ¶ 310, at 147 (2d ed. 2000)).

Here, the *Sanofi* Complaint asserts that Mylan engaged in an overall scheme to monopolize the EAI drug device market. *Sanofi* Complaint ¶¶ 141–43. This alleged scheme included unlawful exclusive dealing and deceptive marketing—alleged anticompetitive conduct that the court already has concluded sufficiently states a plausible claim under the Sherman Act § 2. See *supra* Parts III.A.1 & III.B. This Complaint also alleges that Mylan engaged in other anticompetitive conduct as part of an overall scheme designed to maintain its monopoly power in the relevant market. *Sanofi* Complaint ¶ 142. This alleged conduct includes Mylan’s requirement that schools agree to stock EpiPens<sup>®</sup> exclusively in exchange for the opportunity to participate in Mylan’s discounted EpiPen<sup>®</sup> program. *Id.* ¶¶ 7–8, 80–85, 142. It also includes Mylan’s sharp increase of the EpiPen<sup>®</sup>’s price that—Sanofi contends—enabled Mylan later to

offer larger rebates to payors conditioned on excluding Auvi-Q<sup>®</sup>. *Id.* ¶ 142. The alleged anticompetitive conduct also includes Mylan’s touting of EpiPen<sup>®</sup>’s “preferred” formulary positions even when it didn’t exclude Auvi-Q<sup>®</sup> entirely from third-party payors’ coverage tiers. *Id.* ¶¶ 7, 109, 137, 142. In these circumstances, Sanofi contends, Auvi-Q<sup>®</sup>’s coverage was at less preferential tiers, which produced higher co-pay costs for consumers and increased Sanofi’s costs for co-pay coupons. *Id.* The Complaint’s allegations, viewed in Sanofi’s favor and taken as a whole, allege anticompetitive conduct sufficient to state a plausible claim against Mylan for an overall scheme to monopolize violating Sherman Act § 2.

#### **D. Does the *Sanofi* Complaint Allege Harm to Competition?**

Mylan next asserts that Sanofi fails to state plausible Sherman Act claims as a matter of law because the *Sanofi* Complaint fails to allege harm to competition. A plaintiff asserting an antitrust claim must allege an antitrust injury, as the Sherman Act defines this term. *Cohlmiya v. St. John Med. Ctr.*, [693 F.3d 1269, 1280](#) (10th Cir. 2012) (quoting *Tal v. Hogan*, [453 F.3d 1244, 1253](#) (10th Cir. 2006)). “‘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.” *Id.* (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)); *Reazin v. Blue Cross & Blue Shield of Kan., Inc.*, [899 F.2d 951, 960](#) (10th Cir. 1990) (explaining that a challenged practice must adversely affect competition, not just the business of the plaintiff or another competitor). The antitrust laws thus require a plaintiff to allege “‘an injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants’ acts unlawful.’” *Cohlmiya*, [693 F.3d at 1281](#) (quoting *Tal*, [453 F.3d at 1253](#)).

So, to state a plausible Sherman Act claim, Sanofi must allege harm to competition, not just harm to its own business. *Id.*; *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”). This standard, on a motion to dismiss, requires an antitrust plaintiff to allege facts capable of supporting a finding or inference that the purported anticompetitive conduct produced increased prices, reduced output, or otherwise affected the quantity or quality of the product. *NCAA v. Bd. of Regents*, [468 U.S. 85, 113](#) (1984) (describing raised prices and reduced output as the “hallmarks of anticompetitive behavior”); *see also Cohlmia*, [693 F.3d at 1281](#) (explaining that an antitrust plaintiff must show that the ““challenged conduct affected the prices, quantity or quality of goods or services, not just his own welfare.”” (quoting *Mathews v. Lancaster Gen. Hosp.*, [87 F.3d 624, 641](#) (3d Cir. 1996))).

Here, the *Sanofi* Complaint sufficiently alleges that Mylan’s anticompetitive conduct resulted in increased prices to consumers. Since 2007, Sanofi alleges, Mylan—an entrenched monopolist with a market share exceeding 90%—has raised the price of the EpiPen<sup>®</sup> more than 500%, without losing its extraordinarily high market share. *Sanofi* Complaint ¶¶ 40, 91, 92. Sanofi asserts that Mylan’s purpose for raising prices so sharply was to allow it to absorb the deep conditional discounts that it had given to third-party payors to exclude Auvi-Q<sup>®</sup> from the market. *Id.* ¶¶ 92, 142.

Mylan contends that Sanofi’s allegations only assert that prices increased *before* any alleged exclusionary conduct. Indeed, the Complaint alleges that prices increased significantly from 2009 to 2013, but these increases occurred before Auvi-Q<sup>®</sup>’s launch in 2013. *Id.* ¶ 92. Mylan asserts that price increases can affect competition adversely only when they *result from* exclusionary conduct. [Doc. 57 at 31](#) (citing *Blue Shield of Va. v. McCreedy*, [457 U.S. 465, 482–](#)



83 (1982) (explaining that “an increase in price *resulting from* a dampening of competitive market forces is assuredly one type of injury” that the antitrust laws redress (emphasis added) (further citations omitted)).

The court disagrees with Mylan’s view of the law. The court’s independent research has revealed no case holding that harm to competition must occur after—and not before—a defendant has completed its anticompetitive conduct. And Mylan has cited no such case. Sanofi alleges that Mylan engaged in a scheme to exclude Auvi-Q<sup>®</sup>—a new entrant to the EAI drug device market. This scheme involved Mylan imposing significant price increases in the years leading up to Auvi-Q<sup>®</sup>’s launch so that it later could absorb the deep conditional rebates offered to third-party payors to exclude Auvi-Q<sup>®</sup>. *Sanofi Complaint* ¶ 7 (alleging that Mylan engaged in a “scheme to deprive customers of access to Auvi-Q<sup>®</sup>” that included hiking the price of EpiPen<sup>®</sup> so that it later could offer large, conditional rebates: “With knowledge of when Sanofi could begin marketing Auvi-Q<sup>®</sup>, Mylan ran up the price of the EpiPen<sup>®</sup> substantially before the launch of Auvi-Q<sup>®</sup>. The significantly higher prices ensured that, once Mylan began to offer its new, large conditional rebates from the higher price level, third-party payors would (and did) find it practically impossible to refuse these rebates that Mylan leveraged across its virtual 100% share of the EAI drug device market.”). Sanofi’s allegations about Mylan’s significant price increases allege harm to consumers sufficiently to state an antitrust injury.

Also, Mylan asserts that these allegations cannot assert a plausible antitrust injury because the “charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system.” *Verizon Commc’ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, [540 U.S. 398, 407](#) (2004). It is true. “Simply possessing monopoly power and charging monopoly prices does not violate § 2.” *Pac. Bell Tel. Co. v. Linkline Commc’ns, Inc.*, [555 U.S. 438, 447–](#)

48 (2009). Instead, the Sherman Act “targets ‘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.’” *Id.* (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570–571 (1966)). The *Sanofi* Complaint alleges conduct that could support such a § 2 violation. It asserts that Mylan implemented its steep price hikes to absorb the costs of providing deep, conditional rebates as part of a scheme to maintain its monopoly in the EAI drug market. *Sanofi* Complaint ¶ 7.

Sanofi also alleges that Mylan’s conduct harmed innovation and reduced the quality of EAI drug devices available to consumers in the market. *See Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 318 (3d Cir. 2007) (reversing a district court’s dismissal of a Sherman Act § 2 claim because the Complaint alleged specific anticompetitive conduct that “harmed competition and undermined innovation” in the market sufficient to state an attempted monopolization claim); *United States v. Visa U.S.A., Inc.*, 344 F.3d 229, 241 (2d Cir. 2003) (affirming district court decision that defendants’ exclusionary policies had harmed “product innovation and output”). The Complaint alleges that Mylan’s anticompetitive conduct prevented customers from accessing Auvi-Q<sup>®</sup>—a new entrant to the market that “represented a novel and advanced EAI drug device.” *Sanofi* Complaint ¶ 4. The Complaint describes Auvi-Q<sup>®</sup> as a new product “designed for the smartphone generation to be smaller and easier to carry than the EpiPen<sup>®</sup>.” *Id.* It also “included voice instructions to help patients or caregivers to administer epinephrine during a highly stressful anaphylactic episode, when they may otherwise not have been trained to use the device or might be too panicked to read the written instructions on the device.” *Id.* These allegations allege harm to competition sufficiently because, as Sanofi contends, Mylan’s

conduct prevented consumers from accessing a new and innovative product with allegedly better qualities than EpiPen<sup>®</sup>, the market's dominant product.<sup>8</sup>

Mylan also contends that Sanofi cannot allege harm to competition when the Complaint asserts that the exclusive dealing arrangements lasted no more than one or two years. *Sanofi* Complaint ¶ 67. For example, the Seventh Circuit recently affirmed summary judgment against an exclusive dealing claim, finding no evidence that the contracts at issue had an exclusionary effect “since most of the contracts expire every year or two, giving other [competitors, such as the plaintiff] a shot at obtaining the next contract . . . .” *Methodist Health Servs. Corp. v. OSF Healthcare Sys.*, [859 F.3d 408, 410](#) (7th Cir. 2017). But the Seventh Circuit also recognized that exclusive dealing arrangements can have “dire consequences” if they drive competitors into bankruptcy and thus out of the market. *Id.* And, duration is just one factor that courts consider when determining whether an exclusive dealing agreement harms competition. *See, e.g., McWane, Inc. v. FTC*, [783 F.3d 814, 819, 834–38](#) (11th Cir. 2015) (rejecting argument that an exclusive dealing arrangement could not harm competition because it was “short-term and voluntary” and, instead, the Circuit considered the “market realities” to determine whether the practical effect of the arrangement harmed competition); *Nilavar v. Mercy Health Sys. W. Ohio*, [142 F. Supp. 2d 859, 878–88](#) (S.D. Ohio 2000) (explaining that courts “have considered the duration of a contract to be one of many factors considered in determining whether a given

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<sup>8</sup> Mylan asserts that Sanofi's cited cases differ from the facts alleged here because, in those cases, defendants prevented the product from reaching the market. The *Sanofi* Complaint alleges similar conduct. Although the Complaint never alleges that Mylan prevented Sanofi from soliciting third-party payors to purchase Auvi-Q<sup>®</sup>, the Complaint alleges that Mylan's exclusive dealing arrangements denied consumers access to Auvi-Q<sup>®</sup> because Mylan required third-party payors to exclude Auvi-Q<sup>®</sup> from the drug formularies, thus blocking Auvi-Q<sup>®</sup> from reaching a significant portion of the market. These allegations suffice to allege harm to competition. *See Visa U.S.A.*, [344 F.3d at 241](#) (“By excluding Amex and Discover [the third and fifth largest issuers of payment cards in the United States] from the market for outside card issuers, [defendants] effectively deny consumers access to products that could be offered only by a network in partnership with individual banks” and thus the district court did not err in “finding that competition has been harmed by the defendants’ exclusionary rules.”).

exclusive contract is anti-competitive,” and concluding that plaintiff’s Complaint sufficiently had alleged an antitrust injury even though the contract’s duration was short because “the term of the exclusive contract does not render the contract reasonable, when considered in light of the extent that the relevant market is foreclosed”). Here, although Sanofi alleges that the length of third-party payors’ coverage decisions typically lasted one to two years, the court already has noted other facts that the *Sanofi* Complaint alleges and how they assert harm to competition sufficiently. These factual allegations include Mylan’s targeting of Auvi-Q<sup>®</sup>, specifically, as part of an effort to block a new entrant from the EAI drug market, prevent it from developing a customer base, and maintain unlawfully its market share exceeding 90%.

At the pleading stage of this action, the allegations are sufficient to allege harm to competition in the EAI drug device market. These allegations of antitrust injury are sufficiently plausible to support Sanofi’s Sherman Act § 2 claims.

#### **E. Does the *Sanofi* Complaint Allege Causation?**

Last, Mylan argues that Sanofi has failed to state a claim for relief because the Complaint never alleges that Mylan caused Sanofi’s purported injuries. The Sherman Act requires an antitrust plaintiff to show that its injury was caused “by reason of” the defendant’s anticompetitive conduct. 15 U.S.C. § 15(a). *See also Aspen Highlands*, 738 F.2d at 1519 n.12 (“Of course, the fact of injury and damages suffered *by reason of a violation of the antitrust laws* must also be shown for a private litigant to recover on a claim of monopolization.” (emphasis added)). Thus, an antitrust plaintiff must “establish that defendant’s unlawful conduct caused plaintiff injury in its business or property . . . to recover under the antitrust laws.” *Id.* at 1522–23. *See also Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 126–27 (1969) (explaining that an antitrust plaintiff cannot shoulder its burden to prove an antitrust violation if

the injury is “attributable to its lack of desire, its limited production capabilities, or to other factors independent of [the alleged] unlawful conduct”).

An antitrust plaintiff need not show that defendant’s conduct was the exclusive cause of plaintiff’s injury. *Zenith Radio Corp.*, 395 U.S. at 114 n.9 (“It is enough that the illegality is shown to be a material cause of the injury; a plaintiff need not exhaust all possible alternative sources of injury in fulfilling his burden of proving compensable injury.”). Instead, the “causal connection [must be] sufficient to establish the violation as a substantial factor in the occurrence of damage.” *Motive Parts Warehouse v. Facet Enters.*, 774 F.2d 380, 389 (10th Cir. 1985) (quoting *Reibert v. Atl. Richfield Co.*, 471 F.2d 727, 731 (10th Cir. 1973)).

Mylan’s contention that Sanofi has failed to allege facts capable—if true—of establishing causation consists of two primary theories.

*First*, Mylan asserts, Sanofi made a unilateral and independent decision—not based on any of Mylan’s conduct—to stop competing with Mylan for exclusive or preferred formulary status. But the plain language of the Complaint belies this characterization. Sanofi specifically alleges that it “ultimately decided to return the marketing rights for Auvi-Q<sup>®</sup> back to the creators of the device in part because of the artificial barriers to entry Mylan’s conduct [had] erected.” *Sanofi* Complaint ¶¶ 137, 140, 143. Sanofi also alleges that Mylan’s conduct raised its costs of entry to the market. *Id.* ¶¶ 131, 134. And the Complaint asserts that Mylan’s anticompetitive conduct caused Sanofi to lose hundreds of millions of dollars in sales in the \$1 billion-plus U.S. EAI drug device market. Sanofi contends it would not have sustained these losses but for Mylan’s unlawful acts. *Id.* ¶¶ 137, 140, 143.

The *Sanofi* Complaint also alleges facts about Auvi-Q<sup>®</sup>’s sales in Canada that could support a finding or inference that Mylan caused Sanofi’s purported injuries. Sanofi alleges that

Auvi-Q<sup>®</sup> (known in Canada as Allerject<sup>®</sup>) achieved a stronger performance in Canada, where Mylan did not market the EpiPen<sup>®</sup> and where the playing field was level with open access to drug formularies. *Sanofi* Complaint ¶¶ 9, 106, 107. Sanofi alleges that EpiPen<sup>®</sup> similarly dominated the Canadian EAI drug device market before Sanofi launched the Allerject<sup>®</sup> there. *Id.* ¶ 106. But, by the end of 2013 (its first year on the Canadian market), Allerject<sup>®</sup> exceeded its projections, growing to a 21% market share. *Id.* In 2014 and 2015, Allerject<sup>®</sup> continued to gain market share. *Id.* It reached a 25% market share by the end of 2014, and it peaked at a 32% market share in 2015. *Id.* Mylan alleges “that growth of Allerject<sup>®</sup> in Canada, and physician and patient enthusiasm for the device in Canada, illustrates Auvi-Q<sup>®</sup>’s sales potential where an entrenched competitor is not able to manipulate the market and tip the scales in its own favor.” *Id.*

Mylan asserts that these allegations cannot plausibly support a finding or inference that Mylan caused Sanofi’s purported injuries. Mylan contends that one cannot compare Auvi-Q<sup>®</sup>’s sales performance in Canada to those in the United States because the Complaint concedes that Mylan “does not market the EpiPen<sup>®</sup>” in Canada. *Id.* ¶ 9. The court does not understand this allegation to mean that Mylan does not sell the EpiPen<sup>®</sup> in Canada. Indeed, the Complaint alleges just the opposite. It alleges that “EpiPen<sup>®</sup> similarly dominated the Canadian EAI drug device market before Sanofi launched the Allerject<sup>®</sup>.” *Id.* ¶ 106. Instead, the Complaint alleges that Mylan did not engage in the same anticompetitive conduct in Canada (*i.e.*, offering highly discounted rebates conditioned on exclusivity). *Id.* And Sanofi explains why Mylan could not offer such rebate programs in Canada: In Canada, provincial authorities control drug formularies. *Id.* So, Sanofi alleges, the Allerject<sup>®</sup> was treated at parity with the EpiPen<sup>®</sup> in

Canada. *Id.* And the two devices were equally available for physicians to prescribe to consumers. *Id.*

The court recognizes that Sanofi's allegations are just that. In time, discovery may reveal that the Canadian market differed significantly from the U.S. market, and so it does not provide a proper comparison to infer causation. But accepting the allegations as true—as the court must at the pleading stage—Sanofi's comparison of Auvi-Q<sup>®</sup>'s sales in Canada to those in the United States plausibly asserts that Mylan's conduct caused Sanofi's alleged antitrust injuries. *See, e.g., United States v. Visa U.S.A., Inc.*, [344 F.3d 229, 241](#) (2d Cir. 2003) (holding the district court did not err by finding that competition was harmed by defendants' conduct because, among other things, the evidence showed total exclusion of two major competitors (Amex and Discover) from a segment of the market in the United States but, in the foreign markets (where no exclusivity rules applied) Amex successfully convinced banks that issued Visa cards also to issue Amex cards).

Mylan also takes issue with Sanofi's decisions about the way it marketed Auvi-Q<sup>®</sup>. Mylan contends that Sanofi could have competed with Mylan for exclusivity on the drug formularies but that it chose to refrain from demanding exclusivity and it never offered pricing to match Mylan's rebates. *Sanofi* Complaint ¶¶ 61, 66, 76. Mylan argues that Sanofi's decisions caused Sanofi's injuries—not Mylan's conduct. But, as Professors Areeda and Hovenkamp instruct, “dispositive weight should not be given to lists of possible alternative causes, which virtually any defendant can generate.” IIA Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 338a, at 123 (4th ed. 2014). Instead, “[i]f the plaintiff's claim of causation is plausible, it should not be dismissed summarily merely because alternative causation stories are plausible as

well.” *Id.* The court thus refuses to dismiss Sanofi’s claims at the pleading stage based on Mylan’s arguments that alternative reasons caused the alleged injuries.

*Second*, Mylan argues that Sanofi was forced to exit the EAI drug device market—not because of Mylan’s conduct—but because Sanofi recalled all of its Auvi-Q<sup>®</sup> devices from the market due to manufacturing issues. Indeed, the Complaint asserts that Sanofi undertook a “voluntary recall of Auvi-Q<sup>®</sup>” in October 2015, following reports of manufacturing issues. *Sanofi* Complaint ¶ 110. The Complaint also asserts, however, that recalls are not uncommon for pharmaceuticals. *Id.* ¶ 110 n.53. And, it alleges that Mylan likewise undertook a recall of EpiPens<sup>®</sup> in March and April 2017. *Id.*

Mylan disagrees that the Auvi-Q<sup>®</sup> recall was one common in the industry. Mylan argues that the Auvi-Q<sup>®</sup> recall was significant, citing press reports that, it contends, show the seriousness and unusual dimension of the recall. Mylan contends that this recall drove Sanofi to leave the market and not any alleged anticompetitive conduct by Mylan. [Doc. 57 at 36](#). And, it asserts that the press reports contain Sanofi’s real-time accounts of its reasons for leaving the market that conflict with its allegations in the Complaint that Mylan forced it to exit the market. *Id.*

These arguments merely foreshadow factual disputes that the court cannot resolve on a motion to dismiss. *See Iqbal*, [556 U.S. at 679](#) (explaining, on a motion to dismiss, a court must “assume [the] veracity” of well-pleaded factual allegations “and then determine whether they plausibly give rise to an entitlement to relief”). At the pleading stage, Sanofi plausibly has alleged that Mylan caused its injuries, and that is all a plaintiff must do to survive a motion to dismiss.



**IV. Conclusion**

For reasons explained, the court grants Mylan's Motion to Dismiss in part. The court dismisses Sanofi's exclusive dealing claims based on discounts or rebates that Mylan offered to state or state agencies because the *Noerr-Pennington* doctrine bars them. The court denies Mylan's Motion to Dismiss in all other respects.

**IT IS THEREFORE ORDERED BY THE COURT** that defendants Mylan, Inc. and Mylan Specialty, L.P.'s Motion to Dismiss the *Sanofi* Complaint ([Doc. 43](#)) is granted in part and denied in part.

**IT IS SO ORDERED.**

Dated this 21st day of December, 2017, at Topeka, Kansas.

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