IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

IN RE: EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litigation	CASE NO.: 2:17-MD-02785-DDC-TJJ Hon. Daniel D. Crabtree
SANOFI-AVENTIS U.S., LLC, Plaintiff, v. MYLAN INC., *et al*., Defendants. This document applies to the *Sanofi* case.	CASE NO.: 2:17-CV-02452-DDC-TJJ *Document Filed Electronically*

THE MYLAN DEFENDANTS' REPLY MEMORANDUM IN SUPPORT OF THEIR MOTION TO DISMISS PLAINTIFF'S COMPLAINT

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF AUTHORITIES, Cont'd

Page(s)

TABLE OF AUTHORITIES, Cont'd

Page(s)

TABLE OF AUTHORITIES, Cont'd

Page(s)

TABLE OF AUTHORITIES, Cont'd

Page(s)

Other Authorities

TABLE OF AUTHORITIES, Cont'd

Page(s)

PRELIMINARY STATEMENT

The antitrust laws protect competition. They encourage competitors to offer discounts and rebates to win business and to market their products aggressively, and they recognize that in this competitive process, some companies win and some lose. The antitrust laws do not, however, provide a remedy for the company on the losing end of fierce competition, and certainly not one whose alleged injuries are not attributable to the defendant's conduct.

According to Sanofi's Complaint, and now confirmed by its Opposition, that is just what happened here. Sanofi launched a product that competed with Mylan's EpiPen® ("EpiPen") Auto-Injector, and Mylan in response allegedly offered greater rebates to pharmacy benefit managers ("PBMs") and third-party payers and sought to convince doctors and patients that it had the better product. The fact that Sanofi attempts to assert a claim under the antitrust laws for this alleged conduct betrays Sanofi's fundamental misunderstanding of those laws and the remedies they provide. And the fact that Sanofi withdrew its product from competition because of safety problems, not because of anything Mylan did, underscores that Sanofi has no viable claim.

Sanofi makes various arguments in its Opposition about why Mylan's Motion to Dismiss should be denied. None of those arguments, however, salvages Sanofi's flawed antitrust claims. Instead, Sanofi is left to argue that, while there may be problems with the facts it alleges, courts do not dismiss monopolization claims at the pleading stage. That too is wrong. Courts do not hesitate to dismiss discounting claims that fail to allege below-cost pricing, so-called "exclusive dealing" claims that fail to allege exclusionary conduct, and even monopolization claims based on an alleged "overall scheme" when the elements of the "scheme" do not state a claim. Factual development through discovery cannot save claims like these that lack such allegations—they

fail as a matter of law. For the reasons set forth below, this Court should dismiss these claims.

Rebate claim. As Mylan's brief in support of its Motion to Dismiss explained, unless discounts or rebates involve bundling or tying multiple products, they only violate the antitrust laws if they cause prices to fall below the defendant's cost. Sanofi itself explained as much in *Eisai*, where its counsel argued that "[t]here is nothing about having a successful product or large market share that prohibits a company from going to customers and saying I'm going to give you an even bigger discount if you buy more from me." Hearing Transcript at 6, *Eisai, Inc. v. Sanofi-Aventis U.S., LLC*, No. 08-cv-04168 (D.N.J. June 24, 2009), ECF No. 61 ("*Eisai*, Hr'g Tr.").[1] And here Sanofi alleges neither bundling or tying nor below-cost pricing. Rather, Sanofi argues the below-cost pricing principle does not apply because Sanofi calls its rebate claim "exclusive dealing." Sanofi is wrong, and courts have rejected this type of elevation of nomenclature over substance. Indeed, each of the cases on which Sanofi relies dealt with bundled rebates (which are analyzed differently than single-product rebates), tying, or allegations that a defendant forced its customers into exclusive agreements by threatening to withhold supply or similar coercive measures that restricted the ability of other firms to compete for the business of customers that accepted rebates. Allegations of this sort are completely absent from Sanofi's complaint, which means it should be dismissed. Nor does Sanofi rebut Mylan's argument that the subset of Sanofi's rebate claim related to alleged decisions by State Medicaid agencies to give the EpiPen Auto-Injector preferred formulary position is immune from antitrust

[1] Sanofi incorrectly asserts that reference to statements of Sanofi's counsel in this transcript is somehow "misleading[ ]." Opp. 16. Sanofi is simply wrong to suggest that the Third Circuit's ruling in *ZF Meritor* (described below) in any way detracted from the accuracy of this statement. *Id*. Presumably this is why Sanofi offers no explanation as to how *ZF Meritor* supposedly impacted the accuracy of this statement. Nor does the further sentence referenced by Sanofi change the clear import of the portion of the transcript that was excerpted in Mylan's Motion to Dismiss.

challenge under the *Noerr-Pennington* doctrine.

Deceptive speech claim. The Tenth Circuit is clear that allegedly deceptive or unethical business conduct is not proscribed by the Sherman Act. Sanofi fails to grapple with this binding precedent in its Opposition and instead resorts to arguing that, in theory, some false statements could support an antitrust claim under circumstances where they harm competition. But Sanofi cannot meet its pleading burden by relying on theory. Sanofi fails to allege facts sufficient to state a monopolization claim based on deceptive marketing and speech, and therefore this claim must be dismissed.

"Overall scheme" to monopolize claim. Despite failing to state a claim for monopolization based on rebates or allegedly deceptive speech, Sanofi tries to package these allegations together and adds flawed allegations about other conduct that does not violate the antitrust laws to meet its pleading burden. This simply does not work. None of the cases Sanofi cites in its Opposition suggests that combining a variety of deficient allegations can somehow add up to a monopolization claim. This claim too should be dismissed.

Failure to allege harm to competition. Sanofi's failure to allege harm to competition means that all claims must be dismissed. Sanofi fails to address Mylan's arguments that the allegedly exclusionary formulary decisions are short-term, and that no other competitors were excluded by Mylan's alleged conduct. These failures alone should lead to dismissal. Instead, Sanofi claims that Mylan increased (list) prices, the quality of epinephrine auto-injectors went down, and customers were deprived of choice. The first two alleged harms do not apply here. Instead, the supposed price increases, which are perfectly lawful, began before any alleged exclusionary conduct occurred. And Sanofi does not actually allege a reduction in quality, despite what its Opposition attempts to suggest. As for consumer choice, Sanofi points to no

litigated cases identifying loss of choice as harm to competition for purposes of an antitrust claim.

Failure to allege causation. Finally, Sanofi fails to rebut Mylan's argument that, to the extent it suffered any injuries, those injuries were caused by Sanofi's own decision to compete on different terms than customers desired. Indeed, Sanofi admits that it voluntarily recalled its product for safety reasons, not because of anything Mylan did. Sanofi's argument that its decision, apparently months later, not to re-launch the Auvi-Q® ("Auvi-Q") product was somehow caused by Mylan is far too attenuated to sustain its burden to allege causation. The remaining harm to which Sanofi points in its Opposition—an alleged 50 percent reduction in market share in 2014—is misleading. Sanofi's Complaint omits the fact that Auvi-Q reached its peak sales in 2015, during the very period that Mylan allegedly engaged in exclusionary conduct. Sanofi's argument that its experience in Canada is sufficient to allege causation is similarly misplaced. Those allegations suggest nothing more than that Sanofi allegedly gained somewhat more market share over a different time period, in a different country, with a different regulatory scheme, competing against a different firm marketing the EpiPen Auto-Injector. Sanofi does not allege anything about the competitive conditions in Canada or whether it chose to compete in the same way as in the United States. Sanofi therefore cannot state a claim.

ARGUMENT

I. SANOFI'S REBATE ALLEGATIONS FAIL TO STATE A CLAIM.

Sanofi's version of exclusive dealing law exists only through the looking glass. This starts with the very first sentence of Sanofi's argument in which it suggests that conduct resulting in exclusivity is almost presumptively harmful, asserting that "[t]he federal courts have not hesitated to rigorously scrutinize, and in many cases condemn, exclusive dealing arrangements

undertaken by monopolists." Opp. 8. This flips on its head the clear consensus of courts that "[e]xclusive dealing agreements are often entered into for entirely procompetitive reasons, and generally pose little threat to competition." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 270 (3d Cir. 2012) (citation omitted); *see also Methodist Health Servs. Corp. v. OSF Healthcare Sys.*, 859 F.3d 408, 410 (7th Cir. 2017) ("But what is more common than exclusive dealing? It is illustrated by requirements contracts, which are common, and legal, and obligate a buyer to purchase all, or a substantial portion of, its requirements of specific goods or services from one supplier.").

Far from "[f]alling squarely within" existing case law, Opp. 11, Sanofi's so-called "exclusive dealing" claim fails both because of what it alleges—a single product rebate—and what it does not allege—namely any of the other conduct that courts have recognized as potentially impeding a customer's ability to decline a rebate or discount if another competitor makes a better offer. Sanofi has not alleged that Mylan used rebates to create a tie with another product, that Mylan bundled rebates across multiple products, or that Mylan threatened to terminate supply of EpiPen Auto-Injectors if PBMs or payers declined the alleged rebate. Where allegations of such other exclusionary conduct are absent, and therefore pricing is alleged to be the primary means of exclusion, a single product rebate or discount can only state a claim under Section 2 of the Sherman Act where it is alleged to have resulted in below-cost pricing. This is because absent allegations of additional conduct, if Sanofi "can't outbid" Mylan, "the logical inference is that [Mylan] offered the [PBMs and payers] a better deal." *Methodist Health Servs. Corp.*, 859 F.3d at 411.

Despite Sanofi's assertions to the contrary, courts have not hesitated to dismiss discounting claims where plaintiffs have similarly failed to allege below-cost pricing or other

factors that otherwise resulted in significant foreclosure. *See* Mot. 19 & n.5 (citing *NicSand, Inc. v. 3M Co.*, 507 F.3d 442, 452-53 (6th Cir. 2007) (en banc) (affirming 12(b)(6) dismissal of a complaint alleging rebates that did not result in predatory pricing)); *see also Paddock Publ'ns, Inc. v. Chi. Tribune Co.*, 103 F.3d 42, 47 (7th Cir. 1996) (affirming 12(b)(6) dismissal of exclusive dealing claim based on agreement with a duration of one-year); *PNY Techs., Inc. v. SanDisk Corp.*, No. 11-cv-04689-WHO, 2014 WL 2987322, at *4-6 (N.D. Cal. July 2, 2014) (granting 12(b)(6) dismissal of exclusive dealing claim because plaintiff failed to allege substantial foreclosure and rebates were not alleged to result in below-cost pricing). Sanofi, having failed to allege either other exclusionary conduct or below-cost pricing, cannot state a claim.

A. The price-cost test applies to Sanofi's rebating claim and requires dismissal.

Above-cost single-product discounts and rebates, even if "conditioned on exclusivity," Opp. 23, do not violate the antitrust laws. Sanofi tries to sidestep this conclusion by insisting that it "pleads an exclusive dealing claim, not a predatory pricing claim," Opp. 12, and therefore the price-cost test does not apply. This assertion elevates semantics over substance and is wrong. Indeed, the court in *ZF Meritor*, a case on which Sanofi relies heavily, specifically rejected this argument, holding that "a plaintiff's characterization of its claim as an exclusive dealing claim ***does not*** take the price-cost test off the table." 696 F.3d at 275 (emphasis added). And the Tenth Circuit agrees. *See United States v. AMR Corp.*, 140 F. Supp. 2d 1141, 1193-94 (D. Kan. 2001), *aff'd* 335 F.3d 1109 (10th Cir. 2003) (rejecting "the government's attempt . . . to re-characterize the present action as one grounded[] not on 'predatory pricing' . . . [in order to] evade the [price-]cost analysis mandatory under *Brooke Group*.").

Sanofi pairs this red herring with the misleading suggestion that the price-cost test is a

legal standard distinct from the rule of reason, Opp. 8, and is one that only applies "to distinct predatory pricing claims." Opp. 12. Sanofi is wrong again. As the Third Circuit explained in *ZF Meritor* (and as made clear in Mylan's Motion to Dismiss), "in the context of exclusive dealing, the price-cost test may be utilized as ***a specific application of the rule of reason*** when the plaintiff alleges that price is the vehicle of exclusion." 696 F.3d at 273 (emphasis added) (internal quotation marks omitted); *see also* Mot. 17. In other words, far from being in any way separate or different from the rule of reason, the price-cost test is a form of the rule of reason test that is applicable to claims such as Sanofi's.[2]

The key question, then, is whether price was the "driving force" behind the alleged exclusivity, meaning customers were free to walk away if the defendant's competitors offered better prices. *ZF Meritor*, 696 F.3d at 278. As the Third Circuit later explained in *Eisai*, "[t]his is usually the case when a firm uses a ***single-product loyalty discount or rebate*** to compete with similar products." *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 409 (3d Cir. 2016) (emphasis added). Thus, if customer compliance with an exclusive rebate arrangement is primarily driven by price, the price-cost test applies and those rebates are anticompetitive only if they result in below-cost pricing.

By contrast, the price-cost test does ***not*** apply when—unlike here—customers are

[2] The fact that the price-cost test can be applied to predatory pricing claims and other types of pricing claims is entirely logical because courts have made clear that many of the same principles apply to pricing claims more broadly. For example, in *ZF Meritor*, the court explained that "[t]he lesson of the predatory pricing case law is that, generally, above-cost prices are not anticompetitive, and although there may be rare cases where above-cost prices are anticompetitive in the long run, it is 'beyond the practical ability' of courts to identify those rare cases without creating an impermissibly high risk of deterring legitimate procompetitive behavior (i.e., price cutting)." 696 F.3d at 274-75 (citations omitted). According to that court, "[t]hese principles extend to above-cost discounting or rebate programs, which condition the discounts or rebates on the customer's purchasing of a specified volume or a specified percentage of its requirements from the seller." *Id*. at 275.

coerced through *additional conduct*—beyond pricing or rebates—to accept the rebates or discounts. In *ZF Meritor*, for example, the court declined to apply the price-cost test because "Plaintiffs alleged that Eaton used its position as a supplier of necessary products to persuade [customers] to enter into agreements imposing *de facto* purchase requirements." 696 F.3d at 277 (emphasis in original). As the court explained, Eaton's customers agreed to the various requirements on which the rebate was conditioned because "they were essentially forced to do so or risk financial penalties or supply shortages" in circumstances where "losing Eaton as a supplier was not an option." *Id*. at 277-78. Based on this fundamental dynamic, the court concluded that it was "not a case in which the defendant's low price was the clear driving force behind the customer's compliance with purchase targets, and the customers were free to walk away if a competitor offered a better price." *Id*. at 278.[3]

Sanofi alleges nothing of the sort in its complaint. Even in its Opposition, Sanofi only points to price-related reasons why PBMs and payers allegedly accepted the conditional rebates. For example, Sanofi makes much of the fact that Mylan allegedly "increase[d] EpiPen prices" and states that "[w]ith higher EpiPen prices leveraged across Mylan's 90%+ market share, Mylan was able to penalize payers if they sought to provide patients with access to Auvi-Q and forego large rebates conditioned on exclusive reimbursement for the EpiPen."[4] Opp. 2. Those are

[3] Pursuant to the Court's September 14, 2017 order (Dkt. No. 42), Mylan has incorporated applicable Tenth Circuit case law into its reply brief. Although the Tenth Circuit has not yet addressed a case involving allegedly anticompetitive rebates, the Tenth Circuit's monopolization case law is entirely consistent with the out-of-circuit cases discussed in this brief. *See e.g.*, *Suture Express, Inc. v. Owens & Minor Distribution, Inc.*, 851 F.3d 1029 (10th Cir. 2017); *United States v. AMR Corp.*, 335 F.3d 1109 (10th Cir. 2003).

[4] The "penalty" Sanofi refers to is the loss of a rebate, which numerous courts have recognized does not serve to turn rebates into exclusionary conduct or ordinary exclusivity agreements into anticompetitive behavior. *See Methodist Health Servs. Corp.*, 859 F.3d at 411 (rejecting plaintiff's claim despite allegations that "Saint Francis's exclusive contracts forced insurers and

pricing allegations. Sanofi's theory is that Mylan threatened payers with worse prices if they did not agree to rebates that were tied to exclusivity. Sanofi never alleges that Mylan threatened to discontinue supply or impose other financial penalties on payers or PBMs that declined the rebates, or even that the EpiPen Auto-Injector was a "must have" product.[5] Nor does Sanofi allege that the conditional rebate agreements "locked up" payers and PBMs for an extended period—in fact, Sanofi acknowledges that the formulary decisions made by PBMs lasted only 1-2 years. Opp. 28 n.21.[6]

Accordingly, this case falls squarely under the price-cost test as a matter of law and must be dismissed. Sanofi alleges that Mylan sustained its market share by competing—and winning—on the basis of price, i.e. by offering customers an opportunity for substantial discounts that were conditioned on exclusivity. Sanofi alleges no facts that Mylan otherwise coerced customers or did anything besides offering them a better price. And it would be a perverse result indeed if offering *lower* prices to customers could give rise to a viable antitrust

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ultimately consumers to pay nearly $30 million more than they would have paid in a competitive market.") (internal quotation marks omitted); *see also Eisai*, Hr'g Tr. at 4 (quoting Sanofi's counsel arguing that "every plaintiff that brings a case challenging a discount program makes the same argument, that it's not a discount, it's a penalty for buying less product, but it's still fundamentally a discount program.").

[5] A "must have" product would be one that a payer or PBM must include on its formulary because it is approved for unique indications or for patient populations not served by other approved drugs. *See Methodist Health Servs. Corp.*, 859 F.3d at 410 (describing Saint Francis, which had entered into exclusive contracts with payers, as a "must have" hospital because it is one "with which the insurer must have a contract to provide hospital services, because it provides certain inpatient services that the other hospitals in the tri-county area do not provide."); *see also Eisai*, 821 F.3d at 409 (concluding that the price-cost did not apply because Eisai alleged that it was excluded through bundling and not pricing—specifically, that Sanofi was able to bundle contestable and incontestable demand due to its drug having obtained a unique FDA indication).

[6] Sanofi wrongly asserts that this fact is "of no moment." *Id*. On the contrary, this is yet another factor that weighs against the ability of conditional rebates to foreclose Sanofi from competing effectively. *Methodist Health Servs. Corp.*, 859 F.3d at 410-11.

claim.

In circumstances like these, a competitor like Sanofi cannot be unlawfully foreclosed from the market, because it "need only offer a better product or a better deal to acquire" the business of the PBMs and payers. *Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 997 (9th Cir. 2010) (quoting *Omega Envt'l., Inc. v. Gilbarco, Inc.*, 127 F.3d 1157, 1164 (9th Cir. 1997)).[7] Sanofi alleges no facts explaining why it could not compete for exclusive status. Mot. 32-34. Indeed, Sanofi argues repeatedly that it had the better product. Ultimately, then, Sanofi has failed to state a claim as a matter of law. The theory of its case is that price was the "driving force" behind the alleged exclusivity, which means that the Complaint is governed by the price-cost test. *ZF Meritor*, 696 F.3d at 278. And because Sanofi has not alleged that Mylan priced below cost, there can be no sustainable antitrust claim.

Sanofi's attempt to analogize its allegations to *ZF Meritor* by asserting that the alleged exclusion of Auvi-Q from formularies "is no different than Eaton requiring third-parties to remove Eaton's rival products from materials," Opp. 14, is misplaced. As explained above, in *ZF Meritor*, unlike what Sanofi alleges here, the customers who agreed to exclusivity did so under the real threat of losing their supply altogether if they did not accept Eaton's terms. *ZF Meritor*, 696 F.3d at 277-78. Moreover, although Sanofi has cherry-picked one aspect of the case, the *ZF Meritor* court was clear that the long-term agreements at issue contained "a number of anticompetitive provisions." *Id*. at 277. Specifically, in addition to provisions requiring the

[7] In its Complaint, Sanofi alleges that "Mylan's monopoly market share [made] it mathematically impossible for Sanofi to match its conditional rebates." Compl. ¶ 66. However, Sanofi's argument assumes that the market shares of the EpiPen Auto-Injector and Auvi-Q were fixed and that therefore any discount offered on Auvi-Q would need to be much greater because of Auvi-Q's smaller market share at the time. However, because Sanofi alleges no facts as to why it would not or could not significantly grow its market share by offering a better product at a better price, its allegations that it could not match the alleged Mylan rebates are simply implausible as plead.

removal of ZF Meritor products from customer materials, the court also highlighted the long-term nature of the agreements (each agreement was for a term of at least five years) and provisions requiring that Eaton's direct customers offer preferential pricing on Eaton's transmissions over those of Eaton's competitors, as each also contributing to the overall anticompetitive nature of the agreements. *Id*. at 287-88. There is not even a hint of these kinds of allegations from Sanofi here.

Just as *ZF Meritor* is of no help to Sanofi, nor are the other two Third Circuit cases on which Sanofi relies—*Dentsply* and *LePage's*. Opp. 9-10. In *Dentsply* (a case that does not even address rebates), just as in *ZF Meritor*, the plaintiffs alleged that the defendant threatened to terminate supply altogether of both teeth and other dental products and that customers could not afford to lose Dentsply products. *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 190, 194 (3d Cir. 2005). Sanofi's reliance on *LePage's*—a case addressing bundling allegations—is likewise misplaced. *See LePage's Inc. v. 3M*, 324 F.3d 141 (3d Cir. 2003) (en banc). Courts have been unequivocal in drawing a clear line between claims based on single-product discounts, such as the one brought by Sanofi, and claims based on discounts linking two or more products. *Eisai*, 821 F.3d at 405-06. According to the Third Circuit, *LePage's* reasoning only applies in bundling cases. *Id*. at 405. Indeed, in *ZF Meritor*, the court explicitly rejected the relevance of *LePage's* "where, as here, only one product is at issue and the plaintiffs have not made any allegations of bundling or tying." 696 F.3d at 275 n.11. This is because the circumstances in which a competitor might be excluded by discounts or rebates linking two or more products are fundamentally different than where the discount is only on a single product—specifically, "a single-product producer [may be] excluded through a bundled rebate program offered by a producer of multiple products, which conditions the rebates on purchases across different

product lines." *Id*. Thus, courts have been clear that "the price-cost test applies to market-share or volume rebates offered by suppliers within a single-product market." *Id*. (citing *NicSand*, 507 F.3d at 452); *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1061-62 (8th Cir. 2000) (rejecting the relevance of cases involving allegations of discounts resulting in tying or bundling, including *LePage's*, because plaintiffs' allegations only related to discounts on a single product); *Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227, 236 (1st Cir. 1983)).

Nor do any of the other cases cited by Sanofi provide it refuge from the failure of its allegations. Unlike the plaintiffs in each of the cases included in Sanofi's Opposition, which are described below, Sanofi has failed to allege any facts that would establish that customers accepted the alleged rebates for any reason other than to receive a better price. Specifically, Sanofi has failed to allege any of the following:

- ***Bundled rebates or tying,*** as alleged by the plaintiffs in the following cases:
    - In *Suture Express, Inc. v. Cardinal Health 200, LLC*, 963 F. Supp. 2d 1212, 1217 (D. Kan. 2013), the plaintiff alleged that "defendants attempted to leverage their power in the distribution of a fuller array of med-surg products to coerce customers from buying plaintiff's sutures and endo products" through contracts "which unlawfully tied the sale of sutures and endo products to the sale of other products in the med-surg basket." Although this Court denied defendant's motion to dismiss, it later granted summary judgment, holding that plaintiffs had not established facts on which a reasonable jury could conclude that defendants had market power or that the bundling harmed competition. *Suture Express, Inc. v. Owens & Minor Distribution, Inc.*, No. 12-2760-DDC-KGS, 2016 WL 1377342, at *35 (D. Kan. Apr. 7, 2016), *aff'd*, 851 F.3d 1029 (10th Cir. 2017).
    - In *Caldera, Inc. v. Microsoft Corp.*, 72 F. Supp. 2d 1295, 1304 (D. Utah 1999), the court addressed allegations that Microsoft tied two products together by "using its monopoly in the GUI (i.e. Windows) market, to illegally maintain its monopoly in the operating systems market."
    - In *Universal Hospital Services, Inc. v. Hill-Rom Holdings, Inc.*, No. SA-15-CA-32-FB, 2015 WL 6994438, at *5 (W.D. Tex. Oct. 15, 2015), the plaintiff alleged that Hill-Rom offered below-cost discounts and attempted to create a tie by using "its existing monopoly position in the [Standard Hospital Bed] market to acquire another monopoly by eliminating competition in . . . adjacent . . . rental markets."

Id.

- In *In re Hypodermic Products Antitrust Litigation*, No. 05-CV-1602 (JLL/CCC), 2007 WL 1959224, *1-2 (D.N.J. June 29, 2007), plaintiffs alleged that customers could be penalized by being forced to re-pay past rebates and that Becton bundled or tied rebates for unrelated products by "requiring hospitals to fill a high percentage of one line of products as a condition to receive rebates on that **and** other Becton products." (internal quotation marks omitted) (emphasis in original).

- In *United States v. Microsoft Corp.*, 253 F.3d 34, 70 (D.C. Cir. 2001) (per curiam), Microsoft was again accused of creating a tie to protect its monopoly in the market for operating systems, this time "by closing to rivals a substantial percentage of the available opportunities for browser distribution."

- In *UniStrip Technologies, LLC v. LifeScan, Inc.*, 153 F. Supp. 3d 728, 741 (E.D. Pa. 2015), UniStrip alleged "that each agreement required the buyer to purchase LifeScan test strips—the bundled product—or else rebates and discounts on other LifeScan products, such as the meter [which was a market leading product], would be discontinued or reduced."

- ***Threats to terminate supply,*** as the FTC alleged in *McWane, Inc. v. Fed. Trade Comm'n*, 783 F.3d 814, 834 (11th Cir. 2015), in which the FTC challenged exclusive arrangements that were allegedly "unilaterally imposed by fiat upon all distributors" by McWane, enforced through threats that non-compliance would result in supply being cut off for three months, and "resulted in no competition to become the exclusive supplier." (internal quotation marks and citation omitted).

- ***Long term agreements or other restrictive contractual provisions,*** as in the following cases:

  - In *E.I. du Pont de Nemours and Co. v. Kolon Industries, Inc.*, 637 F.3d 435 (4th Cir. 2011), *dismissed on summary judgment*, 748 F.3d 160 (4th Cir. 2014), the plaintiff alleged "essentially exclusive" multi-year agreements that also contained "meet or release" clauses, which "pose[d] a formidable hurdle to competing for the customers who . . . agreed to these deals." *Id*. at 451-53 (internal quotation marks omitted).

  - In *Dial Corp. v. News Corp.*, 165 F. Supp. 3d 25, 32 (S.D.N.Y. 2016), the length of the exclusive contracts and their staggered terms foreclosed competition by preventing competitors from acquiring a critical mass of retail distribution.[8]

[8] Sanofi also mistakenly attempts to rely on *Duramed Pharmaceuticals, Inc. v. Wyeth-Ayerst Laboratories, Inc.*, No. C-1-00-735, 2001 U.S. Dist. LEXIS 26315 (S.D. Ohio Aug. 2, 2001). Opp. 11. Although the court denied the motion to dismiss, the case settled before further motion practice, and the same court dismissed on summary judgment subsequent antitrust claims brought by direct purchasers based on the same allegations. *J.B.D.L. Corp. v. Wyeth-Ayerst*

Sanofi's claim—regardless of what Sanofi calls it—is about Auvi-Q's alleged exclusion from certain formularies on the basis of price. And yet, incredibly, Sanofi identifies not a single case where an "exclusive dealing" claim based solely on a single product discount was allowed to proceed absent allegations of below-cost pricing. Sanofi's rebate claim must therefore be dismissed.

B. Sanofi's claims based on discounts or rebates to states or state agencies are barred.

Sanofi's arguments with respect to the alleged exclusion of Auvi-Q from State Medicaid drug formularies reflect a strange reading of Sanofi's own allegations and a deep misunderstanding of the *Noerr-Pennington* doctrine. *Noerr-Pennington* protects from antitrust scrutiny efforts to petition the government or otherwise influence government conduct, including efforts to influence administrative bodies. In other words, this doctrine protects efforts of a private actor, such as Mylan, to request something of a government entity, like competing to obtain exclusive formulary status from a State Medicaid Agency. Mot. 20-21.

Sanofi confusingly asserts that "the source of the conduct is Mylan" instead of "government conduct, and thus immunity does not apply." Opp. 17. However, Sanofi does not (and indeed could not) allege that a mere ***request*** by Mylan for exclusive formulary status resulted in the exclusion of Auvi-Q. As an initial matter, this is plainly wrong according to the facts alleged by Sanofi. Mylan does not control State Medicaid formularies—the States themselves do—and therefore the exclusion of which Sanofi complains is not possible without

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Labs., Inc., Nos. 1:01-cv-704; 1:03-cv-781, 2005 WL 1396940, at *5 (S.D. Ohio Jun. 13, 2005). In dismissing those claims, the court rejected an argument similar to Sanofi's, holding that the defendant's "pricing behavior 'plus'—in this case the 'plus' factor being the [exclusivity arrangement]—did not violate Section 2 of the Sherman Act." *Id*. at *17.

action by the states. Interpreting *Noerr-Pennington* as being inapplicable to situations where private actors make requests for government action is also wrong as a matter of law and would read the *Noerr-Pennington* doctrine entirely out of existence. For example, under Sanofi's formulation, no party could ever have *Noerr-Pennington* protection for litigation (a type of conduct that is plainly protected by *Noerr-Pennington* as long as the lawsuit is not objectively baseless) because the party itself would be the "source" of the conduct by bringing the suit.

In a last ditch attempt to avoid *Noerr-Pennington*, Sanofi points to allegations regarding the alleged misclassification of the EpiPen Auto-Injector. Specifically, Sanofi alleges that Mylan misclassified the EpiPen Auto-Injector as a non-innovator drug, and as a result underpaid rebates to Medicaid, which supposedly enabled Mylan to fund its rebates to payers. Opp. 17-18. Sanofi argues that because Mylan misrepresented the proper classification of the EpiPen Auto-Injector to State Medicaid agencies, *Noerr-Pennington* does not apply. Opp. 18. This is misleading. The conduct that is protected by *Noerr-Pennington* here is Mylan's alleged petitioning of State Medicaid agencies to obtain exclusive status on their formularies. That is the conduct that Sanofi (wrongly) claims violates the Sherman Act. Sanofi does not allege that the "misclassification" itself constitutes an antitrust violation, or that any "misclassification" impacted a state's decision to exclude Auvi-Q or had anything to do with such a decision (nor could it). Therefore, the misclassification allegations could not possibly impact the applicability of *Noerr-Pennington* to Sanofi's allegations regarding exclusion from State Medicaid formularies.[9]

[9] Sanofi's reliance on the alleged misclassification of the EpiPen Auto-Injector fails for an additional reason: even alleged misrepresentations do not forfeit *Noerr-Pennington* protection unless the misrepresentation was material, meaning that the government's action was dependent on the misrepresented information. *Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119, 124 (3d Cir. 1999); *Mercatus Grp., LLC v. Lake Forest Hosp.*, 641 F.3d 834, 843 (7th Cir. 2011) ("[A] misrepresentation renders an adjudicative proceeding a sham only if the misrepresentation . . . was material, in the sense that it actually altered the outcome of the proceeding.").

II. SANOFI'S ALLEGATIONS REGARDING MYLAN'S SUPPOSEDLY DECEPTIVE SPEECH FAIL TO STATE A CLAIM.

Nor do Sanofi's allegations regarding Mylan's supposedly deceptive speech and marketing state a plausible claim for relief. It is hornbook law that such conduct is not proscribed by the Sherman Act. *See* PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 770 (3d ed. 2008). As the Supreme Court has put it: "[D]eception . . . can be of no consequence so far as the Sherman Act is concerned." *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 145 (1961); *see also Coll v. First Am. Title Ins. Co.*, 642 F.3d 876, 896-97 (10th Cir. 2011); *Four Corners Nephrology Assocs., P.C. v. Mercy Med. Ctr. of Durango*, 582 F.3d 1216, 1225 (10th Cir. 2009) (Gorsuch J.) ("[T]he vindication of general 'notions of fair dealing'" are not covered by the Sherman Act, but rather "are the subject of many other laws"). Moreover, as Mylan argued in its Motion, "advertising is presumed to have a 'de minimis effect on competition,'" and an antitrust claim premised on speech must therefore overcome a presumption that such speech did not impact competition. Mot. 22 (quoting *Eisai, Inc. v. Sanofi-Aventis U.S., LLC*, No. 08-4168 (MLC), 2014 WL 1343254, at *36) (D.N.J. Mar. 28, 2014)); *see also Retractable Techs., Inc. v. Becton Dickinson & Co.*, 842 F.3d 883, 894-96 (5th Cir. 2016), *cert. denied*, 137 S. Ct. 1349 (2017) (mem.) (noting that at least one Circuit "does not recognize Sherman Act claims based on false advertising," and that numerous other Circuits, including the Tenth Circuit "have viewed such claims critically") (citations omitted).

Rather than engaging with any of these principles or this settled precedent, Sanofi simply ignores them, contending instead that Mylan (i) "does not dispute that false or deceptive statements about a rival can form the basis of a Sherman Act Section 2 claim," and (ii) "further concedes that Sanofi alleges Mylan engaged in [deceptive conduct]." Opp. 18. With respect to the first proposition, what Mylan argued—directly quoting from numerous cases, including one

in which Sanofi was a defendant and took precisely the opposite position as it now takes here, *see Eisai*, 2014 WL 1343254, at *36-37—is that there is a general rule that deception is not actionable as an antitrust violation. Mot. 24. And although there may be "rare" exceptions to that general rule, Sanofi has alleged nothing that would make this such a case. Opp. 18. With respect to ***that*** argument—the one Mylan actually made—Sanofi apparently has no response. With respect to the second proposition, Mylan obviously does not contest that Sanofi included allegations in its Complaint purporting to plead a claim based on deceptive conduct. But whether the allegations are true is another story (they are not), as is the question of whether those allegations plausibly state a Sherman Act claim (they do not).

Sanofi relies on these meaningless contentions to argue that "by Mylan's own admission its arguments aimed at made as to Sanofi's deceptive marketing claims are arguments for a finder of fact." Opp. 18-19. Again, Sanofi is wrong. Sanofi's deceptive conduct allegations fail as a matter of law, and there is accordingly no reason why any factual determination is necessary. *See, e.g.*, *Coll*, 642 F.3d at 896-97 (affirming dismissal of state antitrust claim patterned after Sherman Act § 2, and citing *Noerr* for the principle that the antitrust laws do not proscribe allegedly "deceptive" business conduct"); *New York Jets LLC v. Cablevision Sys. Corp.*, No. 05 Civ. 2875(HB), 2005 WL 2649330, at *7, *12 (S.D.N.Y. Oct. 17, 2005) (dismissing antitrust claims based on "alleged public misrepresentations" about a competitor at the 12(b)(6) stage).

Moreover, while Sanofi attempts to distinguish some of the cases Mylan cited in its Motion on the basis that those cases were decided at the summary judgment stage, *see* Opp. 20-21, this misses the point. Those cases—*Four Corners,* and *American Council of Certified Podiatric Physicians & Surgeons v. American Board of Podiatric Surgery, Inc.*, 323 F.3d 366,

370 (6th Cir. 2003)—all stand for the proposition that, as *a matter of law*, antitrust claims based on misleading advertising must overcome a presumption that such practices have a *de minimis* effect on competition. *See, e.g.*, *Four Corners*, 582 F.3d at 1227 (holding that "monopolization and attempted monopolization claims fail[ed] as a matter of law" where allegations in support of such claims constituted "competitive-not anticompetitive-conduct"). Such presumptions are equally applicable at the motion to dismiss stage, and the allegations in Sanofi's complaint do not overcome this presumption. *See, e.g.*, *Duty Free Ams., Inc. v. Estee Lauder Cos.*, 946 F. Supp. 2d 1321, 1336-38 (S.D. Fla. 2013) (dismissing attempted monopolization claim based on disparaging statements where complaint failed to allege facts demonstrating that such statements had more than a *de minimis* impact on competition). And entirely absent from Sanofi's opposition is any attempt whatsoever to explain Sanofi's about-face with respect to the position it took in *Eisai*—namely, that there is no remedy "through the antitrust laws" for deceptive marketing practices. 2014 WL 1343254, at *36-37. While that omission is striking, it is not surprising. There is no way to distinguish *Eisai*, and Sanofi's position in that case was correct.

Nor do any of the cases Sanofi cites change the result. For one, every case Sanofi cites is out of Circuit, and therefore not binding on this court. But more importantly, none of these cases wrestled with the well-recognized point that the Sherman Act is not the vehicle for claims regarding fair dealing or deceptive conduct. *See, e.g.*, *Four Corners*, 582 F.3d at 1225. And all of Sanofi's cases are distinguishable. In each, the alleged misrepresentations were not made in the course of competing on the merits or the quality of competing products, and plaintiffs alleged that the statements actually harmed competition. In *West Penn Allegheny Health System, Inc. v. UPMC*, 627 F.3d 85, 96 (3d Cir. 2010), along with many other allegedly anticompetitive acts, the defendant allegedly made false statements to investors related to West Penn's financial

health, which caused West Penn "to pay artificially inflated financing costs on its debt." *Id.* Similarly, *United States v. Microsoft Corp.*, 253 F.3d at 76, and *Caldera, Inc. v. Microsoft Corp.*, 87 F. Supp. 2d 1244, 1249 (D. Utah 1999), involved false statements relating not to the merits of the Microsoft product, but to the timing of their introduction and the compatibility of other products with the Microsoft *operating system*, which enjoyed a dominant position in the market. And in *International Travel Arrangers, Inc. v. Western Airlines, Inc*., 623 F.2d 1255, 1260, 1268 (8th Cir. 1980), the court concluded that the false statements were designed to prevent travel group charters, a would-be market entrant, from becoming an effective competitor and were successful.[10]

By contrast, Sanofi itself alleges that it was able to successfully combat the alleged misrepresentations through basic pharmaceutical marketing efforts—namely speaking "with key thought leaders and key allergy advocacy groups." Compl. ¶ 94. Sanofi makes clear that these efforts were successful because "[m]any physicians even wrote articles or letters to payers in support of Auvi-Q" *Id*. at ¶ 100. These facts confirm that Sanofi bears no resemblance to the "nascent firm[s]" referenced by the Areeda & Hovenkamp treatise and quoted in Sanofi's Opposition (at 19) that have "no established customer base and typically lack[] the resources to answer the dominant firm's deception effectively." PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 782b (3d ed. 2008). Thus, the fact that Sanofi, a long-established, global pharmaceutical firm, apparently needed only to engage in standard marketing

[10] The other two cases on which Sanofi relies—*Caribbean Broadcast System, Ltd. v. Cable & Wireless PLC*, 148 F.3d 1080, 1087 (D.C. Cir. 1998) and *In re Warfarin Sodium Antitrust Litigation*, No. MDL 98-1232-SLR, 1998 WL 883469, at *2 (D. Del. Dec. 7, 1998), *rev'd*, 214 F.3d 395 (3d Cir. 2000)—are likewise inapposite because in both cases the allegations of misleading statements against a competitor were analyzed by the court together with allegations of sham petitioning—conduct squarely actionable as antitrust violations under the *Noerr-Pennington* rule.

practices to overcome these alleged misrepresentations renders wholly implausible its claim that these misrepresentations constituted anything more than competition. Therefore, Sanofi's deceptive conduct claim must fail.

III. NONE OF THE OTHER CONDUCT ALLEGED BY SANOFI STATES AN ANTITRUST CLAIM.

Far from being limited to mere "factual disagreement[s]," Opp. 21, Sanofi's claim that Mylan violated the antitrust laws through an "overall scheme to monopolize" fails as a matter of law. Sanofi asserts, without citation or explanation, that its "factual allegations . . . far exceed the pleading requirement for an overall scheme to monopolize." *Id*. However, Sanofi confirms that this claim consists of nothing more than the substance of its other two claims (which fail for the reasons discussed above), combined with allegations regarding the EpiPen4Schools® Program ("EpiPen4Schools") and Mylan's alleged "artificial raising of Sanofi's co-pay and other costs." *Id*. Nothing in Sanofi's Opposition resolves the plain deficiencies of those allegations.

First, Sanofi does not even try to address its undisputed failure to allege that Mylan's EpiPen4Schools program foreclosed Auvi-Q from a substantial portion of a relevant market for a sufficient period of time. That failure is fatal to these allegations. Mot. 26. Instead, Sanofi argues that the EpiPen4Schools allegations help state a claim because the program was allegedly the subject of a government investigation. Opp. 22. This assertion is belied by the very same cases on which Sanofi relies. Each of those cases examines whether allegations of parallel conduct supported a plausible inference of conspiracy. This is a fundamentally different question than whether Sanofi's allegations are sufficient to state a monopolization claim, one on which the presence or absence of a government investigation has no bearing.[11] Thus, nothing in

[11] Indeed, the existence of a government investigation on its own is far from sufficient even in the context of alleged concerted activity. The sentence that Sanofi quotes from *Hinds County,*

these cases even remotely suggests that Sanofi, having failed to allege the key facts necessary to an exclusive dealing claim, can escape dismissal simply by noting the presence of a government investigation.

Sanofi also references Mylan's purported "artificial raising of Sanofi's co-pay and other costs." Opp. 21. Sanofi fails, however, to respond to the arguments and case law raised in Mylan's Brief, which establishes that these allegations do not plead a claim because any additional costs borne by Sanofi are the result of Mylan's status as an incumbent and Sanofi's decision not to compete for formulary status—and not any supposed anticompetitive conduct on the part of Mylan. Mot. at 27-28.

Nor is there, as Sanofi suggests, any special caution against dismissing overall scheme claims on the pleadings. Opp. 22. In all three cases on which Sanofi relies, the plaintiffs showed or alleged several types of conduct, each of which was sufficient on its own to survive dismissal. *See Reazin v. Blue Cross & Blue Shield of Kan., Inc.*, 899 F.2d 951, 973 (10th Cir. 1990) (sufficient evidence to support jury verdict for plaintiffs on Section 2 claim based on the same conduct that was sufficient to support the verdict under Section 1 of the Sherman Act); *Meredith Corp. v. SESAC LLC*, 1 F. Supp. 3d 180, 223 (S.D.N.Y. 2014) (fact dispute precluded summary judgment on Section 2 claim when "the claimed exclusionary conduct [was] much the same as formed the basis of the [Section] 1 claim"); *Biovail Corp. Int'l v. Hoechst Aktiengesellschaft*, 49

Mississippi v. Wachovia Bank N.A., makes clear that government investigations "may not constitute the entirety of [the] nonconclusory allegations against . . . defendants." 708 F. Supp. 2d 348, 361 (S.D.N.Y. 2010) (ultimately dismissing plaintiff's claim). Nor can the mere existence of a government investigation itself render viable a claim that is otherwise plainly insufficient. *Starr v. Sony BMG Music Entertainment*, 592 F.3d 314, 323-24 (2d Cir. 2010) (existence of government investigation listed near the end of a long list of allegations that supported the plausibility of the Section 1 claim at issue there, including extensive and specific allegations that "the parallel conduct alleged was the result of an agreement among [competitors].").

F. Supp. 2d 750, 762 (D.N.J. 1999) (denying motion to dismiss in light of five independent forms of allegedly anticompetitive conduct). By contrast, the conduct that Sanofi alleges is not sufficient to state a claim individually or when combined together. The case law shows that this is a ground for dismissal. *See City of Groton v. Conn. Light & Power Co.*, 662 F.2d 921, 928-29 (2d Cir. 1981) (rejecting "the notion that if there is a fraction of validity to each of the basic claims and the sum of the fractions is one or more, the plaintiffs have proved" an antitrust violation"). Sanofi's claim of an overall scheme to monopolize should therefore be dismissed.

IV. SANOFI FAILS TO ALLEGE HARM TO COMPETITION.

Sanofi fails to allege harm to competition. Mylan's opening brief explained that, absent special circumstances like those found in *Dentsply, supra* p. 10, short-term agreements for exclusivity generally do not harm competition. Mot. 35-36. Sanofi responds, in a footnote, by arguing that the term of the alleged agreement is one factor that courts consider. That is correct to a point—it is one *particularly important* factor. *Omega Envt'l*, 127 F.3d at 1163 (explaining that "the short duration and easy terminability of . . . agreements [can] negate substantially their potential to foreclose competition." (footnote omitted)). And Sanofi fails to explain how its complaint could allege harm to competition when the formulary decisions it argues are exclusionary "typically" last for only "one or two years." Compl. ¶ 67.

Mylan also pointed out that Sanofi ***admits*** that no other competitors were allegedly excluded by Mylan's rebates. Mot. 30. This is the paradigmatic example of alleging harm to one competitor but not harm to competition as a whole, which does not suffice to state an antitrust claim. *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977). Sanofi fails to respond to this argument in its Opposition.

With nothing in its Complaint that alleges harm to competition, Sanofi falls back on its

familiar refrain that simply because certain things have been found to constitute harm to competition in other cases, by using the same words to describe its allegations, Sanofi's claims also pass muster. This is not so. Simply alleging in conclusory fashion that competition was harmed, without alleging facts that would actually establish harm, is plainly insufficient. *Spanish Broad. Sys. of Fla., Inc. v. Clear Channel Commc'ns, Inc.*, 376 F.3d 1065, 1079 (11th Cir. 2004). Although Sanofi now claims that it alleges price increases and reductions in quality as harm to competition, the list price increases to which it refers began in 2009—years before Auvi-Q was launched and thus years before the alleged exclusion, Compl. ¶ 92, and nowhere in Sanofi's complaint does it actually allege a decrease in quality of epinephrine auto-injectors. Sanofi also repeats its argument that reductions in consumer choice can constitute harm to competition. But as Mylan explained in its opening brief, the law says otherwise.

List price increases. Sanofi asserts that it has alleged harm to competition because "Sanofi alleges inflated EpiPen prices ***as part*** of Mylan's exclusive dealing behavior." Opp. 23 (emphasis added). Even Sanofi, however, concedes that these supposed list price increases "began…***before*** the launch of Auvi-Q . . . ." and thus prior to the alleged exclusionary conduct that Sanofi challenges. *Id*. (emphasis added). Indeed, Sanofi makes clear that these alleged price hikes were done to put Mylan in a position to "offer rebates that were conditioned on exclusivity," not as a result of the alleged rebates or exclusion of Auvi-Q. *Id*. The same is true of Sanofi's allegations regarding Mylan's supposed underpayment of rebates to Medicaid, which Sanofi again concedes was done *before* Mylan allegedly engaged in any anticompetitive conduct. *Id*. "[I]ncreases in price, or decreases in output or quality," are only "substantial adverse effects on competition," *id*., where they *result* from exclusionary conduct. *See, e.g.*, *Blue Shield of Va. v. McCready*, 457 U.S. 465, 482-83 (1982) (recognizing as a cognizable competitive harm "an

increase in price resulting from a dampening of competitive market forces"); *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 344 (1990) (holding that "a plaintiff can recover only if the loss stems from a competition-*reducing* aspect or effect of the defendant's behavior.") (emphasis in original); *Conwood Co. v. U.S. Tobacco Co.*, 290 F.3d 768, 789 (6th Cir. 2002) (citing cases holding that plaintiffs failed to state a claim under the antitrust laws because they failed to show that any alleged anti-competitive conduct on behalf of the defendant produced the alleged harm to competition). Thus, none of these supposed price hikes follow or are the result of any supposed exclusionary conduct and therefore plainly cannot constitute harm to competition for purposes of Sanofi's claims.[12]

Innovation/quality. Sanofi argues that "Mylan's conduct significantly reduced the quality of EAI drug devices available to U.S. consumers" and also reduced innovation. Opp. 26. But Sanofi fails to identify any paragraph of the Complaint where it alleges that quality of EAI devices was reduced. Nor could it make such an allegation because the cases on which Sanofi relies make clear that reduced innovation is a cognizable harm to competition only if the purportedly innovative product is ***prevented*** from reaching the market. *See Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 318 (3d Cir. 2007) (defendant was accused of a range of conduct, including abuse of standard setting processes, aimed at inhibiting the development of competing UMTS products); *United States v. Visa U.S.A., Inc.*, 344 F.3d 229, 241 (2d Cir. 2003) (making clear that the conduct at issue in the case prevented Amex and Discover from offering the

[12] A monopolist increasing price, or otherwise charging 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).

products as outside card issuers).[13] Sanofi cannot plausibly allege that there was any reduction in the quality of epinephrine auto-injectors available to payers, PBMs, and patients because the only point in time in which they could not choose Auvi-Q was when Sanofi was forced to recall it from the market for safety reasons.

Consumer choice. Unable to rebut the case law directly on point as described in Mylan's Motion to Dismiss, Sanofi relies on two unlitigated cases—Federal Trade Commission consent orders arising from ***vertical mergers***—to support its assertion that elimination of consumer choice is a valid form of harm to competition. Opp. 24-25. It is not. Both of the FTC decisions involved mergers where a pharmaceutical manufacturer proposed to combine with firms that would otherwise be on the other side of negotiations and so the transaction could have changed the firm's incentives in choosing between various drugs. Here, Sanofi has not alleged conduct by Mylan that would have changed the incentives of PBMs and payers to choose between epinephrine auto-injectors on a competitive basis (i.e. price and quality). Where a reduction in consumer choice is "fully consistent with a free, competitive market," it cannot plausibly be alleged to constitute harm to competition. *See Brantley v. NBC Universal, Inc.*, 675 F.3d 1192, 1202 (9th Cir. 2012). *Blue Shield of Va. v. McCready* is likewise inapposite. That case dealt with whether a health plan subscriber suffered antitrust injury, and therefore had

[13] The *Reazin* case is likewise of no help to Sanofi as there the court made clear that the impairment of alternative delivery systems was only relevant because it meant that Blue Cross & Blue Shield of Kansas had the "power to control prices"—something which Sanofi does not allege here. *Reazin v. Blue Cross & Blue Shield of Kan., Inc.*, 663 F. Supp. 1360, 1417-18 (D. Kan. 1987). Also, the court in *Lorain Journal Co. v. United States* did not address in any detail the nature of the harm to competition, and a more straightforward reading of the case is that the radio station posed a threat as a source of competition on price for advertisers—in other words, it was not any purported reduction in innovation that was the issue in that case, but instead the fact that Lorain Journal was seeking "to eliminate the threat of competition from the [radio] station." 342 U.S. 143, 148 (1951).

standing to sue, as a result of an alleged conspiracy.[14] 457 U.S. at 476-84. The parties did not contest, and the Court did not address, whether the plaintiff had alleged harm to competition in the first instance.[15]

Sanofi's inability to allege harm to competition is not surprising because, as explained in Mylan's Motion, "[i]t . . . is well established that exclusive agreements do not harm competition when there is competition to obtain the exclusive contract." *Spinelli v. Nat'l Football League*, 96 F. Supp. 3d 81, 117 (S.D.N.Y. 2015). This is because "[s]uch a situation may actually encourage, rather than discourage, competition, because the incumbent and other [competitors] have a strong incentive continually to improve the . . . prices they offer in order to secure exclusive positions." *Id*. at 119 (quoting *Balaklaw v. Lovell*, 14 F.3d 793, 799 (2d Cir. 1994)). Sanofi argues that cases like *Methodist Health* can be distinguished because "there was evidence that the plaintiff competed for, but lost, exclusive contracts because it did not offer the full range of hospital services that the defendant offered." Opp. 27. According to Sanofi, its claim is different because "Auvi-Q entered the market on equal therapeutic terms as the EpiPen." *Id*.

[14] In *McCready,* a health plan subscriber alleged a conspiracy between her insurer, Blue Shield, and a professional association of psychotherapists to deny coverage for services provided by psychologists. The subscriber alleged that she had been denied coverage after seeing a psychologist, and sued as a result. The question for the Court was whether the subscriber had standing to sue even though she was not the target of the alleged conspiracy. However, denial of her coverage was the very mechanism by which the conspiracy operated, so the Court held that she had suffered an antitrust injury and had standing. *McCready*, 457 U.S. at 479-80.

[15] Sanofi's reliance on state-court proceedings in West Virginia—in which Mylan sought a preliminary injunction to prevent the Secretary of the West Virginia Department of Health and Human Resources from removing the EpiPen Auto-Injector from the State Medicaid formulary—is misplaced. Opp. 26. Mylan did not assert any antitrust claims in that case. And in any event, the irreparable-harm requirement for injunctive relief is different from the harm-to-competition requirement for antitrust claims. Mylan's brief in the West Virginia proceeding shows this distinction. In that case, Mylan was concerned about harm that would occur to patients *as patients*—i.e., safety concerns—and not harm to these patients as consumers, which is what matters for purposes of stating an antitrust claim. Opp. Ex. A, at 21-22.

Quite the opposite is true, however. In *Methodist Health*, the Seventh Circuit made clear that there was "no evidence . . . that Methodist could not duplicate the special services…that make[ ] Saint Francis so special." *Methodist Health Servs. Corp.*, 859 F.3d at 410. Thus, just as there was nothing that prevented Methodist Health from competing for exclusive treatment, Sanofi has alleged nothing that would have prevented it from doing the same. Mot. 32-34. Sanofi cannot escape its failure to allege harm to competition by simply borrowing the language of other cases where the plaintiffs alleged more than that they were merely on the losing side of vigorous price competition.

V. SANOFI FAILS TO ALLEGE THAT ITS INJURIES WERE CAUSED BY MYLAN'S ALLEGED CONDUCT.

Sanofi's Opposition does not change the fact that Sanofi's complaint is devoid of facts that would establish that Mylan's alleged conduct caused Sanofi's alleged harms. Sanofi fails to rebut the core of Mylan's argument, which is that according to its own allegations, Sanofi made a *unilateral* decision not to compete with Mylan for exclusive or preferred formulary status. Mot. 36-40. Sanofi attempts to twist this argument by asserting that Mylan is merely "speculat[ing] about various alternative ways Sanofi could have competed with Mylan." Opp. 28 n.28. Sanofi has simply not alleged, however, that it tried, but was prevented from, competing on the terms sought by customers as result of Mylan's conduct. Absent such allegations, each of the harms identified by Sanofi is just as consistent with a unilateral decision not to compete as with being foreclosed from competition.

Nor can Sanofi claim (as a matter of law or logic) that it was harmed by any price increases by Mylan. Opp. 2 ("Sanofi alleges that part of Mylan's exclusionary conduct was to intentionally *increase* EpiPen prices . . . ."). Courts have long recognized that competitors cannot be harmed by allegedly higher prices. *See, e.g.*, *Matsushita Elec. Indus. Co. v. Zenith*

Radio Corp., 475 U.S. 574, 577-79 (1986) (denying competitors standing to recover damages for any conspiracy among competitors to charge higher than competitive prices because the plaintiffs stood to gain from such a conspiracy); *Sprint Nextel Corp. v. AT & T Inc.*, 821 F. Supp. 2d 308, 320 (D.D.C. 2011) ("[A]n increase in market prices alone does not harm competitors.").

Sanofi also unsuccessfully attempts to dodge the true cause of its exit from the market by misleadingly equating its total recall of Auvi-Q with a partial recall conducted by Mylan, and asserting that this establishes that "[v]oluntary recalls are therefore not uncommon." Opp. 28 & n.20. That misses the point. The issue is that Auvi-Q could no longer compete because of the safety recall (no matter how common or uncommon) and not due to any conduct by Mylan.

Sanofi's alleged decision to relinquish its rights to Auvi-Q also cannot be attributed to Mylan in anything more than a remote and speculative manner. The Supreme Court has been clear in its instruction that "Congress did not intend the antitrust laws to provide a remedy in damages for all injuries that might conceivably be traced to an antitrust violation." *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 534 (1983) (quoting *Hawaii v. Standard Oil Co.*, 405 U.S. 251, 263 n.14 (1972)). Accordingly, courts require that the alleged injury be proximately caused by the defendant's alleged conduct. *Id*. at 531-33 & nn. 24-28. Thus, the alleged injury must be a direct result of the alleged conduct—"vaguely defined links" between the two will not suffice. *Id*. at 540. Far from being a decision that was the "direct result of Mylan forcing Auvi-Q to be a fringe player," Opp. 28, contemporaneous press reports from the time confirm that it was the ***manufacturing issues and resulting recall*** that drove Sanofi to walk away. *See* Dan Stanton, *Sanofi abandoning Auvi-Q after dosage problems led to total recall*, IN-PHARMATECHNOLOGIST.COM (Feb. 23, 2016), http://www.in-pharmatechnologist.com/Processing/Sanofi-abandoning-Auvi-Q-after-dosage-

problems-led-to-total-recall (emphasis added). Thus, Sanofi's own conflicting real-time account forecloses its ability to now plausibly allege that its injury was caused by Mylan conduct.

This decision also reflects the seriousness of the Auvi-Q recall, which was anything but common. *See* Opp. 28 n.20. The recall involved the complete removal of ***all*** devices from the market and occurred after the FDA received 26 reports of device malfunctions that resulted in patients not receiving the intended dose of epinephrine. U.S. FOOD & DRUG ADMINISTRATION, *Company Announcement: UPDATED: Sanofi US Issues Voluntary Nationwide Recall of All Auvi-Q® Due to Potential Inaccurate Dosage Delivery* (Oct. 30, 2015), https://www.fda.gov/safety/recalls/ucm469980.htm. Auvi-Q also remained off the market for well over a year, returning only in February 2017. Meg Tirrell, *EpiPen competitor Auvi-Q comes back Feb. 14 with a pricing scheme that will blow your mind*, CNBC (Jan. 19, 2017), https://www.cnbc.com/2017/01/19/epipen-competitor-auvi-q-comes-back-feb-14.html.[16]

Indeed, the only actual harm to which Sanofi points in its Opposition—a supposed 50% drop in market share in early 2014—is misleading. The fact that the chart found in paragraph 69 of Sanofi's Complaint is cut off at June 2014 is anything but a coincidence. Press reports confirm that 2015, the year after Sanofi's market share allegedly dipped, was Auvi-Q's best year in terms of sales, ***despite Mylan's alleged engagement in exclusionary conduct throughout this time period***. Matthew Herper, *EpiPen Competitor Auvi-Q To Return To Market, Promising*

[16] This contrasts sharply with the partial EpiPen-device recall that Sanofi references. Opp. 28 n.20; *see also* Compl. ¶ 110 n.53. Mylan's recall was limited, involving 13 lots of EpiPen devices manufactured over a 6.5 month period. U.S. FOOD & DRUG ADMINISTRATION, News Release, FDA alerts consumers of nationwide voluntary recall of EpiPen and EpiPen Jr. (Mar. 31, 2017), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm550170.htm.

Lower Costs For Patients, FORBES (Oct. 26, 2016).[17]

Finally, neither Mylan nor this Court need credit Sanofi's argument that its allegations regarding Canada as a "but-for" world establish causation. Even accepting the allegation that Sanofi's market share grew faster in Canada than in the U.S., that fact does not in any way establish that the difference was attributable to any conduct by Mylan, let alone any illicit conduct. In any event, Sanofi itself concedes that Mylan did not market the EpiPen Auto-Injector in Canada. Opp. 27. This makes Sanofi's allegations completely different than those brought by plaintiffs in either *Visa* or *Meredith* because in both cases the "but-for" world under consideration was one where the defendant was actually present. *Visa*, 344 F.3d at 241 (different subsidiary, but same parent company operated the Visa network in foreign countries); *Meredith*, 1 F. Supp. 3d at 220 (comparing periods of time where same defendant was and was not subject to a consent decree). Sanofi has alleged no facts that would support the validity of any comparison to Canada, and therefore these allegations are not plausible as alleged.

Having failed to plausibly allege that its alleged injuries were the result of anything other than its own decisions, Sanofi's antitrust claims must fail.

CONCLUSION

For these reasons, Mylan respectfully requests that the Court dismiss Sanofi's Complaint with prejudice.

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[17] Publicly available information regarding Sanofi's sales and reasons driving Sanofi's decision to walk away from Auvi-Q—which are integral to the allegations in Sanofi's Complaint—can be considered on a motion to dismiss. *See, e.g.*, *Van Woudenberg ex rel. Foor v. Gibson*, 211 F.3d 560, 568 (10th Cir. 2000) ("[T]he court is permitted to take judicial notice of its own files and records, as well as facts which are a matter of public record.") (*abrogated on other grounds by McGregor v. Gibson*, 248 F.3d 946 (10th Cir. 2001); *Gallup Med Flight, LLC v. Builders Tr. of New Mexico*, 240 F. Supp. 3d 1161, 1199 (D.N.M. 2017); 5C CHARLES ALAN WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE, § 1327, at 762-63 (2d ed. 1990).

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Respectfully submitted,

/s/ Arnold B. Calmann

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CERTIFICATE OF SERVICE

I hereby certify that on October 6, 2017, I electronically filed the foregoing MYLAN DEFENDANTS' REPLY MEMORANDUM IN SUPPORT OF THEIR MOTION TO DISMISS PLAINTIFF'S COMPLAINT with the Clerk of Court for the United States District Court, District of Kansas by using the Court's CM/ECF system, which will serve electronic notification of this filing to all counsel of record.

/s/ Arnold B. Calmann