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
This Document Relates To : SANOFI-AVENTIS U.S. LLC, Plaintiff, v. MYLAN Inc., *et al.*, Defendants.	CASE NO.: 2:17-CV-02452-DDC-TJJ **ORAL ARGUMENT REQUESTED** *Document Filed Electronically*

PLAINTIFF SANOFI-AVENTIS U.S. LLC'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

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I. PRELIMINARY STATEMENT

This case challenges Mylan's use of exclusionary commercial practices to unlawfully maintain its EpiPen® monopoly from 2013 to 2015 in violation of Section 2 of the Sherman Act. Sanofi's 67-page Complaint plausibly explains how Mylan engaged in a range of anticompetitive conduct to prevent Auvi-Q®—Sanofi's new, innovative, rival product—from having access to the epinephrine auto-injector (EAI) market, and to prevent consumers from obtaining Auvi-Q®.

The centerpiece of Mylan's multi-faceted effort to block competition from Sanofi was Mylan's widespread use of exclusive dealing contracts with critical commercial third-party payors. This substantially limited the ability of patients to obtain reimbursement for Auvi-Q®. Mylan also targeted doctors—the front-lines for patient awareness and treatment of allergic reactions—by engaging in deceptive marketing to chill doctors from writing prescriptions for Auvi-Q® altogether. In addition, Mylan locked up schools by requiring written certifications that they could only buy EpiPens® as the emergency treatment option for students. Moreover, Mylan artificially raised Sanofi's costs where Auvi-Q® managed to be covered by a third-party payor, but at a higher co-pay level than the EpiPen®. For those patients, Sanofi had to spend significantly more than Mylan to compete on a level playing field for their business.

Mylan's exclusionary conduct against Sanofi cut off the legs of Auvi-Q® as it was rising in its launch year. Mylan's goal was to drive Auvi-Q® out of the EAI drug device market or artificially limit the use of Auvi-Q® by patients so that Mylan could maintain its EpiPen® monopoly. Mylan's conduct caused clear competitive harm by limiting consumer choice and the quality of available EAI drug devices. As a result, Mylan wrongfully deprived Sanofi of hundreds of millions of dollars in sales of Auvi-Q®, Mylan artificially increased Sanofi's costs to make sales of Auvi-Q®, and Sanofi ultimately decided to abandon the EAI drug device market by returning the rights to sell Auvi-Q® to Sanofi's licensor.

Faced with a compelling (indeed true) story of how a monopolist crushed a brand new competitor to the detriment of consumers, Mylan has filed a reflexive motion to dismiss. Mylan's arguments either ignore the well-pled facts and re-write Sanofi's claims, or are contrary

to overwhelming antitrust authority, or both. Similarly, Mylan's motion to dismiss relies heavily on cases that were determined on a full record, at summary judgment or even after trial. But at this stage, the allegations in Sanofi's Complaint must be accepted as true.

Tellingly, Mylan *does not* challenge the sufficiency of Sanofi's allegations that: 1) U.S. EAI drug devices is a relevant market; 2) Mylan had monopoly power with a durable 90%+ market share where high entry barriers insulated the EpiPen® from competition; and 3) Mylan blocked Auvi-Q® from 50%+ of the market focusing on the key distribution channels for EAI drug devices. The only question left is whether Sanofi adequately pleads that Mylan's conduct crossed the line of legitimate competition on the merits. The answer is unequivocally yes.

First, Mylan cannot dismiss Sanofi's exclusive dealing claim where it is undisputed that the Complaint alleges that a monopolist has foreclosed over half of the market to a new rival resulting in higher prices and less choice for consumers. The federal courts—led by the Third Circuit in *ZF Meritor v. Eaton Corp.*, 696 F.3d 254 (3d Cir. 2012), *cert. denied*, 133 S.Ct. 2025 (2013), and *United States v. Dentsply Int'l*, 399 F.3d 181 (3d Cir. 2005), *cert. denied*, 126 S. Ct. 1023 (2006), where this case will return following completion of common fact discovery—have repeatedly applied the "rule of reason" test to condemn similar exclusive dealing schemes by dominant firms. *That is why Mylan fails to cite a single case that rejected an exclusive dealing claim like the one Sanofi pleads at the motion to dismiss stage.*

Instead, Mylan attempts improperly to re-write the Complaint as if Sanofi brought a "predatory pricing" claim. But Sanofi did not do so and nothing in the exclusive dealing jurisprudence requires it to do so. Thus, Sanofi is not required to allege that Mylan's rebates resulted in EpiPen® prices below some measure of Mylan's costs. In any event, Sanofi alleges that part of Mylan's exclusionary conduct was to intentionally *increase* EpiPen® prices leading up to and through the launch of Auvi-Q® in 2013. With higher EpiPen® prices leveraged across Mylan's 90%+ market share, Mylan was able to penalize payors if they sought to provide patients with access to Auvi-Q® and forego large rebates conditioned on exclusive reimbursement for the EpiPen®. Moreover, Sanofi alleges that Mylan subsidized its exclusive

dealing with commercial payors by underpaying rebates to Medicaid for years. This led to a $465 million fine Mylan has agreed to pay to resolve a *qui tam* complaint that Sanofi investigated and brought on behalf of the federal government under the False Claims Act. Under these circumstances, Mylan seeks to turn antitrust law on its head by advocating for immunity of its exclusive dealing to protect its monopoly under the guise of "low prices."

Mylan also mistakenly points to an exclusive dealing case that Sanofi won (*Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394 (3d Cir. 2016)) involving a different product and facts demonstrating no exclusionary conduct. In *Eisai*, Sanofi's rebates were conditioned on Sanofi having *equal* access to hospital drug formularies as its competitors, *not on excluding* competitors from formularies. That is a fundamental difference with this case. Moreover, even in *Eisai*, the motion to dismiss was denied and the Third Circuit applied the "rule of reason" analysis, not the "price-cost" test. Thus, Mylan cannot shoehorn Sanofi's exclusive dealing claim into a predatory pricing claim.

Second, Mylan does not dispute that a deceptive marketing monopolization claim can be cognizable. Mylan's defense of its misleading marketing is nothing more than a premature argument for a fact-finder. Mylan also ignores Sanofi's allegations about deceptive studies that Mylan funded. Ultimately, Mylan relies on factually distinguishable cases, or cases that were not motion to dismiss rulings, further underscoring that its argument is baseless at the pleading stage.

Third, Mylan similarly cannot deny that an overall scheme monopolization claim can be cognizable. Whether viewed individually or as a whole, Sanofi has easily challenged (with factual specificity) a range of anticompetitive conduct undertaken by Mylan with the purpose and effect of cementing Mylan's dominance over the market. Mylan's motion simply ignores and mischaracterizes Sanofi's allegations, and should be rejected.

Fourth, Mylan agrees that a monopolist intentionally raising prices or blocking a new product from the market harms competition. Mylan attempts, however, to shirk responsibility for its conduct by blaming third-party payors for this harm to competition. But here, again,

Mylan ignores Sanofi's allegations that Mylan itself caused a reduction in choice due to its deep, conditional rebates off inflated EpiPen® prices and other anticompetitive conduct. At minimum this is a factual dispute requiring third-party and economic expert testimony to resolve.

Finally, Mylan falsely points the finger at Sanofi and claims that Sanofi's injury was self-inflicted and not caused by Mylan. It is rare in antitrust cases to be able to identify a "but for" market showing how competition would look without the illegal conduct by a monopolist. But here Sanofi pleads that such a market existed in the real world. In Canada, where Mylan did not market the EpiPen®, Sanofi never saw a 50% drop in market share as a result of Mylan's anticompetitive conduct going into effect, as Auvi-Q® saw in the United States. Rather, Sanofi's growth continued after its launch until it captured over 30% of the market less than three years after launch. True competition on the merits in Canada quickly led to *one in every three* patients choosing Auvi-Q® over the EpiPen®. The hundreds of millions of dollars of lost sales of Auvi-Q® in the United States due to Mylan blocking Sanofi's access to over half of the marketplace is a clear injury. Beyond lost sales, Sanofi alleges that Mylan's full range of exclusionary conduct artificially raised Sanofi's costs, and, as Mylan intended, caused Sanofi to be a fringe player and abandon the EAI drug device market by returning the rights to sell Auvi-Q® to its licensor. Contrary to Mylan's assertions, Sanofi's allegations of harm are cognizable and, if proven, automatically entitle Sanofi to treble damages under Section 4 of the Clayton Act.

In sum, Mylan's motion to dismiss amounts to nothing more than a 40-page attempt to shield its business practices from scrutiny. It is replete with arguments and authorities that are wholly inapplicable at the pleading stage. Overwhelming authority confirms that Sanofi's Complaint more than adequately alleges that Mylan has engaged in the exact type of "bold, relentless and predatory commercial behavior" designed to "destroy threatened competition" that the Supreme Court has proscribed, *Lorain Journal v. United States*, 342 U.S. 143, 149, 154 (1951), and which "would be inimical to the purpose of the Sherman Act to allow monopolists free reign to squash nascent, albeit unproven, competitors at will." *United States v. Microsoft*

Corp., 253 F.3d 34, 79 (D.C. Cir. 2001) (*en banc*) (*per curiam*). Accordingly, Sanofi respectfully submits that Mylan's motion to dismiss should be denied.

II. FACTUAL BACKGROUND[1]

From 2007 to 2015, Mylan marketed the EpiPen® in the United States and had a virtual monopoly, with more than 90% of all sales of EAI drug devices. Compl. ¶ 39, ECF No. 1.[2] In 2013, Sanofi launched Auvi-Q®, an innovative EAI drug device designed to be easy to carry and easy to use. *Id.* ¶ 50. In the first few months after its launch, Auvi-Q® quickly gained market share. *Id.* ¶ 9. Suddenly faced with a threat—for the first time—to its EpiPen® monopoly, Mylan erected artificial barriers to U.S. consumers' access to Auvi-Q®. *Id.* ¶ 6.

Specifically, Mylan offered new and unprecedented rebates to third-party payors, including commercial insurance companies, pharmaceutical benefit managers, and state-based Medicaid agencies. *Id.* However, Mylan's rebates were ***conditioned exclusively*** on those payors' agreement not to reimburse for the purchase of Auvi-Q® by U.S. consumers. *Id.* The EAI drug device class had not previously been restricted by third-party payors because it did not fit the criteria for management of a drug class. *Id.* ¶¶ 36-37.

Mylan subsidized its enhanced exclusionary rebates by misclassifying the EpiPen® to the federal and state governments. *Id.* ¶ 7. For years Mylan paid substantially less in required rebates for patients covered by Medicaid, and the hundreds of millions of dollars it saved on those Medicaid rebates allowed Mylan to pay increased rebates to commercial payors to exclude Auvi-Q®. *Id.* Mylan's sales and marketing practices have resulted in substantial public scrutiny and government investigations.[3] *Id.* ¶ 8.

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[1] Mylan's EpiPen® business practices have already been the subject of widespread federal and state government antitrust and fraud regulatory scrutiny. *See id.* ¶ 8.

[2] The facts are summarized briefly here for the Court's convenience, and are more fully detailed in Sanofi's Complaint (Dkt. No. 1).

[3] Charles Duhigg, "Outcry Over EpiPen Prices Hasn't Made Them Lower," N.Y. TIMES, June 4, 2017 (when Mylan executives told Mylan's Chairman that EpiPen® price hikes could be viewed as "unethical profiteering," "Mr. Coury replied that he was untroubled. *He raised both his middle fingers and explained, using colorful language, that anyone criticizing Mylan, including its employees, ought to go copulate with themselves.* Critics in Congress and on Wall Street, he said,

Mylan knowingly ran up the price of EpiPen® before Auvi-Q® launched. *Id.* ¶¶ 91-92. Because of Mylan's 90%+ market share, its rebates on an inflated price, leveraged across all of its EpiPen® volume, were impossible for Sanofi to match. *Id.* ¶ 62. Third-party payors were penalized if they chose to forego these large conditional rebates offered by Mylan. *Id.* As a result of Mylan's unlawful exclusive dealing, Auvi-Q® was blocked from nearly 50% of the EAI drug device market nationally, and the blockage was even higher in some of the largest states. *Id.* ¶ 68. As a new entrant with small volume, Sanofi would have had to offer rebates in excess of its revenues from Auvi-Q® in order to compensate third-party payors for the rebates they would lose by turning down Mylan's rebates. *Id.* Due to Mylan's conduct, Sanofi had to lose money with third-party payors just for a chance to compete in the market. *Id.*

Mylan also engaged in other unlawful and exclusionary conduct to maintain and enhance its monopoly power, including: engaging in misleading marketing designed to sow distrust in the marketplace for Auvi-Q® (*id.* ¶ 93); explicitly requiring schools to certify in writing that they would not use rival EAI drug devices as a condition of Mylan's EpiPen® discount program for schools (*id.* ¶ 80); and artificially raising Sanofi's co-pay coupon and other costs to market Auvi-Q®, and patients' costs to purchase Auvi-Q®, by ensuring that Auvi-Q® (to the extent it was covered) would be covered with a higher co-pay than the EpiPen® (*id.* ¶ 71). All of this conduct had a significant negative spillover impact on Auvi-Q® and foreclosed Auvi-Q® from over 50% of the EAI drug device market for most of the time that Sanofi sold Auvi-Q®. *Id.* ¶¶ 101-102.

As a result of Mylan's unlawful conduct, Sanofi's market share, which had grown quickly in 2013 after Auvi-Q®'s launch, precipitously fell by nearly 50% when Mylan's conditional rebates went into effect in January 2014. *Id.* ¶ 104. However, where Auvi-Q® was unrestricted (by certain U.S. third-party payors and in Canada), Sanofi's market share continued to skyrocket in less than three years to over 30%. *Id.* ¶ 9. Mylan's conduct deprived consumers

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should do the same. And regulators at the Food and Drug Administration? They, too, deserved a round of anatomically challenging self-fulfillment.") (https://www.nytimes.com/2017/06/04/business/angry-about-epipen-prices-executive-dont-care-much.html) (emphasis added).

of access to Auvi-Q® and cost Sanofi hundreds of millions of dollars in lost sales which, in addition to artificially raising Sanofi's costs to sell Auvi-Q®, ultimately caused Sanofi to return the rights to sell Auvi-Q® to its licensor. *Id.* ¶ 137.

III. LEGAL STANDARD

The Federal Rules of Civil Procedure require that a complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (citation and quotation marks omitted). The plaintiff must plead sufficient allegations that, when accepted as true, "state a claim to relief that is plausible on its face." *Id.* at 570. The Supreme Court has made clear that "[a]ntitrust cases are not subject to a heightened pleading standard", *id.*, and the plausibility requirement is not a *probability* requirement, *id.* at 556. To meet the plausibility requirement, a plaintiff need only show that it has pled sufficient factual allegations "to allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "In considering a motion to dismiss, a court must accept all of the plaintiff's allegations as true and construe them in the light most favorable to the plaintiff." *Suture Exp., Inc. v. Cardinal Health 200, LLC*, 963 F.Supp.2d 1212, 1219 (D. Kan. 2013).

IV. ARGUMENT

To plead a claim under Section 2 of the Sherman Act, a plaintiff must allege "(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). Tellingly, Mylan's motion to dismiss does not dispute the sufficiency of Sanofi's Complaint on the first element of its monopolization claims. In particular, that: (1) U.S. EAI drug devices is the relevant market (Compl. ¶¶ 116-121), and (2) Mylan has monopoly power in the EAI market with a durable 90%+ market share where high entry barriers have insulated the EpiPen® from competition (*id.* ¶¶ 39, 126-134).

The only issue raised by Mylan's motion to dismiss is whether the second element of Sanofi's monopolization claims (called "exclusionary conduct") is met by the well-pled allegations in the Complaint. The Supreme Court has held that exclusionary conduct involves "behavior that not only (1) tends to impair the opportunities of rivals, but also (2) does not further competition on the merits or does so in an unnecessarily restrictive way." *Aspen Skiing Co. v. Aspen Highlands Corp.*, 472 U.S. 585, 605 n.32 (1985). As set out below, overwhelming antitrust authority confirms that Sanofi's detailed factual allegations satisfy this test.

A. Sanofi Plausibly States a Claim for Unlawful Exclusive Dealing Under the Rule of Reason Analysis

The federal courts have not hesitated to rigorously scrutinize, and in many cases condemn, exclusive dealing arrangements undertaken by monopolists. Indeed, "[e]xclusive dealing arrangements are of special concern when imposed by a monopolist" because "[a] monopolist may use its power to break the competitive mechanism and deprive customers of the ability to make a meaningful choice." *ZF Meritor*, 696 F.3d at 271, 285; *see also McWane, Inc. v. F.T.C.*, 783 F.3d 814, 832 (11th Cir. 2015), *cert. denied*, 136 S. Ct. 1452 (2016) ("[A]n exclusive dealing arrangement can be harmful when it allows a monopolist to maintain its monopoly power by raising its rivals' costs sufficiently to prevent them from growing into effective competitors."). As noted above, Mylan cannot and does not challenge Sanofi's allegations that Mylan is a monopolist.

To show that exclusive dealing is exclusionary conduct, Sanofi must allege that Mylan "foreclose[d] competition in a substantial share of the line of commerce affected." *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 327 (1961). Courts overwhelmingly apply the "rule of reason" test to evaluate exclusive dealing claims. *See, e.g., ZF Meritor,* 696 F.3d at 271 ("exclusive dealing agreements . . . [are] judged under the rule of reason"); *McWane*, 783 F.3d at 835 ("Lower federal courts . . . interpret[] *Tampa Electric* as authorizing a rule of reason approach to exclusive dealing cases."); *Suture Express, Inc.*, 963 F. Supp. 2d at 1228 (applying

rule of reason analysis);[4] *see also* 1 ABA Section of Antitrust Law, Antitrust Law Developments 251 (8th ed. 2017) ("[M]ost courts consider exclusive dealing in much the same way as other monopolization claims, conducting a rule of reason analysis to determine if the exclusive dealing conduct caused anticompetitive harm.").

The Third Circuit, where this case originated and where it will return after completion of common fact discovery,[5] has decided a number of leading exclusive dealing cases.[6] Applying the rule of reason, the Third Circuit has on three occasions *condemned exclusive dealing by monopolists* that had the effect of shutting out competitors from access to the key marketplace distribution channels to compete.[7] *See ZF Meritor*, 696 F.3d at 287 (affirming a jury verdict finding a violation of section 2 of the Sherman Act: stating that "the key question [is] not

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[4] Sanofi notes that the Court granted summary judgment to defendants in *Suture* after discovery based on a full fact and expert evidentiary record. *Suture Express, Inc. v. Owens & Minor Distribution, Inc.*, 2016 WL 1377342 (D. Kan. Apr. 7, 2016), *aff'd*, 851 F.3d 1029 (10th Cir. 2017). Notably the evidence in that record contained substantial material differences from the facts alleged in this case, including (among other differences) that defendants' shares had *declined or remained* flat due to competition from plaintiff and *other competitors*. *Id.* at *22. Here, during the relevant period, Mylan was the dominant firm with a 90%+ share with the EpiPen®. Compl. ¶ 39. Also, Mylan's exclusionary conduct caused Sanofi's initial market share to drop in half in a one-month span, with that share returning to Mylan. *Id.* ¶ 69. Further, prior rivals to the EpiPen® (Adrenaclick and Twinject) did not grow and were relegated to fringe player status in the EAI drug device market. *Id.* ¶ 42.

[5] Remand to the transferor court will be appropriate after common discovery is complete. *In re Epipen Marketing, Sales Practices and Antitrust Litigation*, MDL No. 2785, Dkt. No. 59 ("the transferee judge may recommend Section 1407 remand of Sanofi in advance of other actions if he deems it appropriate" (*citing In re McCormick & Co., Inc., Pepper Prods. Mktg. & Sales Practices Litig.*, 148 F. Supp. 3d 1364, 1366 (J.P.M.L. 2015))); *see also* 28 U.S.C. § 1407 ("the panel may separate any claim, cross-claim, counter-claim, or third-party claim and remand any of such claims before the remainder of the action is remanded").

[6] The District of Kansas follows the D.C. Circuit's decision in *In re Korean Air Lines Disaster of Sept. 1, 1983*, 829 F.2d 1171, 1176 (D.C. Cir. 1987), which held that the law of a transferor forum "merits close consideration" though it may not be binding precedent. *Id.* at 1176; *see also In re Urethane Antitrust Litig.*, No. 04-1616-JWL, 2013 WL 6587972 (D. Kan. Dec. 6, 2013); *In re Baseball Bat Antitrust Litig.*, 75 F. Supp. 2d 1189, 1200 (D. Kan. 1999).

[7] The attached Appendix identifies the substantial number of illustrative cases in the Third Circuit and elsewhere cited herein rejecting motion to dismiss attempts, and/or finding liability for exclusive dealing claims like the one pled by Sanofi here.

whether alternative distribution methods allowed a competitor to 'survive' but whether the alternative methods would 'pose a real threat to the defendant's monopoly'") (citations omitted); *Dentsply*, 399 F.3d at 196 (reversing a dismissal and entering judgment for the government after a bench trial: "Dentsply's grip on its . . . authorized dealers effectively choked off the market for artificial teeth, leaving only a small sliver for competitors."); *LePage's Inc. v. 3M*, 324 F.3d 141, 159-60 (3d Cir. 2003) (*en banc*), *cert. denied*, 542 U.S. 953 (2004) (affirming a jury verdict finding an antitrust violation under Section 2: "in this case, the jury could have reasonably found that 3M's exclusionary conduct cut LePage's off from key retail pipelines necessary to permit it to compete profitably.") (citations omitted).[8] Moreover, all of these cases were determined on a full record.[9]

Other courts, including in the Tenth Circuit, have likewise held that exclusive dealing by a monopolist foreclosing key distribution channels violates the antitrust laws. *See*, *e.g.*, *Suture Express, Inc.*, 963 F. Supp. 2d at 1228 (denying motion to dismiss and finding that defendant's arguments are "part of a rule of reason analysis which in this context is not so straightforward that the court can rule at the pleading stage that plaintiff's exclusive dealing claim is implausible."); *Caldera, Inc. v. Microsoft Corp.*, 72 F. Supp. 2d 1295, 1306 (D. Utah 1999) (denying summary judgment: "Section 2 prohibits a monopolist from engaging in anticompetitive practices that are designed to deter potential rivals from entering the market or

[8] Though it filed its motion to dismiss in the District of New Jersey, Mylan incredibly failed to address the Third Circuit's ruling in the DOJ's civil antitrust enforcement action in *Dentsply*. And, Mylan's half-hearted reliance on the seminal *United States v. Microsoft* case is revealing because the D.C. Circuit *affirmed* a finding for the United States of illegal monopoly maintenance where Microsoft's exclusive dealing "help[ed] keep usage of Navigator *below the critical level* necessary for Navigator or any other rival to pose a real threat to Microsoft's monopoly." 253 F.3d at 70-71 (emphasis added).

[9] The district courts in *ZF Meritor* and *LePage's* each denied defendants' motions to dismiss. There was no motion to dismiss filed in *Dentsply*. *See LePage's Inc. v. 3M*, 1997 WL 734005 (E.D. Pa. Nov. 14, 1997); *ZF Meritor v. Eaton Corp.*, No. 06-CV-623, Dkt. No. 17 (D. Del. June 13, 2007). Motions to dismiss were also denied in tag-along purchaser actions challenging the same conduct as in *LePage's*. *Bradburn Parent/Teacher Store, Inc. v. 3M (Minnesota Mining & Mfg. Co.)*, 2000 WL 34003597, at *5 (E.D. Pa. July 25, 2003).

from preventing existing rivals from increasing their output, no matter how flagrant or subtle the violation."); *Universal Hosp. Servs., Inc. v. Hill-Rom Holdings, Inc.*, No. CIV.A. SA-15-CA-32, 2015 WL 6994438, at *13-15 (W.D. Tex. Oct. 15, 2015) (denying motion to dismiss: finding that 66% foreclosure in regional markets and 12-15% foreclosure nationally was sufficient to state a claim where plaintiff alleged the likely future impact of defendant's conduct would be to foreclose an even greater percentage of the regional and national markets); *McWane*, 783 F.3d at 838 (affirming FTC determination of anticompetitive conduct);[10] *E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc.*, 637 F.3d 435, 451-53 (4th Cir. 2011) (reversing grant of motion to dismiss); *Microsoft*, 253 F.3d at 67-74 (affirming violation after trial); *In re Hypodermic Prod. Antitrust Litig.*, 2007 WL 1959224, at *17 (D.N.J. June 29, 2007) (denying motion to dismiss); *Duramed Pharm., Inc. v. Wyeth-Ayerst Labs., Inc.*, 2001 U.S. Dist. LEXIS 26315 at *16-21 (S.D. Ohio Aug. 2, 2001) (denying motion to dismiss: "Duramed alleges that Wyeth has offered discounts and rebates in order to entice health plans into entering into overt exclusive dealing contracts or that the discount programs themselves are de facto, or 'disguised' exclusive dealing contracts because the incentives are too attractive, or in the alternative, too punitive, financially to pass up . . . The alleged result of the discounts is not predatory pricing but rather foreclosure of the market.").

Falling squarely within this substantial antitrust authority, Sanofi alleges in detail that Mylan's exclusive dealing alone blocked Auvi-Q® from being covered by many of the largest commercial third-party payors representing more than 40-50% of all sales in the EAI drug device market. Compl. ¶ 6. Sanofi further alleges that Mylan engaged in the same behavior to block Auvi-Q® from being covered by some of the largest states with patients covered by Medicaid. *Id.*[11] Sanofi alleges that Mylan's conduct foreclosed Auvi-Q® from close to 50% of the U.S. EAI

[10] A motion to dismiss was also denied in a tag-along purchaser challenging the same conduct as in *McWane*. *See In re Ductile Iron Pipe Fittings ("DIPF") Direct Purchaser Antitrust Litig.*, 2013 WL 812143 (D.N.J. 2013).

[11] *See also* Ike Swetlitz, *Mylan offered EpiPen discounts to states in exchange for privileged status, documents show*, STAT News, June 22, 2017

drug device market, and in some key states, like Florida, well over 50%. *Id.* ¶¶ 67-69.[12] Sanofi also alleges that, in addition to blocking key distribution channels, Mylan's conduct unlawfully raised Sanofi's costs of entry into the market. *Id.* ¶¶ 108-109; *see also Dentsply*, 399 F.3d at 195 ("[S]uch exclusive dealing could either exclude the nondominant [firm] or else raise its costs in comparison to the costs of the dominant firm.") (quoting Herbert Hovenkamp, Antitrust Law ¶ 1802e3, at 78–79 (2d ed. 2002)). Notably, Mylan neither challenges the sufficiency of these allegations ***nor cites a decision of any court*** applying the rule of reason to dismiss exclusive dealing claims like Sanofi's at the pleading stage. Based on well-settled antitrust law applied to the factual allegations, Sanofi easily pleads a plausible exclusive dealing monopolization claim.

1. The Price-Cost Test Does Not Apply Here

With no plausible motion to dismiss argument under a rule of reason analysis, Mylan improperly attempts to shoehorn Sanofi's Complaint into the "price-cost" test framework applied to distinct predatory pricing claims. Mem. at 13-20. Mylan's effort to re-write Sanofi's Complaint violates the basic principle that, on a motion to dismiss, the allegations in the Complaint must be accepted as true. Sanofi pleads an exclusive dealing claim, *not* a predatory pricing claim. Compl. ¶¶ 135-137.

(https://www.statnews.com/2017/06/22/mylan-epipen-discount-medicaid-preferred/) ("In one email, dated Oct. 29, 2015, an employee of Magellan Health, which helps the state negotiate drug prices for Medicaid patients, wrote to a Nebraska state employee that the EpiPen rebate offers available to Nebraska and other states 'provide enhanced savings for making EpiPen the exclusive epinephrine delivery systems [sic] on the [preferred drug list].'… In another email sent from a Magellan employee, dated Sept. 19, 2013, an attached document states that the 'Epipen Offer requires it to be the only preferred product in the class so that neither epinephrine generic nor Auvi-Q can be preferred.'").

[12] Mylan also cites cases challenging exclusive dealing under Section 1 of the Sherman Act, *see*, *e.g.*, *Paddock Publ'ns, Inc. v. Chi. Tribune Co.*, 103 F.3d 42 (7th Cir. 1996), rather than under Section 2, which is Sanofi's claim. It is well-recognized that "a monopolist's use of exclusive contracts, in certain circumstances, may give rise to a § 2 violation even though the contracts foreclose less than the roughly 40% or 50% share usually required in order to establish a § 1 violation." *Microsoft*, 253 F.3d at 366. But Sanofi adequately alleges that Mylan foreclosed far more than 40%-50% of the EAI drug device market. *See* Compl. ¶¶ 68-69.

In any event, Mylan's argument runs directly contrary to Sanofi's underlying factual allegation that Mylan repeatedly *increased* the EpiPen®'s price, resulting in higher prices even after its rebates. *Id.* ¶ 58. After all, Sanofi alleges that Mylan thwarted off competition from Auvi-Q® by offering rebates from inflated prices conditioned on exclusive reimbursement for the EpiPen®. *Id.* ¶¶ 58-59. Leveraged across its 90%+ market share, Mylan was thus able to penalize payors if they sought to provide patients with access to Auvi-Q® and forego these rebates. *Id.* ¶¶ 61-66.

Not surprisingly, Mylan cites no analogous case where a court dismissed an exclusive dealing claim at the pleading stage by finding that a plaintiff was limited to bringing a predatory pricing claim. *See generally* Mem. at 13-20.[13] To the contrary, and as even Mylan is forced to acknowledge (*id*. at 19), in *ZF Meritor* the monopolist-defendant made the very same argument and it was *rejected* on a full record affirming a jury verdict for the plaintiff. 696 F.3d at 278. The Third Circuit explained in that case that for the "price-cost" test to apply, price must be "the clearly predominant mechanism of exclusion." *Id.* at 274-75. The Third Circuit reasoned that this narrow test was not met because, among other evidence, the defendant-monopolist required original equipment makers to "remove competitors' products from its data book entirely" so that their customers could only see the defendant's products. *Id.* at 265. Other courts have likewise rejected efforts by monopolists to apply the price-cost test when pricing is not clearly the lone exclusionary tool. *See*, *e.g.*, *Dial Corp. v. News Corp.*, 165 F.Supp.3d 25, 32 (S.D.N.Y. 2016) (denying summary judgment: "the prices paid by News Corp. in their contracts with retailers are

[13] Mylan's reliance on *NicSand, Inc. v. 3M Co.*, 507 F.3d 442, 452-53 (6th Cir. 2007) (*en banc*), underscores how much Mylan is stretching the case law for its motion to dismiss. Mem. at 19 n. 5. Among other notable distinctions, in *NicSand* the *plaintiff* had "controlled 67% of the market" before the defendant, a new company entered the market, and plaintiff sued. Here, Sanofi alleges that Mylan had a 90%+ market share for years and engaged in specific actions targeted to excluding Auvi-Q®, a new entrant, from the market. Compl. ¶¶ 39, 59-60, 93-99. Mylan's citations to *Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227 (1st Cir. 1983), and *Virgin Atlantic Airways Ltd. v. British Airways PLC*, 257 F.3d 256, 265-66 (2d Cir. 2001), are equally inapposite, as both were decided on a fully developed record. And, in *British Airways*, plaintiffs actually brought a claim for predatory pricing. 257 F.3d at 265.

not the clearly predominant method of exclusion" (citing *ZF Meritor*), where the defendant also staggered end dates of key contracts to prevent competitors from acquiring a "critical mass" of customers); *UniStrip Techs., LLC v. LifeScan, Inc*, 153 F. Supp. 3d 728, 736 (E.D. Pa. 2015) (denying motion to dismiss: plaintiff alleged that defendant offered rebates on the condition that customers not purchase its competitors' products and the district court stated that "when a plaintiff's allegations of exclusive dealing are not centered on pricing practices alone, the rule of reason test applies to determine if the arrangement will foreclose on competition in such a substantial share of the relevant market so as to adversely affect competition").

Sanofi's allegations likewise compel the conclusion that Mylan's exclusionary conduct is not subject to the price-cost test. Sanofi alleges that Mylan required third-party purchasers to "remove competitors' products"—competing EAI drug devices from coverage for reimbursement by patients. This is no different than Eaton requiring third-parties to remove Eaton's rival products from materials, from which end users could order. Sanofi's Complaint goes further, and alleges that Mylan specifically *targeted* Auvi-Q® and, at least as to some third-party payors, required that only Auvi-Q® be removed whereas other EAI drug devices were permitted by Mylan to remain covered. Compl. ¶ 59. Sanofi alleges that Mylan then touted the EpiPen®'s widespread and exclusive coverage—in comparison to only Auvi-Q®'s lesser coverage—to physicians to "poison the well" for Auvi-Q®. *Id.* at ¶ 98. Thus, despite Mylan's rote incantation of the word "price", under any fair reading of the allegations, Sanofi's exclusive dealing claim should be assessed under the long-standing rule of reason analysis.

2. *Eisai v. Sanofi* Does Not Support Mylan's Argument

In an effort to distract from Sanofi's well-pled allegations, Mylan twists Sanofi's claims in this present case to re-litigate *Eisai v. Sanofi*. In *Eisai*, the plaintiff, which sold the drug Fragmin, sued its competitor, Sanofi, which sold the drug Lovenox, challenging Sanofi's agreements with hospitals as harming competition in the anticoagulant drug market. *Eisai*, 821 F.3d at 398-99. Mylan has grasped onto the Third Circuit's holding that the plaintiff there did not demonstrate that the defendant's conduct foreclosed hospitals' abilities to purchase

competing drugs or "cause[d] anticompetitive effects in the relevant market." *Id*. at 407. Mylan does so in an effort to argue that Sanofi's Complaint here (involving a different product, market, and conduct) should somehow therefore be dismissed. Mylan is wrong for at least two key reasons.

First, the motion to dismiss in *Eisai*, as is clear from the transcript submitted by Mylan, was *resoundingly rejected*. As the district court reasoned, a premature dismissal was improper "based upon what to this Court and its reading of the case law is at least a plausible economic theory of a rule of reason adverse economic effect based upon the ability to monopolize through these [exclusive dealing] contracts," and "[f]ew, if any, of the cases that I have seen here have been dismissed on 12(b)(6) failure to state a claim grounds." *Eisai, Inc. v. Sanofi-Aventis, U.S., LLC*, No. 08-cv-04168, Tr. of Oral Argument at 71:6-73:16 (D.N.J. June 12, 2009), Dkt. 61 ("Eisai, Tr. of Oral Argument"). Ultimately, *Eisai* was decided on *summary judgment*, based on a complete record. *Id.* at 408. Moreover, the Third Circuit (again) applied the *rule of reason* to what it viewed as an exclusive dealing claim. *Id.*

Second, Eisai's complaint included a challenge to Sanofi's formulary access clause. *Sanofi, however, did not prevent Eisai or other rivals from having access to hospital drug formularies. Id.* at 400 ("In essence, the contract ***did not prohibit*** members from putting other anticoagulant drugs on their formularies, but did prohibit them from favoring those drugs over Lovenox") (emphasis added). This is a fundamental difference between the two cases.[14] Mylan

[14] There are a number of other factual distinctions that make *Eisai* inapposite. For example, Fragmin was not a new product to the market (being sold by Pharmacia and then Pfizer before Eisai obtained the rights) and Sanofi launched its discount program before Eisai began selling Fragmin. *See Eisai Inc. v. Sanofi-Aventis U.S.,* LLC, 2014 WL 1343254, at *1, *32 (D.N.J. Mar. 28, 2014). In contrast, Sanofi alleges that Mylan specifically targeted Auvi-Q® as a new market entrant *after* it had initial success in its launch year. Compl. ¶ 54. As another example, Eisai and Arixtra (another seller of a rival product in that market) both increased their market share over the relevant period. *See Eisai*, 2014 WL 1343254 at *26. Conversely, Auvi-Q®'s market share plummeted 50% in one month between December 2013 and January 2014, which is exactly when all of Mylan's conditional rebates targeting Auvi-Q® took effect. Compl at ¶ 69.

used its monopoly power to prevent Sanofi from having access to third-party payor drug formularies.

Further, in its misguided attempt to draw parallels to *Eisai*, Mylan misleadingly cites the June 2009 Transcript of Oral Argument in its motion. Mylan includes a statement made by other counsel for Sanofi about the use of discounts by companies in a so-called dominant position in the market. Mem. at 11-12. Not only did *Eisai* involve materially different facts than are at issue in this case, but (1) the statement was made before the Third Circuit's guidance in *ZF Meritor*; and (2) **Mylan omitted** the final sentence from the excerpted quote: "That is not unlawful in and of itself", thus stripping the statement of its context and important limitation rendering it of no utility here. Eisai, Tr. of Oral Argument at 6. Sanofi's position here is entirely consistent, in that Sanofi does not dispute that rebates can be lawful in some circumstances. Compl. at ¶ 55. Unlike in *Eisai*, Sanofi here alleges that Mylan blocked 50% or more of the market to a brand new rival product, in a drug category that was never before restricted and where there had been no real innovation, in response to Auvi-Q®'s initial success in the market, to the detriment of competition. Thus, Mylan's heavy reliance on *Eisai* is a red herring.

3. The *Noerr-Pennington* Doctrine Does Not Immunize Mylan's Behavior

Mylan also attempts to immunize its conditional rebates provided to states to exclude Auvi-Q® by arguing for a sweeping interpretation of the *Noerr-Pennington* doctrine. Mem. at 20-21. Unfortunately for Mylan, that doctrine is intended to shield "*valid* effort[s] to influence governmental action." *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 499 (1988) (emphasis added) (internal quotation omitted). The Supreme Court has held that this exemption should be construed narrowly. *See United States v. Nat'l Ass'n of Sec. Dealers, Inc.*, 422 U.S. 694, 737 (1975); *FMC v. Seatrain Lines, Inc.*, 411 U.S. 726, 733 (1973). Also, the Supreme Court has rejected defendants' arguments for immunity when their actions could "more aptly be characterized as commercial activity with a political impact." *Allied Tube*, 486 U.S. at

507; *see also Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 707 (1962); *FTC v. Superior Court Trial Lawyers Ass'n (SCTLA)*, 493 U.S. 411, 425 (1990).

In *Allied Tube*, the Supreme Court ruled that the test for *Noerr-Pennington* immunity depends on the source, context, and nature of the challenged conduct. 486 U.S. at 499. Here, like *Allied Tube*, the source of the conduct is Mylan, a private actor with no quasi-legislative authority. While Mylan argues that its "alleged attempt to influence these State Medicaid agencies' drug policies and the agencies' final coverage decisions are precisely the sort of core First Amendment activities and government actions that Noerr-Pennington protects," Mem. at 20, Sanofi alleges that Mylan's anticompetitive efforts were to unlawfully maintain its EpiPen® monopoly. Compl. ¶¶ 7-8.

Similarly, Mylan's reliance on *Bristol-Myers Squibb Co. v. IVAX Corp.*, 77 F. Supp. 2d 606, 612-15 (D.N.J. 2000), is unavailing. In that case the district court determined that the government agency's conduct gave rise to plaintiff's injury when it decided to enter into a license with Bristol-Myers, and thus *Noerr-Pennington* immunity applied. *Id.* at 615. Here, as noted above, the injury to Sanofi flows from Mylan's conduct, rather than government conduct, and thus immunity does not apply.

In addition, Mylan cannot invoke Noerr-Pennington immunity due to the misrepresentation exception to the doctrine. As set forth in the Complaint, Mylan provided false and misleading information to federal and state governments by misclassifying the EpiPen® as a non-innovator drug under Medicaid—and now has agreed to pay a $465 million fine. *See* Compl. ¶¶ 7-8, 86, 88. As a result, Mylan paid substantially less in required rebates to Medicaid. In turn, Mylan used those savings to provide additional rebates, on the condition of EpiPen® exclusivity, to all third-party payors, including states. *Id.* ¶ 7.

Mylan's argument that the "misclassif[ication of] the EpiPen® as a 'non-innovator' drug in the Medicare and State-based Medicaid space" does not "relate to an element of any of Sanofi's claims" (Mem. at 25 n.9) fails, and Mylan knows it is not true. Sanofi alleges competitive harm from Mylan's misclassification in its qui tam complaint, which Sanofi

originated in 2014 as a confidential whistleblower and which was made public on August 17, 2017, regarding Mylan's violations of the False Claims Act. *See* Press Release, Mylan Agrees to Pay $465 Million to Resolve False Claims Act Liability: Mylan Underpaid Medicaid Rebates on EpiPen (Aug. 17, 2017) ("'Mylan misclassified its brand name drug, EpiPen, to profit at the expense of the Medicaid program,' said Acting United States Attorney William D. Weinreb. 'Taxpayers rightly expect companies like Mylan that receive payments from taxpayer funded programs to scrupulously follow the rules. We will continue to root out fraud and abuse to protect the integrity of Medicaid and *ensure a level playing field for pharmaceutical companies. We commend Sanofi for bringing this matter to our attention.*'") (emphasis added) (https://www.justice.gov/usao-ma/pr/mylan-agrees-pay-465-million-resolve-false-claims-actliability).

As the Supreme Court has made clear, "[m]isrepresentations, condoned in the political arena, are not immunized when used in the adjudicatory process." Cal. Motor Transp. Co. v. Trucking Unlimited, 404 U.S. 508, 513 (1972); *see also Allied Tube,* 486 U.S. at 499-500 (1988) ("unethical and deceptive practices can constitute abuses of administrative or judicial processes that may result in antitrust violations") (citations omitted). On this independent basis, Mylan cannot immunize its conduct directed towards the states.

B. Sanofi Plausibly States a Claim for Deceptive Conduct by Mylan in Violation of Section 2 of the Sherman Act

Mylan does not dispute that false or deceptive statements about a rival can form the basis of a Sherman Act Section 2 claim. *See* Mem. at 24. Mylan further concedes that Sanofi alleges Mylan engaged in such activity, including by: circulating marketing materials to physicians falsely suggesting that Auvi-Q® was not bioequivalent to EpiPen® and that formularies had listed Auvi-Q® as "Not Covered" or "Prior Authorization" based on clinical recommendations; and by funding and promoting a misleading study intended to undermine the FDA's conclusion that Auvi-Q® demonstrated bioequivalence to the epinephrine in the EpiPen®. *See id.* at 23; Compl. ¶¶ 93-97, 139. As such, by Mylan's own admission, its arguments aimed at Sanofi's deceptive

marketing claims are arguments for a finder of fact. Sanofi's deceptive conduct claims must be allowed to proceed to a full record for this reason alone.

Indeed, it is widely recognized that false or deceptive representations by a monopolist can support a Sherman Act Section 2 claim. *See, e.g., W. Penn Allegheny Health System, Inc. v. UPMC*, 627 F.3d 85, 109 (3d Cir. 2010) (reversing dismissal of Section 2 claim where anticompetitive conduct alleged included, among other things, false statements about the plaintiff to potential investors); *Microsoft*, 253 F.3d at 76-77 (affirming judgment of antitrust liability and finding that Microsoft's deception of code developers to thwart competitive threats from other operating systems constituted a stand-alone antitrust violation); *Caribbean Broad Sys., Ltd. v. Cable & Wireless PLC*, 148 F.3d 1080, 1087 (D.C. Cir. 1998) (holding that misleading statements could support a Section 2 claim); *Int'l Travel Arrangers, Inc. v. Western Airlines, Inc.*, 623 F.2d 1255 (8th Cir. 1980) (upholding treble damages antitrust award against airline with monopoly power after finding sufficient evidence that airline placed false, deceptive, and misleading advertisements discouraging public patronage of rival travel group charters); *Caldera, Inc. v. Microsoft Corp.*, 87 F. Supp. 2d 1244, 1249 (D. Utah 1999) (holding that misleading statements could support a Section 2 claim); *see also* Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 782b (3d ed. 2008) ("misrepresentations and organized deception by a dominant firm may have §2 implications when used against a nascent firm just as it is entering the market").

The *Warfarin* case is particularly analogous. *In re Warfarin Sodium Antitrust Litig.*, No. MDL 98-1232-SLR, 1998 WL 883469 (D. Del. Dec. 7, 1998), *rev'd on other grounds*, 214 F.3d 395 (3d Cir. 2000). In *Warfarin*, a competitor plaintiff alleged that defendant DuPont, the leading warfarin sodium manufacturer, disseminated false and misleading information about plaintiff's generic competitor as part of a scheme to monopolize, including communicating to health care professionals, government agencies, and the public that DuPont's product was safer, that the generic was not equivalent to DuPont's, and issuing promotional warnings about switching to generic substitutes. *Id.* at *3-4. DuPont made the same argument that Mylan now

does; that false and misleading speech is not exclusionary activity for Section 2 purposes. But the *Warfarin* court rejected that argument, holding that the plaintiff's claims were sufficient to support a section 2 claim. *Id.* at *10-11. The same result is warranted here.

By contrast, Mylan's reliance on *Santana Products, Inc. v. Bobrick Washroom Equipment, Inc.*, 401 F.3d 123 (3d Cir. 2005), is inapposite. Mem. at 22-24. First, that case was determined at summary judgment. Second, the *Santana* plaintiff's claims were based on a group boycott theory, where the defendants acted to persuade the adopters of architectural standards to specify their products as meeting the standards, rather than the plaintiff's product. There, the court found that "in no real sense is Santana excluded" from the market. *Id.* at 133. Here, however, Mylan, a monopolist, circulated materials intended to undermine the FDA's conclusion that Auvi-Q® demonstrated bioequivalence to the epinephrine in the EpiPen®, and that Auvi-Q® had been left off formularies based on clinical recommendations, thus enhancing the effects of the conditional rebates to further block Sanofi from the market.

Mylan otherwise relies on post-motion to dismiss cases which are inapplicable at this stage. *See*, *e.g.*, *Four Corners Nephrology Assocs., P.C. v. Mercy Med. Ctr. Of Durango*, 582 F.3d 1216, 1225 (10th Cir. 2009); *Am. Council of Certified Podiatric Physicians & Surgeons v. Am. Bd. Of Podiatric Surgery, Inc.*, 323 F.3d 366, 370 (6th Cir. 2003). The other purportedly contrary case law cited by Mylan is likewise easily distinguishable, and none of those cases involve similar facts at the pleading stage. *See, e.g., Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961) (false statements made as part of legislative lobbying campaigns); *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, No. 13-MD-2445, 2017 WL 36371 (E.D. Pa. Jan. 4, 2017) (deception claim was "simply recasting" a duty to deal claim involving promises to license technology on FRAND terms).

Indeed, at least one of the cases cited by Mylan actually *reversed dismissal* of a Sherman Act Section 2 claim based on deceptive statements in a letter disparaging a rival drug company. Mem. at 22 (citing *Nat'l Ass'n of Pharm. Mfrs., Inc. v. Ayerst Labs.*, 850 F.2d 904, 914-17 (2d Cir. 1988)). In *Ayerst Labs.*, the Second Circuit concluded that a district court erred in not

allowing the plaintiff "to go forward with the discovery process to substantiate its claim that the Letter was clearly false, clearly material, and clearly likely to induce reasonable reliance." *Id.* at 916. As in *Ayerst Labs.*, Sanofi certainly states a plausible claim for deceptive conduct by Mylan in violation of Section 2 of the Sherman Act.

C. Sanofi Plausibly States a Claim for Overall Scheme to Monopolize in Violation of Section 2 of the Sherman Act

Here, too, Mylan does not seriously dispute that an overall scheme to monopolize claim can be cognizable under Section 2 of the Sherman Act. Mem. at 28-29. Tenth Circuit courts have recognized the viability of such claims. *See, e.g., 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) ("Plaintiff's evidence should be viewed as a whole…. It is enough that taken together they are sufficient to prove the monopolization claim."); *Caldera*, 72 F. Supp. 2d at 1309 ("The Court finds nothing in the relevant law that prevents a plaintiff from asserting one overarching claim of a § 2 violation.").

Sanofi's detailed allegations of Mylan's anticompetitive conduct—viewed "in their totality"—adequately allege that Mylan "engaged in a comprehensive multifaceted scheme to monopolize the market." *In re Neurontin Antitrust Litig.*, No. 02-1390, 2009 WL 2751029, at *16 (D.N.J. Aug. 28, 2009) (denying motion to dismiss). In addition to Mylan's exclusive dealing (*supra* IV.A) and deceptive marketing (*supra* IV.B), Sanofi's Complaint challenges Mylan's coercive EpiPen® School Discount Program (Compl. ¶¶ 7-8, 80-85), and artificial raising of Sanofi's co-pay and other costs (Compl. ¶¶ 7, 109, 137). Mylan's conduct—locking up schools and forcing Sanofi to absorb substantially higher costs to obtain only partial marketplace access and compete for sales—were part of Mylan's overall scheme to maintain its EpiPen® monopoly. The supporting factual allegations Sanofi pleads far exceed the pleading requirement for an overall scheme to monopolize claim.

Of course Mylan's factual disagreement with Sanofi's allegations does not defeat a well-pled complaint. For example, Mylan's bald-faced denial that schools receiving free EpiPen® devices were prevented from purchasing competitor devices (Mem. at 26), is directly

contradicted by Mylan's own documents cited in Sanofi's Complaint. Compl. ¶ 80.[15] Moreover, Mylan fails to address Sanofi's allegation that Mylan abandoned this policy only after the Antitrust Bureau of the New York Attorney General's office launched an investigation. Compl. ¶¶ 84-85. This fact only adds to the plausibility of the overall scheme allegations as Sanofi pleads. *See Hinds Cty., Miss. v. Wachovia Bank N.A.*, 708 F. Supp. 2d 348, 361 (S.D.N.Y. 2010) (denying motion to dismiss: "government investigations may bolster" allegations in an antitrust case.); *Starr v. Sony BMG Music Entm't*, 592 F.3d 314, 324 (2d Cir. 2010) (reversing grant of motion to dismiss where allegations of government investigations supported an inference of unlawful conduct).

Equally unavailing is Mylan's reliance on inapposite decisions in *City of Groton* and *Microsoft*. Mem. at 28-29 (citing *City of Groton v. Conn. Light & Power Co.*, 662 F.2d 921, 928-29 (2d Cir. 1981), and *Microsoft*, 253 F.3d at 78). Both of those cases were decided on full records after trials. Other courts have, at a minimum, rejected premature attempts to dismiss similar overall scheme to monopolize claims or condemned such schemes by dominant firms. *See, e.g., Reazin v. Blue Cross & Blue Shield of Kansas, Inc.*, 899 F.2d 951, 973 (10th Cir. 1990) (remanded on appeal on other grounds) (affirming jury verdict finding violation of Section 2: "Blue Cross' total conduct in this case—threatening to terminate Wesley's contracting provider agreement and reducing the maximum allowable payments for the remaining Peer Group V hospitals, thereby coercing other hospitals into not doing business with Blue Cross competitors—constituted willful maintenance of its monopoly power."); *Meredith Corp. v. SESAC LLC*, 1 F. Supp. 3d 180, 220 (S.D.N.Y. 2014) (denying summary judgment in part:

[15] In any event, Mylan has admitted publicly that its exclusionary program existed. *See* Letter from Mylan to Senators (Sept. 12, 2016), https://www.baldwin.senate.gov/imo/media/doc/2016-9-12_Mylan_Response.pdf (stating that while Mylan "no longer offered the two-tier discount program," at one point it required schools to either "pay a highly discounted price, or it could pay an *ever more deeply discounted price if the school certified that it would not purchase competitive products to EpiPen over the following twelve months*.") (emphasis added). On a motion to dismiss, the Court may take "judicial notice of a fact which is not subject to reasonable dispute," including "facts which are a matter of public record." *JP Morgan Tr. Co. Nat. Ass'n v. Mid-Am. Pipeline Co.*, 413 F. Supp. 2d 1244, 1258 (D. Kan. 2006).

defendant "engaged in an overall anti-competitive course of conduct designed to eliminate meaningful competition to its blanket license" and monopolized the market for access to musical works in its repertory); *Biovail Corp. International v. Hoechst Aktiengesellschaft*, 49 F. Supp. 2d 750, 772 (D.N.J. 1999) (denying motion to dismiss: allegations that the "defendants' various anticompetitive acts have 'foreclosed' [plaintiff] and other potential competitors from the market," were sufficient to allege "precisely the type of injury that the antitrust laws were intended to prevent"). The result should be the same here.

Thus, Sanofi states a plausible overall scheme to monopolize claim.

D. Sanofi More Than Adequately Alleges Harm to Competition

Mylan's argument that the Complaint should be dismissed because Sanofi does not sufficiently allege harm to competition must also fail. Mem. at 29-36. As a threshold matter, Sanofi alleges that Mylan began a series of EpiPen® price hikes before the launch of Auvi-Q® so that Mylan had an intentionally inflated price level in order to offer rebates that were conditioned on exclusivity. Compl. ¶¶ 61-62. Sanofi also alleges that Mylan substantially underpaid rebates to Medicaid (and thus illegally overcharged Medicaid) to subsidize its deep commercial rebate strategy to block Auvi-Q®. *Id.* ¶ 89; *see also supra* IV.A.3. It is well-settled that increases in price, or decreases in output or quality, are "substantial adverse effects on competition." *United States v. Visa U.S.A., Inc.*, 344 F.3d 229, 238 (2d Cir. 2003). Mylan's motion to dismiss for lack of harm to competition can be denied on this basis alone as Sanofi alleges inflated EpiPen® prices as part of Mylan's exclusive dealing behavior.

There can also be no serious question that reduced innovation, a decline in product quality, and the elimination of consumer choice in the EAI drug space all constitute harm to competition. Courts have consistently recognized that reduced innovation is evidence of harm to competition and competitors. *See, e.g.*, *Lorain Journal*, 342 U.S. at 154 (holding monopolist-newspaper liable when it refused to do business with advertisers that also did business with an upstart news competitor in the then-new radio medium); *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 318 (3d Cir. 2007) (plaintiff's allegations of anticompetitive conduct that led to

"harmed competition and undermined innovation" were "sufficiently specific to satisfy the first element of an attempted monopolization claim."); *Reazin v. Blue Cross & Blue Shield of Kansas, Inc.*, 663 F. Supp. 1360, 1416-18 (D. Kan. 1987) (a finding of anticompetitive effect can be supported by the fact that defendants' conduct "slowed or inhibited the spread of alternative [products]"); *Visa*, 344 F.3d at 241 (upholding district court's finding of harm to competition where "product innovation and output has been stunted").[16]

Additionally, as Mylan itself has acknowledged (Mem. at 24), a plaintiff may allege harm to competition by alleging that the defendant's conduct led to a reduction in quality in goods and services. *See, e.g.*, *W. Penn Allegheny Health Sys., Inc.*, 627 F.3d at 100 ("Anticompetitive effects include increased prices, reduced output, and reduced quality."); *see also Radio Music License Comm., Inc. v. SESAC, Inc.*, 29 F. Supp. 3d 487, 502 (E.D. Pa. 2014) (denying defendants' motion to dismiss where plaintiff alleged that defendant's conduct led to a decrease in the quality of service "insofar as customers only have the option of purchasing a blanket [music] license"); *Meredith Corp. v. SESAC, LLC*, No. 09 CIV. 9177 NRB, 2011 WL 856266, at *13 (S.D.N.Y. Mar. 9, 2011) (same); *Meredith*, 1 F. Supp. 3d at 220 (same at summary judgment).

Similarly, the FTC's enforcement actions have identified the elimination of consumer choice in the pharmaceutical industry as a clear harm to competition. For example, when the FTC challenged a merger between Merck, a brand name drug maker, and Medco, a pharmaceutical benefit manager, the FTC alleged that competition could be harmed by Medco's drug formulary being manipulated:

> The effects of Merck's acquisition of Medco may be substantially to lessen competition in the relevant markets . . . in the following ways, among others:
> (a) Products of manufacturers other than Merck are ***likely to be foreclosed from Medco's formularies***; and
> ***

[16] *See also Aventis Envtl. Sci. USA LP v. Scotts Co.*, 383 F. Supp. 2d 488, 504 (S.D.N.Y. 2005) (denying summary judgment); *Funai Elec. Co. v. LSI Corp.*, No. 16-CV-01210-BLF, 2017 WL 1133513, at *7–8 (N.D. Cal. Mar. 27, 2017) (denying motion to dismiss).

> (e) Pharmaceutical prices are likely to increase and the ***quality of the pharmaceuticals available to consumers is likely to diminish***.

See In re Merck & Co. and Merck-Medco Managed Care, L.L.C., Docket No. C-3853 (F.T.C. Feb. 18, 1999) (emphasis added); *see also* Press Release, *FTC Gives Final Approval to Lilly Order; Pledges Continued Monitoring for Anticompetitive Practices* (July 31, 1995) (noting that the FTC alleged that Eli Lilly's acquisition of McKesson Corporation would "substantially lessen competition in the manufacture and sale of pharmaceuticals, potentially leading to higher prices and *reduced quality*.") (emphasis added) (https://www.ftc.gov/news-events/press-releases/1995/07/eli-lilly-and-company).[17]

The Supreme Court also has recognized harm to competition when unlawful conduct leaves customers with a "Hobson's choice" either to receive reimbursement by foregoing the treatment of their choice, or to select their preferred treatment but forego reimbursement. *Blue Shield of Virginia v. McCready*, 457 U.S. 465, 483 (1982):

> [Plaintiff] alleges that Blue Shield sought to induce its subscribers into selecting psychiatrists over psychologists for the psychotherapeutic services they required, and that the heart of its scheme was the offer of a Hobson's choice to its subscribers. Those subscribers were compelled to choose between visiting a psychologist and forfeiting reimbursement, or receiving reimbursement by forgoing treatment by the practitioner of their choice. In the latter case, the antitrust injury would have been borne in the first instance by the competitors of the conspirators, and inevitably-though indirectly-by the customers of the competitors in the form of suppressed competition in the psychotherapy market; in the former case, as it happened, the injury was borne directly by the customers of the competitors.

The Department of Justice has similarly recognized that exclusive dealing agreements like the ones at issue in this case can harm competition. *See* Fiona Scott-Morton, U.S. Department of Justice, *Contracts that Reference Rivals* at 5, 15 (Speech presented at the Georgetown University Law Center Antitrust Seminar, April 5, 2012) (noting that "[t]he economic literature is clear that harm to consumers and competition *can* flow" from contracts

[17] *Cf. In re Pool Corporation*, No. C-4345 (F.T.C. Nov. 21, 2011) (non-merger enforcement action by FTC: "The Commission has seen this pattern before. The targets of anticompetitive exclusion are often the new rivals that incumbents foresee as most likely to shake up the market and benefit consumers at the expense of incumbents.").

that reference rivals, and that such contracts are most likely to harm consumers and competition when they involve "dominant firms possessing market power and a high market share.") (emphasis in original) (https://www.justice.gov/atr/file/518971/download).

As Sanofi sets forth in detail in its Complaint, Mylan's conduct significantly reduced the quality of EAI drug devices available to U.S. consumers. By blocking Auvi-Q® from significant portions of the U.S. market, Mylan prevented many consumers from accessing Auvi-Q®. Auvi-Q® represented innovation in the EAI drug device market with voice instructions, which helped patients and caregivers administer epinephrine, and a small size and shape, which made it easy to carry. *See* Compl. ¶ 4. Moreover, Sanofi alleges that Mylan's exclusive rebate offer to third-party payors explicitly targeted Auvi-Q® as opposed to other EAI drug devices. *Id.* ¶¶ 54-60. Thus, while Sanofi alleges that it has itself suffered harm, it also alleges a well-recognized harm to competition more broadly. *See Broadcom Corp.*, 501 F.3d at 308 ("Conduct that impairs the opportunities of rivals and either does not further competition on the merits or does so in an unnecessarily restrictive way may be deemed anticompetitive."); *Microsoft*, 253 F.3d at 79 ("[I]t would be inimical to the purpose of the Sherman Act to allow monopolists free reign to squash nascent, albeit unproven, competitors at will.").

In fact, Mylan itself has acknowledged that consumers are harmed when they are prevented from purchasing the EAI drug device that they prefer. In 2015, Mylan sought a preliminary injunction against the Secretary of the West Virginia Department of Health and Human Resources (the "West Virginia Action"), to enjoin her from removing the EpiPen® as a "preferred" drug on West Virginia's Medicaid Preferred Drug List and replacing it with Auvi-Q®. *See* Hochstadt Decl. (Ex. A) at 1. In its brief supporting its motion for a preliminary injunction, Mylan boldly stated: "Most significantly, however, thousands of West Virginia Medicaid recipients will be irreparably harmed as a consequence of the Revised [Preferred Drug List], which will *effectively deprive them of the EpiPen®* . . . ." *Id.* at 7 (emphasis added).

Mylan's arguments here that exclusive dealing by a monopolist does not harm competition ignore the law. While Mylan relies on the Seventh Circuit decision in *Methodist*

Health, that decision is yet another example of a case determined at summary judgment on a full record, rather than on the pleadings. *Methodist Health Servs. Corp. v. OSF Healthcare Sys.*, 859 F.3d 408 (7th Cir. 2017). Moreover, in that opinion Judge Posner acknowledged that some forms of exclusive dealing run afoul of the Sherman Act, for example those that have the "dire consequences" of driving a competitor out of the market. *Id.* at 410. Finally, *Methodist Health* involved vastly different facts than are present here, where 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. *Id.* In this case, Sanofi alleges that the Auvi-Q® entered the market on equal therapeutic terms as the EpiPen®, as the FDA determined that it delivered a bioequivalent dose of epinephrine. Compl. ¶¶ 45-53. In sum, Sanofi's Complaint alleges facts that support a well-recognized harm to competition under black letter antitrust law.[18]

E. Sanofi Clearly Pleads that Its Injuries Flowed From Mylan's Anticompetitive Conduct

At the tail end of its brief, Mylan argues that the injuries alleged in Sanofi's Complaint were not caused by Mylan. Mem. at 36-40. But again, Mylan simply ignores the extensive and detailed allegations in the Complaint which clearly allege that Sanofi's injuries directly flow from Mylan's anticompetitive conduct. For example, Mylan fails to credit Sanofi's allegations that in Canada, where Mylan did not market the EpiPen® and where there is open access to drug formularies, Auvi-Q®'s market share grew at a similar rate as it did in the United States in 2013 after launch, then continued to grow, reaching more than 30% share in late 2015. *See, e.g., Visa*, 344 F.3d at 240-41 (analyzing "but for" world in foreign markets absent the alleged anticompetitive conduct); *Meredith*, 1 F. Supp. 3d at 220 (analyzing "but for" world during a

[18] Courts have rejected attempts by monopolists, like Mylan, to argue at the motion to dismiss stage that their business practices are perfectly defensible under the antitrust laws. *See, e.g., Am. Airlines, Inc. v. Travelport Ltd.*, No. 4:11-CV-244-Y, 2011 WL 13047291, at *8 (N.D. Tex. Nov. 21, 2011), *order vacated in part on other grounds on reconsideration*, No. 4:11-CV-244-Y, 2012 WL 12507645 (N.D. Tex. Feb. 28, 2012) ("Sabre insists that its contractual arrangements with airlines … are perfectly kosher under the antitrust laws, as are its contracts with travel agents. While the factfinder may eventually find otherwise, at this stage of the litigation the Court is simply not able to say that the aforementioned allegations are, as a matter of law, insufficient to support a monopolization claim under section 2.").

period of time where defendant's licensing rates were subject to third-party neutral arbitral review). In the United States, where Auvi-Q® was harmed by Mylan's conduct, Auvi-Q®'s share *dropped* by nearly 50% in one month as a direct result of Mylan's anti-competitive conduct. Compl. ¶¶ 9, 106-107. Sanofi also alleges that Mylan's conduct raised its costs of entry, which is a well-recognized theory in economic literature.[19] *Id*. ¶¶ 131, 134. Indeed, Sanofi alleges that it was forced to give significant rebates on an entirely unrelated leading drug product simply to gain back access for Auvi-Q® at a major third-party commercial payor. *Id*. ¶ 143. Further, Sanofi alleges that it decided to return the rights to Auvi-Q® to its licensor as a direct result of Mylan forcing Auvi-Q® to be a fringe player against the EpiPen®. *Id*. ¶¶ 137, 140, 143.[20] Indeed, Mylan itself recognized in its preliminary injunction brief in the West Virginia Action that similar harm—EpiPen®'s removal from a "preferred" category of a drug formulary—would constitute "irreparable harm" to Mylan's reputation and a market share loss that would be irretrievable to regain. *See* Hochstadt Decl. Ex. A at 17.[21] In sum, Sanofi's pleading of the

[19] *See Dentsply*, 399 F.3d at 195 ("such exclusive dealing could either exclude the nondominant [firm] or else raise its costs in comparison to the costs of the dominant firm") (quoting Herbert Hovenkamp, Antitrust Law ¶ 1802e3, at 78–79 (2d ed. 2002)).

[20] Mylan's speculations about various alternative ways Sanofi could have competed with Mylan, or reasons for Sanofi's decision to return the rights to Auvi-Q® to its licensor, *see* Mem. at 38-40, should not be considered at the motion to dismiss stage. *See* Areeda & Hovenkamp, Antitrust Law ¶ 338a (3d ed. 2008) ("dispositive weight should not be given to lists of possible alternative causes [of injury], which virtually any defendant can generate. If the plaintiff's claim of causation is plausible, it should not be dismissed summarily merely because alternative causation stories are plausible as well"). Moreover, Mylan's heavy reliance on Sanofi's voluntary recall of Auvi-Q® is misplaced as Mylan itself is undergoing a voluntary recall of the EpiPen®. Compl. ¶ 110 n. 53. Voluntary recalls are therefore not uncommon.

[21] It is of no moment that the Mylan's conditional rebate offers did not last for more than 1-2 years. Mem. at 35-36. Courts have rejected the argument that short-term exclusive dealing agreements are presumptively not anticompetitive. *See*, *e.g.*, *Dentsply*, 399 F.3d at 193–94; *Masimo Corp. v. Tyco Health Care Grp., L.P.*, No. CV 02-4770 MRP, 2006 WL 1236666, at *6 (C.D. Cal. Mar. 22, 2006), *aff'd*, 350 F. App'x 95 (9th Cir. 2009) (upholding a verdict where a reasonable jury could have found that the agreements at issue were not terminable on short notice and constituted de facto exclusive dealing arrangements); *McWane, Inc.* 783 F.3d at 193-94 (rejecting argument that exclusive program was presumptively lawful because it was "short-term and voluntary"); *Nilavar v. Mercy Health Sys. W. Ohio*, 142 F. Supp. 2d 859, 877-78 (S.D. Ohio 2000) (holding that "duration of the exclusive contract is merely a factor which the Court will consider, when presented with relevant evidence"); *United States v. Microsoft Corp.*, No.

hundreds of millions of dollars of lost sales of Auvi-Q® due to Mylan dramatically reducing Sanofi's marketplace access in the United States is a clear injury resulting from Mylan's conduct and a classic measure of damages in exclusive dealing cases. *See* Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 397b (3d ed. 2008) ("In an exclusion case, the firm's loss is the present value of the profit stream that would have been enjoyed but for the exclusion.").

It is no wonder, then, that the cases Mylan cites in furtherance of its causation argument are not in the motion to dismiss context, *see Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100 (1969), *Read v. Med. X-Ray Ctr., P.C.*, 110 F.3d 543 (8th Cir. 1997), or involve the dismissal of claims under legal and factual circumstances completely inapposite to the ones here. *See Holmes v. Sec. Inv'r Prot. Corp.*, 503 U.S. 258 (1992) (plaintiff nonprofit corporation brought RICO claim alleging indirect injury stemming from unpaid claims of customers of broker-dealers for whom plaintiff was required to provide financial protection); *Assoc. Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 539 (1983) (plaintiff "was neither a consumer nor a competitor in the market in which trade was restrained" and it was "not clear whether [the plaintiff's] interests would be served or disserved by enhanced competition in the market"); *City of Pittsburgh v. W. Penn Power Co.*, 147 F.3d 256, 269 (3d Cir. 1998) (plaintiff city claimed that proposed merger of electric utilities violated antitrust laws, despite that there was never any competition between the utilities due to regulatory requirements, and any injury to the city was the result of "the structure of the regulated industry"). Mylan's

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CIV. 98-1232, 1998 WL 614485, at *20 (D.D.C. 1998) (the short term of agreements at issue "may be appropriate to consider in a final determination of whether the agreements unreasonably restrain trade. It is, however, only one among many factors the Court will consider…."); *Duramed*, 2001 U.S. Dist. LEXIS 26315 at *19 ("Other than *Roland Machinery*, the Court's review of the cases tends to indicate that the duration of the contract is but one factor for consideration. Therefore, the Court holds that the duration of the contract and whether it is easily terminable are merely factors for considering whether competition is substantially foreclosed.") (internal citations omitted). And most of the cases that Mylan cites for this point were decisions on a full record, not on the pleadings. *See Barry Wright Corp.*, 724 F.2d 227; *Omega Envtl., Inc. v. Gilbarco, Inc.*, 127 F.3d 1157 (9th Cir. 1997); *Roland Mach. Co. v. Dresser Indus., Inc.*, 749 F.2d 380 (7th Cir. 1984) (*en banc*).

conclusory arguments regarding causation ignore the well-pled allegations in Sanofi's Complaint, are misplaced in a motion to dismiss, and should be rejected.

V. CONCLUSION

Sanofi's Complaint properly pleads a wide range of anti-competitive conduct by Mylan. Consistent with *Twombly*, Sanofi certainly alleges enough facts to raise a reasonable expectation that discovery will reveal evidence of unlawful monopoly maintenance. Mylan's motion to dismiss ignores overwhelming antitrust authority condemning exactly the type of behavior Sanofi challenges, and heavily relies on arguments only appropriate after full discovery. For the foregoing reasons, Mylan has failed to meet its burden to show the Complaint is implausible. Accordingly, Mylan's motion to dismiss should be denied.

DATED: August 17, 2017 /s/ Eric S. Hochstadt

Respectfully submitted,

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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
This Document Relates To : SANOFI-AVENTIS U.S. LLC, Plaintiff, v. MYLAN Inc., *et al.*, Defendants.	CASE NO.: 2:17-CV-02452-DDC-TJJ *Document Filed Electronically*

CERTIFICATE OF SERVICE

I hereby certify that on August 17, 2017, I caused a copy of the foregoing Plaintiff Sanofi-Aventis U.S. LLC's Memorandum Of Law In Opposition To Defendants' Motion To Dismiss to be filed electronically on all interested parties via ECF, in compliance with Rule 5.4.9 of the Rules of Practice of the United States District Court for the District Of Kansas.

Dated: August 17, 2017

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