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 Hon. Teresa J. James
SANOFI-AVENTIS U.S. LLC, Plaintiff/ Counterclaim-Defendant, v. MYLAN Inc., *et al.*, Defendants/ Counterclaim-Plaintiffs. **This Document Relates to the *Sanofi* Case.**	CASE NO.: 2:17-CV-02452-DDC-TJJ *Document Filed Electronically*

SANOFI-AVENTIS U.S. LLC'S MEMORANDUM OF LAW IN OPPOSITION TO MYLAN'S MOTION FOR SUMMARY JUDGMENT

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PRELIMINARY STATEMENT

To hear Mylan tell it, this is a case in which it merely engaged in modest and common price competition and the only reason it prevailed is because Sanofi (i) "chose" not to compete on price and (ii) was forced to recall the Auvi-Q. This is a fairy tale. In reality, this is a classic antitrust case involving a monopolist driving its competitor out of the market through anticompetitive conduct for no legitimate business reason other than to maintain its monopoly power.

First, Mylan did much more than engage in price competition. In anticipation of Auvi-Q's launch, Mylan did not innovate the EpiPen or lower prices to make the EpiPen more competitive: it did just the opposite. Mylan raised the price of the same old EpiPen by more than 30% in the 12 months leading up to Auvi-Q's launch and more than doubled the price of EpiPen in the years that Auvi-Q was on the market so that it could set up its anticompetitive scheme of coercive rebates conditioned on excluding Auvi-Q and denying millions of children and adults at risk for anaphylaxis the opportunity to choose a new and innovative treatment option. As Mylan put it, "we will only pay rebates" to payors if they are "willing to exclude Auvi-Q." Mylan was able to do this because it was a monopolist, with a stranglehold on more than 90% of the U.S. epinephrine auto-injector ("EAI") market before Auvi-Q's launch.

Second, once Mylan secured exclusive arrangements locking Auvi-Q out from critical access to the market, it used every other tool in the shed to "hammer" Sanofi. It was not remotely fair competition on a level playing field when Mylan lied to government agencies in order to pay lower fees for Medicaid coverage and then used the ill-gotten gains to fund their deep conditional rebates for commercial payors. Nor was it fair competition to mislead consumers about the safety and effectiveness of Auvi-Q or improperly obtain and misuse competitively sensitive information to create an uneven playing field. No traditional competitor puts "strings attached" to budget-constrained schools requiring them not to stock a single life-saving Auvi-Q if they also want the

cheapest available EpiPen. Mylan had no legitimate business reason for its conduct. This company-wide scheme was endorsed by the most senior executives of the company who have lined their pockets from wrongdoing. The purpose was simple: crush an innovative and superior new product in order to protect the $1 billion per year crown jewel EpiPen. The antitrust laws of this country do not permit this kind of behavior by a monopolist.

Third, Mylan's scheme to maintain its monopoly hurt consumers and competition. Fiona Scott Morton, a Ph.D economist at Yale and pharmaceutical industry expert who served as Deputy Assistant Attorney General for Economic Analysis with the Antitrust Division of the Department of Justice, has concluded that Mylan's conduct was anticompetitive and cost patients—in the form of higher prices, lower output, reduced quality and innovation, and less choice.

Fourth, Mylan's breaking of the competitive process also harmed Sanofi significantly. Sanofi expected Auvi-Q to be an important growth-driver throughout the life of its patents through 2029. And given that EpiPen was a $1 billion per year product at the height of Mylan's monopoly, it is no surprise that Sanofi's damages total nearly $4 billion.

As set forth below, there is abundant evidence to create genuine issues of material fact to deny summary judgment and have a jury to decide whether Mylan illegally maintained its monopoly power through exclusionary or anticompetitive conduct.

ADDITIONAL STATEMENT OF MATERIAL FACTS THAT MYLAN IGNORES

I. Auvi-Q Was the First Innovative EAI Device in Over 20 Years

1. Since 1987, patients at risk for anaphylaxis have had essentially one treatment option: the Epipen. *See* Ex. 3 at ¶ 27. In 2013, however, the status quo for anaphylaxis patients changed when Sanofi launched the Auvi-Q. Ex. 3 at ¶¶ 33-34.[1]

[1] Sanofi also incorporates by reference its Memorandum of Law in Support of its Motion for Summary Judgment and its Memorandum of Law in Opposition to Mylan's Motion for Summary Judgment, including all defined terms, cited facts, and evidence, as if fully set forth herein. Unless otherwise noted, emphasis is added to cited documents and

2. Anaphylaxis is a life-threatening allergic reaction that requires immediate treatment with epinephrine. *Id.* at ¶ 9. It is estimated that between 2% and 5% of the U.S. population are at risk for anaphylaxis. *Id.* at ¶ 12. Common causes of anaphylaxis, such as foods, insect stings, or medications, are found everywhere. *Id.* at ¶ 10. When an emergency allergic reaction happens, patients and caregivers—including parents, babysitters, teachers, counselors, and coaches—often panic about how to administer epinephrine. *Id.* at ¶ 23. Because anaphylaxis can occur anywhere and to anyone, it is critical that patients at risk for anaphylaxis and caregivers carry an EAI drug device that is easy to use and easily accessible. *Id* at ¶ 13; *see* Sanofi MSJ SMF at ¶¶ 6-15.

3. Auvi-Q was the invention of twin brothers Eric and Evan Edwards, who both suffered from severe allergies, but were dissatisfied with the EpiPen's design. Ex. 4. Inspired by their own experiences, the brothers created the Auvi-Q as a "slimmer device shaped like a smartphone" to address their needs and the patient needs of other EpiPen users. *Id.*

4. Auvi-Q was the first EAI drug device that was not shaped like a pen and that was smaller than the EpiPen. *See* Ex. 5 at § 5.1.3; Ex. 3 at ¶ 33. Auvi-Q is the size of a credit card and easily fits in the palm of the hand or a small pocket. Ex. 3 at ¶ 34. Auvi-Q is the only EAI device that provides audio cues that instruct the patient or caregiver during an emergency situation on how to use the device and when the injection is completed. *Id.* Auvi-Q is the only EAI device that does not require users to "swing and jab" the device into their own leg or the leg of another in-need in order to administer the injection. *Id.* at ¶ 33. Auvi-Q is the only EAI device with a needle

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testimony throughout Sanofi's Opposition. "Sanofi Opp-RSMF" refers to the section in this brief titled "Response to Mylan's Statement of Material Facts." "Sanofi Opp-ASMF" refers to the section in this brief titled "Additional Statement of Material Facts that Mylan Ignores." "Mylan MSJ" refers to Mylan's June 28, 2019 Memorandum of Points and Authorities in Support of its Motion for Summary Judgment [ECF No. 1673]. "MTD Order" refers to this Court's Dec. 21, 2017 Order on Mylan's Motion to Dismiss [ECF No. 98]. *See In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litig.*, No. 17-2785, 2017 WL 6524839 (D.Kan. Dec. 21, 2017). "Sanofi MSJ SMF" refers to the Statement of Undisputed Material Facts in Sanofi's June 28, 2019 Memorandum of Law in Support of its Motion for Summary Judgment [ECF No. 1692].

that automatically retracts into the device when the injection is complete. *See* Ex. 6 at 55:10-56:14.

5. Over the last two decades, a rise in food-related allergies has increased the need for access to EAI devices. Ex. 5 at § 4.0. Unfortunately, it is well-documented that many patients at risk for anaphylaxis fail to carry an EAI device at all times. Ex. 3 at ¶ 22.

6. Auvi-Q's innovative features gave anaphylaxis patients new options for the first time. Its smaller size made it easier for some users to carry their EAI device at all times. Ex. 7. The audio cues also gave calming instructions to patients and caregivers during what are often high stress, life-threatening situation. Ex. 3 at ¶¶ 34, 39. The retractable needle allowed users to administer epinephrine without fear of seeing a needle. Ex. 8 at 155:15-156:11; 265:21-267:4. In short, patients for the first time had the opportunity to choose a device that best suited their needs, increasing the chances of being prepared for an emergency. Ex. 3 at ¶ 38.

II. [redacted]

7. In 2008, Mylan and the Pfizer EpiPen Manufacturer [redacted]. Ex. 9 at 32:14-33:6. Mylan viewed Auvi-Q as an "[redacted]" with "[redacted]" technology. Ex. 10 at Slide 2.

8. After an in-person meeting between Mylan, [redacted], at which confidential information was shared, the [redacted] commented that Auvi-Q "[redacted]." Ex. 11 (emphasis in original). Mylan believed Auvi-Q would provide "[redacted]" to [redacted]." Ex. 10 at Slide 2. Mylan particularly viewed Auvi-Q as an attractive option for teenage boys, who did not "[redacted]" and [redacted] as Auvi-Q [redacted] Ex. 9 at 31:6-32:8. Auvi-Q

was an "[redacted]" solution to a "[redacted]" that Mylan acknowledged. *Id*.

9. Mylan and the Pfizer EpiPen Manufacturer submitted a [redacted], and Mylan's then-President expressed "[redacted]" Ex. 12 at -190; Ex. 9 at 67:21-69:9.

10. In December 2009, Intellijject instead chose to license Auvi-Q exclusively to Sanofi to market in the U.S. and Canada. Ex. 4.

III. Mylan Viewed Auvi-Q as a Major Threat

11. Mylan viewed Auvi-Q as a significant threat to its monopoly. *See* Sanofi MSJ-SMF ¶ 58; Ex. 13 at -505 (recognizing that Mylan "[redacted]"); Ex. 14 (Foster Dep.) at 212:10-20 ("[redacted]"); Ex. 15 (Willing Dep.) at 253:11-16 ("Q. [redacted]."); Ex. 253 at -101 (Mylan physician research: [redacted].").

12. For years before Auvi-Q's launch, EpiPen was the only EAI drug device with more than 10% of the U.S. EAI drug device market. *See* Ex. 16 (RFA No. 15) ([redacted]).

13. However, Mylan knew that "[redacted]." Ex. 17 at -505. Indeed, Mylan's market research found that [redacted]," and [redacted]

[redacted]." *Id*; *see also* Ex. 18 at -648 ("[redacted]); Ex. 19 at -921 [redacted]."); Ex. 20 at -064 ("[redacted].").

14. As John Thievon, Mylan's then-President stated in 2012, Auvi-Q [redacted] Ex. 19 at -921.

IV. [redacted]

15. [redacted] Mylan began to explore the prospect of developing a "[redacted]" that was [redacted]" and "[redacted]" to allow it to compete with the new Auvi-Q technology. *See* Ex. 9 at 95:22-109:19. Later designs of Mylan's "[redacted] also depicted [redacted]." Ex. 21 at slide 8.

16. All of the "[redacted] *See id*. at slides 8, 14 and 15.

17. Mylan's CEO, Heather Bresch, made clear that the [redacted]" when Auvi-Q was expected to launch. *See* Ex. 23; Ex. 9 (Handel Dep.) at 112:6-18 (noting that Mylan expected [redacted]). Mylan [redacted] Ex. 24 at -496. It was therefore in Mylan's [redacted]. Ex. 11.

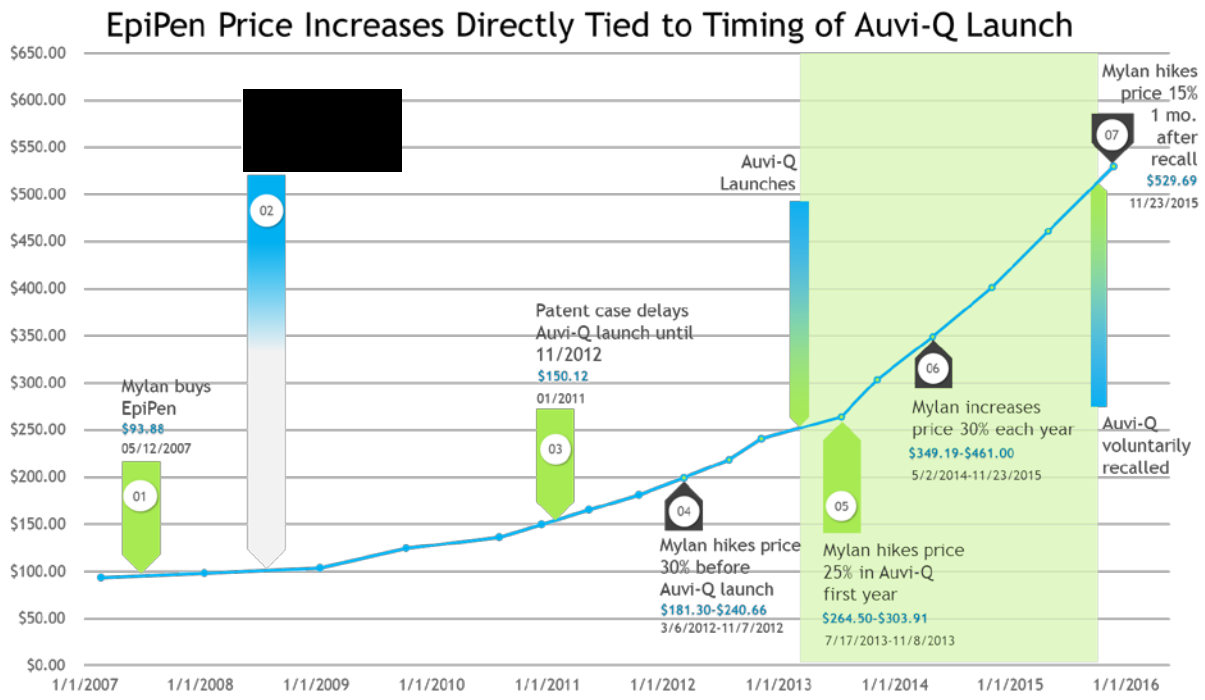
18. Ultimately, Mylan did not move forward with the [redacted]. *See* Ex. 9 at 94:20-95:9, 114-116; Ex. 24 at -498. Since 2009, Mylan has not sold [redacted]. *See* Ex. 25 at 25:20-22.

V. Unable to Innovate and Compete on the Merits, Mylan Pivoted and Implemented a Company-Wide Scheme to Exclude Auvi-Q from the U.S. EAI Drug Device Market

A. Mylan Inflates EpiPen's List Price in Anticipation of Auvi-Q's Launch

19. One part of Mylan's scheme was to dramatically revise its contracting strategy to proactively offer large rebates to pharmacy benefit managers ("PBMs") and insurance companies (payors) who excluded Auvi-Q. *See infra* § V.B. To afford the larger rebates, Mylan first strategically inflated the wholesale acquisition cost ("WAC") price of EpiPen several times before Auvi-Q's launch. *See* Sanofi MSJ SMF at ¶¶ 43-45; Ex. 26 at 13 (recommending [redacted]."); Ex. 25 at 169:25-175:13; Ex. 27 at slide 8 (Oct. 2012 Pricing Committee presentation providing Mylan's rationale for a [redacted]."); Ex. 28 at -955 ("[redacted]").

20. The following graph shows how Mylan substantially increased prices on the EpiPen leading up to, during, and after the time period that Auvi-Q was on the market. *See* Sanofi MSJ-SMF at ¶¶ 43-55; Ex. 29 at 271 ("Epinephrine Auto-Injectors Class Price History"); Ex. 22 at ¶¶ 86-89, 184; Ex. 30 at Figure 1.C.



B. Mylan Used Its Monopoly to Block Auvi-Q from Key Payor Drug Coverage

21. Payors do not manage all drug classes the same. For some drug classes, payors may create tiered formularies (usually three) to attempt to influence consumer choice by covering some drugs on tiers with lower co-payments and others on tiers with higher co-payments. *See* Ex. 22 at ¶ 40. If a drug is listed on formulary the end consumer often pays a co-pay or some other amount that is less than the full list price. *See id.* On the other hand, some payors may exclude particular drugs from their formularies altogether—meaning a consumer would have to pay the full list price to get such drugs. *See id.* at ¶ 41. Other tools payors may use include requiring prior authorization from a doctor or step therapy, which requires a "[redacted]" of the first-prescribed drug. *See id.*; Ex. 134 at 32:7-11.

22. However, payors do not always go to the trouble of managing a drug class. For certain drug classes—particularly those with relatively low costs or that are used infrequently—the benefits to be gained from managing a class can be relatively small and outweighed by the costs of doing so. Ex. 22 at ¶ 42; Ex. 148 at 24 (Sanofi 2011 Market Access Research noting:

"Philosophy right now is to just provide all the agents that are available. … There would be a possibility to be able to manage one product over another, but there are no significant financial benefits available for us doing so.").

23. Before Auvi-Q's launch and Mylan's actions, payors did not heavily manage the EAI drug device class. *See, e.g.*, Ex. 31 at 279:3-13 (Anthem testified that EAIs "were not" the type of "[redacted]"); Ex. 32 at 292:24-293:3 (Mylan's Corporate Designee: "Q. [redacted]."); Ex. 33 at 143:23-144:2 (BCBS Horizon: "Q. [redacted]"). Unlike other medications, EAI drug devices are prescribed infrequently – typically only once per year. Ex. 3 at ¶ 38. And unlike other classes of drugs that are heavily managed where a payor might want a patient to try and fail one product before trying another; in the case of an EAI device, requiring a patient to "fail" on one device could result in death. *Id.* at ¶ 9.

24. Mylan developed a strategy to "[redacted]" and "[redacted]" Auvi-Q (then known as e-cue) from securing key formulary coverage; in order to get rebates on EpiPen, payors had to exclude or restrict Auvi-Q in exchange for rebates on EpiPen. Ex. 34 at -136; Ex. 35 at -406 (Under [redacted]); Ex. 36 at -194 (Presentation titled "EpiPen Auto-Injector Global Brand Plan 2012-2016" slide 6 "[redacted]

[redacted]"); Ex. 37 at -504 (Harry Jordan: [redacted]).

25. In 2011, Mylan's senior leadership, including then-CEO, Robert Coury, [redacted]." Ex. 38; *see also* Ex. 39 at -539 (Tom Hadley: [redacted]). Mylan executed this strategy through a "[redacted]." Ex. 40 at -398 (Harry Jordan: [redacted]."); Ex. 41 at -562 (Alexander Falto: [redacted]

26. Mylan sought to [redacted] or other types of benefit exclusion on Auvi-Q and stressed the "[redacted]." Ex. 39 at -593; Ex. 42 at slide 32; Ex. 43 at -393 (Dec. 2011 presentation "[redacted]"); Ex. 44 at slide 34 (listing Mylan's strategy to [redacted]); Ex. 13 at -687 ("[redacted]"); Ex. 204 at -393 ("[redacted]"). As one Mylan employee put it: "We will ***only pay rebates if a client is willing to exclude Auvi-Q***." Ex. 240.

27. Mylan's exclusionary strategy targeting Auvi-Q was a complete shift in the norm for EAI drug devices. Mylan's previous contracts offered only small rebates as "[redacted]" and not to obtain exclusivity. Ex. 14 at 212:7-213:2; *see* Ex. 45 (Jordan Dep. Tr.) at 39:2-8 ("Q. In 2011, when you started at Mylan, in general, what kind of rebates was Mylan offering to insurance pay[o]rs and PBMs on the EpiPen? [redacted]."); Ex. 46 (Willig Report) at Ex. 6 (showing the average rebate on EpiPen from 2011-2012 was [redacted] compared with the average rebate on EpiPen from 2013-2015 between [redacted]); Ex. 47 at slide 12 ("Pre-Auvi-Q [redacted] access rebates" and "[redacted]"). Prior to Auvi-Q, Mylan's previous contracts kept a level playing field with other products on the market, stating that [redacted]." Ex. 48. However, Mylan's rebate agreements after Auvi-Q's launch [redacted] Ex. 212 at -245.

28. The record evidence shows that Mylan encouraged, and ultimately drove, numerous payors to exclude or disadvantage Auvi-Q:

MYLAN AGGRESSIVELY PUSHED FOR EXCLUSIVITY	
Prime	Ex. 15 (Willing Dep.) at 73:13-75:3: "[redacted] *** Ex. 49, Nicole Willing: "[redacted]

	[redacted] *** Ex. 50, Bruce Foster: [redacted]
Humana	Ex. 51: [redacted] *** Ex. 52: [redacted] *** Ex. 53: [redacted]
CVS	Exs. 54 and 55: After Auvi-Q became co-preferred with EpiPen on CVS's Commercial performance drug list in July 2014, Mylan came back in July 2015 offering a [redacted]
Kaiser	Ex. 56: "[redacted]
ESI and Anthem	Ex. 31 (Anthem Dep.) at 197:7-11: [redacted] *** *Id.* at 201:1-14: [redacted] *** Ex. 57: Explaining why ESI excluded Auvi-Q: "I was told today that Mylan came back [to ESI] with an exclusive offer that 'they couldn't refuse.'"
MedImpact	Ex. 58: Bruce Foster's talking points for a meeting with MedImpact state: [redacted]

C. Mylan Flaunted EpiPen's Contrived Formulary Advantage to Discourage Doctors from Prescribing Auvi-Q and Exploited "Spillover Effects"

29. Once Mylan secured its formulary advantage with the largest payors, it leveraged that status to take advantage of "spillover effects." *See, e.g.*, Ex. 59 at -261 (stating that Mylan's offer to [redacted]."). Prescribers are concerned with which EAI drug device is covered by a patient's insurance so that their patients will be able to fill the prescription. Ex. 5 at § 6.3 ("[I]f one device is substantially different in coverage and out of pocket cost, that tends to be the device that is prescribed."). Since patients are insured by a number of plans, physicians are unable to track which specific plans cover specific products, and instead default to the product that they know is widely available in their region. Ex. 22 at ¶ 135. This is the spillover effect.

30. When large payors agreed to restrict or exclude Auvi-Q, Mylan leveraged its contrived formulary advantage to dissuade doctors from prescribing Auvi-Q altogether, regardless of their patients' coverage plans. Ex. 60 ("[redacted]"); Ex. 61 (explaining the importance of [redacted]

31. Mylan exploited the spillover effect by advertising EpiPen's widespread formulary coverage and Auvi-Q's disadvantaged status to doctors, especially "[redacted]" Ex. 62 at slides 3-4; Ex. 236 ("[redacted]."). Mylan Specialty President, Roger Graham,

encouraged the sales team to "[redacted]

[redacted]

[redacted]"

Ex. 63. Examples of Mylan's self-described "***anticompetitive messaging***" to Health Care Providers specifically targeting Auvi-Q are set out below:

MYLAN'S ANTICOMPETITIVE MESSAGING TO HCPS
[redacted] x. 64 at -588.
A Mylan sales representative described a conversation with a doctor where the sales representative [redacted] Ex. 65 at -919.
Mylan regional sales manager instructed his team to [redacted] Ex. 66 at -839.
Mylan Sales reps were [redacted] Ex. 67 at -144.
[redacted] Ex. 68 at -230.
In an email stating that Coventry Health [redacted] " Ex. 69 at -372.
[redacted] " Ex. 70 at -820.
Email titled "***Foot on their throat***" stating: "These wins are HUGE! We've got to leverage them beyond belief!" Ex. 71 at -150.

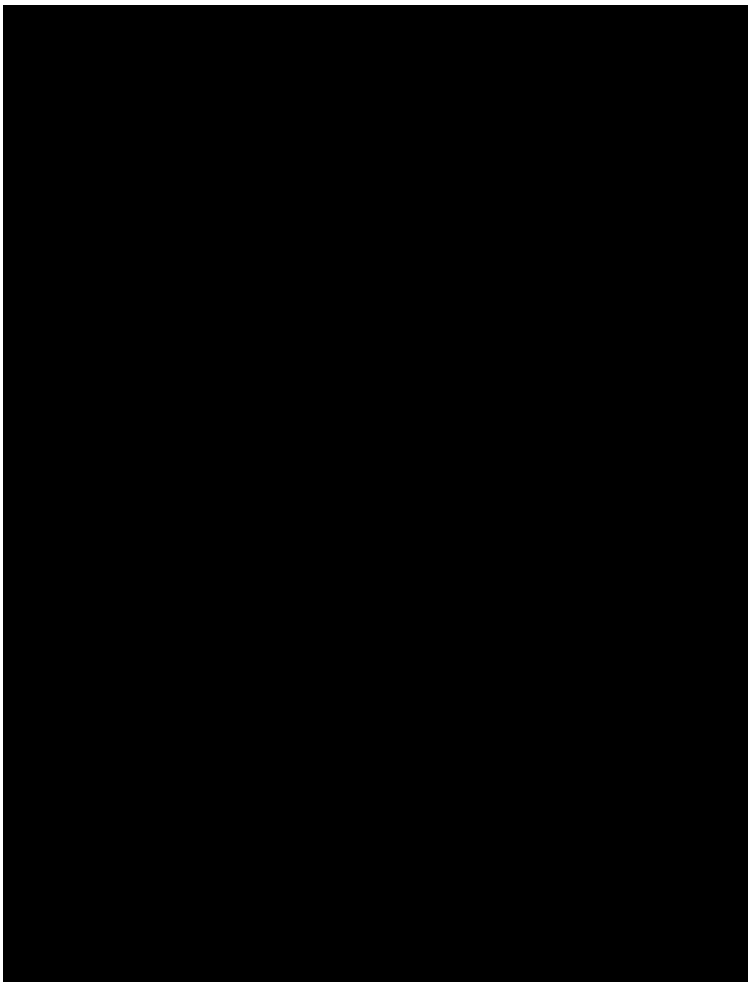
MYLAN'S ANTICOMPETITIVE MESSAGING TO HCPS
Mylan's sales force was specifically [redacted] ." Ex. 72 at -685.
"Q. [redacted] ." Ex. 73 (Jones Dep.) at 42:13-25.
"Q. [redacted] ." *Id.* at 215:3-216:15.
"Q. But that wasn't saying that EpiPen had good formulary coverage. That was saying that EpiPen's competitor had bad formulary coverage. So why was that frickin' awesome? A. Again, as a marketing guy, if my product has advantages, I'm happy about that. Q. And the advantage, in that instance, was that EpiPen had better formulary coverage than Auvi-Q, correct? A. Yes." Ex. 74 (Arcara Dep.) at 152:18-153:5.
"[redacted] Ex. 75 at -317.
Mylan sales rep reported, "[redacted] ." Ex. 76 at -338.
Presentation discussing "[redacted] ." Ex. 77 at -729.
Mylan "Competitive Action Plan" on "[redacted] ." Ex. 62 slide 3.

32. Some payors, including BCBS of Illinois, [redacted] Ex. 78 at -592 (Mylan email noting that [redacted] ."). Mylan ignored [redacted]

[redacted]." *Id.* at -591; Ex. 79 at -744 ("[redacted]").

D. Mylan Implemented a Deceptive Marketing Campaign to Further Ensure Doctors Would Be Reluctant to Prescribe Auvi-Q

33. Mylan also improperly marketed to doctors Auvi-Q's (and not any other competitor's) disadvantaged position on major formularies. Ex. 80 at -872. Even worse, Mylan executives, including, Sherry Korczynski, the former VP of EpiPen Marketing who was paid over $15,000 for her preparation and testimony, encouraged Mylan's sales representatives to [redacted] the fact that [redacted] Ex. 61; Ex. 82 at 13:23-15:9. President of Mylan Specialty and Mylan's corporate designee, Roger Graham, admitted that Mylan had *no basis* to make statements about whether payors preferred EpiPen for clinical reasons because [redacted]]" and payors "[redacted]." Ex. 81 at 178:13-179:21. Korczynski likewise could not identify [redacted]. Ex. 82 at 81:3-82:15. Nevertheless, Mylan advertised that the payors' decision to not cover Auvi-Q was based on "[redacted]," which was false. There is no evidence that decision not to cover Auvi-Q were based on anything other than coercive rebates.



Ex. 80 at -872. Mylan's pharmaceutical industry expert, Gary Zieziula, testified that he "did not see any information that would indicate that PBMs or national insurers did not cover AUVI-Q™ for clinical reasons." Ex. 6 at 25:25-26:11.

34. Mylan also misled physicians by telling them the epinephrine in Auvi-Q was not bioequivalent to that in EpiPen. Mylan did so despite the FDA's finding that the epinephrine in both products "demonstrated bioequivalence." *See* Ex. 83 at 2 ("The [pharmacokinetics] trial...demonstrated bioequivalence" between the epinephrine in Auvi-Q and EpiPen). Mylan funded and presented a misleading study titled: "Auvi-Q versus EpiPen Auto-Injectors: Failure to Demonstrate Bioequivalence of Epinephrine Delivery Based on Partial Area Under the Curve." Ex. 84 at -675.

35. Mylan's medical and pharmaceutical industry experts admit that the products are equivalent. *See* Ex. 8 at 197:14-25, 199:1-2 (Dr. Blaiss testifying that he alternated between Auvi-Q and EpiPen on a "whim" when prescribing because he did not "think that one was superior to the other."); *id.* at 214:5-8 ("it's my feeling that -- that these devices have equal clinical effectiveness. They have equal safety."); Ex. 6 (Zieziula Dep.) at 26:17-20 ("[B]oth products have the same amount of epinephrine and deemed bioequivalent by the FDA.").

E. Mylan Also Used EpiPens in Schools to Block Auvi-Q

36. The EpiPen4Schools program was [redacted]. Ex. 85 at 142 (Mylan presentation noting that the objective of the EpiPen4Schools program was to [redacted] As summarized by Mylan's senior executives in charge of EpiPen, "[redacted] Ex. 86.

37. Mylan knew that getting EpiPens into schools or summer camps was "[redacted]" to cementing its position in the U.S. EAI market. Ex. 87 at slide 19 ("[redacted]"); Ex. 58 at -218 ("[redacted]."); Ex. 88 at -761 (stating that getting EpiPens in summer camps "[redacted]")

38. Mylan launched EpiPen4Schools in the fall of 2012 before Auvi-Q launched. The program offered two EpiPen 2-packs (4 devices) to qualifying schools with [redacted] Ex. 16 (RFA No. 42). However, any school seeking more than four devices had to certify that "[redacted]

[redacted]. Ex. 90 at -051. Schools [redacted] Ex. 16. Any school that stocked Auvi-Q was forced to pay higher prices for EpiPen. Ex. 25 at 119:12-120:21 (admitting that [redacted]).

39. Mylan's market research showed that the EpiPen4Schools program was successful in blunting Auvi-Q. Mylan found that Auvi-Q [redacted] Ex. 92 slide 34 at -542 ("[redacted]"); Ex. 91 at -221 (tying [redacted]).

F. Mylan Misclassified EpiPen to Allow it to Offer Steep Commercial Rebates Without Consequence on Government Prices

40. For nearly a decade, Mylan misclassified EpiPen to state and federal Medicaid agencies and thus paid substantially less in Medicaid rebates. Ex. 93 (DOJ Press Release announcing $465 settlement to "ensure a level playing field for pharmaceutical companies."). This unlawful conduct enabled Mylan to offer steep discounts on the commercial side without concern that it would affect its Medicaid pricing. Mylan's illicit actions on the Medicaid and commercial sides were linked.

41. The cost of an EAI drug device for a patient covered by commercial insurance is dictated by the insurer's rebate agreement with the manufacturer. However, for patients covered by Medicaid, the cost is dictated by a formula. The formula takes into account the "best price" that a product is sold for, including in commercials channels. Mylan misclassified EpiPen as a generic product in order to pay less in discounts to Medicaid, even though EpiPen was a branded product.

Ex. 94 at -543 ("Every data point we have suggest the Epipen is a brand (because it is); however; they have been paying federal rebates...as if it was a generic. I know a few states have been in contact with CMS on the issue and the response from CMS was that they intend to pursue the issue. If CMS requires Mylan to recalculate their rebates to reflect a branded status as we are expecting, the federal rebate has the potential to increase drastically."). Mylan's unlawful conduct saved Mylan hundreds of millions in discounts to Medicaid and allowed it to in turn offer steep discounts on commercial products without concern that it would impact their Medicaid pricing. Bruce Foster admitted that [redacted]. Ex. 95 at -769 (Email from Bruce Foster [redacted].").

G. Mylan Took Other Steps to Maintain Its Monopoly

42. Additionally, Mylan shared competitively sensitive rebate information with payors so they knew the terms and conditions competing payors were getting to exclude Auvi-Q. For example, Mylan emailed the [redacted]" (a separate payor) and note that [redacted] Ex. 96 at -563. Mylan also volunteered [redacted] *Id.* There are other examples in the record of Mylan employees sharing competitively sensitive rebate information. *See* Ex. 97 at -965 ("[redacted]."); Ex. 98 at -428 ("[redacted]

[redacted].").

43. Mylan also made clear to payors that they would be at a [redacted] who took Mylan's coercive rebates to exclude Auvi-Q. *See* Ex. 58 at -218 [redacted]

44. Worse, Mylan improperly obtained and used confidential information about Sanofi's marketing efforts. Mylan and Sanofi both contracted with the same agency, Digitas Health, for their EAI marketing campaigns. Mylan breached a confidentiality wall to obtain inside information from the Digitas Health team working for Sanofi in order to plan for its anticompetitive efforts against Auvi-Q. For example, a Mylan and Pfizer EpiPen Manufacturer Joint Commercial Committee meeting in December 2013, attended by senior Mylan leaders, included a slide titled "[redacted]" stating: "[redacted]." Ex. 89 at slide 40.

45. Throughout the following year, Mylan relentlessly pursued Sanofi's confidential information. In June 2014, [redacted]." Ex. 99 at -498. [redacted]." Ex. 100 at -222. Following this directive, Korczyzinski forwarded the email to [redacted]. *Id.* With insider information of [redacted]

[redacted], Mylan then [redacted] Ex. 101 at -763 ("[redacted].").

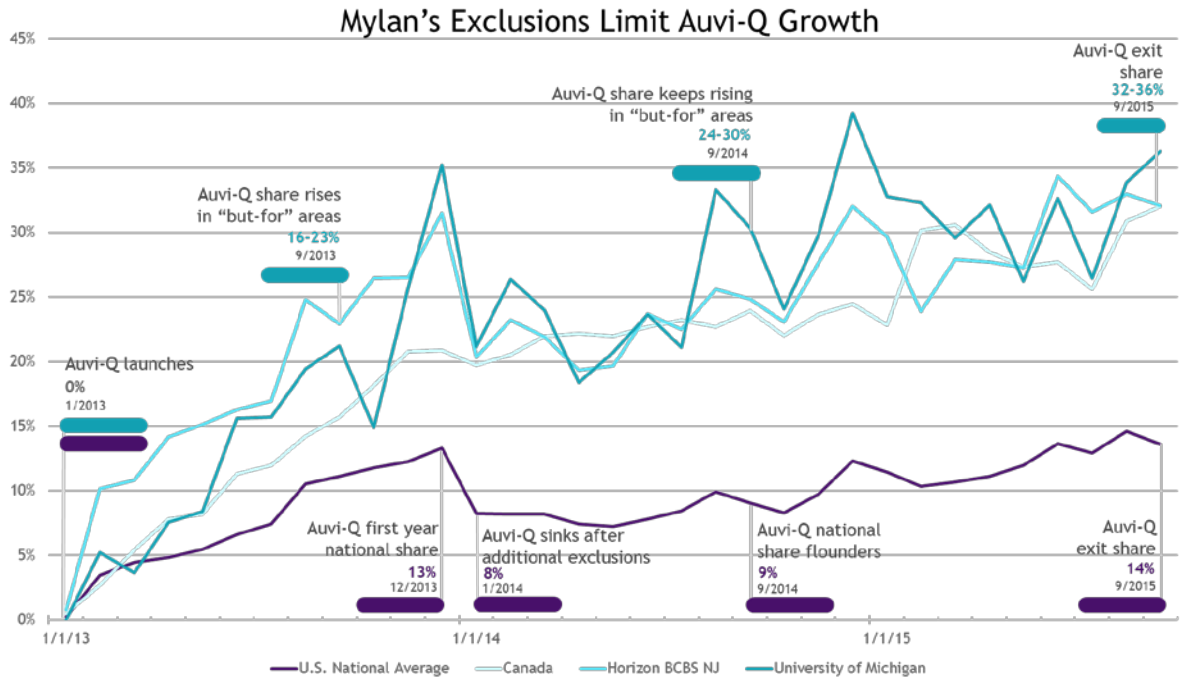
46. Mylan continued to pressure [redacted] Ex. 102 at -010. Following up internally, and [redacted] *Id.* at -090.

47. Mylan also used [redacted] Ex. 103 at -376. In a presentation titled "2013 EpiPen Digital Media Recommendation," Mylan's proposed strategy was to "[redacted]." Ex. 104 at slide 19. Specifically, Mylan states, "[redacted]." *Id.* at slide 20.

VI. Mylan's Conduct Resulted in Lost Auvi-Q Sales and Ultimately Forced Sanofi to Exit

48. Before Mylan's anticompetitive scheme, both Sanofi and Mylan believed Auvi-Q would achieve ***more than*** [redacted] ***market share***. *See* Ex. 22 at ¶ 201; Ex. 105 (April 2010 Mylan forecast projected [redacted] market share for Auvi-Q two years after launch and [redacted] share four years after launch); Ex. 36 at -246 (November 2011 Mylan forecast projected Auvi-Q would have [redacted] share by 2015); Ex. 265 at -800-802 (same); Ex. 106 at -593 (projecting [redacted] market share by

2015 and [redacted] share in the fourth year after launch). Indeed, in Canada and on two U.S. formularies where Auvi-Q had equal access to EpiPen, Auvi-Q did reach market share of at least 30% three years after launch. *See* Ex. 22 at ¶¶ 202-206; Ex. 107 (Fairest Dep. Tr.) at 24:6-14; 237:7-11. The following chart compares Auvi-Q's market share when operating on a level playing field (*i.e.* in Canada, Horizon BCBS NJ, and Univ. of Michigan) versus Auvi-Q's national average share when impacted by Mylan's anticompetitive behavior:



Ex. 22 at Figure 14. In a but-for world where Sanofi and Mylan operated on this type of level playing field across the U.S. EAI market, Dr. Scott Morton projected that Sanofi would have achieved profits of $25 million in the 2013-2015 time period. Ex. 22 ¶ 209; Ex. 108 at 1.

49. For 2013-2015, Mylan's conduct caused Sanofi to incur significantly increased costs and lose $103 million. Ex. 22 at ¶ 210. As set forth in Dr. Scott Morton's reports, those losses (of $103 million) combined with the profits Sanofi would have earned but for Mylan's anticompetitive conduct resulted in actual damages of $128 million, or $189 million in present value. Ex. 22 at ¶ 211; Ex. 30 at ¶¶ 208-09; Ex. 109; Ex. 110 at 404; Ex. 108 at 1.

50. Sanofi's contemporaneous internal documents, as well as sworn testimony from its senior executives, reflect that Sanofi expected Auvi-Q to be a "long-term growth driver" for the company. *See* Ex. 111 at -017 ("Near-term product opportunity with sustainable, long-term growth"); Ex. 112 at slide 2 ("Long term: Demonstrate continued strong [year-over-year] growth to solidify Auvi-Q as a long -term growth driver with 2029 LoE"); Ex. 113 at -419; Ex. 114 at 329:2-330:17; Ex. 115 at -014; Ex. 116 at 272:6-9, 357:13-358:15; Ex. 117 at 13:22-15:7.

51. Sanofi's senior executives—including CEO, Christopher Viehbacher, and Executive VP, Peter Guenter—had been aware of Mylan's anticompetitive conduct since 2014. *See* Ex. 118 at -526. Sanofi considered various options at the time, including possibly an early return of rights to Auvi-Q's inventors. *See* Ex. 119 at slide 2 (Nov. 2014 presentation discussing various options, including to "Walk-Away" or return the rights to Auvi-Q). In addition, Sanofi's attempts in 2014 to re-negotiate its royalty agreement with kaleo for Auvi-Q were unsuccessful. *See id.* at slide 4 (noting that when Sanofi and kaleo signed the deal in 2009, neither company anticipated "the aggressive tactics that Mylan would employ"); Ex. 111 at -017 (2009 royalty between Sanofi and Intellijject assuming "Strong Formulary Access" for the Auvi-Q).

52. Then after the October 2015 voluntary recall of Auvi-Q, Sanofi reflected on the possibility of bringing Auvi-Q back to market. However, Mylan's anti-competitive conduct dampened that optimism. Indeed, Mylan anticipated that Sanofi would "[redacted]" bring Auvi-Q back to market. Ex. 15 at 233:5-18. But Sanofi had no reason not to believe that Mylan's illicit conduct would simply continue were Sanofi to re-launch Auvi-Q, nor that Sanofi could overcome such conduct. *See* Ex. 118 at -526; Ex. 120 at at 340:4-341:7; *see also* Ex. 121 at -467 (concluding that: "EpiPen's high market share coupled with a high discount creates an obstacle that cannot be overcome via discounting."); Ex. 122 (Ordover Dep. Tr.) at 177:21-178:8 (acknowledging that

"Sanofi's senior leadership observed and believed that Mylan was using anticompetitive business practices to protect its EpiPen and to block Auvi-Q's access to the market.").

53. Accordingly, Sanofi ultimately decided to return Auvi-Q to kaléo in late 2015:

- Ex. 117 (Barry 30(b)(6) Dep.) at 37:24-38:14:
  "Q. Why was the decision made to return the rights to Auvi-Q to Kaleo?
  A. Considering the market environment and considering the behaviors of the competitor, and assuming that there was a likelihood that they would continue to try to blunt our launch in terms of using their lion's share of the market inappropriately and the level of investment that would be required to achieve a relaunch, we determined that based on the pro forma of the general medicines team that it would be best to put those investments somewhere else and then to then transition the product back to Kaleo and ensure a smooth transition so that ultimately at the end of the day patients could have choice and physicians could have choice in an alternative epinephrine auto-injector."
- *Id.* at 44:2-7: "We felt like [Mylan's conduct] would be something that would continue over the life of the product, that Mylan would continue to use a very large dominant market share to try to make it very difficult for pay[o]rs to put Auvi-Q on formulary."
- Ex. 116 (Guenter Dep.) at 327:9-14: "And then relaunching the product, restarting from scratch, with a market share of zero, re-contracting for access, anticipating that Mylan with EpiPen would be probably more aggressive than ever to try to avoid that we would regain access."
- *Id.* at 333:17-21: "And that was a very, very heavy lifting in front of us also with a very heavy competitor in front of us that would try to block us from access. I think that was a pretty clear business decision not to relaunch the brand."

RESPONSE TO MYLAN'S STATEMENT OF MATERIAL FACTS

The following paragraphs in Mylan's Statement of Material Facts are Undisputed: 2-3, 8, 11-15, 17-18, 21, 52-53, 56, 60, 65, 73-74, 77, 81-82, 84, 86-88, 91-94, 96-98, 101, 103, 105, 118-120, 124, 143, and 145.

I. "Mylan's Sale and Distribution of the EpiPen Auto-Injector"[2]

1. **Disputed in part.** Sanofi disputes that Mylan's products "play a vital role in lowering the costs of prescription drugs." Mylan's anticompetitive scheme actually *raised* the cost of EpiPen and resulted in Mylan's senior executives receiving substantial compensation. *See*

[2] Sanofi also disputes Mylan's headings in its "Statement of Material Facts" as misleading, irrelevant, and unsupported by the evidence. Sanofi uses these headings solely to aid the Court's review.

Sanofi Opp-ASMF ¶¶ 19-20; Ex. 266 (NYT Article reporting that Mr. Coury was paid $97 million in 2016); Ex. 267 at 58 (SEC filing showing that Ms. Bresch's 2013-2015 compensation was between $9 and $25.8 million). Mylan's pricing practices for other products is under serious question. *See In re Generic Pharm. Pricing Antitrust Litig.*, Case No. 16-md-02724 (E.D.Pa. Oct. 16, 2018), ECF No. 721 (denying motion to dismiss antitrust regulators' claims that Mylan engaged in a "broad, well-coordinated and long running series of schemes to fix the prices and allocate markets for a number of generic pharmaceuticals").

4. **Disputed in part.** Mylan's assertion that it "enhanced access" to EAIs is wrong. Mylan prevented consumers from accessing competing EAIs. *See* Sanofi Opp-ASMF ¶¶ 21-28.

5. **Disputed in part.** If these facts are intended to imply that [redacted], this material risk to Mylan's business has never been publicly disclosed, and therefore either the implication is not true, or it is a massive failure to disclose material facts to investors and the public. Indeed, recent reports suggest that Mylan's successor will be acquiring the Pfizer EpiPen Manufacturer and expanding Mylan's EpiPen franchise, [redacted]. Ex. 124 at 3 (SEC filing disclosing that Pfizer and Mylan have agreed to discuss transfer of the Meridian/EpiPen business).

II. "Sanofi's Auvi-Q"

6. **Disputed in part.** The facts regarding Sanofi's size and revenue are not "material" to any claim or defense. *See Dewitt v. Sw. Bell Tel. Co.*, 845 F.3d 1299, 1306 (10th Cir. 2017) ("A fact is material if, under the governing law, it could have an effect on the outcome of the lawsuit.") (hereinafter, the "Immaterial" objection).

7. **Disputed in part.** Mylan's citation to Mr. Viehbacher's deposition testimony is misleading, as it omits the following relevant testimony on Sanofi's royalties to Intelliject: "I've

done quite a few licensing deals over my 30 years in this business, and...these are actually pretty low milestone payments for a product that was at this stage." Ex. 120 at 21:8-12

9. **Disputed in part.** Mylan's assertion regarding clinical data on Auvi-Q's superior safety or efficacy is misleading, as it ignores preference studies finding Auvi-Q was preferred over EpiPen. *See* Ex. 125 at ¶ 8.

10. **Disputed in part.** Mylan omits that the recall was voluntary. Ex. 198 at ¶¶ 56–67.

III. "The Distribution and Pricing Of Branded Prescription Drug Products"

16. **Disputed in part.** It is not clear what Mylan means by "highly consolidated."

19. **Disputed in part.** Sanofi does not dispute that payors generally use different formularies. However, Mylan's generalized assertions regarding unspecified payors, drugs, and formularies fail to account for the unique characteristics of the U.S. EAI market that Mylan monopolized. Mylan's assertion purports to characterize in one broad stroke all drug classes, all payors, and the U.S. healthcare system at large, and not the U.S. EAI market specifically. Both Sanofi and Mylan witnesses have testified that each therapeutic category or market is different:

- Ex. 126 (Bresch Dep.) at 446:22-447:1: [redacted]."
- Ex. 127 (Navarro Dep.) at 46:15-19: "The application of utilization management tools such as prior authorizations, step edits and such can ***vary based upon the therapeutic category*** as well as the different formularies, managed."
- *Id.* at 127:24-128:3: "[H]ow the utilization management controls are applied ***can be dependant*** [sic] ***upon a particular class***. And it varies from health plan to health plan, PBM to PBM."
- Ex. 128 (Schur Dep.) at 86:19-21: "[E]very market is very unique. ***You need to think about the uniqueness of every single market***."
- Ex. 6 (Zieziula Dep.) at 97:14-16: "It's ***a different product, different category, a different patient pool***."
- *Id.* at 64:3:10: "You're asking me about minor changes to [another product], which ***is a different category altogether***, so I am having -- I am uncomfortable jumping to the

conclusion that you are asking me to jump to this morning regarding those situations being exactly the same."

The record is also clear that each payor operates differently:

- Ex. 127 (Navarro Dep.) at 159:3-8: "[Q.] What about 80 percent, 80 percent market share or above, does that, would you consider that a high market share? [A.] 80 percent is high, but again it ***depends upon the category, but also the plan or the PBM***."
- Ex. 81 (Graham 30(b)(1) Dep.) at 191:18-192:3: "[redacted]."
- Ex. 73 (Jones Dep.) at 31:12-15: "[E]ach PBM and each payor has different formulary controls they implement, and that can vary by class, can vary by drug."

Moreover, the evidence in this case show that the EAI drug device class, in particular, is unique:

- Ex. 126 (Bresch Dep.) at 248:12-16: "[redacted]."
- Ex. 129 (Letter from Mylan to Cabinet Secretary Karen Bowling, West Virginia Dep't of Health and Human Resources, WV Brief Ex. E): ***"[E]pinephrine auto-injectors are different from most drugs on the PDL and the decision about which product is preferred requires consideration of issues that do not arise with most other drugs on the PDL***."
- Ex. 130 (Eaton Dep.) at 122:17-21: "He didn't say that those categories were equivalent analogs to the epinephrine auto-injector category, which was -- it's a ***very unique category in the fact patients get one prescription per year***."
- Ex. 131 (Loreaux Dep.) at 213:17-22: "I would say that based on the nature of the category, the EAI category, where you predominantly had one market player that had near—nearly a hundred percent of the market share, ***the dynamics that we experienced at launch were—were very unique.***"
- Ex. 132 (OptumRx Dep.) at 333:8-9: "This was a ***unique category in that the dominant market share for EpiPen was so dominant***."

As such, Sanofi disputes this assertion and other claims throughout Mylan's "Statement of Material Facts" that erroneously conflate all drug classes, all payors, the U.S. healthcare system at large, or that otherwise fail to account for the unique characteristics of the EAI drug device market

(hereinafter, the "Unique EAI Market" objection).

20. **Disputed in part.** Mylan's generalized assertions regarding unspecified formularies fail to account for the Unique EAI Market and Mylan's monopoly power therein.

22. **Disputed in part.** Mylan's generalized assertions regarding unspecified formularies and health plans fail to account for the Unique EAI Market and Mylan's monopoly power therein and also misleadingly imply that all formulary decisions made by payors accurately reflect patient choice. *See* Ex. 133 at 22 (In response to formulary restrictions, "[s]ome patients will choose to reduce medication or discontinue treatment entirely rather than switch to PBM's preferred choice, even if that choice is less expensive"). Commercial payors are intermediaries in the pharmaceuticals market who have a financial obligation to their shareholders to seek higher revenues and never even take title to the drug products. *See* Ex. 25 at 173-174. To therefore state that their decisions accurately reflect patient choice is misleading.

23. **Disputed in part**. Mylan's generalized assertions regarding unspecified "UM techniques" fail to account for the Unique EAI Market and Mylan's monopoly power therein.

24. **Disputed in part.** Mylan's generalized assertions on unspecified drug categories and copayments fail to account for the Unique EAI Market and Mylan's monopoly power therein.

25. **Disputed in part.** Mylan's generalized assertions regarding step edits for unspecified drug categories fail to account for the Unique EAI Market and Mylan's monopoly power therein. *See* Ex. 134 at 32:7-11 (step therapy means that there first must be a "trial or failure" of the first-prescribed drug); Ex. 15 (Willing Dep.) at 62:4-8 ("Q. Okay. And the ones where there's an EpiPen failure, what was your understanding as to what an EpiPen failure would be? ***A.*** [redacted]."); Ex. 135 at -367 ([redacted] email: [redacted]

[redacted]

[redacted] Ex. 71 at -150 ("Just learned Aetna is not covering Auvi-Q in 2014. And not [only] that, ***they put a step edit in place requiring an EpiPen failure…whatever that means***.").

26. **Disputed in part.** Mylan's generalized assertions on prior authorizations for unspecified drug categories fail to account for the Unique EAI Market and Mylan's monopoly power therein. *See* Sanofi Opp-RSMF at ¶ 25. Mylan's documents reflect that it considered benefit exclusions and prior authorizations to be high controls. *See* Ex. 27 at slide 7 ("[redacted].").

27. **Disputed in part.** Mylan's generalized assertions regarding PBMs and payors excluding some unspecified drugs fail to account for the Unique EAI Market and Mylan's monopoly power therein.

28. **Disputed in part.** Mylan's generalized assertions regarding unspecified PBMs and payors and "management tools" fail to account for the Unique EAI Market and Mylan's monopoly power therein. *See* Sanofi Opp-ASMF ¶¶ 22-23 (citing evidence that prior to Auvi-Q's launch, formularies generally did not manage the EAI class); Ex. 136 at 213:22-214:10; Ex. 32 at 292:3-293:3. Moreover, Mylan's citation misleadingly omits the following clarification: "[redacted]" Ex. 138 at 122:25-123:9.

29. **Disputed in part.** Mylan's generalized assertions regarding unspecified PBMs and payors, drugs, and manufacturers fail to account for the Unique EAI Market and Mylan's monopoly power therein. *See* Ex. 137 (FSM Dep. at 62:16-21) ("The thing about EpiPen is that it has this entrenched share. It has a familiarity and a reputation in the marketplace, and consumers who are not going to shift away. And what that does is it limits the ability of the PBM to have more bargaining power."); Ex. 22 at ¶¶ 180-184.

30. **Disputed in part.** Mylan's assertions and evidence cited discussing competitive markets are misleading and fails to account for the Unique EAI Market and Mylan's monopoly power therein. *See* Ex. 137 at 61-62; Ex. 22 at ¶¶ 180-184.

31. **Disputed in part.** Sanofi does not dispute that it is common in competitive markets for drug manufacturers to pay some rebates to PBMs, or that Sanofi has paid some rebates for its insulin product, [redacted]. However, any assertion that the competitive environment in which [redacted] is sold and the extent and timing of Sanofi's rebating practices regarding [redacted] are in any way analogous to Mylan's monopoly position in the U.S. EAI drug market or Mylan's conduct at issue in this litigation, or that Mylan's conduct is common in the pharmaceutical industry is misleading, immaterial, and fails to account for the Unique EAI Market and Mylan's monopoly power therein, and Sanofi disputes it. *See* Ex. 127 at 202:22-203:13 (failing to provide even one other example of a drug with over 80% market share offering high rebates to exclude a new market entrant). As explained by Dr. Scott Morton, "the competitive market in which [redacted] operates [is] fundamentally different from" and should not be compared to the U.S. EAI drug device market. *See* Ex. 30 at ¶ 8. "Sanofi did not pursue a strategy of exclusive contracts." *Id*. Sanofi never devised an aggressive strategy leveraging coercive rebates to block [redacted], from coverage by a number of key payors, or to prevent [redacted] from entering the market and competing on a level playing field. Ex. 138 (Borneman 30(b)(1) Dep.) at 206:4-11 ("[redacted]

[redacted]

[redacted]

[redacted]."). Indeed, [redacted]

[redacted]

[redacted]

[redacted]. *See id.* at 206:13–208:05; Ex. 139 at 3. Sanofi offered rebates on [redacted] *See* Ex. 138 at 133:03–134:24; Ex. 140; *see also* Ex. 30 at ¶¶ 67–69 (detailing why [redacted]'s "competitive environment" is "not comparable" to that of EAIs). Moreover, when Mylan had the opportunity to question a Sanofi corporate deponent about the conditions and rebates underlying the relevant [redacted], Mylan declined to do so. *See* Ex. 197 at 27:17–31:04 (Topic 27) (hereinafter, the "False [redacted] Comparison" objection).

32. **Disputed in part.** Mylan's generalized assertion that price protection is "commonly" negotiated is misleading and fails to account for the Unique EAI Market and Mylan's monopoly power therein. *See* Ex. 22 at ¶ 125 (citing evidence that [redacted]); Ex. 141 at slide 5; Ex. 14 at 91:16-92:21, 233:1-234:21; Ex. 142 at -481.

33. **Disputed in part.** Mylan's generalized assertions regarding unspecified formularies, drug classes, and rebates fail to account for the Unique EAI Market and Mylan's monopoly power therein.

34. **Disputed in part**. Mylan's generalized assertions regarding rebate solicitations for unspecified drug categories fail to account for the Unique EAI Market and Mylan's monopoly power therein.

35. **Disputed in part.** Mylan's generalized assertions regarding unspecified manufacturers, rebates, and drugs fail to account for the Unique EAI Market and Mylan's monopoly power therein. *See* Ex. 30 at ¶¶ 58-69.

36. **Disputed in part.** Mylan's generalized assertions regarding what "most" agreements supposedly include are misleading and fail to account for the Unique EAI Market and Mylan's monopoly power therein. *See* Sanofi Opp-ASMF ¶ 28 (citing evidence of Mylan's bid

grids "heavily weighted" to exclusive categories).

37. **Disputed in part.** The evidence cited does not support the assertion that PBMs "often" sign rebate agreement with multiple manufacturers if there are multiple drugs.

38. **Disputed in part.** None of the evidence cited supports the assertion that "Payors generally reserve the right to alter their commercial formularies at any time, and the *only* consequence is that the Payor or its clients might not be eligible for rebates." Moreover, this generalized assertion fails to account for the Unique EAI Market and Mylan's monopoly power therein. *See* Ex. 30 at ¶ 112.

39. **Disputed**. Mylan's generalized assertions fail to account for the Unique EAI Market and Mylan's monopoly power therein. *See id.* Moreover, the terms "generally" and "variation" are unclear. Each Mylan rebate agreement is different and speaks for itself.

40. **Disputed**. Mylan's generalized assertions regarding the duration, renegotiation, and terms of rebate agreements fail to account for the Unique EAI Market and Mylan's monopoly power therein. *See* Ex. 30 at ¶ 112. Moreover, it is not clear what Mylan means by the vague terms: "frequently," "most," "most often," "typically," and "sometimes," *each of which show that there are admitted questions of fact*. Each Mylan and Sanofi rebate agreement is different and speaks for itself. Also, none of the evidence cited supports the assertion that rebate agreements are "frequently" renegotiated or that such renegotiation is done "most often at the instigation of Payors seeking better rebates." There is overwhelming evidence in the record that Mylan [redacted] its rebates and price concessions after the Auvi-Q voluntary recall and Sanofi returned the rights to kaleo. *See* Sanofi MSJ-SMF ¶¶ 67-69; Ex. 143; Ex. 15 at 243; Ex. 144; Ex. 145 at -538; Ex. 146. Further, if Mylan's position were true, no offer would ever be rejected as [redacted] a position Mylan otherwise repeats. *See* Mylan MSJ ¶ 90.

41. **Disputed in part.** It is not clear what Mylan means by the term "most." Each Mylan and Sanofi rebate agreement is different and speaks for itself.

42. **Disputed in part.** These generalized assertions regarding unspecified payors and drug categories fail to account for the Unique EAI Market and Mylan's monopoly power therein.

43. **Disputed in part.** Mylan's generalized assertions regarding unspecified drug categories fail to account for the Unique EAI Market and Mylan's monopoly power therein. *See* Ex. 22 at ¶¶ 179-184 (concluding, based on the evidence, that Mylan's conduct did not result in lower prices); Ex. 30 at ¶¶ 30-40 (same).

44. **Disputed in part.** Mylan's assertions on how rebate negotiations generally work in competitive markets are misleading and fail to account for the Unique EAI Market and Mylan's monopoly power therein. *See* Ex. 137 at 61-62; Ex. 22 at ¶¶ 1879-184; Ex. 30 at ¶¶ 30-40.

IV. "Sanofi's Launch Of Auvi-Q In 2013"

45. **Disputed**. Sanofi's detailed market research prior to Auvi-Q's launch showed that PBMs did not intend to heavily manage the EAI drug class. Ex. 147 at slide 10 ("The EAI market is a small under the radar market in which payers will not look to heavily manage."); Ex. 148 at slide 4 ("When it comes to management of the EAI category, most payers said that their main objective is to provide easy and open access to the products."). Moreover, the evidence shows that *Mylan* encouraged, and ultimately drove, numerous PBMs and payors to exclude or disadvantage Auvi-Q—[redacted]. *See* Sanofi-Opp-ASMF ¶ 28; *infra* at pg. 72-73.

46. **Disputed in part**. Mylan's assertions regarding CVS's exclusion list fail to account for the Unique EAI Market and Mylan's monopoly power therein. Neither Auvi-Q nor EpiPen were ever placed on CVS's exclusion list, which consisted of "chronic medications that are used on a daily basis." Ex. 130 at 170:15-171:16.

47. **Disputed in part**. Mylan's assertions regarding ESI's exclusion list fail to account for the Unique EAI Market and Mylan's monopoly power therein. *See* Sanofi Opp-RSMF ¶ 45. Mylan encouraged [redacted] *See* Ex. 149 at -648; Ex. 150 at -727. The reason [redacted] Ex. 151 at -863.

48. **Disputed in part**. Mylan's characterization that the whitepaper describes [redacted] is misleading. Sanofi circulated this whitepaper before it knew that [redacted] *See* Ex. 118 at -526.

49. **Disputed in part**. Mylan's general assertion regarding ESI's exclusion list fails to account for the Unique EAI Market and Mylan's monopoly power therein, as well as EpiPen's entrenched demand. *See infra* at pg. 63-66; Ex. 22 at ¶¶ 76-82.

50. **Disputed in part**. Mylan's general assertions regarding UHC's formulary exclusions fail to account for the Unique EAI Market and Mylan's monopoly power therein, as well as EpiPen's entrenched demand. *See infra* at pg. 63-66; Ex. 22 at ¶¶ 76-82.

51. **Disputed in part**. Sanofi does not dispute that payors value price protection especially where, as here, Mylan significantly increased the WAC price of EpiPen repeatedly before, during, and after Auvi-Q's launch. *See* Sanofi Opp-ASMF ¶¶ 19-20; Ex. 22 at ¶ 125. However, Mylan was the one pushing for price protection in exchange for exclusivity. *See* Ex. 22 at ¶ 165; Ex. 142 at -481 [redacted]

54. **Disputed**. Sanofi disputes that it "was not prepared to offer Payors deep discounts for formulary position, even when Payors planned to cover just one EAI device." Mylan

misrepresents Ex. 152, an internal Sanofi email discussing how Kaiser was very interested in Auvi-Q and may have considered covering both it and EpiPen on formulary, which in no way supports Mylan's incorrect assertion. Moreover, Mylan's misclassification of the EpiPen allowed it to [redacted] Ex. 120 at 51:17–22 (discussing Ex. 153). This left Sanofi to compete for commercial coverage on an uneven playing field and allowed Mylan to use the funds obtained by an improper Medicaid rebate classification plus Epipen's [redacted] to generate offers that were [redacted] *See* Ex. 114 at 94:5–95:6 (hereinafter the "Medicaid Misclassification" objection).

55. **Disputed**. Sanofi disputes that it decided, pre-launch, not to match any [redacted] that Mylan offered to [redacted] Mylan misrepresents Ex. 154, which is a Nov. 2012 internal Sanofi presentation. Slide 11 lists a number of contingency plans. Under the first plan, if Mylan "offers an aggressive [EpiPen] discount to all priority accounts in exchange for exclusivity position," Sanofi will, ***among other things***, "[c]ontinue to drive the message of unmet need, innovation, ease of use and [the] importance of having unrestricted access to [more than one] life-saving product." Slide 11 does not, as Mylan suggests, state that Sanofi will not match "aggressive discounts" that Mylan offers to "priority accounts." In fact, just the opposite: Slide 11 ***presumes*** competition, and affirmatively states that Sanofi believed that the "Tier 2 target [was still] within range." Moreover, Mylan's Medicaid Misclassification left Sanofi to compete for commercial coverage on an uneven playing field.

57. **Undisputed**. However, Sanofi [redacted] abandoned its initial guidelines once payors started [redacted] *See* Ex. 155 at

100:3–19. Mylan was making "offers" that the PBMs simply "couldn't refuse." Ex. 151 at -863. Not [redacted] *See* Ex. 32 at 292:24–293:03; *see* Sanofi Opp-RSMF ¶¶ 45-47, 50. Sanofi drafted its initial guidelines before it knew that [redacted] *See* Ex. 118 at -526. In addition, Mylan's Medicaid Misclassification left Sanofi to compete for commercial coverage on an uneven playing field.

58. **Disputed in part**. Mylan's citations omit important context provided by Patrick Barry: "[T]he economics of the product made sense based on our understanding of the market environment [at the time of launch]. What we couldn't have foreseen...was the unprecedented rebates that were given competitively by Mylan which forced us then into an aggressive rebating strategy...[redacted] Ex. 117 at 31:25–32:24. Moreover, Bryan Downey testified that [redacted] Ex. 114. at 118:22–119:18. Auvi-Q is an EAI drug device, "not [] a pill." *Id*.

59. **Disputed in part**. Sanofi disputes the assertion that Auvi-Q's COGS prevented it from competing in 2013. To the contrary, Sanofi "competed all the way through." *Id.* at 33:17–35:02. Mylan's rebates were [redacted] and its market share allowed it to [redacted] *See id.* at 309:25–312:01. Sanofi [redacted] overcome that, regardless of its COGS. *Id.* Moreover, Mylan's Medicaid Misclassification left Sanofi to compete for commercial coverage

on an uneven playing field.

61. **Disputed**. The cited evidence does not state that PBMs viewed Auvi-Q as [redacted] Moreover, Mylan omits evidence that PBMs viewed Auvi-Q as a [redacted] *See* Ex. 33 at 56:11-57:10; 141:12-142:7. Furthermore, the record shows that ***Mylan*** encouraged, and ultimately drove, numerous PBMs and payors to exclude or disadvantage Auvi-Q—[redacted] *See* Sanofi Opp-ASMF ¶ 28; *infra* at pg. 72-73.

62. **Disputed**. The record evidence shows that *Mylan* encouraged, and ultimately drove, numerous PBMs and payors to exclude or disadvantage Auvi-Q. Mylan repeatedly went back to PBMs that decided they wanted to make Auvi-Q available in an effort to persuade them to restrict Auvi-Q. *See infra* at pg. 72-73. Mylan also omits that many payors were not looking to manage the EAI class. *See* Ex. 33 at 56:11-57:10; 141:12-142:7; Ex. 31 at 280. Instead, the evidence shows that Mylan leveraged EpiPen's entrenched demand to coerce PBMs and payors into entering into exclusive agreements. Ex. 22 at ¶¶ 76-82; Sanofi Opp-ASMF ¶¶ 21-28.

63. **Disputed**. *See* Sanofi Opp-RSMF ¶ 62. Moreover, Mylan mischaracterizes the evidence cited. [redacted] wanted to manage the EAI class. Ex. 156. Indeed, Ex. 157 makes clear that *Mylan* was [redacted] Ex. 158 also does not evince a threat from [redacted] Finally, Cigna did not tell Mylan that it [redacted] Cigna, instead, told Mylan that it [redacted] *See* Ex. 159.

64. **Disputed in part**. Sanofi disputes any suggestion that ESI sought to exclude Auvi-

Q. ESI excluded Auvi-Q because Mylan made it an offer it "couldn't refuse." Ex. 151 at -863.

V. "2013 And 2014 Coverage For Auvi-Q And EpiPen"

66. **Disputed in part**. Sanofi disputes Mylan's assertion that PBMs generally sought to "manage[] the EAI class." *See* Sanofi Opp-RSMF ¶ 45.

67. **Disputed in part**. Sanofi disputes that it was ever afforded the "opportunity to compete" in the EAI drug device market. *See* Sanofi Opp-RSMF ¶ 62.

68. **Disputed**. Sanofi disputes that Mylan's exclusionary offers allowed payors to make "independent coverage determination[s] for the EAI class, based on the interests of their clients." *See* Sanofi Opp-RSMF ¶ 62. Mylan's own documents also contradict its assertion that it never [redacted] *See* Ex. 58; Ex. 160.

69. **Disputed**. Mylan's assertion that Auvi-Q was not excluded when Sanofi offered a lower per-unit price for Auvi-Q than Mylan did for EpiPen is misleading. As explained by Dr. Scott Morton, given EpiPen's entrenched demand, [redacted] Ex. 137 at 154; Ex. 22 at ¶ 118. Instead, PBMs and payors considered their ***total*** cost for purchasing across all of its EAI drug device volume. *See infra* at pg. 68. Moreover, there are several instances in the record where, compared with Mylan, Sanofi offered [redacted] and Auvi-Q still remained disadvantaged. *See infra* at pg. 68-69.

70. **Disputed**. *See* Sanofi Opp-RSMF ¶¶ 62, 69.

71. **Disputed**. Sanofi disputes that Mylan never contracted to sell EpiPen at a price that was below its manufacturing costs. Mylan misclassified the EpiPen for nearly a decade, which allowed it to offer steep discounts on commercial products without concern that it would impact Mylan's Medicaid pricing. *See* Sanofi Opp-RSMF ¶ 54. Mylan's experts admitted in their depositions [redacted]

[redacted] Ex. 161 at 327:12-329:22; Ex. 122 at 54. Moreover, the Inspector General found that taxpayers may have overpaid for the EpiPen by as much as $1.27 billion over 10 years due to Mylan's Medicaid Misclassification. Ex. 162.

72. **Disputed in part.** Mylan's chart depicting Auvi-Q as covered in yellow when a step edit or prior authorization was in place, and where Auvi-Q was [redacted] is misleading and fails to account for the Unique EAI Market and Mylan's monopoly power therein. *See* Sanofi Opp-RSMF ¶ 25. Mylan documents show that it considered Auvi-Q as "not covered" when it was excluded and also when a step therapy or prior authorization was in place. Ex. 163 at -397 (showing Auvi-Q as [redacted]).

75. **Disputed in part**. Sanofi disputes Mylan's descriptions of the PBM negotiations as described below in paragraphs 76-113.

76. **Disputed in part.** Sanofi disputes Mylan's assertion that Sanofi had an "initial strategy to offer minimal rebates for Auvi-Q" and "assum[ed] Auvi-Q would automatically qualify for at least T3 status." Sanofi's strategy for Auvi-Q had always been to secure insurance coverage with the largest payors in the United States by offering rebates on Auvi-Q that were consistent with payors' perspective that the EAI drug class has a low budget impact and deserves minimal utilization management. *See* Ex. 164 at slide 16 ("Pay[o]rs agreed that anaphylaxis is managed similarly to other life threatening diseases, but point out that the drug class has a low budget impact compared to asthma"). The only variable that Sanofi did not, and could not, account for was Mylan's anticompetitive strategy to foreclose competition in the EAI drug.

78. **Disputed in part.** Neither document on which Mylan relies supports its assertions that [redacted] nor that [redacted]

[redacted] Mylan ignores evidence suggesting that the reason [redacted] *See, e.g.*, Ex. 165. Mylan also omits that in over half of the columns in its [redacted] Ex. 166 at -928.

79. **Disputed in part.** Sanofi disputes Mylan's assertion that ESI [redacted] as Ex. 167 and Ex. 22 say no such thing. Moreover, Sanofi disputes Mylan's footnote 160 to the extent it contradicts its previous assertion that Sanofi offered [redacted]

80. **Disputed in part.** Mylan's assertions regarding non-EAI drugs are Immaterial and fail to account for the Unique EAI Market and Mylan's monopoly power therein.

83. **Disputed in part.** Sanofi disputes Mylan's assertion that "[n]either company responded to CVS's invitation to [redacted] This statement contradicts Mylan's internal documents showing that its former Director of Trade Relations, Thomas Theiss, "follow[ed] up with" CVS *three times* over the course of about two weeks, asking about "the possibility of an exclusive position for EpiPen." *See* Ex. 168 at -510. Indeed, Mylan's former Director of National Accounts, Nicole Willing, later (admittedly) lamented, [redacted] Ex. 169 at -441.

85. **Disputed in part.** Sanofi disputes Mylan's implication that it had not [redacted]

[redacted] Mylan's own documents highlight that a question of fact exists. *See* Ex. 170 at slide 22 (listing [redacted]). Ex. 171 also does not support Mylan's assertion that [redacted]

89. **Disputed in part.** Sanofi disputes Mylan's assertion to the extent it omits relevant testimony from OptumRx stating that [redacted] Ex. 132 at 331.

90. **Disputed in part.** Sanofi disputes Mylan's assertion to the extent it omits OptumRx testimony stating that for Auvi-Q, the rebate agreement's [redacted] *Id.* at 337:20-338:3.

95. **Disputed in part**. Sanofi disputes Mylan's assertion to the extent it omits that Mylan "tried to get Prime to exclude Auvi-Q and they did not bite." Ex. 172.

99. **Disputed in part**. Mylan was instrumental in forcing MedImpact to choose between EpiPen and Auvi-Q. *See*, *e.g.*, Ex. 58 at -219 ([redacted]).

100. **Disputed in part.** Mylan's assertion concerning its January 2013 offer to MedImpact is unsupported by the evidence cited.

102. **Disputed in part.** Mylan omits that in March 2013 it offered a maximum [redacted]

[redacted] *See* Ex. 173 at -031.

104. **Disputed in part.** Sanofi disputes that MedImpact [redacted] The record provides other evidence of MedImpact's decision, including that it told Sanofi that its decision was based on "the potential for disruption" and "observation of market adoption rates." *See* Ex. 174 at -551.

106. **Undisputed.** However, for some custom clients of MedImpact, Auvi-Q remained in a high copay tier or restricted position. *See* Ex. 175 at -338 (email describing MedImpact's custom client [redacted].

107. **Disputed in part.** Mylan's assertion is misleading, as it omits that the [redacted] Ex. 176 at -722.

108. **Disputed in part.** Mylan's assertion misleadingly omits that Mylan described its offer for the same period— [redacted] Ex. 177 at -011.

109. **Disputed in part.** Mylan omits that for the same period, it was only paying rebates of [redacted] access. Ex. 178 at -532.

110. **Disputed in part.** Sanofi disputes Mylan's assertion that Auvi-Q was covered on Cigna's [redacted] Ex. 179 at -052. Cigna's corporate representative testified that its Standard and Performance plans had the most membership and that

[redacted] Ex. 180 at 79:12-23. At no time between 2013 and 2015 was Auvi-Q listed on any [redacted] Ex. 179 at -052.

111. **Disputed in part.** Sanofi disputes Mylan's assertion that its [redacted] Ex. 181 at -291.

112. **Disputed in part.** Sanofi disputes that "Auvi-Q remained on T3 with no rebate agreement." While [redacted] Ex. 182 at -529.

113. **Disputed in part.** Mylan's assertion that payors "each made its own independent coverage decision based on the benefit goals of its members" is misleading. *See* Sanofi Opp-RSMF ¶ 62. Mylan also omits contrary evidence demonstrating payors believed that Auvi-Q was the best EAI drug device for its members, yet Mylan's deep, exclusionary rebates undermined their ability to cover Auvi-Q. *See, e.g.*, Ex. 183 at 64-66 (Mr. Stalas: "… [redacted]).

VI. "Sanofi's Successful Negotiations Improved Auvi-Q's 2015 Formulary Coverage"

114. **Disputed in part.** Mylan's assertion that it "changed tacks" and "embarked on a plan to [redacted] is misleading. Sanofi's plan for Auvi-Q had always been to secure [redacted] with the largest payors in the United States. *See*

Ex. 184. Mylan also ignores evidence demonstrating it increased Sanofi's costs by offering deep, unprecedented rebates to payors conditioned on their exclusion of Auvi-Q from insurance coverage. *See, e.g.*, Ex. 185 at -009 (Mylan email discussing [redacted]). Mylan understood that its EpiPen market share and volume meant payors could not forego the exorbitant rebate dollars that Mylan was offering to exclude Auvi-Q from formulary. *See, e.g.*, Ex. 22 at ¶¶ 76-82; Ex. 183 at 64-66 [redacted].

115. **Disputed in part.** Mylan's assertions are misleading and ignore language clarifying that Sanofi was responding to Mylan's exclusionary rebate offers:

> Mylan continues to be aggressive with their contracting and rebate offers. As previously identified as a risk, we received formal confirmation from ESI (-20% contribution of EAI TRXs) that Auvi-Q will not be covered at the start of 2014. There were several offers placed in front of ESI, but the highly aggressive Mylan offer included the requirement that Auvi-Q be removed from formulary. ESI has committed to continue negotiations in early 2014 and we will continue to leverage our organizational strengths/opportunity with the goal of regaining access by July.

Ex. 186 at -881; *see also* Ex. 118 at -528.

116. **Disputed in part.** Sanofi disputes Mylan's vague and misleading assertion that Sanofi secured access with payors when it was "aggressive." Mylan's exclusionary conduct forced

Sanofi to offer exorbitant rebates that even Mylan employees referred to as "ridiculous," just to secure formulary access. Ex. 187 ("From the payer side, we are hearing Sanofi is getting desperate and aggressive with bids for an exclusive position and even for equal status. ***Really demonstrates what a good job we've done locking them out***."); Ex. 188; Ex. 189 at 3. Auvi-Q's increased share in 2015 was very modest, and came at the cost of effectively giving Auvi-Q away, and Sanofi still could never overcome Mylan's exclusionary conduct. *See* Sanofi Opp-ASMF ¶ 48 ("Mylan's Exclusions Limit Auvi-Q's Growth"). Mylan overstates the purported success of Sanofi in 2015, as Auvi-Q lost [redacted] Ex. 30 at ¶ 169. Mylan's assertions regarding Auvi-Q securing exclusive coverage on a small ESI formulary is also misleading. *See* Ex. 190 at -511 ("Please note that the HP formulary is less than 2% of all ESI lives.").

117. **Disputed in part.** Mylan's assertion that Sanofi offering additional rebates (equating to nearly [redacted] to ESI) on [redacted], an insulin drug competing in a completely different market—on top of those Sanofi was offering for Auvi-Q—was a way for Sanofi to compete on a "level" playing field in the ***EAI market*** is misleading. *See* Ex. 207; Ex. 238. Rather, this was an "unprecedented" and "desperate" move by Sanofi to attempt to secure access for Auvi-Q. *See* Ex. 138 (Borneman 30(b)(1) Dep. Tr. at 138:18-139:7); *see also* Ex. 114 (Downey 30(b)(1) Dep. Tr. at 39:18-40:13) (Sanofi's offering up to [redacted] rebates plus additional points on [redacted] "still wasn't financially enough to move the needle" against EpiPen). As Sanofi's former Head of North America Anne Whitaker testified, smaller companies, without other products to financially leverage in other markets, would never be able to compete if this were permissible: [redacted]

[redacted] Ex. 191 at 237:5-11.

121. **Disputed in part.** Sanofi disputes Mylan's assertion that "[i]n 2015, Sanofi failed to obtain favorable coverage only when [redacted] Instead, the evidence shows that Mylan leveraged EpiPen's [redacted] into exclusive agreements that Sanofi could not contract around. *See* Ex. 22 at ¶¶ 76-82; Sanofi Opp-ASMF ¶ 28.

122. **Disputed in part.** Mylan's selective representation of Sanofi's rebate negotiations with MedImpact in 2014 is misleading. Mylan ignores the following language in Exhibit 211 from MedImpact demonstrating the power of Mylan's solidified monopoly power: [redacted] *See* Ex. 192 at -745.

123. **Disputed in part.** Mylan's assertions are misleading and omit that payors like Prime sought price protection and deeper discounts due to Mylan's [redacted] significantly increasing the WAC price of EpiPen before, during, and after Auvi-Q's launch. *See* Ex. 193 at -511; Sanofi Opp-ASMF ¶ 20; Ex. 22 at ¶ 125.

125. **Disputed in part.** Mylan's assertion that the graph in Sanofi's complaint "shows [redacted] is misleading. *See* Sanofi Opp-RSMF ¶¶ 116-117; Sanofi Opp-ASMF ¶ 48.

VII. "Role Of Market Share And Contestability Of EAI Demand"

126. **Disputed.** Mylan's assertion is misleading and ignores overwhelming evidence of EpiPen's entrenched demand. *See infra* at 65 ("Evidence of EpiPen's Entrenched Demand" Chart).

127. **Disputed in part.** Mylan's assertions are misleading and ignore contrary evidence, including testimony from its current CFO that it was [redacted] *See* Ex. 194 at 205:11-19 ([redacted]

[redacted]); *infra* at 65 ("Evidence of EpiPen's Entrenched Demand" Chart).

128. **Disputed in part.** Mylan's assertions regarding other, non-EAI devices and markets are Immaterial and fail to account for the Unique EAI Market and Mylan's monopoly power therein, and also EpiPen's entrenched demand. *See infra* at 65 ("Evidence of EpiPen's Non-Contestable Demand" Chart).

129. **Disputed in part.** Mylan's vague assertions regarding "how PBMs operate" are misleading and fail to account for the Unique EAI Market and Mylan's monopoly power therein, as well as EpiPen's entrenched demand. *See infra* at 65 ("Evidence of EpiPen's Non-Contestable Demand" Chart).

130. **Disputed in part.** Mylan's selective quoting in this paragraph and its proposition that [redacted] is misleading. For example, in Ex. 195 at -146, Mylan ignores that the entire quote reads, "Looks like Value [Formulary] is still holding share while ACF is all but gone." In other words, Mylan ignores that Ex. 195 ***supports*** Dr. Scott Morton's opinion that EpiPen had entrenched share between [redacted] through the second quarter of 2015. Ex. 30 at ¶¶ 82-87.

131. **Disputed in part.** Mylan's assertions regarding Auvi-Q securing exclusive coverage on a small ESI formulary are misleading. *See* Ex. 190 at -511 [redacted]; Ex. 30 at ¶¶ 79-81 (EpiPen maintained over 60% market share even while excluded on ESI's High Performance Formulary).

VIII. "Impact Of Rebate Negotiations"

132. **Disputed in part.** Mylan's misleading assertion omits the additional opinion of Dr. Scott Morton on total EAI output resulting from Auvi-Q's market, not from Mylan's conduct. *See* Ex. 30 at ¶ 40 ("It is a clearly established principle in the economic literature that, when a

differentiated product enters the market, particularly one that will depress prices, and creates a more competitive environment, output will increase. Accordingly, my opinion has not changed that, in a but-for world where Mylan had not engaged in the anticompetitive conduct described in my Initial Report, output would have been higher than it was in the actual world.").

133. **Disputed.** Mylan's assertion is misleading, as it omits that the EpiPen average net price [redacted] overall from 2013-2015, as well as for the remainder of 2015 beyond the first quarter. *See* Ex. 22 at Figure 8. Sanofi also disputes Mylan's assertion that its economic expert, Dr. Robert Willig, [redacted] Dr. Willig opined on Mylan's rebating practices lowering net EpiPen prices, but Sanofi contends, and the evidence supports, that the EpiPen net prices rose in the actual world from 2013-2015 with Mylan's anticompetitive conduct and remained higher relative to the but-for world without Mylan's anticompetitive conduct. *See id.* at ¶ 87. Sanofi therefore disputes Mylan's assertion that Dr. Scott Morton [redacted]

134. **Disputed.** Mylan's assertion that [redacted] is misleading. As explained by Dr. Scott Morton, EAI prices rose relative to the but-for world due to Mylan's anticompetitive conduct. *See* Ex. 30 at ¶ 40.

135. **Disputed in part.** Mylan's assertions regarding government investigations are unsupported by any evidence or citation. Mylan's opening of this door also is misleading, as Mylan omits that it recently agreed to pay $30 million to resolve an SEC probe related to the EpiPen. Ex.196. This is in addition to the $465 million False Claims Act settlement Mylan paid due to the same Medicaid Misclassification—a misclassification which Mylan's own witness acknowledged

provided Mylan the opportunity to rebate as it did on the commercial side. Ex. 93; Ex. 95.

IX. "EpiPen4Schools Program"

136. **Disputed in part.** Mylan's citations do not state that "Mylan has given away more than 1,000,000 free EpiPen products to schools." Moreover, Mylan's description is misleading, as it omits that the purpose was to [redacted] *See* Sanofi Opp-ASMF ¶ 36.

X. "Sanofi's Own Drug Rebates For Positioning And Exclusivity"

137. **Disputed in part**. Mylan's citations to Congressional testimony regarding rebates in general and/or for non-EAI products are misleading, Immaterial, and fail to account for the Unique EAI Market and Mylan's monopoly power therein.

138. **Disputed**. Mylan's assertion that Sanofi's or Mylan's rebating practices for EAIs are comparable to those for non-EAI devices is Immaterial, misleading, fails to account for the Unique EAI Market and Mylan's monopoly power therein, and is a False [redacted] Comparison. Sanofi also disputes Mylan's assertion that it "routinely offered [redacted]—which directly conflicts with Mylan's assertion in paragraph 56 of its brief that Sanofi's strategy at launch was to negotiate for tier three coverage. Sanofi only began offering so-called "ridiculous" rebates in an effort to secure formulary access after Mylan had successfully locked Auvi-Q out. *See* Ex. 187; Ex. 189 at 3.

139. **Disputed in part**. Mylan's assertion that Sanofi's or Mylan's rebating practices for EAIs are comparable to those for non-EAIs is Immaterial, misleading, fails to account for the Unique EAI Market and Mylan's monopoly power therein, and is a False [redacted] Comparison.

140. **Disputed in part**. Mylan's assertion that rebating practices for Auvi-Q are comparable to those for non-EAIs is Immaterial, misleading, fails to account for the Unique EAI Market and Mylan's monopoly power therein, and is a False [redacted] Comparison.

141. **Disputed**. Mylan's assertion that Sanofi's or Mylan's rebating practices for Auvi-Q are comparable to those for non-EAIs is Immaterial, misleading, fails to account for the Unique EAI Market and Mylan's monopoly power therein, and is a False [redacted] Comparison.

XI. "The Complete Class I Recall Of Auvi-Q And Sanofi's Return Of Rights"

142. **Disputed in part**. Sanofi disputes that its voluntary Class I recall "abruptly halted Auvi-Q's upward [] trajectory." As Lawrence Stevens, the only regulatory expert in this case, explains in his unchallenged expert report, Sanofi could have "easily overcome any challenges" related to the *voluntary* recall. Ex. 198 at ¶¶ 56–67; *id.* at ¶¶ 39-44 (discussing Class I recalls of EpiPen that Mylan has overcome).

144. **Disputed**. Sanofi disputes the date when it was [redacted] *See* Ex. 199.

146. **Disputed in part**. Mylan's assertions regarding the amount of time a Sanofi-driven relaunch would have taken are misleading, as they ignore evidence forecasting re-entry within 9-12 months. Ex. 200 at slides 3-4; Ex. 198 at ¶ 64 (concluding that "Sanofi clearly had the ability and the capacity to relaunch and certainly could have done it sooner than kaleo"); *see also* Ex. 30 at ¶ 207 (evidence that Sanofi could have re-launched Auvi-Q in less than 14 months was consistent with interview with Dr. Huang). Mylan also ignores that while kaleo took 16 months to relaunch the product, Sanofi had the ability and capacity to relaunch sooner than kaleo because it already had a manufacturing line in place and an experienced sales team. Ex. 198 at ¶¶ 62-64. Mylan's assertions regarding the [redacted] are also misleading. *See* Ex. 30 at ¶ 165 (explaining how the four non-EAI products differ significantly from Auvi-Q). Instead, one of these products, Tysbari, generated $1.86 billion in sales in 2018. *See* Ex. 201.

147. **Disputed in part**. Mylan's assertions regarding Mr. Guenter's testimony on the

recall are misleading, as they omit testimony explaining that: [redacted] Ex. 116 at 358:17-359:15. Mylan also omits other testimony explaining that Mylan's conduct—not the voluntary recall—was the decisive factor in Sanofi's decision to return the Auvi-Q rights to kaleo. *See* Sanofi Opp-ASMF ¶ 53.

LEGAL STANDARD

Summary judgment is appropriate only when, after construing the evidence in the light most favorable to the non-moving party and drawing all reasonable inferences in its favor, "the movant shows that there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." *Tolan v. Cotton*, 572 U.S. 650, 656–57 (2014) (quoting Fed. R. Civ. P. 56(a)). The Supreme Court has made clear that "the evidence of [Sanofi] is to be believed" and "[Sanofi's] version of any disputed issue of fact is [] presumed correct." *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 456 (1992). Further, "[s]ummary judgment should not be used to prevent the necessary examination of conflicting testimony and credibility in the crucible of a trial." *Fisher v. Shamburg*, 624 F.2d 156, 162 (10th Cir. 1980). "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge[.]" *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

Additionally, in antitrust cases, "plaintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each." *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962). In evaluating claims under Section 2 of the Sherman Act, "it would not be proper to focus on

specific individual acts of an accused monopolist while refusing to consider their overall combined effect…. We are dealing with what has been called the 'synergistic effect' of the mixture of elements." *See City of Anaheim v. S. California Edison Co.*, 955 F.2d 1373, 1376 (9th Cir. 1992).

ARGUMENT

Sanofi's Section 2 claims contain two elements: (1) Mylan "possess[ed] monopoly power in the relevant market" and (2) Mylan willfully acquired or maintained its monopoly power through exclusionary or anticompetitive conduct. *United States v. Grinnell Corp.*, 384 U.S. 563 570-71 (1966). Mylan's motion concerns only the second fact-intensive element. Exclusionary conduct includes "behavior that not only (1) tends to impair the opportunities of rivals, but also (2) either does not further competition on the merits or does so in an unnecessarily restrictive way." *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 605 n.32 (1985). As set out below, the record is replete with evidence that Mylan engaged in a range of exclusionary conduct.

I. THERE IS VOLUMINOUS EVIDENCE FOR A JURY TO FIND THAT MYLAN ENGAGED IN UNLAWFUL EXCLUSIVE DEALING

In denying Mylan's Motion to Dismiss, this Court found that Sanofi's allegations supported an exclusive dealing claim in violation of Section 2 under the rule of reason. MTD Order at *8 (the Court must decide if "the 'probable effect' of 'performance of the contract will foreclose competition in a substantial share of the line of commerce affected'") (citing *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 327-29 (1961)). Sanofi has uncovered overwhelming evidence for a jury to find that Mylan's exclusive dealing substantially foreclosed Auvi-Q from the market.

A. Exclusive Dealing Cases Present Complex Issues For a Jury

As a preliminary matter, Mylan does not challenge—and thus concedes—that it entered into exclusive agreements. *See* Mylan MSJ at 61-62. Mylan also recognizes that "courts evaluate [exclusive dealing] under the rule of reason." *Id.* at 61. The rule of reason is a holistic analysis that "weighs all of the circumstances of a case in deciding whether a restrictive practice should be

prohibited[.]" *Continental T.V., Inc. v. GTE Sylvania, Inc.*, 433 U.S. 36, 49 (1977). Given the complicated and fact-intensive inquiries at play, courts typically find a trial necessary to adjudicate rule of reason cases. *See Roxul USA, Inc. v. Armstrong World Indus. Inc.*, 2019 WL 1109868, at *18 (D.Del. Mar. 2019) (denying summary judgment and applying rule of reason: "Combined with evidence of [defendant's] share of the market, a reasonable jury could credit [plaintiff's] evidence and decide Armstrong's exclusivity agreements prevent meaningful competition by its rivals."); *Complete Entm't. Res. LLC. v. Live Nation Entm't, Inc.*, 2017 WL 6512223, at *3 (C.D.Cal. Oct. 16, 2017) ("[G]iven the balancing inherent in a rule-of-reason analysis—this cannot be resolved by way of summary judgment."); *Meredith Corp. v. SESAC, LLC*, 1 F.Supp.3d 180, 196 (S.D.N.Y. 2014) ("The evidence would also comfortably sustain a finding that [plaintiff]…engaged in an overall anti-competitive course of conduct designed to eliminate meaningful competition[.]"). Nearly half of Mylan's cited cases passed summary judgment. This case also implicates many genuine issues of material fact that preclude summary judgment.

B. Courts Closely Scrutinize Monopolists—Like Mylan—for Exclusive Dealing

Mylan's exclusive agreements were anticompetitive, and its citations to generalized propositions that exclusive agreements ***can be*** procompetitive are unavailing. *See* Mylan MSJ at 61. As this Court explained, "[e]xclusive dealing arrangements are of ***special concern when imposed by a monopolist***." MTD Order at *8[3] (citing *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 271 (3d Cir. 2012)) (emphasis added). Indeed, 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 285. There is ample evidence for a jury to make that finding here.

Mylan has long occupied a "dominant position" in the U.S. EAI market with share from

[3] This Court previously stated that it "closely considers the law of the Third Circuit (where the Sanofi case originated)" and will be tried before a jury. *See* MTD Order, at *6 n.2 (citation omitted).

83% to virtually 100%. *See* Sanofi MSJ, at 46-49. Mylan did not even move on monopoly power. Given that "[a]n exclusive dealing arrangement is most likely to present a threat to competition in…a market that is highly concentrated," Mylan's long-standing monopoly in essentially [redacted] places Mylan's scheme in proper context. *See* Sanofi MSJ at 45-58.

As a result, this Court's decision in *Suture Express, Inc. v. Owens & Minor Distribution, Inc.*—which did ***not*** involve a monopolist and analyzed Section 1 tying claims—is not the proper analytic framework. 2016 WL 1377342, at *17, *19 (D.Kan. Apr. 7, 2016) ("[D]efendants are not monopolists."), *aff'd* 851 F.3d 1029 (10th Cir. 2017). Mylan also disregards material differences in the factual record. In *Suture Express*, there was robust competition among national and regional competitors as well as manufacturers. *Id.* at *9-11. The Court opined that: the "facts describe[d] a market rife with competitive rivals…growing and expanding their business while [defendants'] market shares ha[d] declined or remained relatively flat." *Id.* at *24. Here, Mylan was the dominant firm engaging in conduct to prevent Sanofi from gaining a foothold. And prior "rivals" never posed any real threat to EpiPen. *See* Sanofi MSJ-SMF at ¶ 41. Also, contrary to this case where barriers to entry are high and EpiPen's entrenched demand hampered switching, *see infra* at 61-62, in *Suture Express* the "record [wa]s filled with examples of customers who, in fact, ha[d] switched distributors on a regular basis." 2016 WL 1377342, at *22. *Suture Express* is therefore inapposite.

C. There Is Overwhelming Evidence that Mylan's Exclusionary Contracts With PBMs and Payors Were Anticompetitive

Courts routinely recognize that "if the defendant occupies a dominant position in the market"—as Mylan does in the U.S. EAI drug device market—"its exclusive dealing arrangements invariably have the power to exclude rivals." *ZF Meritor*, 696 F.3d at 284; *see also United States v. Dentsply, Int'l Inc.*, 399 F.3d 181, 191 (3d Cir. 2005) (finding for plaintiff after trial); *United States v. Microsoft Corp.*, 253 F.3d 34, 70 (D.C. Cir. 2001) (same); *McWane, Inc. v. FTC*, 783

F.3d 814, 832 (11th Cir. 2015) (same). In these situations, competitors are driven out "***not because they cannot compete on a price basis, but because they are never given an opportunity to compete, despite their ability to offer products with significant customer demand***." *ZF Meritor*, 696 F.3d at 281 (emphasis added). At the pleadings stage, this Court summarized Sanofi's key allegations of Mylan's scheme, finding that they could amount to exclusive dealing. MTD Order at *7, 10. In discovery, Sanofi uncovered voluminous evidence supporting its allegations.

1. Mylan Deliberately Implemented a Company-Wide Scheme to Exclude Auvi-Q from the Highly Concentrated EAI Drug Device Market

Discovery revealed that "Mylan had no legitimate business purpose for offering [its] large rebates but used the program, instead, to ***block a new entrant—Auvi-Q—from the market*** and to protect its 90%-plus market share." MTD Order at *7 (emphasis added). Courts deny summary judgment where "Plaintiffs present ample evidence that [defendants] intended to use their exclusive [] contracts to do just that—to exclude rivals." *Dial Corp. v. News Corp.*, 165 F.Supp.3d 25, 37 (S.D.N.Y. 2016); *see also Minn. Mining & Mfg. Co. v. Appleton Papers, Inc.*, 35 F.Supp.2d 1138, 1146 (D.Minn. 1999) (denying summary judgment). This Court should do the same.

Before Auvi-Q's launch, Mylan's contracts with payors rarely referenced prior rivals. Sanofi Opp-ASMF ¶ 27. Mylan provided [redacted] rebate offers—[redacted] *Id.* [redacted] *See* Ex. 203 ([redacted]). That all changed when Auvi-Q threatened Mylan's long-standing monopoly. As observed by Mylan at the time, [redacted] Sanofi Opp-ASMF ¶ 11.

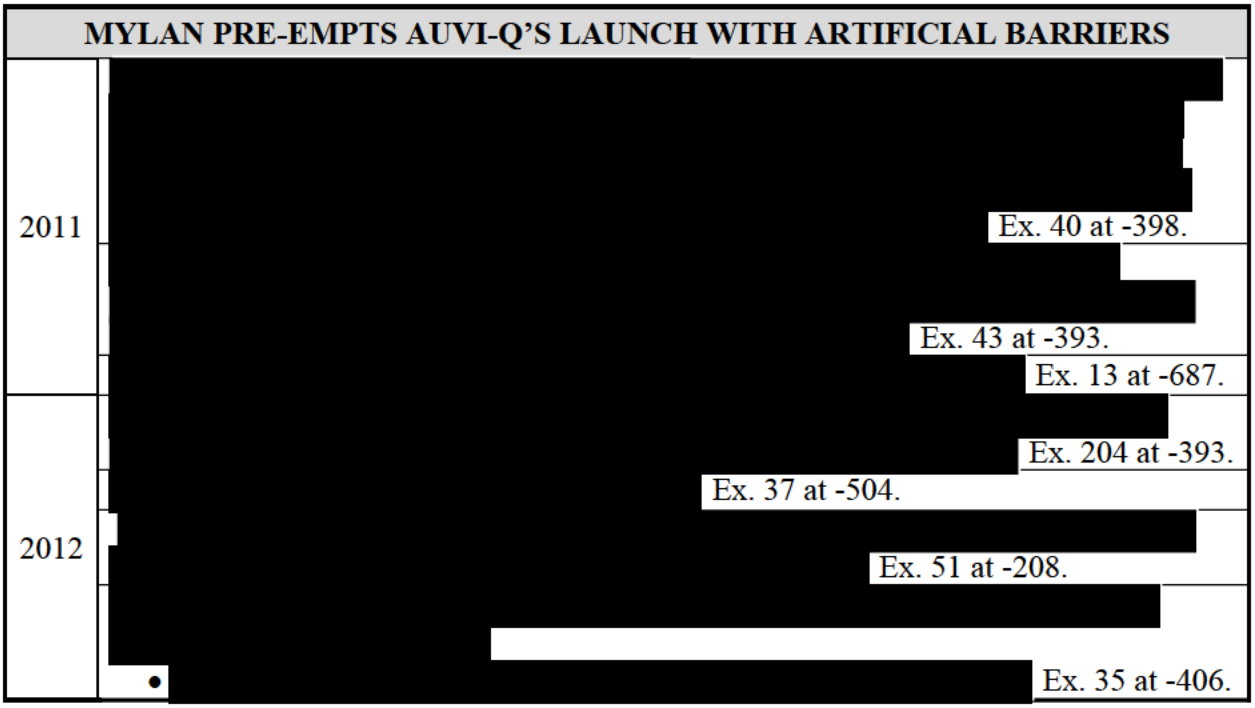
[redacted]

[redacted]

[redacted] *Id.* at ¶¶ 24-26. The record shows a company-wide directive from Mylan's then-CEO and now Chairman, instructing employees to [redacted] Ex. 38. As explained by Mylan's documents: [redacted]

[redacted] Sanofi Opp-ASMF ¶ 25. Mylan proactively began "to identify opportunities to restructure [its] contracts for ***exclusivity*** language," and to "negotiate, where possible, language requiring plans to put EpiPen in sole preferred position[.]" *Id.* at ¶ 24. Mylan's goal was to ***disadvantage Auvi-Q*** on formularies by "[e]ncourag[ing] pay[o]rs to require prior authorization on e-cue" and by "explor[ing] benefit exclusions with pay[o]rs" for Auvi-Q. Ex. 30 at ¶ 98. And that is precisely what Mylan did.

Overwhelming evidence from Mylan's own files and testimony illustrate Mylan's dramatic shift in contracting to target and exclude Auvi-Q:



As the next step, Mylan artificially raised EpiPen's WAC price so that it could offer much

larger discounts to payors to convince them to exclude Auvi-Q—at the same time that EpiPen profits spiked. Sanofi Opp-ASMF ¶ 20. Mylan sought its consultants' feedback on price increases:

[redacted]

Sanofi Opp-ASMF ¶ 19. [redacted] Sanofi Opp-RSMF ¶ 26. [redacted] Sanofi Opp-ASMF ¶ 19. [redacted] *Id.* This was unprecedented based on past EpiPen price increases. [redacted] Ex. 27 at slide 15 ([redacted]).

2. Mylan's Justification for Its Exclusionary Contracts Was to Block Auvi-Q

The record is devoid of any legitimate business justification for Mylan's exclusionary scheme; its sole purpose was to prevent Auvi-Q from gaining a foothold in order to preserve its monopoly. Not a single Mylan fact or expert witness even proffered a pre-textual business justification for these exclusive agreements. Mylan is well aware of the effects of monopolistic conduct on a new pharmaceutical rival, arguing elsewhere that "[a]ny preemptive blocking…of Mylan's launch would seriously and irreparably harm Mylan." *In re Restasis Antitrust Litig.*, No. 18-02819, ECF 169 (E.D.N.Y. Oct. 31, 2018). In this case, Mylan has "perfected the monopoly

power to exclude competitors." *Grinnell*, 384 U.S. at 576 (affirming Section 2 liability for "restrictive agreements that pre-empted" competition and other anticompetitive conduct).

Since Mylan's documents are littered with evidence of its scheme to exclude Auvi-Q, Mylan argues that intent is irrelevant and should be shielded from this Court. Mylan is wrong. "The Supreme Court has made clear that ***intent is relevant to proving monopolization***." *LePage's, Inc. v. 3M*, 324 F.3d 141, 163 (3d Cir. 2003) (emphasis added); *see also Aspen Skiing*, 472 U.S. at 602 (considering intent because "no monopolist monopolizes unconscious of what he is doing"). Courts consider "evidence of intent" to determine "the question of whether the challenged conduct is fairly characterized as exclusionary or anticompetitive." *Dial Corp.*, 165 F.Supp.3d at 36. Mylan's cited authority, *Race Tires America Inc. v. Hoosier Racing Tire Corp.*, even recognizes that "resolution of a summary judgment motion is often an especially difficult task in the antitrust context, particularly in light of the inherent factual complexities typically involved as well as the ***paramount importance of motive and intent in the legal analysis***." 614 F.3d 57, 73 (3d Cir. 2010) (emphasis added). Here, there is substantial evidence for a jury to conclude that Mylan's "business purpose" was to block a new entrant through an anticompetitive strategy. Here are just a few examples of the "colorful" language that Mylan tries to write off as mere [redacted]

Make Auvi-q our B*&^% ...let's drive that to 0 !!!

Foot on their throat.....

Ex. 161 at 63:13-64:14; Ex. 205; Ex. 206. [redacted]

[redacted] Ex. 161 at 63:14-64:14.

Mylan's citations to a handful of authorities outside of this context are unhelpful.[4] And,

[4] *See SCFC ILC, Inc. v. Visa USA, Inc.*, 36 F.3d 958, 969 (10th Cir. 1994) (joint venture case: the "central antitrust question posed" under Section 1 is not intent but "whether the alleged restraint is reasonably related" to the conduct); *A.A. Poultry Farms, Inc. v. Rose Acre Farms, Inc.*, 881 F.2d 1396, 1402 (7th Cir. 1989) ("[W]e now hold that intent is not a basis of liability (or a ground for inferring the existence of such a basis) in a predatory pricing case[.]").

Mylan misconstrues this Court's reasoning in *Suture Express* about the Court's inability to find ***monopoly power*** from intent. Mylan MSJ at 75. But Mylan has monopoly power here. *See* Sanofi MSJ at 45-52. Mylan also ignores this Court's cite in *Suture Express* to *Board of Trade of City of Chicago v. United States*, 246 U.S. 231, 238 (1918), that "knowledge of intent may help the court to interpret facts and to predict consequences." At the very least, intent sheds light on Mylan's actions for a jury to determine if Mylan's commercial practices were anticompetitive.

3. Mylan's Contracts Offered Significant, Unprecedented Discounts "Expressly Conditioned" on the Exclusion of Auvi-Q

Turning to Mylan's contracting scheme, Sanofi alleged—and this Court found sufficiently pled—that Mylan "offer[ed] unprecedented rebates to third-party payors (30% or higher) ***but expressly conditioned those rebates on excluding Auvi-Q***." MTD Order at *7 (emphasis added). Sanofi has adduced overwhelming evidence in support of this core allegation.

After Auvi-Q's launch, Mylan, [redacted] Ex. 56. [redacted] as explained by numerous Mylan documents. *See* Ex. 159; Ex. 209 [redacted]. Whereas Mylan typically offered [redacted] rebates for formulary access before 2013, Mylan changed course upon Auvi-Q's launch to offer significantly higher rebates and price protection ***contingent on Auvi-Q's exclusion***. As shown by Dr. Scott Morton, the average discount offered by Mylan to large PBMs to exclude Auvi-Q while on the market was [redacted][5] And that discount increased substantially for Mylan's 2014 and 2015

[5] Ex. 30 at ¶ 146. Dr. Scott Morton calculated the discount percentage as the total value of rebates, administration fees, and price protection for 17 of Mylan's contracts from 2013 to 2015 with Aetna, Cigna, CVS, Express Scripts, MedImpact, Optum, and Prime. *See id.* at Fig. 3A.

contracts. Compare, for example, Mylan's contract with Optum before and after Auvi-Q's entry:

- **PRE AUVI-Q: 2010 Contract** (Ex. 210 at -791)
  - [redacted]
  - [redacted]
- **POST AUVI-Q: 2015 Contract** (Ex. 211 at -729)
  - [redacted]
  - [redacted]

Mylan's exclusive contracts targeting Auvi-Q (the new branded EAI) became standard practice:

MYLAN'S CONTRACTS DISADVANTAGING RIVALS, SPECIFICALLY AUVI-Q	
Aetna	[redacted] Ex. 212 at -245.
Coventry	[redacted] Ex. 213.
Express Scripts	[redacted] Ex. 166 at -928.
MedImpact	[redacted] Ex. 214 at -316.
Wellpoint	[redacted] Ex. 215 at -919.

Dr. Scott Morton explained why Mylan's contracts targeting Auvi-Q are anticompetitive:

> Contracts that reference rivals such as those used by Mylan raise concerns because they directly raise the cost of rivals by "taxing" transactions between the monopolist's customers and the rival and make them more expensive for the customer. Ex. 22 at ¶ 111.

Unable to dispute this evidence from which a jury could find unlawful exclusive dealing, Mylan draws false comparisons to *Eisai Inc. v. Sanofi-Aventis U.S., LLC*. *See* Mylan MSJ, at 56-57. As this Court previously recognized, "*Eisai* involved different facts." MTD Order at n.3. Mylan incorrectly claims that "as in *Eisai*, the only 'penalty' for including Auvi-Q on formulary was a lower discount." Mylan MSJ at 69. But as the district court and Third Circuit recognized, there was no penalty for including competing products on formulary. In *Eisai*, the "terms of [Sanofi's] contracts ***did not prohibit hospitals from purchasing competitor [ ] drugs***." 2014 WL 1343254,

at *26 (D.N.J. Mar. 28, 2014) (emphasis added); *see also Eisai Inc. v. Sanofi-Aventis U.S. LLC*, 821 F.3d 394, 400 (3d Cir. 2016) (affirming in part). Contrary to Mylan's EpiPen contracts, *Eisai* involved a "market share discount" that "required ***equal treatment*** for Lovenox® only and did not restrict the ability of hospitals to place Fragmin® on their formularies." 2014 WL 1343254, at *29. Put simply, Sanofi's contracts did not require hospitals to exclude or restrict competitors. That stands in stark contrast to Mylan's contracts in this case.

The same is true for *Concord Boat v. Brunswick Corp.* as the "discount programs were not exclusive dealing contracts and its customers were not required to…refrain from purchasing competitors in order to receive the discount." 207 F.3d 1039, 1062-63 (8th Cir. 2000). The court in *Eisai* even stressed this distinction: "The Eighth Circuit in *Concord Boat* similarly concluded that market-share and volume discounts…that did not preclude buyers from purchasing from competitors did not violate antitrust laws." *Eisai*, 2014 WL 1343254 at *35. If anything, Mylan's cited cases underscore why summary judgment is inappropriate on this record.

4. Mylan's Comparisons to Other Drug Products are Misguided

Mylan's attempted comparison to Sanofi's practices for [redacted] are also misguided as a matter of fact and law. First, Sanofi did not proactively seek or push for exclusivity on [redacted] Sanofi typically offered market access rebates, allowing up to "four products" on formulary. *See* Sanofi Opp-RSMF ¶ 31. In fact, [redacted] had preferred formulary status on nearly all of the top ten formularies for 2014 and 2015. *Id.* And not only does the [redacted] but so does the relevant market, number of competing drugs, market shares, and degree of competition—all of which must be considered on a "case-by-case basis" for a monopolization claim. *See Armstrong*, 2019 WL 1109868, at *11 ("We are not similarly persuaded by cases evaluating other strategies in other markets."). Further, as Mylan made clear in a case where it was the plaintiff: "what Mylan [as ***plaintiff***] does is not a defense to

what [***defendant***] does, and ***there is no in pari delicto defense in antitrust***." Ex. 216 at 51:9-11.

D. A Jury Could Reasonably Find that Mylan Exploited and Increased EpiPen's Entrenched Demand to Exclude Auvi-Q

As explained by Dr. Scott Morton, "non-contestable" or "entrenched" demand is the "portion of the market that—even in the face of entry of an alternative—will not switch away from the incumbent's product, at least in the shorter term." Ex. 22 at ¶ 76. This is basic economics: a portion of the demand for EpiPen is inelastic meaning that it is "sticky" and not sensitive to changes in EpiPen's price or the availability of alternatives. *Id.* And due to the uniqueness of EAIs, "switching from one EAI device to another is very different from substituting between one pill and another—EAI devices are differentiated products." Ex. 30 at ¶ 72.

Notably, Mylan's economic expert, Dr. Willig, acknowledged in his scholarship—before he was retained by Mylan—that entrenched demand can cause anticompetitive harm if leveraged by a monopolist. *See* Ex. 217. Dr. Willig analyzed the FTC's case against Intel, concluding that "[b]ecause Intel consistently has enjoyed a microprocessor market share of over 75%, any such lock-in effect will strongly favor Intel…The share of [] purchases locked into Intel microprocessors at any given point in time ***cannot be contested effectively*** by AMD." *Id.* Mylan cites Professor Hovenkamp questioning non-contestable demand in the context of this FTC action, Mylan MSJ at 78, but it conspicuously omits any mention of their own Dr. Willig's article on this subject. Thus, Mylan cannot credibly argue that EpiPen's non-contestable demand is irrelevant.

Next, Mylan argues that entrenched demand is "fickle" and "simply a result of "ephemeral customer preference." Mylan MSJ at 77-78. But Mylan's own admissions undermine this claim. In a public judicial filing to enjoin the state of West Virginia from switching Medicaid patients to Auvi-Q, Mylan's Senior Director of Global Medical Affairs swore in an affidavit that "substitution of one EAI for another presents a distinct concern for patient safety" because "each of the distinct

currently-marketed EAIs is visually and physically different," and they are used in stressful emergency situations. *See* Ex 129 at 6. Likewise, in an attempt to downplay consumer harm from a delayed EpiPen generic, Mylan argued to this Court in the *Class Case* that "patients already comfortable with the EpiPen device may be reluctant to switch." ECF No. 1623, at 3; *see also id.* at 7 ("Dr. Blaiss has seen patients reluctant to switch from one EAI to another numerous times in practice …most of them felt very comfortable with their EpiPen and that the school's trained and the grandparents are trained, etc., and they didn't want to switch."). At a public conference, Mylan also touted the difficulty for any EAI, even a generic, to shift this entrenched share from EpiPen:

> "We believe that given the brand equity, given the fact that you only renew a script for EpiPen one time per year, not every single month, given the importance of the product for it being used in a life-saving situation, we don't believe that even in a situation where a competitor was to receive a generic approval that the uptake would be anything near let's say a typical oral solid dose product generic uptake." Ex. 218 at 7.

At best, Mylan raises a fact dispute by contesting the weight of the evidence supporting EpiPen's entrenched demand. As Mylan put it, "Sanofi relies on only a few pieces of evidence out of the hundreds of thousands of documents produced in this case[, n]one [of which] is convincing." Mylan MSJ at 79. Whether evidence is "convincing" is the province of the jury. Nevertheless, here there is a surplus of evidence.

A jury could reasonably conclude from the evidence that EpiPen's non-contestable share is [redacted] of the EAI market, as calculated by Dr. Scott Morton. *See* Ex. 22 at ¶¶ 151-153. Mylan knew that PBMs were concerned with significant "patient disruption" if EpiPen was excluded because they could not realistically shift patients quickly or easily to a new EAI—no matter how large the PBM. Mylan therefore leveraged EpiPen's demand in its negotiations:

[redacted]

[redacted] Ex. 58 at -219.

Mylan's internal estimate that it would retain a [redacted] is consistent with Dr. Scott Morton's figure.[6] Tellingly, Mylan's expert Dr. Willig ignored a 2008 example, in line with the above evidence, that EpiPen kept a ***majority share*** at a large payor , United, when Twinject briefly secured an exclusive formulary position over EpiPen. Ex. 161 at 161:19-164:24.

Instead, the great weight of evidence, summarized below, shows a reasonable jury could conclude that due to Mylan's "position as the dominant supplier" of EpiPen, "no [Payor] could satisfy customer demand without at least" some affordable access to EpiPen, "and therefore no [Payor] could afford to lose" Mylan as a supplier. *ZF Meritor,* 696 F.3d at 283.

EVIDENCE OF EPIPEN'S ENTRENCHED DEMAND

[redacted] Ex. 219.

[redacted] Ex. 220 at -255.

[redacted] Ex. 59, -61.

[redacted] Ex. 58 at -218.

[redacted] Ex. 45 (Jordan Dep.) at 133:5-11.

[redacted] Ex. 32 (May Dep.) at 163:19, 237:21-238:01.

[redacted] Ex. 183 at 64.

"[P]hysicians are familiar with... EpiPen, because it had been in the market by Dey for at least in the late '90s. There is a lot of familiarity with the product. And because of familiarity,

[6] Mylan argues that Mr. Foster's talking points are irrelevant [redacted] *See* Mylan MSJ at 79. But the entire purpose of Mr. Foster's pitch was to convince MedImpact to choose EpiPen ***over Auvi-Q*** in its ***commercial formulary*** because of the share that EpiPen would retain even if blocked from formulary. In any event, Mylan's attack on its own modeling is a factual dispute for the jury to decide.

EVIDENCE OF EPIPEN'S ENTRENCHED DEMAND
doctors are very comfortable with the product when they write for that. New products to the market, the Impax product, Auvi-Q, and others, they are a little different. And ***sometimes it is easier to just go with what you know***…than to use a new product and train someone … on a newer device." Ex. 221 (Magellan Dep.) at 48:18-49:09.
[redacted] Ex. 26 at slide 13.

E. Mylan Did Not Out-Compete Sanofi on the Merits

Mylan claims that it out-competed Sanofi because Auvi-Q cost more and Sanofi did not offer the terms or prices that payors wanted. *See* Mylan MSJ at 57-58. Mylan is wrong, and these hotly disputed fact-intensive arguments are inappropriate for summary judgment.

1. Auvi-Q Exceeded Mylan's Expectations Until Its Exclusion Took Effect

[redacted] *See* Ex. 22 at ¶ 171. Mylan was alarmed that [redacted] Ex. 223 at slide 1, [redacted] Ex. 224 at slide 13. In mid-2013, [redacted] Ex. 225 at slide 20; *see also* Ex. 226 at -454 [redacted]. Mylan panicked that [redacted] Ex. 227 at -105. Mylan even prepared talking points for its Board of Directors, [redacted] Ex. 228 at -934. Mylan's own damages expert, Dr. Ordover, observed in his report that [redacted] Ex. 229 ¶ 42.

Auvi-Q's initial success halted when Mylan's anticompetitive efforts paid off. Threatened by Auvi-Q's share gains, Mylan doubled its efforts to secure exclusion. As the President of Mylan Specialty said, [redacted]

[redacted] Ex. 230 at -458. And that is exactly what Mylan did. By 2014, more of Mylan's exclusive contracts with the largest payors kicked in, and Sanofi's share plummeted. *See* Ex. 202 at -416 [redacted]. Sanofi gained back a little share in 2015, but it could not overcome Mylan's exclusionary conduct. *See* Sanofi Opp-ASMF ¶ 48.

Absent Mylan's unlawful conduct, Sanofi's sales and share would have continued to increase with access, surpassing a "critical level" and becoming a meaningful choice for patients. *See Microsoft*, 253 F.3d at 71 ("Microsoft's deals…help keep usage of Navigator below the critical level necessary for Navigator or any other rival to pose a real threat to Microsoft's monopoly."). Courts "have found monopolists liable for anticompetitive conduct where…the targeted rival gained market share—but less than it likely would have absent the conduct." *McWane*, 783 F.3d at 838; *Conwood Co. L.P. v. U.S. Tobacco Co.*, 290 F.3d 768, 789 (6th Cir. 2002) (affirming jury verdict where plaintiff's "market share did grow slightly between 1990 and 1998"). As in *Microsoft*, *McWane*, and *Conwood*, a trial is warranted to render a determination if Mylan's exclusive dealing had the same anticompetitive effect on Sanofi.

2. Sanofi Competed Hard But Mylan Leveraged Its Volume to Block Auvi-Q

Mylan's false narrative is that Auvi-Q lost because payors compared rebates and net prices on a per-EAI unit basis and chose EpiPen. Mylan MSJ at 57. But there is substantial evidence that payors considered their ***total cost*** for purchasing all EAIs—EpiPen, Auvi-Q, or both—and Mylan leveraged EpiPen's entrenched demand to tilt the playing field decidedly in Mylan's favor.

ESI testified that it has [redacted] Ex. 231 at 135:08-13. Considering their total cost, MedImpact explained that [redacted]

[redacted] Ex. 232 at -791. Anthem likewise said, [redacted] Ex. 31 at 293:1-5.

Mylan artificially structured its contracts to negatively impact payors by increasing their total costs if they covered Auvi-Q. Mylan only offered payors 30% or higher rebates (with price protection and administrative fees) if Auvi-Q was excluded. *See supra* at 60-62. If a payer covered Auvi-Q and gave patients a choice, then the payor forfeited Mylan's significant discount. But the payor would still need to buy the [redacted] of EpiPen volume that was non-contestable—and now it would be at a much higher cost. Ex. 22 ¶¶ 118, 151. Mylan's contracts thus imposed a "large penalty" on Auvi-Q. Ex. 137 at 372:5-9. With the payor having to reimburse Mylan for the non-contestable EpiPen volume at near-WAC price, Dr. Scott Morton calculated the burden imposed on Sanofi (the "Effective Entrant Burden") to overcome Mylan's contracts. *Id.* at ¶¶ 158-64. She concluded that Mylan's contracts "required Sanofi to offer much higher rebates on Auvi-Q just to try to forestall being excluded from PBM formularies," and in some cases to give away "almost the entire value of the product." *Id.* at ¶¶ 164, 166. After gaining insight into Mylan's contracting strategy, Sanofi concluded in 2014 that [redacted] Ex. 121 at 471. Sanofi "simply could not provide dealers with a comparable economic incentive to switch." *Dentsply*, 399 F.3d at 195.

Despite an uneven playing field, Sanofi still offered aggressive rebates and discounts to try to gain favorable, or any, access for Auvi-Q. Mylan's claim that it universally provided better offers is disputed. For example, Sanofi [redacted] *See* Exs. 233, 234, 258. The big difference, however, was that Sanofi [redacted]

[redacted] Ex. 235 at -398. [redacted] Ex. 189 at -735. In Mylan's own words, [redacted] Ex. 188. The evidence shows this was due to Mylan leveraging EpiPen's non-contestable demand.

Ultimately, to get any formulary access for Auvi-Q, Sanofi had to offer rebates on ***other products in other drug classes***. Mylan's version that Sanofi simply increased its discounting for 2015 [redacted] *See* Ex. 237 at -816 ("The [redacted] is predicated on ESI removing Auvi-Q from the exclusions list 7/1/2014."). Sanofi also paid these rebates on [redacted] for its 2015 contract with ESI, which equated to nearly [redacted]. Ex. 207; Ex. 238 at -870. [redacted] *See* Ex. 138 (Borneman 30(b)(1) Dep. Tr. at 138:18-139:7); Ex. 114 (Downey 30(b)(1) Dep. Tr. at 39:18-40:13). But as Mylan, summed up, "[f]rom the payer side, we are hearing Sanofi is ***getting desperate*** and aggressive with bids for an exclusive position and even for equal status. ***Really demonstrates what a good job we've done locking them out***." Ex. 187 at -665. Even with [redacted] rebates, Auvi-Q was still excluded from a substantial portion of the market in 2015, and its share remained flat. Mylan thus did not out-compete Sanofi on price, but succeeded through an exclusionary contracting strategy that "block[ed] access to the key dealers." *Dentsply*, 399 F.3d at 189 (reversing and entering judgment against the monopolist).

3. Mylan Used Its Ill-Gotten Gains from Defrauding Medicaid to Fund Its Unprecedented Commercial Rebates to Exclude Auvi-Q

Notably, one significant reason why Mylan could offer such high commercial rebates for EpiPen was due to its Medicaid misclassification. Mylan explained in 2016 to Optum:

[redacted]

Ex. 95 at -769. In other words, if Mylan had properly classified EpiPen, it never could have offered the commercial rebates that it did. But due to Mylan's illegal conduct, it had an unfair and improper advantage. As DOJ explained in announcing the $465 million settlement with Mylan, Mylan's conduct prevented a "level playing field for pharmaceutical companies." *See* Ex. 93 at 1.

F. Mylan Pushed Contingent Rebates and Price Protection to Coerce PBMs and Payors into Exclusive Contracts at the Expense of Patients

1. Mylan Is Responsible for Its Anticompetitive Conduct, Not Payors

While Mylan attributes its success to its proactive and exclusionary strategy in its internal documents, *see* Sanofi Opp-ASMF ¶¶ 24-28, Mylan now blames the pharmaceutical industry for a conveniently-timed "shift toward increased formulary management…***right as Auvi-Q was coming to market***." Mylan MSJ at 70 (emphasis added). But Mylan disregards the unique characteristics of EAIs that made this drug class unfit for formulary management that would limit treatment options to one EAI. *See* Ex. 148 at slide 4 [redacted]. Unlike therapies for chronic conditions where a patient can try one product and then switch to another if it fails, EAIs are for emergency situations. *See* Ex. 3 at ¶ 38. [redacted] Ex. 15 at 62:7-8. That is why one payor stated in 2013, [redacted] Ex. 135 at -367. EAIs require training and familiarity by patients and caregivers; they are an inappropriate class for

Mylan's exclusive contracts given the life-threatening nature of anaphylaxis and the need for an EAI in an emergency. Yet Mylan entered into these exclusive contracts and admits it.

Mylan also tries to point the finger at payors, claiming they demanded exclusivity and "Mylan cannot be condemned…when ***customers*** requested it." Mylan MSJ at 67-70 (emphasis added). But even if payors asked for an exclusive offer, they are "middlemen." *See Complete Entm't*, 2017 WL 6512223, at *3 n.5 (denying summary judgment: "[O]ne cannot simply assume that [third parties'] voluntary economic choices will prevent anticompetitive harm to…consumers"). In this case, the consumers are patients, children, and caregivers who need an EAI drug device, and they were the ones deprived of a meaningful choice. Mylan's Executive Chairman, Robert Coury, agreed that [redacted] Ex. 239 at 165:25-166:2. Mylan's argument is thus nothing more than a distraction from the harm it caused to the real consumers—patients.

In any event, Mylan's claim that Auvi-Q's exclusion was driven by payors is undermined by the record. One payor expressly testified, "I don't believe we were seeking out exclusive offers." Ex. 31 at 280:11-12. And there is ample evidence that Mylan pushed for exclusivity even when PBMs said no. "[I]n the absence of such competition, a dominant firm can impose exclusive deals on downstream dealers to strengthen or prolong its market position." *McWane*, 783 F.3d at 827. That is precisely what happened here. It is neither new nor groundbreaking that payors wanted higher discounts; but Mylan took advantage of their requests to coerce them into exclusivity.

Indeed, [redacted] Ex. 150. [redacted] Ex. 31 at 197:7-11. [redacted]

[redacted] Ex. 15 at 63:21-64:3. As one Mylan employee even more succinctly stated: "We will ***only pay rebates if a client is willing to exclude Auvi-Q***." Ex. 240.

At best, Mylan's revisionist history—that it merely "took the initiative to offer certain Payors bids for exclusivity," Mylan MSJ at 67—presents the jury with a factual dispute. These post-hoc rationalizations cannot sweep away the abundant evidence that Mylan continuously pushed for exclusivity, implementing its well-planned scheme. Even in instances where payors covered Auvi-Q, [redacted] For example, when [redacted] Ex. 241. [redacted] Ex. 248 at -51. The story is the same with ESI. [redacted] Ex. 57.

As an additional inducement, having artificially raised EpiPen's price to create room to rebate conditioned on Auvi-Q's exclusion, Mylan offered price protection (a contractual cap) on future EpiPen price increases. Mylan knew full well that it would need to address this side effect of its anticompetitive scheme as payors began to react to EpiPen price increases. *See* Sanofi Opp-ASMF ¶ 18. Mylan knew that it would keep increasing prices and that [redacted] Ex. 149. Against the backdrop of past and future price increases, Mylan made the choice clear for payors: [redacted] Ex. 142 at -481. Mylan therefore used price protection as additional leverage to force payors into exclusivity.

Mylan's related contention that "[n]o payors complained about Mylan's exclusive offers" is false. MSJ at 69. Mylan made extensive efforts to push Prime into exclusivity despite Prime's repeated and expressed desire for an open formulary. Shortly after Auvi-Q's launch, [redacted] Ex. 243 at -26. [redacted] Ex. 244 at -304. [redacted] *See* Ex. 185 at -009. While Prime ultimately declined to exclude Auvi-Q, it was not for lack of Mylan's efforts. As Mylan's National Account Director, put it, [redacted] Ex. 172 at -47.

To highlight just a few more examples of Mylan's continued push for exclusivity:

MYLAN PUSHED PBMS AND PAYORS TO EXCLUDE AUVI-Q	
Aetna	[redacted] Ex. 41 at -562.
Anthem	[redacted] Ex. 149 at -648.
BCBS Illinois	[redacted] x. 49.
CVS/ Caremark	[redacted] Ex. 168 at -509.
HealthPlus of Michigan	[redacted] Ex. 245 at -20.

Highmark	Ex. 246 at -83.
Humana	Ex. 52 at -04.
Unity Health Plans	Ex. 247 at -50.

2. Mylan Engaged in Other Forms of Coercion

There is ample evidence in the record for a jury to conclude that Mylan used other tactics to coerce payors into exclusive contracts. First, Mylan threatened to withdraw all EpiPen discounts if the PBM refused exclusivity. As Mylan explained during negotiations with MedImpact:

Ex. 58 at -219.

Ex. 160, -24.

Mylan's claim that it did not make "all or nothing" discounts is also specious. *See* Sanofi Opp-RSMF ¶ 78. Mylan's offers were so heavily weighted towards exclusion that they essentially functioned as "all-or-nothing" offers. *See* Ex. 166 . Mylan's rebates thus compelled payors "to maximize

their discounts by dealing exclusively with the dominant market player"—Mylan—as they could only obtain the most substantial discounts by excluding Auvi-Q. *LePage's*, 324 F.3d at 159.

Mylan cannot inoculate this anticompetitive behavior by citing *Race Tires*. *See* Mylan MSJ at 65-66. That case centers on a decision by "sanctioning bodies in the sport of dirt oval track racing" to adopt a "single tire rule," which the Court found had procompetitive justifications. *Race Tires*, 614 F.3d at 62. The Third Circuit stated that "the role played by sanctioning bodies…is of special importance here," and that "sports-related bodies should be given leeway with respect to their adoption of equipment requirements as well as their related decision to enter exclusive contracts with the respective suppliers." *Id.* at 63, 80. Neither Mylan nor the payors it seeks to blame are entitled to special deference under the antitrust laws. *See SESAC*, 1 F.Supp.3d at 220 ("[I]t is no answer that the development of the modern market…may not be SESAC's fault"). And as the Third Circuit flagged in *Race Tires*, the ***plaintiff*** proposed the very exclusivity that it then sued over. 614 F.3d at 67. That is most certainly not the case here. At stake are life-saving EAIs and a scheme hatched by Mylan—not Sanofi—to prevent patients from accessing Auvi-Q.

3. Mylan's EpiPen Contracts Resulted in a Continued and Durable Lock Out

Mylan also cannot excuse its exclusive dealing by arguing that the contracts were short-term. *See* Mylan MSJ at 62-64. First, it is not true: [redacted] *See, e.g.*, Ex. 249 at -52 [redacted]; Ex. 250 [redacted]; Ex. 251 at -547 [redacted]. And, as this Court noted, "duration is ***just one factor*** that courts consider when determining whether an exclusive dealing agreement harms competition." MTD Order at *17 (emphasis added). The Third Circuit and others have rejected Mylan's argument. *See McWane*, 783 F.3d at 833 (affirming violation even though defendant's program "was short-term and voluntary (rather than a binding contract of a longer

term)"); *Dentsply*, 399 F.3d at 194 (same). Mylan cites *Methodist Health Servs. Corp. v. OSF Healthcare Sys.*, 859 F.3d 408, 410 (7th Cir. 2017), but this Court already distinguished *Methodist*, "recogniz[ing] that an exclusive dealing arrangement can have 'dire consequences' if they drive competitors into bankruptcy and thus out of the market"—just as Sanofi was driven out here. MTD Order at *17 (citing *Methodist*, 859 F.3d at 410). Moreover, *Methodist* is distinguishable as it involved a competitive market with no evidence of harm to consumers. 859 F.3d at 411.

Here, the stated duration of Mylan's contracts is also not dispositive because it ignores the "reality of the marketplace" and that "the practical effect of [Mylan's contracts] was to make it economically infeasible for distributors to [] switch" to Auvi-Q. *McWane*, 783 F.3d at 834. As explained by Dr. Scott Morton, "[e]ven if the parties negotiate again shortly after they first reach agreement, if the circumstances have not changed, the outcome would continue to be that Mylan and the PBM agree to a contract that Sanofi cannot match." Ex. 30 ¶ 112. Thus, the "practical effect" was that Mylan continued to exclude Auvi-Q regardless of whether the contracts had a one or five-year term. [redacted] Ex. 252, -89. [redacted] Ex. 129 at 20, [redacted] It makes switching increasingly difficult as more patients become familiar with and entrenched on EpiPen.

Relatedly, both the record and Mylan's own arguments belie any contention that payors could realistically terminate their contracts at any time. [redacted] Mylan MSJ at ¶ 90. But if the contracts were truly meaningless, the payor could have accepted a new offer at any time. That did not happen, though, because of the realities at play in the EAI market, including EpiPen's entrenched demand. Despite the "legal ease with

which the relationship c[ould allegedly] be terminated, the [PBMs] had a strong economic incentive to adhere to the terms of [Mylan's agreements], and therefore were not free to walk away from the agreements and purchase products from the supplier of their choice." *ZF Meritor*, 696 F.3d at 287 (citing *Dentsply*, 399 F.3d at 194); *see also Minn. Mining*, 35 F.Supp.2d at 1151 (denying summary judgment where there were genuine disputes about whether the contracts were realistically terminable-at-will). Thus, the termination provisions are not dispositive either.

G. Mylan's Exclusionary Contracts Substantially Foreclosed Sanofi from the U.S. EAI Drug Device Market

Mylan argues that a jury cannot find substantial foreclosure because the highest percentage that Sanofi provided was [redacted], Mylan MSJ at 71-73. Mylan is wrong as a matter of law and fact. Mylan's contracts need only "substantially foreclose competition" in the EAI market. *Tampa Elec.* 365 U.S. at 334. "The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." *Dentsply*, 399 F.3d at 191. What is "substantial" depends on the facts of the case. Courts recognize that when a ***monopolist***—like Mylan—enters into exclusive contracts, it may be unlawful "even though the contracts foreclose ***less than the roughly 40% or 50% share*** usually required to establish a § 1 violation." *Microsoft*, 253 F.3d at 70 (emphasis added). Mylan cites *McWane* for a 40% threshold, but it omits the line that "courts have found that a lesser degree of foreclosure is required when the defendant is a monopolist." 783 F.3d at 837. In *McWane*, "the Commission did not place an exact number on the percentage foreclosed[.]" *Id.* at 838. And scholars observe that "[c]ourts have found liability in some cases even when the amount of 'foreclosure' is ***zero***" and "if price, output, quality, choice, or innovation have been harmed, the lack of percentage foreclosure is ***no defense***."[7]

[7] Ex. 109 (citing four cases, including *Microsoft*, 253 F.3d at 70-71: "Netscape was not 'foreclosed' at all…. [;]" and *Avery Dennison Corp. v. ACCO Brands, Inc.*, 2000 WL 986995, at *18-21 (C.D.Cal. Feb. 2000) (denying summary judgment): "[W]here the amount of 'foreclosure' was essentially zero, the restraints…enhanced or protected the defendants' market power, and that was a sufficient basis for illegality.").

Regardless, the record is replete with evidence that Mylan substantially foreclosed Auvi-Q. Mylan targeted important payors, recognizing that these exclusive contracts would be a severe blow to Auvi-Q's patient access ***and*** have a negative "spillover" on other plans. [redacted] Ex. 257 [redacted]. Recognizing that "Auvi-Q is the greater concern," Ex. 242, Mylan even sacrificed EpiPen profits to secure exclusivity with ESI in 2013. Ex. 22 ¶¶ 185-189. In a contemporaneous analysis, Mylan calculated that it would earn higher profits with its equal access offer to ESI than its exclusionary offer. *See* Ex. 259, 6-7. So, Mylan willingly lost money to induce ESI into exclusion. *See LePage's*, 324 F.3d at 164 (exclusionary conduct is when a firm "trades a part of its monopoly profits, at least temporarily, for a larger market share") (citation omitted).

Just as in *Dentsply*, "[t]he reality in this case is that the firm that ties up the key dealers rules the market." 399 F.3d at 190. Mylan celebrated as [redacted] Ex. 202 at -416; *see* Ex. 254 at -333 [redacted]. The fact that Mylan "tied up the key dealers" leading to a dramatic drop in Auvi-Q share provides sufficient evidence "that the foreclosure was substantial and problematic." *McWane*, 783 F.3d at 838; *Microsoft*, 253 F.3d at 366-67 (affirming substantial foreclosure finding); *Dial Corp.*, 165 F.Supp.3d at 33 ("[P]laintiffs raise material questions of fact as to whether the effect of these contracts was to 'substantially foreclose' rivals from obtaining a toehold…Such questions should be resolved by a jury.").

In this case, Dr. Scott Morton concluded that "Mylan's anticompetitive conduct...[wa]s sufficiently successful" in foreclosing Auvi-Q from "***more than half the market***." Ex. 137 at 131:16-132:13. Indeed, Sanofi was foreclosed from [redacted]—the percentage of EpiPen's non-

contestable or entrenched demand. *See supra* p. 63-66. The "effective entrant burden" test applied by Dr. Scott Morton "can be used to assess foreclosure" and "show that Mylan's overall course of anticompetitive conduct imposed a burden on Sanofi that dramatically distorted competition, so that Sanofi could not viably compete in the EAI market." Ex. 30 at ¶¶ 132-33. Given that Sanofi could not shift this substantial share regardless of the financial incentives offered to payors, EpiPen's non-contestable demand provides a valid foreclosure measure.

Further, Mylan calculated its own metric based on exclusionary contracts with key payors, lauding its success in [redacted]:

[redacted]

Ex. 222, -707. Mylan tracked its increasing foreclosure metric as it locked up additional contracts:

- In September 2013, [redacted] Mylan identified [redacted] Ex. 270.
- In October 2013, Mylan [redacted] Ex. 1 at slide 21.
- A month later, Mylan's [redacted] Ex. 2 at slide 2.
- By December 2013 and as of March 2014, Mylan's [redacted] Ex. 89 at 40; Ex. 208 at 28.

While Mylan's metrics provide a lower bounds for a jury to find substantial foreclosure, they ***underestimate*** the actual degree of foreclosure. Following these [redacted] Mylan took advantage of "spillover effects." As Dr. Scott Morton explained, "[t]hese effects arise because Mylan was able to leverage the exclusionary restrictions it secured at some of the largest PBMs and use them to foreclose patients under other PBMs in the same geographic region from procuring an Auvi-Q." Ex. 22 at ¶ 134. Mylan understood that, [redacted] Ex. 14 (Foster Dep.) at 278:6-9. Mylan purposefully leveraged these spillover effects:

- "[B]oth the United and ESI advantages for EpiPen as the exclusive product on formulary will have a positive effect and ***spillover effect on the perception of coverage*** for other (and all plans)." Ex. 60.
- [redacted] Ex. 71.
- [redacted] Ex. 61.

Taking Mylan's metric that it [redacted], accounting for the statistically significant spillover effects from those key payor contracts, *see* Ex. 22 at ¶ 138; App. C, and adding Mylan's EpiPen4Schools program (which Mylan [redacted]), *see id.* at ¶ 149, Sanofi was substantially foreclosed from over 40% of the market ***at the very least***. Indeed, Dr. Scott Morton found that Auvi-Q was blocked from over 50% or "more than half the market." Ex. 137 at 131:16-132:13. There is at a bare minimum a genuine dispute that the effect of Mylan's foreclosure was substantial.

II. THIS COURT ALREADY REJECTED MYLAN'S ATTEMPTS TO PAINT SANOFI'S CLAIMS AS PREDATORY PRICING OR BUNDLING

Unable to credibly dispute that it engaged in exclusive dealing, Mylan spends half of its brief defending against claims that Sanofi did not bring: (1) predatory pricing, and (2) bundling.

Both arguments are not only misguided, but have already been rejected by this Court.

As a threshold matter, the Supreme Court has made clear that "legal presumptions that rest on formalistic distinctions rather than actual market realities are generally disfavored in antitrust law." *Kodak*, 504 U.S. at 466–67. That is because "[a]nticompetitive conduct can come in too many different forms, and is too dependent on context, for any court or commentator ever to have enumerated all the varieties." *LePage's*, 324 F.3d at 152. Mylan's attempts to recast this case into one that it wants to defend violates this basic principle. Mylan does not—and cannot—cite "any legal rule that says that an antitrust defendant prevails in a rule-of-reason case if a plaintiff's legal theory of anticompetitive harm cannot neatly fit in a preexisting legal 'box.'" *Complete Entm't*, 2017 WL 6512223, at *4. Mylan's attempts to siphon off parts of its conduct, shove them into separate buckets, and apply formalistic rules are nothing more than an effort to avoid having a jury see the full range of Mylan's unlawful conduct and its harm to competition.

A. Price Was Not Mylan's "Clearly Predominant" Method of Exclusion

Mylan's second attempt to shoehorn Sanofi's exclusive dealing claim into predatory pricing is meritless. The price-cost test does not apply unless "price is the clearly predominant mechanism of exclusion." MTD Order at *6 (citing *ZF Meritor*, 696 F.3d at 275). Mylan does not provide any new or convincing reason why this Court should alter its prior conclusion that "[t]he price-cost test thus does not apply to Sanofi's exclusive dealing claim." *Id*.

Mylan does not cite a single case where a court actually applied the price-cost test to rebating conduct brought as an ***exclusive dealing claim***—not even *Eisai*. Mylan repeatedly cites the district court decision in *Eisai* but conspicuously omits that the Third Circuit ***rejected*** the price-cost test: "[W]e disagree. ***We are not persuaded that Eisai's claims fundamentally relate to pricing practices***." 821 F.3d at 408 (emphasis added). The same result is warranted here.

This is not a predatory pricing case where Mylan cut prices to drive a competitor from the

market; instead, Mylan offered large, unprecedented rebates expressly conditioned on Auvi-Q not being covered. The Court highlighted this distinction when it found that Sanofi's allegations of Mylan's alleged behavior "involved anticompetitive conduct—beyond pricing itself—that was designed to block customer access to Auvi-Q." MTD Order at *7. There is now voluminous evidence in support. Additionally, Mylan asks this Court to ignore the evidence of its other non-price conduct that was part of it scheme: sharing confidential information among payors to encourage them to exclude Auvi-Q, "anticompetitive messaging" to doctors, seeding the marketplace with false information about Auvi-Q's safety, and improperly obtaining Sanofi's commercially sensitive information. *See infra* pg. 89-90. Mylan cannot escape liability by applying the price-cost test to one sliver of its scheme; to do so runs afoul of U.S. antitrust law, which requires courts to analyze a monopolist's conduct "as a whole." *Cont'l Ore*, 370 U.S. at 699.

Even if the price-cost test applied (which it does not), there are genuine disputes over whether EpiPen's sales pass muster. First, when Dr. Scott Morton re-ran the price-cost test applied by Mylan's expert, Dr. Willig, and accounted for EpiPen's share of entrenched demand, several Mylan contracts ***failed***. *See* Ex. 30 at ¶ 155, Fig. 3.B. One simple adjustment to confirm Dr. Willig's analysis to the voluminous evidence of EpiPen's non-contestable demand shows that Mylan's contracts for [redacted] fell below Mylan's costs. A jury is entitled to hear these factual disputes.

Lastly, Dr. Willig admitted that he did not account for Mylan's Medicaid misclassification in applying the price-cost test. *See* Sanofi Opp-RSMF at ¶ 54.To date, Mylan has paid government agencies nearly $500 million to settle its Medicaid fraud claims, representing only a fraction of the nearly $1.3 billion that Mylan profited as a result of its illicit actions. *See* Ex. 162 at 2. If that figure was accounted for in Mylan's costs of selling EpiPen—or if Mylan categorized EpiPen lawfully—

Mylan very well could have priced EpiPen below cost for many more of its contracts.

B. Sanofi Did Not Bring A "Novel" Bundling Theory

Mylan also mischaracterizes Sanofi's claims as "bundling," trying to frame it as a novel theory under the price-cost test. Mylan MSJ at 75. But again there is no reason to revisit this Court's finding that an exclusive dealing framework applies here. *See* MTD Order at *9-10 ("To state a viable exclusive dealing claim based on a rebate program, Mylan asserts, courts require a plaintiff to allege other exclusionary conduct… such as bundling or tying the rebates to the sale of other products…The court disagrees.").

Mylan is wrong that EpiPen's entrenched demand "offers no guidance to the Court on whether Sanofi can show the elements of its claim under established traditional exclusive dealing jurisprudence." Mylan MSJ at 77. Courts have recognized that a dominant supplier can plausibly condition rebates on non-contestable demand to exclude competitors. *See Pfizer Inc. v. Johnson & Johnson*, 333 F.Supp.3d 494, 504 (E.D.Pa. 2018) (recognizing that a monopolist could plausibly use non-contestable demand to exclude competition and deprive consumers of a meaningful choice); *In re Remicade Antitrust Litig.*, 345 F.Supp.3d 566, 580 (E.D.Pa. 2018) (denying motion to dismiss exclusive dealing claim where allegations of defendant's conduct, including conditional rebates on a product with non-contestable demand, made it plausible that competition was substantially foreclosed). Far from being novel, after Sanofi filed this lawsuit, Mylan's supplier and co-defendant, Pfizer, brought a similar case as a plaintiff. *See Pfizer*, 333 F.Supp.3d at 504.

Finally, Mylan argues that this Court should apply the traditional attribution test rather than the "efficient entrant burden" test proffered by Dr. Scott Morton. Mylan MSJ at 80-84. But as explained by Dr. Scott Morton, the discount attribution test "***is still a predatory pricing test***: the only question it answers is whether Mylan was pricing below its costs, not whether the conditional discounts associated with Mylan's exclusionary contracts with PBMs would be able to foreclose

Sanofi from the EAI market." Ex. 30 at ¶ 131. That is why Mylan's cited cases involve non-monopolists, the bundling of multiple products, and/or tying. *See Suture Express*, 2016 WL 1377342, at *15 (tying by non-monopolists); *Cascade Health Solutions v. PeaceHealth*, 515 F.3d 883, 894 (9th Cir. 2008) (bundling of multiple products); *Inline Packaging, LLC v. Graphic Packaging Int'l, LLC*, 351 F.Supp.3d 1187, 1206-08 (D.Minn. 2018) (where defendant was not a monopolist). Since price is not the clearly predominant method of exclusion in this exclusive dealing case, the "effective entrant burden" test is more appropriate because it "allows for evaluation of foreclosure, and not just predation." Ex. 30 at ¶ 132.

In sum, Sanofi's claim does not boil down to bundling or predatory pricing, but is based on extensive evidence that Mylan took all means necessary to substantially foreclose competition. Exploiting EpiPen's entrenched demand and dominant market share is in no way novel; it was embraced by Mylan's expert before he was retained on this case. As one court noted, "[t]he means of illicit exclusion…are myriad." *Microsoft*, 253 F.3d at 58. This Court should reject Mylan's attempts to create "formalistic distinctions" and instead adjudicate Sanofi's claims "on a case-by-case basis, focusing on the particular facts disclosed by the record." *Kodak*, 504 U.S. at 466-67.

III. THERE IS SUBSTANTIAL EVIDENCE OF MYLAN'S DECEPTIVE SPEECH

In denying Mylan's motion to dismiss, this Court found that the following key allegations, if proven, would result in liability for Mylan:

- Mylan funded and promoted a misleading study entitled "Auvi-Q versus EpiPen Auto-Injectors: Failure to Demonstrate Bioequivalence of Epinephrine Delivery Based on Partial Area Under the Curve" intended to undermine the FDA's conclusion that Auvi-Q demonstrated bioequivalence to the epinephrine in the EpiPen;
- Mylan misleadingly suggested that the decision to exclude Auvi-Q from the formularies was based on clinical recommendation and not Mylan's huge conditional rebate offers.

MTD Order at 23-28. Sanofi has since uncovered extensive evidence supporting (and, at minimum, creating genuine issues of material fact regarding) these allegations.

Ignoring the record, Mylan argues that its marketing statements were not false or misleading and that Sanofi cannot overcome the presumption that its statements had a *de minimis* effect on competition. Mylan MSJ at 84-87. Mylan is wrong as a matter of fact and law.

As an initial point, neither the Tenth nor the Third Circuit has adopted the rebuttable *de minimis* presumption or required a plaintiff asserting a deceptive speech claim under Section 2 to present evidence on all six factors. *See Lenox MacLaren Surgical Corp. v. Medtronic, Inc.*, 762 F.3d 1114, 1128 n.9 (10th Cir. 2014) ("We need not determine whether a plaintiff must satisfy all six factors to overcome the *de minimis* presumption."); *Ayaya Inc., RP v. Telecom Labs, Inc.*, 838 F.3d 354, 420 n.7 (3d Cir. 2016) (Third Circuit "is not among those that have adopted this presumption and six requirements"); *In re Suboxone (Buprenorphine Hydrochloride & Nalaxone) Antitrust Litig.*, 2015 WL 12910728, at *3 (E.D.Pa. Apr. 14, 2015) ("[W]here recognized, courts generally only apply the *de minimis* presumption in the context of antitrust actions based solely on misrepresentations or false statements by competitors.").

Instead, the standard is whether the evidence of Mylan's anticompetitive conduct as a whole—not just its deceptive marketing conduct in isolation—creates genuine issues precluding summary judgment. *See, e.g., Caldera, Inc. v. Microsoft Corp.*, 72 F.Supp.2d 1295, 1318-20 (D. Utah Nov. 3, 1999) (denying summary judgment where defendant's misleading statements did not alone violate Section 2 but did when "viewed in context with other alleged anticompetitive behavior"). And as demonstrated above, Sanofi's Section 2 claims should proceed to trial because it has presented sufficient evidence to easily meet that standard. *See Conwood*, 290 F.3d at 782-788 (finding sufficient evidence to support jury finding that defendant's entering into exclusive agreements and providing misleading information was anticompetitive under Section 2).

Even if the rebuttable *de minimis* presumption applied, there is at least a question of fact

on all six factors. *See* MTD Order at 26-27 (noting—without applying—that a plaintiff may overcome it with proof that the statements were (1) clearly false, (2) clearly material, (3) clearly likely to induce reasonable reliance, (4) made to buyers without knowledge of the subject matter, (5) for prolonged periods, and (6) not readily susceptible to neutralization or offset by rivals).

A. Mylan's Marketing Statements Were Clearly False and Misleading

As to the first factor, Mylan cannot dispute that the epinephrine in Auvi-Q is bioequivalent to that in EpiPen. *See* Sanofi Opp-ASMF ¶ 34. Mylan's marketing expert, Mr. Zieziula, admitted that the epinephrine had been "deemed bioequivalent by the FDA." Ex. 6 at 25:25-26:20. Mylan, nevertheless, funded and presented its study—titled "Auvi-Q versus EpiPen Auto-Injectors: ***Failure to Demonstrate Bioequivalence*** of Epinephrine Delivery Based on Partial Area Under the Curve"—to sway key thought leaders and advocacy groups against Auvi-Q. Sanofi Opp-ASMF ¶ 34. *See Caldera*, 72 F.Supp.2d at 1318 (denying summary judgment where defendant instituted a deceptive marketing "campaign to create doubts about the compatibility" between the parties' products). Faced with Mr. Zieziula's admission, Mylan argues that it is "highly debatable" whether the title of its study was false and misleading. *See* Mylan MSJ at 86. This is a fact question.

Second, the record shows Mylan's deceptive efforts to convince doctors not to prescribe Auvi-Q by falsely implying that PBMs excluded it from formularies for clinical reasons:

MYLAN'S DECEPTIVE MESSAGING TO DOCTORS
Directing sales managers to [redacted] Ex. 61.
[redacted] Ex. 65 at -918.

Instructing Mylan sales team that: [redacted] Ex. 255 at -98.
Mylan's [redacted] Ex. 80 at -872.

Numerous Mylan witnesses admitted that Mylan had ***no basis whatsoever*** to claim that [redacted] Sanofi Opp-ASMF ¶ 33. Mr. Zieziula's admission in his deposition that such statements "***could be***" false and misleading is enough, standing alone, to preclude summary judgment.[8] And Dr. Willig's opinion that "all major PBMs determined that EpiPen and Auvi-Q were clinically interchangeable"—if true—means that Mylan's statements to doctors implying that Auvi-Q was excluded for "clinical" reasons cannot also be true. *See* Ex. 46 at ¶ 30. Mylan cannot have it both ways.

B. Mylan's Marketing Statements Were Clearly Material and Likely to Induce Reasonable Reliance by Doctors

The record also shows that Mylan's deceptive marketing statements were clearly material, and in fact did, induce reasonable reliable by doctors. Dr. Willig testified that doctors have an "important influence" over patient choice because they "write the prescriptions as well as giv[e] advice to the patients and listen[] to the patients' own desires which influence what prescriptions are written." Ex. 161 at 56:1-13. Similarly, Dr. Michelis explained that marketing statements and sales meetings "can have a meaningful impact on prescribing behavior." Ex. 3 at ¶¶ 47-48. And Mr. Zieziula testified that comparative advertising can have a "significant impact" on prescribing physicians. Ex. 123 at 4. Mylan's argument that its marketing statements were "immaterial"

[8] Ex. 6 at 39:12-40:13 ("[A] [redacted] …Q. What part of the comparison between the EpiPen and the Auvi-Q is clinical? A. I don't know if there is a clinical part. Q. There isn't one, right? A. The products [were] equivalent – bioequivalent.")

because they were made to doctors instead of PBMs, *see* Mylan MSJ at 87, is mistaken.

Additionally, the evidence shows that Mylan's deceptive marketing campaign ensured that doctors would be reluctant to prescribe Auvi-Q. *See* Sanofi Opp-ASMF ¶ 31; *see Lenox*, 762 F.3d at 1127-1128 (holding that plaintiff satisfied factor four with evidence that even "sophisticated" consumers like hospitals would rely on defendant's false statements). Sanofi has therefore presented sufficient evidence to create questions of material fact on factors two, three, and four.

C. Mylan's Deceptive Statements Continued for a Prolonged Period and Were Not Readily Susceptible to Neutralization

As to the fifth factor, Mylan's arguments about the sufficiency of Sanofi's pleading on whether Mylan's deceptive speech continued for a prolonged period have already been rejected by this Court. Mylan MSJ at 87; MTD Order at 28. As to factor six, Mylan's argument that its deceptive statements to doctors were "easily neutralizable" directly contradicts Mylan's own statements. Mylan submitted sworn testimony from senior executives to a West Virginia court about the irreparable injury to Mylan because doctor would "***erroneously presume***" that EpiPen's lack of formulary access was due to safety, resulting in "***substantial harm to Mylan Specialty's reputation and goodwill***." Ex. 129 at ¶ 12. Further, Mylan's position now that its deceptive statements were "easily neutralizable" by Sanofi is unsupported, and at the very least a question of fact. *See Lenox*, 762 F.3d at 1127 (evidence that defendant's deceptive statements made hospitals unwilling to purchase product due to safety concerns created fact dispute on factor six).[9]

In sum, Sanofi has presented more than sufficient evidence to create questions of material fact that preclude summary judgment on its deceptive speech claim.

IV. SANOFI UNCOVERED VOLUMINOUS EVIDENCE OF MYLAN'S OVERALL SCHEME TO MONOPOLIZE THE EAI DRUG DEVICE MARKET

[9] Mylan's cited cases are inapposite. Unlike those cases: (1) Sanofi's Section 2 claims are premised on host of anticompetitive conduct (not just deceptive advertising); and (2) Sanofi's deceptive speech claim is based on Mylan's written and oral statements to doctors (not just distribution of flyers).

Finally, Mylan has failed to show why Sanofi's overall scheme to monopolize claim merits summary judgment. *See* Mylan MSJ at 84-88. Mylan tries to strip out individual acts, claiming that each is procompetitive when viewed by itself. But for a monopolization claim, "courts must look to the monopolist's conduct ***taken as a whole*** rather than considering each aspect in isolation." *LePage's*, 324 F.3d at 162 (emphasis added). The Tenth Circuit has likewise stated that each action "viewed in isolation need not be supported by sufficient evidence to amount to a § 2 violation." *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). Here, the record shows abundant evidence supporting not only Mylan's exclusive dealing and deceptive marketing, but also a host of other anticompetitive and unethical conduct aimed at monopolizing the EAI drug device market.

While Mylan focuses on only its EpiPen4Schools program here, and its supposedly charitable nature, as described in detail above, the scheme covers the entirety of Mylan's unlawful conduct. This includes Mylan's scheme to (1) force payors into exclusive EpiPen contracts (Sanofi Opp-ASMF ¶¶ 21-28), (2) exploit spillover effects (*Id.* at ¶¶ 29-32), and (3) deceptively claim that plans decided Auvi-Q was clinically inferior (*Id.* at ¶¶ 33-35).

As to the EpiPen4Schools program, Mylan used the program to entrench EpiPen demand and to block Auvi-Q. *See* Sanofi Opp-ASMF ¶¶ 36-39. EpiPen4Schools was timed to "blitz" the market before Auvi-Q launched. *Id.* As explained by Mylan, [redacted] Ex. 86. Mylan documents confirm the program's goal: [redacted] Ex. 87. Mylan [redacted] *See* Ex. 256. If Mylan's objective was to

provide schoolchildren with access to EAIs, then Mylan would not have restricted schools' ability to obtain other life-saving EAIs. As further evidence, Mylan [redacted] Ex. 92. Mylan [redacted] *Id.*

Mylan also engaged in numerous other unlawful tactics:

- Mylan misclassified EpiPen to government agencies, paying substantially less in Medicaid rebates and then using those excess funds for commercial offers (*See id.* at ¶¶ 40-41);
- Mylan shared competitively sensitive rebate information among PBMs/payors to encourage them to exclude Auvi-Q (*See* Sanofi Opp-ASMF ¶¶ 42-43); and
- Mylan improperly obtained and used confidential information about Sanofi's marketing (*See id.* at ¶¶ 44-47).

Mylan engaged in this conduct with the blessing and knowledge of its executives. CEO Heather Bresch said there was "room in the market for a competitor" when Auvi-Q launched. Ex. 126 at 248:3-249:6. Based on the myriad evidence from Mylan that it never thought would see the light of day, a jury is entitled to decide if Bresch lied to maintain EpiPen's $1 billion monopoly.

V. THERE IS SUBSTANTIAL EVIDENCE THAT MYLAN HURT COMPETITION

At the pleadings stage, this Court held that Mylan's conduct, if proven, could harm competition through increased prices, reduced innovation, stunted output, and less choice for patients. MTD Order, at *32-35. The record contains substantial evidence of these and other harms.

Price. The record shows—as Sanofi alleged—that Mylan raised EpiPen's WAC price over 500% from 2009 to 2016. *See* Sanofi Opp-ASMF ¶ 20. And as demonstrated above (*supra* pg. 38), "Mylan's purpose for raising prices so sharply was to allow it to absorb the deep conditional discounts that it had given to third-party payors to exclude Auvi-Q from the market." MTD Order, at *32. As evidence of Mylan's scheme to inflate prices and increase is revenues, EpiPen's [redacted]. Ex. 22 at ¶ 87, Fig. 8. Mylan's "rebates" were therefore illusory. As explained by Dr. Scott Morton, "The bottom line

is that, while Mylan used the inducements of conditional discounts and price protection to exclude Auvi-Q from formularies, because Mylan continued to raise its list price, [redacted] *Id.* at ¶ 184.

Mylan's assertion that "but for Mylan's challenged rebates, EpiPen's net prices in 2013, 2014, and 2015 would have been higher," is a gimmick. Mylan MSJ at 90. Dr. Scott Morton explains and shows that "but for" Mylan's anticompetitive scheme, there would have been no need for Mylan to jack up EpiPen's price to target Auvi-Q's launch with deep rebates tied to exclusion; thus, EpiPen's "but for" net price would have been ***lower*** than the EpiPen net price that Mylan actually charged from 2013 to 2015. Ex. 30 at ¶ 37, Fig. 2. Mylan may disagree with Dr. Scott Morton's analysis and calculation, but that is a classic "battle of the experts" for trial.

Quality and Innovation. Mylan mistakenly argues that its "failure to innovate" EpiPen is not a cognizable harm. Mylan MSJ, at 92. But courts have recognized reduction in innovation as evidence of harm to competition. *See, e.g.*, *Lorain Journal Co. v. United States*, 342 U.S. 143, 154 (1951) (monopolist-newspaper liable when it refused to do business with advertisers that worked with an upstart competitor in the then-new radio medium); *United States v. Visa U.S.A., Inc.*, 344 F.3d 229, 241 (2d Cir. 2003) (upholding harm to competition where "product innovation and output ha[d] been stunted"); *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 318 (3d Cir. 2007) (crediting allegations that defendant "harmed competition and undermined innovation"); *Aventis Envtl. Sci. USA LP v. Scotts Co.*, 383 F.Supp.2d 488, 504 (SDNY 2005) (denying summary judgment where evidence of "retardation of innovation" could amount to harmed competition).[10]

Moreover, Mylan concedes that the "quality of goods" is relevant under the antitrust injury

[10] Mylan cites *VBR Tours, LLC v. Nat'l R.R. Passenger Corp.*, 2015 WL 225328 (N.D.Ill. Jan. 15, 2015) where the court held that lack of innovation alone—without "acts that reduce output or raise prices to consumers"—did not cause antitrust injury. *Id.* at *4. The record here show all of these harms.

standard. *See* Mylan MSJ at 92. And despite yet another attempt to portray every facet of Sanofi's case as novel, ***innovation affects the quality of goods***. This Court credited Sanofi's allegation that "Mylan's conduct prevented consumers from accessing a new and innovative product with allegedly better qualities than EpiPen." MTD Order, at 35. Sanofi has now provided evidence in support. As this Court held in *Suture Express* and Mylan cited, "antitrust laws…were enacted to promote competition so that ***market participants could decide who had a better mousetrap***." Mylan MSJ at 88 (citing *Suture Express*, 2016 WL 1377342, at *26) (emphasis added). Mylan's exclusionary conduct prevented patients from doing just that. Mylan's own consultant [redacted] Ex. 76 at -337.

Contrary to the "unelaborated" superiority allegations in *NicSand, Inc. v. 3M Co.*, 507 F.3d 442, 456 (6th Cir. 2007) (en banc), Mylan MSJ at 91,—a case where Mylan ignores that the ***plaintiff*** was originally "the dominant player, holding a 67% share of the market"—Auvi-Q's features were heralded by doctors, patients, and even Mylan. *See* Ex. 260 (Class Pl. Dep.) at 87:5-10 ("I was excited for a competitor, for somebody else to come in, especially with the AUVI-Q, because it was small, and it would fit in, you know, the back pocket. You didn't have to carry a big pouch."). Recognizing the appeal of this new EAI, Mylan and Pfizer [redacted] *See* Sanofi Opp-ASMF at ¶ 7. Mylan's market research found [redacted] *Id.* at ¶ 8. At CEO Heather Bresch's urging, Mylan wanted (but failed) to [redacted] *Id.* at ¶ 15.

Rather than innovating EpiPen, Mylan responded to Auvi-Q's launch by wielding its monopoly power to exclude Auvi-Q. *See Aventis*, 383 F.Supp.2d at 504 (evidence that defendant

never introduced an allegedly improved version of product "could qualify as a harm to competition and consumers"). Mylan did not only harm consumers by depriving them of Auvi-Q, but also by depriving them of the benefit of an improved EpiPen. *See* Ex. 137 (Morton Dep.) 179 ("[I]f we don't have innovation in pharmaceutical markets, then we're paying high prices for an EpiPen and it's 35 years old and we're never getting any innovation. And that's really harmful to consumers and that's one of the major reasons why there's anticompetitive harm here."); Ex. 22 ¶ 194.

Choice. Courts and the antitrust agencies have recognized that reducing patient choice also qualifies as harm to competition. *See Dentsply*, 399 F.3d at 194 ("An additional anti-competitive effect is seen in the exclusionary practice here that limits the choices of products open to dental laboratories, the ultimate users."); *In re Merck & Co. and Merck-Medco Managed Care, L.L.C.*, No. C-3853 (F.T.C. Feb. 18, 1999) (Merck acquisition of Medco could foreclose rival products from formularies). Evidence of Mylan's harm to competition was borne out by the testimony of consumers in the *Class Case*, who stated that were deprived of a meaningful choice:

- "Q. What kind of harm did you allegedly suffer because of [Mylan's] conduct? A. ***Lack of options available to me*** and incremental costs." Ex. 261 (Class Pl. Dep.) at 35:24-36:3.
- "Q. Do you know if your insurance would have covered other epinephrine autoinjectors other than the EpiPen? A. When Auvi-Q came on the market, it wasn't covered. ***I asked for it and I couldn't get it.***" Ex. 262 (Class Pl. Dep.) at 157:17-22.

Output. By denying patients a meaningful choice, Mylan also succeeded in reducing EAI output. As explained by Dr. Scott Morton, absent Mylan's exclusionary conduct, "we would have [had] all the output expansion that would be generated by Auvi-Q." Ex. 137, 243:19-21. While output increased, it was ***lower than it would have been*** if Auvi-Q was allowed to compete. Sanofi Opp-ASMF ¶ 132. Mylan itself recognized that the entry of a new and innovative device should have increased output, predicting that [redacted] Ex. 263, 22. And as described by Dr. Scott Morton, "when the product is differentiated as Auvi-Q is, it's

going to appeal to a whole other set of people and that's going to…expand the market." Ex. 137, 245:11-14. So "if we imagine the but-for world where Mylan was acting within the law and not trying to exclude Auvi-Q, we would expect a larger increase in total prescriptions." *Id.* at 243:3-6. But Mylan's exclusionary conduct prevented Auvi-Q from expanding the market, reducing overall EAI output. *See LePage's*, 324 F.3d at 159 (recognizing that "even the foreclosure of 'one significant competitor' from the market may lead to higher prices and reduced output"); *Lenox*, 762 F.3d at 1129 (reversing district court and denying summary judgment on monopolization claims: "[T]he fact-finder could infer harm to competition from concentration of the market[.]").

The facts here are therefore quite different from *Indeck Energy Servs., Inc. v. Consumers Energy Co.*—a motion to dismiss case—that Mylan cites in its brief. In *Indeck*, the court observed ***at the pleadings stage*** that "[n]o allegation in the complaint indicate[d] in any manner whatsoever how…customers in the energy market suffered." 250 F.3d 972, 977 (6th Cir. 2000). With a full record, there is ample evidence for a jury to decide if patients were harmed and deprived of choice.

VI. THERE IS SUBSTANTIAL EVIDENCE THAT MYLAN DAMAGED SANOFI

Mylan's anticompetitive conduct also directly harmed Sanofi. *See ZF Meritor*, 696 F.3d at 289 ("[W]e have no difficulty concluding that there was [] sufficient evidence that Plaintiffs suffered antitrust injury" where defendant's conduct forced plaintiffs to exit the market "because they could not maintain high enough market share to remain viable"). The record shows that as a result of Mylan's conduct, Sanofi suffered tremendous losses and "was unable to secure the substantial market share that both it and Mylan forecasted it would." Ex. 22 at ¶ 197.

A. Sanofi Was Not Required to Disaggregate Damages

Mylan argues that Sanofi's damages fail as a matter of law because Dr. Scott Morton's model does not disaggregate between allegedly pro- and anticompetitive conduct. Mylan MSJ at 95-96. But a plaintiff need not disaggregate damages when it would be impractical to do so because

the conduct at issue is intertwined. *See Conwood*, 290 F.3d at 784. As explained by the Seventh Circuit, "Not requiring strict disaggregation of damages among the various unlawful acts of the defendant serves to prevent a defendant from profiting from his own wrongdoing and makes sense when damages arise from a series of unlawful acts intertwined with one another." *MCI Commc'ns Corp. v. Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1161 (7th Cir. 1983).

Here, Mylan's monopolistic scheme was "sufficiently varied and effective to render more exact proof of damage impossible." *Spray-Rite Serv. Corp. v. Monsanto Co.*, 684 F.2d 1226, 1243 (7th Cir. 1982), *aff'd*, 465 U.S. 752 (1984); *see ZF Meritor LLC v. Eaton Corp.*, 2013 WL 6729509, at *3 (D.Del. Dec. 20, 2013) (finding that "disaggregation [was] unnecessary, if not impossible"). There was no reason for Dr. Scott Morton to disaggregate damages because Mylan's conduct formed "a package" with its "different behaviors reinforce[ing] each other" as "part of the same strategy." Ex. 137 at 263-64. Antitrust law does not permit Mylan to profit from its overarching scheme and then demand an exacting level of précising for the damages it caused.

B. 2013-2015 Damages

Before Mylan developed its anticompetitive scheme, Sanofi and Mylan made remarkably similar projections for Auvi-Q's success. Mylan projected Auvi-Q would achieve [redacted] share within two years and [redacted] within four years. Sanofi Opp-SMF at ¶ 48. Sanofi likewise projected that Auvi-Q would gain 35% within two years, and 40% within four years. *Id.* at ¶ 48. Tellingly, in Canada and on two U.S. formularies where Auvi-Q had equal access, these shares were realized. *Id.* at ¶ 48. Therefore, Dr. Scott Morton's model projected that Sanofi would have hit Auvi-Q's forecasted share and earned profits of $25 million from 2013 to 2015—rather than lose over $100 million—in the but-for world where Mylan competed on the merits. *Id.* at ¶¶ 48-49. In reality, Mylan blocked Auvi-Q from market access, from gaining share, and from earning any profits. Dr. Scott Morton accordingly subtracted Sanofi's actual earnings on Auvi-Q sales ($103 million ***loss***)

from the profits Sanofi would have earned but for Mylan's anticompetitive conduct ($25 million), resulting in actual damages of $128 million, or $189 million in present value. *Id.* at ¶ 49.

C. Relaunch Damages

Mylan next contends that Sanofi's claim for post-relaunch damages are speculative and that Auvi-Q's voluntary recall—rather than Mylan's anticompetitive scheme—caused Sanofi to return the rights to Auvi-Q. Here, too, Mylan is incorrect as a matter of law and fact.

First, Mylan's cases apply where the ***fact*** of damages is speculative—***not the amount***. Mylan MSJ at 98-100; *see Coleman Motor Co. v. Chrysler Corp.*, 525 F.2d 1338, 1353 (3d Cir. 1975) ("[D]amage issues in [antitrust] cases are rarely susceptible of the kind of concrete, detailed proof of injury which is available in other contexts."). Once damages are established, courts give plaintiffs the benefit of the doubt in determining the amount. *See* ABA ANTITRUST SECTION, ANTITRUST LAW DEVS. § 9B1 (8th ed. 2017) ("ALD") ("Once a plaintiff has proved fact of injury, it is allowed considerable latitude in proving the amount of damages resulting from that injury.").

Moreover, Mylan's reliance on *Telecor* is misplaced, as that case was not decided on summary judgment, the plaintiff was not forced out of the market, and the Tenth Circuit affirmed a verdict at trial rendered on a general jury form. *Telecor Commc'ns, Inc. v. Sw. Bell Tel. Co.*, 305 F.3d 1124, 1128, 1143 (10th Cir. 2002). Similarly, *Webb* was not decided on summary judgment and instead turned on a fact/case-specific review of the record ***after trial***. *Webb v. Utah Tour Brokers Ass'n*, 568 F.2d 670, 676 (10th Cir. 1977). Mylan's arguments can be raised to the trial judge and dealt with in the normal course with a special verdict form with interrogatories as is routine in antitrust cases. *See* 9B Arthur R. Miller, FEDERAL PRACTICE & PROCEDURE § 2511, Westlaw (3d ed. updated April 2019); *see also Stevens & Sons, Inc., v. Jeld-Wen, Inc.*, 2018 WL 1459759 (E.D.Va. Feb. 15, 2018) (special jury verdict form awarding $12 million for damages sustained and $46 million for future lost profits). Mylan's premature argument is a tactic to avoid

the standard for a jury's damages award that "'must be allowed to stand, unless all reasonable men, exercising an unprejudiced judgment, would draw an opposite conclusion from the facts.'" *Telecor*, 305 F.3d at 1143 (quoting *Story Parchment Co. v. Paterson Parchmant Paper Co.*, 282 U.S. 555, 566 (1931)).

As for causation, "the plaintiff need ***not*** prove that the defendant's wrongful actions were the ***sole proximate cause*** of the injuries suffered." *Terrell v. Household Goods Carriers' Bureau*, 494 F.2d 16, 20 (5th Cir. 1974) (emphasis added). Sanofi "must show only, as a matter of fact and with a fair degree of certainty that defendant's illegal conduct materially contributed to the injury." *Id.*[11] Here, the record shows that Mylan's conduct was a substantial factor in Sanofi's decision to return Auvi-Q. Well in advance of the recall, "Sanofi's senior leadership observed and believed that Mylan was using anticompetitive business practices to protect its EpiPen and to block Auvi-Q's access to the market." Sanofi Opp-ASMF at ¶ 52. Sanofi had no reason to believe that Mylan's anticompetitive conduct would stop. Accordingly, and as numerous Sanofi executives testified, Sanofi ultimately decided to return Auvi-Q to kaleo. *Id.* at ¶ 53. Sanofi was not "obliged to pursue any imaginable alternative, regardless of cost or efficiency, before it can complain that a practice has restrained competition." *Buffalo Broad. Co. v. ASCAP*, 744 F.2d 917, 925 (2d Cir. 1984).

In addition, Mylan disregards expert testimony explaining that recalls are common in the pharmaceutical industry and rarely cause a company to abandon a product. Ex. 198 (Stevens Report) at ¶¶ 28-38. Mylan knows this all too well as the EpiPen has faced critical manufacturing issues, including a worldwide recall of over 1 million units and an FDA warning letter related to patient deaths. *Id.* at ¶¶ 39-44. Nevertheless, EpiPen has remained on the market with continued prescriptions and use. *See* Ex. 125 ¶ 19. [redacted]

[11] Sanofi "is not required to prove that defendant's alleged antitrust violation was ***the sole cause of its injury***[.]." ABA MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES, at pp. 300-01 [Instruction 1] (2016 ed.).

[redacted]. Sanofi Opp-ASMF at ¶ 52. And Mylan's argument is also belied by the fact that Auvi-Q ***was quickly*** relaunched by kaléo—albeit as a niche product due to kaléo's deliberate "high-price, low-volume strategy." *See* Ex. 229 at ¶¶ 101-102.

A jury could reasonably find that Mylan's exclusionary conduct prevented Sanofi from relaunching Auvi-Q and award relaunch damages. *See Aspen Highlands*, 738 F.2d at 1523 (jury verdict awarding plaintiff damages for four ski seasons ***after*** the defendant-monopolist refused to deal with plaintiff on a joint ski lift ticket); *Int'l Wood Processors v. Power Dry, Inc.*, 593 F.Supp. 710, 723 (D.S.C. 1984), *aff'd* 792 F.2d 416 (4th Cir. 1986) (rejecting that damages were speculative and "***awarding lost future profits to a business with no actual sales record***"); *see also Terrell*, 494 F.2d at 23-24 (affirming jury verdict awarding lost profits on sales plaintiff "could reasonably have expected to sell" over a 13-year period "if he had remained in business"). Indeed, courts award lost profits in exclusion cases even when a plaintiff ***never*** launches. *See Int'l Wood*, 593 F.Supp. at 724 ("An antitrust plaintiff in a market exclusion case is not precluded from proving damages as lost profits simply because its nascent business has shown no past profits."). As the ABA MODEL JURY INSTRUCTIONS IN CIVIL ANTITRUST CASES explain, "[l]ost future profits will be an issue when plaintiff has been eliminated from a market because of the alleged antitrust violation." Ch. 6(B)(9), Note on Damages for Competitors – Future Lost Profits (ABA 2016 ed.). At trial, the jury can "make a reasonable estimate of (1) the amount of profits, if any, that [Sanofi] would have earned in future years, and (2) the length of time for which it would have earned those profits" without demanding "absolute mathematical certainty or precision" or engaging in "guesswork or speculation." *Id.* Mylan may be afraid of having a jury decide damages but that is what trials are for and the jurors will be instructed on how to discharge their civic duty.

Finally, Dr. Scott Morton's relaunch damages are sufficiently grounded in the factual

record. It was reasonable for Dr. Scott Morton to find that it is consistent with the economic evidence that Sanofi would have re-launched Auvi-Q twelve months after the recall and marketed Auvi-Q until patent expiry in 2029 ***absent Mylan's anticompetitive conduct***. She thereafter projected that post-relaunch profits from 2017 to 2029 would have been $3.7 billion. Ex. 22 at ¶¶ 225-26; Ex. 30 at ¶¶ 208-09; Ex. 30. Combined with the 2013 to 2015 period, the total damages that Mylan's conduct caused to Sanofi over the life of this innovative product was over $3.9 billion. Ex. 30 at ¶ 209. Dr. Scott Morton even tested her conclusions with various benchmarks, including Mylan's own forecasts for Auvi-Q. *See* Ex. 22 at ¶¶ 201-26; Ex. 30 at ¶¶ 173-209.

Mylan cannot dispute that Dr. Scott Morton "rested h[er] estimates in part on facts that, though in dispute, could from the evidence be found in favor of [Sanofi] and would support the assumptions on which [her] opinion evidence was based." *Terrell*, 494 F.2d at 24 (citation omitted). A jury could reasonably find that Dr. Scott Morton's damages calculation accurately measured Sanofi's lost profits attributable to Mylan's anticompetitive conduct. *See Int'l Wood*, 593 F.Supp. at 724-26 (upholding expert's damages determination as "supported by the evidence," including forecasts that "clearly show[ed] his assumptions and method of computing lost profits"); *see also* ALD § 9B1 (8th ed. 2017) ("So long as the evidence presented provides a reasonable basis upon which the jury may estimate the amount of damages, weakness or imperfections in the evidence are for the jury's consideration."); *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 123 (1969) (Courts must "observe the practical limits of the burden of proof which [may] be demanded of a treble-damage plaintiff who seeks recovery for injuries."); *Bigelow v. RKO Radio Pictures*, 327 U.S. 251, 265 (1946) (observing that the wrongdoer, not the victim, shall bear "the risk of the uncertainty which is own wrong created"). Mylan could have submitted an alternative relaunch damages estimate (as it did for 2013 to 2015) but declined to do so. Mylan's

strategic choice is not a basis to prevent Sanofi's relaunch damages from going to the jury.

Mylan's quibbling with Dr. Scott Morton about the role of future generic competition in the U.S. EAI market is also not a basis for summary judgment. Dr. Scott Morton considered future generics, including the authorized EpiPen generic, but concluded based on her experience in the pharmaceutical industry—and ***Mylan's own documents***—that [redacted] *See* Ex. 22 at ¶¶ 216-22. Mylan disregards that Dr. Scott Morton's damages account for entry, including generics, by growing the overall market with Auvi-Q having a relatively smaller market share over time as new products enter. Ex. 30 at ¶ 202.

Finally, in a last-ditch effort to cast doubt on Dr. Scott Morton's post-relaunch damages calculation, Mylan hypocritically fights (what it calls) speculation with its own conjecture. Mylan MSJ at 99. First, Mylan claims post-relaunch damages should be cut off based on testimony from Thomas Handel, President of Meridian Medical Technologies, [redacted] *Id*. If true, this would be material, non-public information that neither Mylan nor Pfizer had disclosed to its shareholders to date. But this is merely a fabricated argument resting on the speculative premise as to what Mylan claims ***might*** happen in 2020. Indeed, Mylan and a Pfizer entity recently entered into a merger agreement that specifically contemplates Mylan acquiring Meridian (the EpiPen manufacturer). Ex. 124 at 3. Notably, Dr. Ordover, Mylan's damages expert ***said nothing*** about Mylan's EpiPen supply agreement in his critique of Dr. Scott Morton's damages, nor did he even consider Mr. Handel's testimony on it, further showing how this is nothing more than a last minute argument concocted by lawyers and not grounded in reality.

CONCLUSION

For the foregoing reasons, Mylan's motion for summary judgment should be denied.

DATED: August 9, 2019 */s/ Yehudah L. Buchweitz*

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