Case No. 21-3005

In the

United States Court of Appeals

for the

Tenth Circuit

In re: EPIPEN (EPINEPHRINE INJECTION, USP) MARKETING, SALES PRACTICES AND ANTITRUST LITIGATION

SANOFI-AVENTIS U.S., LLC,
Plaintiff, Counterclaim-Defendant and Appellant,

v.

MYLAN, INC.,
Defendant and Appellee,

MYLAN SPECIALTY, LP,
Defendant-Counterclaimant and Appellee.

Appeal from a Decision of the United States District Court for the District of Kansas - Kansas City
Case No. 2:17-MD-02785-DDC-TJJ · Honorable Daniel D. Crabtree, U.S. District Judge

APPELLANT'S OPENING BRIEF (PUBLIC - REDACTED)

Oral Argument Requested

YEHUDAH L. BUCHWEITZ, ESQ.
ERIC S. HOCHSTADT, ESQ.
GREGORY SILBERT, ESQ.
WEIL GOTSHAL & MANGES LLP
767 Fifth Avenue, Suite 3301
New York, New York 10153
(212) 310-8000 Telephone
(212) 310-8007 Facsimile

JOSHUA HALPERN, ESQ.
WEIL, GOTSHAL & MANGES LLP
2001 M Street NW, Suite 600
Washington, District of Columbia 20036
(202) 682-7000 Telephone
(202) 857-0940 Facsimile

Attorneys for Appellant Sanofi-Aventis U.S., LLC

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Plaintiff-Appellant Sanofi-Aventis U.S. LLC certifies that it is a wholly owned subsidiary of Sanofi, and no publicly held company owns 10% or more of its stock.

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GLOSSARY

EAI – Epinephrine Auto-Injector

ESI – Express Scripts

PBM – Pharmacy Benefit Manager

STATEMENT OF PRIOR OR RELATED APPEALS

Pursuant to Circuit Rule 28.2(C)(3), Sanofi-Aventis U.S. LLC states that there are no prior or related appeals.

PRELIMINARY STATEMENT

Millions of Americans suffer from anaphylaxis, a life-threatening allergy condition that can occur anywhere at any time. When they experience anaphylactic shock, they need an immediate injection of epinephrine. For years, they had, for practical purposes, only one way to get it: Mylan's EpiPen.[1] As Mylan put it: "*we are the market for anaphylactic shock* with over 98% market share." 6-JA-1142.[2] And Mylan reaped big rewards from its stranglehold on the market for these life-saving devices: EpiPen's U.S. sales alone reached $1 billion and accounted for almost 40% of Mylan's global profits.

That conquest had consequences. Mylan was able to raise EpiPen prices at will—*over 500%* between 2008 and 2016 alone. And it made no meaningful innovations to EpiPen's dated battlefield technology to justify the ever-increasing list price. Not to its bulky design, too big for many users' pockets. Not to its traumatic swing-and-jab application. Mylan had no need to improve EpiPen. It *was* the market. High barriers to entry and network effects—patients, spouses, grandparents, all trained on EpiPen—kept it that way.

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[1] "Mylan" includes Defendants-Appellees Mylan Inc. and Mylan Specialty, L.P.

[2] This brief adds emphasis to quotations from the record unless otherwise specified, and cites to the Joint Appendix using both volume and page range (*e.g.*, Volume Number-(Sealed) Joint Appendix-Page Range).

Until 2013, that is, when Sanofi launched Auvi-Q, the first "significant threat" to EpiPen's monopoly.[3] Auvi-Q was the "[redacted]"—smaller than EpiPen, easier to carry, and easier to use. Mylan knew it could not sit still. It first tried to license Auvi-Q (no deal) and then tried to copy it (too expensive). Then it pivoted to a different plan: Mylan would "[redacted]." 51-SJA-11498.

Laser focused on blocking competition, Mylan jacked up prices even higher in the year leading up to Auvi-Q's launch. Then it made an offer many payors could not refuse: a steep rebate off EpiPen's inflated list price, but only if insurance plans cut off patients' access to Auvi-Q's life-saving technology. Mylan's entrenched monopoly volume gave it the edge it needed to keep Auvi-Q out of patients' reach. Because insurers collect rebates for each and every prescription filled through a plan, a rebate multiplied by EpiPen's sky-high utilization would go much farther than the same—or even a better rebate—on Auvi-Q, the new entrant. As the largest payor candidly told Sanofi, no rebate on Auvi-Q (*even 100%*) would be enough to access the market. Mylan pursued these exclusive contracts so aggressively because it knew that even a handful of strategic exclusions would "impact physician prescribing in general," making it increasingly difficult for *any patient anywhere in the country* to

[3] "Sanofi" is Plaintiff-Appellant Sanofi-Aventis U.S. LLC.

access Auvi-Q. And Mylan's plan worked exactly as intended: it foreclosed Auvi-Q from over half the market, while repeatedly raising EpiPen's list price.

All of this was a textbook violation of the antitrust laws. Section 2 of the Sherman Act, 15 U.S.C. § 2, forbids monopolists like Mylan from foreclosing rivals and maintaining their monopoly by competing on a "basis other than the merits." *LePage's, Inc. v. 3M*, 324 F.3d 141, 147 (3d Cir. 2003) (en banc). Mylan did exactly that: it leveraged its entrenched monopoly to block competition, maintain its monopoly, and saddle consumers with higher prices, fewer choices, and less innovation. Discovery unearthed a mountain of supportive evidence (*infra* at 5-44), easily sufficient to bring Sanofi's claims to a jury.

In concluding otherwise, the district court committed multiple legal errors and took a balkanized view of the evidence that badly missed the forest for the trees. At a high level, the court misconstrued the record to conclude that Mylan was able to exclude Auvi-Q by supposedly offering payors better deals. But in its 157-page opinion, the court never reckoned with the basic math: Mylan's exclusionary rebates were always going to be worth much more than Sanofi's because Mylan had nearly 100% of the volume. And Mylan used that leverage to block consumers' access to Auvi-Q, so EpiPen's monopoly would continue. Some of those exclusionary contracts, the court noted, lasted "only" two and a half years. But Mylan's monopoly had no termination date, and that was all it needed to block competition. According

to the district court, the competitive process must have worked because Sanofi was eventually able to reverse some of the exclusions. Wrong again. Sanofi resorted to desperate, unsustainable measures to claw back *mere access* that never should have been denied in the first place—like sacrificing tens of millions of dollars from products in *other markets* because even giving Auvi-Q away for free would not have been enough to let patients choose the better mousetrap. Applying the correct legal standard, a jury could easily conclude Mylan violated the antitrust laws when it blocked Auvi-Q from more than half the relevant market.

ISSUES PRESENTED

1. Is there a triable question whether Mylan's conduct had the probable effect of substantially foreclosing competition?

2. Is there a triable question whether Mylan caused antitrust injury to Sanofi by harming competition?

JURISDICTION

The district court entered final judgment on December 17, 2020. 22-JA-4971. Sanofi appealed on January 13, 2021. 13-JA-2748-49. The district court's jurisdiction was founded on 28 U.S.C. § 1331. This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE CASE

I. FACTUAL BACKGROUND

For decades, Mylan's EpiPen dominated the market for epinephrine auto-injectors ("EAIs"), a life-saving device. EpiPen's market stranglehold went effectively unchallenged until Sanofi launched Auvi-Q, an innovative and more "consumer friendly" product. 15-JA-3306. But Mylan had a plan to protect its monopoly: it would exploit EpiPen's dominant position to ensure that insurers would not cover the new entrant and physicians would not prescribe it. That scheme was not competition on the merits, and it foreclosed Sanofi from more than half the EAI market.

A. Mylan's EpiPen Monopoly

EAIs are the accepted method for treating anaphylaxis, a life-threatening allergy condition. Because anaphylaxis can occur anywhere, doctors stress that patients carry their EAIs at all times. 15-JA-3126, 15-JA-3132-33. But two-thirds of patients—including over 70% of children—fail to carry their EAIs as prescribed. 19-JA-4230-31, 7-JA-1385.

EpiPen is the oldest EAI on the market, approved by the FDA in 1987. 13-JA-2852-54, 13-JA-2855-56. EpiPen is shaped like an oversized pen and does not fit comfortably in patients' pockets. 13-JA-2855-56, 15-JA-3134, 15-JA-3139. Adapted originally from a battlefield device designed to counteract nerve agents,

EpiPen requires that patients "swing and jab" the needle into their thigh to administer the epinephrine. 13-JA-2855-56, 15-JA-3134.

Mylan began marketing EpiPen in the United States in 2007 and has dominated the EAI market ever since. EpiPen "accounted for at least 90% of [EAI] prescriptions in the United States for each year between 2007 and 2012," 6-JA-1153, and had *over 99% percent market share* immediately prior to Auvi-Q's 2013 launch, 13-JA-2860-61, 36-SJA-8093, 35-SJA-7682, 6-JA-1216.

Mylan credited that dominance to "[redacted]" that "[redacted]" of new devices. 35-SJA-7688. It knew FDA approval had stalled several competitors, 13-JA-2848-49, 13-JA-2884-85, 36-SJA-7963-64, 35-SJA-7731-32, 9-JA-1869, 9-JA-1883, and it stressed to investors that EpiPen's patent portfolio added yet "another barrier to entry," 14-JA-2894. In addition, the upfront marketing costs to enter "a [market] defined by a single brand for decades" were "huge." 20-JA-4358, 13-JA-2848-49. EpiPen was the "Kleenex" of the industry, and doctors would prescribe it "automatically" because it was "the first thing that comes to mind." 15-JA-3349, 56-SJA-12516, 20-JA-4496. Before Auvi-Q, Mylan faced just two competitors (Adrenaclick and Twinject), and neither posed a real threat to its monopoly. 13-JA-2857-88, SJ-Op.8 (12-JA-2598), 35-SJA-7749.

EpiPen was Mylan's crown jewel. Primarily a generics company, Mylan sells "thousands of drugs" and fills hundreds of millions of prescriptions. 5-JA-1001. Yet,

EpiPen's U.S. sales alone accounted for nearly *40%* of Mylan's global profits. 36-SJA-7927, SJ-Op.20 (12-JA-2610). Between 2008 and 2016, Mylan raised the list price of EpiPen by *over 500%*—from under $100 in 2008 to over $600 by 2016. 37-SJA-8316 (Mylan return on investment analysis: "Approximately 60% of revenue growth attributable to [EpiPen] price increases"), SJ-Op.20 (12-JA-2610). Mylan's executives had a "significant economic incentive" to protect their crown jewel at all costs. 51-SJA-11386; 5-JA-1011.

B. The Threat of Auvi-Q

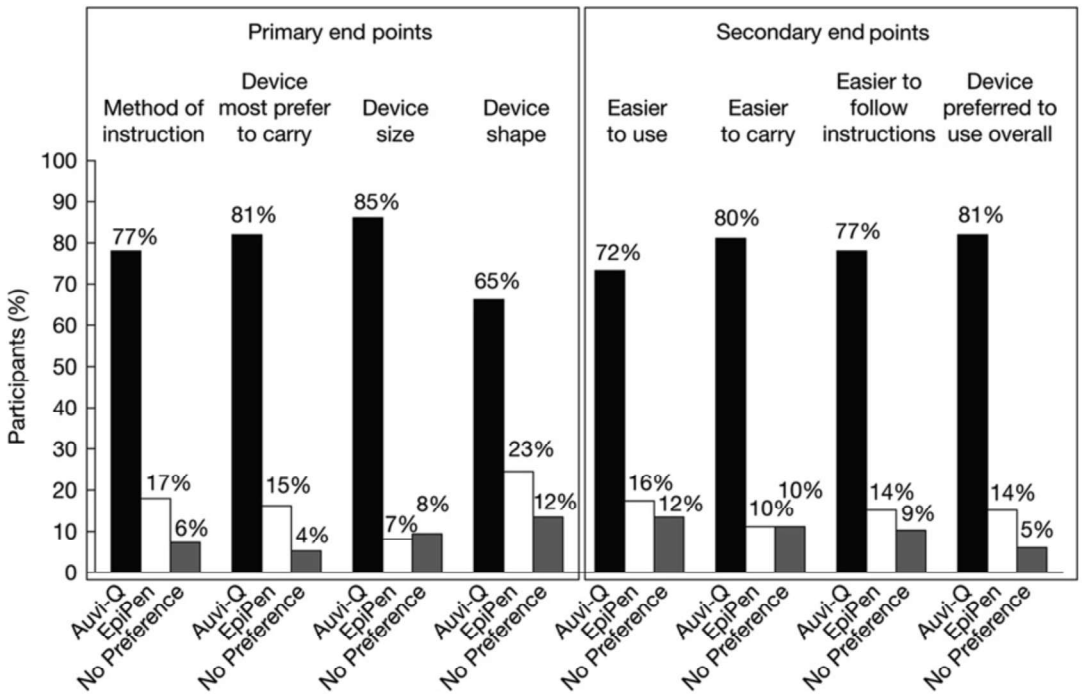
Auvi-Q was the first real innovation in the EAI market in over 25 years, and the first genuine threat to EpiPen's dominant position. SJ-Op.8 (12-JA-2607), 15-JA-3136. Developed by twin brothers with severe food allergies, Auvi-Q answered EpiPen's most enduring challenge: that patients (especially children) fail to carry their devices as prescribed. 19-JA-4230-31, 7-JA-1384-85. Shaped like a credit card, with the thickness of a smartphone, Auvi-Q can slide easily into a child's pocket. 15-JA-3139. Auvi-Q also eliminated the traumatic swing-and-jab method, instead allowing users to press the device against their thighs. 15-JA-3140-41. Auvi-Q's automatically retractable needle minimizes the risk of skin lacerations, another serious problem among children who use EpiPen, 15-JA-3140-41, and its audio

instructions guide users step-by-step through the high-stress injection process. 15-JA-3138.[4]

7-JA-1402, 15-JA-3132 ("Side-by-side comparison of Auvi-Q and EpiPen").

Market research confirmed that Auvi-Q would be heavily favored among patients. Sanofi's surveys showed that 81% preferred to carry Auvi-Q over EpiPen, 85% preferred Auvi-Q's size, 7-JA-1419, 55-SJA-12390, and 85% percent would "pay more for Auvi-Q versus Epipen," 53-SJA-11954. Sanofi corroborated these results in a peer-reviewed study:

[4] *See Auvi-Q: Meet the Family*, Auvi-Q, https://www.auvi-q.com/about-auvi-q (last visited May 25, 2021).



7-JA-1404. Mylan knew "many doctors will think [Auvi-Q] is a better device," 50-SJA-11221, SJ-Op.10 (12-JA-2600), because of its "[redacted]," 50-SJA-11219, 58-SJA-12957-60. While the two products were "bioequivalent" in the narrow sense that both contain "the same amount of epinephrine," 6-JA-1196, patients and prescribers discerned a world of difference. 36-SJA-8022, 56-SJA-12516-18.

In 2008, Mylan met with Auvi-Q's inventors to license the device and "[redacted]" prior to launch. SJ-Op.8 (12-JA-2598), 38-SJA-8435, 50-SJA-11196, 15-JA-3256-57, 50-SJA-11169. Following the meeting, Mylan's manufacturer acknowledged Auvi-Q "will be a significant threat to our EpiPen business" because it would "offer patients a solution to one of the most significant problems associated with EpiPen: its size and shape." SJ-Op.8 (12-JA-2598), 50-

SJA-11196; 15-JA-3256, 50-SJA-11180. In November 2009, the inventors licensed Auvi-Q to Sanofi instead. 20-JA-4293, 7-JA-1385.

Mylan knew that, in Sanofi's hands, Auvi-Q posed "a significant threat to EpiPen market share." SJ-Op.9 (12-JA-2599), 37-SJA-8332, 50-SJA-11206, 15-JA-3279. Though EpiPen had ruled the market for nearly *three decades*, Mylan anticipated Auvi-Q would capture 30% to [redacted]% share within just *three years*. 38-SJA-8460, 51-SJA-11495, SJ-Op.55 (12-JA-2645). In August 2011, Mylan explored the concept of a "new Epipen"—a [redacted] version with "voice instructions," and no swing-and-jab. SJ-Op.10 (12-JA-2600), 50-SJA-11171-75, 50-SJA-11244, 50-SJA-11250-51, 36-SJA-7973. Mylan's CEO "specifically stressed" the need to launch "before mid-2013" to preempt Sanofi's momentum. 38-SJA-8441, SJ-Op.10 (12-JA-2600), 37-SJA-8287.

But entry barriers proved insuperable. With a projected [redacted] spend and a [redacted] launch timeline, Mylan declined to implement improvements. 50-SJA-11171, 50-SJA-11176, 50-SJA-11260, 37-SJA-8286. Instead, it would find a cheaper and faster way to "[redacted]." 51-SJA-11498 (Mylan email).

C. The Prescription Drug Industry

The supply chain in the pharmaceutical industry is straightforward: Manufacturers supply wholesalers, who distribute to pharmacies, who dispense to

patients with a doctor's prescription. 13-JA-2850-51. The flow of money, on the other hand, is more complex, and it created "opportunities" for Mylan to leverage its monopoly power against Auvi-Q. 13-JA-2850-51. The manufacturer sells to the wholesaler; the wholesaler sells to the pharmacy; and the insured patient makes a co-payment (a fixed dollar amount) or co-insurance payment (a fixed percentage of the list price) to the pharmacy. 13-JA-2850-51. The insurance company then reimburses the pharmacy based on the list price, and circles up with the manufacturer to collect a negotiated "rebate" on each prescription filled. 13-JA-2850-51, 36-SJA-7941. Because insurance companies (rather than patients or doctors) largely foot the bill, manufacturers can sometimes raise list prices substantially without patients switching to lower-cost alternatives. 13-JA-2850; Michael A. Carrier, *Three Challenges for Pharmaceutical Antitrust*, 59 Santa Clara L. Rev. 615, 616 (2020).

In response, many insurers have turned to pharmacy benefits managers ("PBMs") to manage prescription-drug benefits for their patients. 13-JA-2850; SJ-Op.12 (12-JA-2602). These intermediaries consolidate millions of insured patients and attempt to negotiate for higher rebates. 13-JA-2850. As of January 2015, seven firms—PBMs and insurance companies (collectively "payors")—held the keys to 86% of covered commercial lives in America: Express Scripts (38%), CVS Caremark (20%), OptumRx/United Healthcare (10%), Prime Therapeutics (7%),

MedImpact (6%), Cigna (4%), and Aetna (1%). SJ-Op.12 (12-JA-2602). Within Auvi-Q's first year, Mylan blocked Auvi-Q at more than half of them for 2014.

1. Management techniques

Payors utilize several techniques to influence patient choice. 36-SJA-7939-40. The most common is the "formulary"—a list of prescription drugs covered by a patient's insurance plan. 36-SJA-7939-40, SJ-Op.12-13 (12-JA-2602-03). Formularies typically consist of multiple "tiers," corresponding to different levels of co-payment. Under the common three-tiered structure, generics are the lowest tier (Tier 1) with the lowest co-pay; "preferred" branded products are on Tier 2 (T2) with a higher co-pay; and non-preferred branded options are on Tier 3 (T3) with the highest co-pay. 36-SJA-7939-40, SJ-Op.14 (12-JA-2604). In theory, payors can use co-pay differentials to steer patients to drugs on a lower tier. 8-JA-1558.

Payors can also deploy more drastic tools to steer patients to preferred products: "benefit exclusions" require patients to pay the full list price out of pocket, SJ-Op.15 (61-SJA-13711); "step edits" require that patients first experience failure with a preferred product before utilizing the less preferred alternative, 36-SJA-7939-40; and "prior authorizations" require that physicians make formal requests for specific drugs based on specialized criteria, SJ-Op.15 (61-SJA-13711). Mylan viewed all of these as "restriction[s] on Auvi-Q." 53-SJA-11830, 53-SJA-11835, 17-JA-3631, 50-SJA-11146, 38-SJA-8519 [redacted]

[redacted]"), 50-SJA-11316, 38-SJA-8410 (Mylan: [redacted]).

2. The bidding process, rebates, and administrative fees

In a competitive market, manufacturers can avoid restrictions and access the preferred tier by offering payors a rebate off a drug's list price. SJ-Op.16 (61-SJA-13712). Manufacturers pay rebates "retrospective[ly]" to defray the overall costs to the insurance plan from patients' utilization of the rebated drug. SJ-Op.16 (61-SJA-13712), 13-JA-2850-51. In addition, manufacturers pay PBMs an "administrative fee"—a fixed percentage of the list price for each prescription filled through the formulary. 57-SJA-12865, 50-SJA-11306, 37-SJA-8351. Manufacturers can also offer "price protection"—an agreement that, if the manufacturer increases its price above a contracted-for percentage, it will rebate back to payors anything above the contractual threshold. SJ-Op.16 (61-SJA-13712).

With a signed rebate agreement, payors can submit claims for rebates and administrative fees on each prescription filled. 12-JA-2607, 36-SJA-7941. Because payors collect rebates for each prescription, the rebates' overall value depends not only on the net per-unit price (*i.e.*, the list price less the rebate and administrative fee), but even more so on the drug's overall utilization. 58-SJA-13082 ("The Rebate is calculated by [redacted]."). A

lower rebate on a product with high utilization—like EpiPen—could easily be worth more than a deeper rebate from a less-used competitor. 14-JA-2912.

Rebate bids generally fall into the following categories: there are bids for *equal access* to the formulary, and bids to *exclude or disadvantage* competitors. SJ-Op.16-17 (61-SJA-13712-13), 52-SJA-11629. Access rebates require payors to cover a product without restriction. SJ-Op.25 (12-JA-2615); 36-SJA-7985-86. By contrast, exclusive rebates require payors to disadvantage rival products with management techniques. SJ-Op.13-17 (61-SJA-13709-13), 56-SJA-12724, 56-SJA-12726. In between, there are bids for "copreference"—coverage alongside a fixed number of competitor products. 25-SJA-5642.

3. Management norms in the EAI market

PBMs considering whether to manage a particular drug class may weigh the health benefits of patient choice against the opportunities to extract additional rebates through restrictions. 16-JA-3535, 16-JA-3507. Naturally, that balance will "differ[] from product to therapeutic category." 16-JA-3412, 16-JA-3422.

Though some large commercial payors began excluding drugs as early as 2005, 10-JA-2151-52 (ESI 2005), 26-SJA-5885 ([redacted] 2006), none had *ever* excluded an EAI before Auvi-Q's launch, 51-SJA-11486, 15-JA-3296, 15-JA-3308, 16-JA-3355-56. From a clinical standpoint, "substitution of one [EAI] for another presents a real concern for patient safety": patients "require unique training" on each

device to acquire the competence necessary to administer it in a life-threatening emergency. 4-JA-775, 4-JA-835. Aggressive management could put lives at risk by forcing patients to switch from devices they are trained on and most comfortable with. 4-JA-835, 13-JA-2889, 37-SJA-8180.

As Auvi-Q was preparing to launch, payors widely reported that their "main objective [was] to provide easy and open access" to all EAIs. 16-JA-3535, 55-SJA-12372. The consensus understanding was that "[redacted]" to Auvi-Q. 51-SJA-11368 (Mylan managed-care consultant) (emphasis in original). "Coverage of EAIs was considered the 'cost of doing business' given the life-threatening nature of anaphylaxis." 16-JA-3501, 51-SJA-11367-68. "[C]linical program[s] such as step therapy" were deemed especially inappropriate, 54-SJA-12127 ([redacted]), given that "failure" with one EAI means "death," 15-JA-3275. The financials similarly favored patient choice: "Payors generally [did] not see a need to impose restrictions," 16-JA-3535, because EAIs are a "once a year patient spend," 53-SJA-11954, and constitute an "infinitesimal" fraction of payors' overall costs. 16-JA-3507, 53-SJA-11954; *compare* 16-JA-3426 (CVS's exclusion "list" consisting of "chronic medications" that represent substantial portion of payors' overall spend).

Mylan's pre-Auvi-Q rebate agreements reflected this commitment to equal access. Mylan required that EpiPen "be listed in *equal* position," without singling

out rivals for exclusion. SJ-Op.25 (12-JA-2615), 52-SJA-11658, 52-SJA-11612-13. Indeed, Mylan could not "identify a single formulary that excluded all non-EpiPen EAI devices prior to 2012." 13-JA-2871.

D. Mylan's Scheme to Block Patient Access to Auvi-Q

Mylan recognized "PBMs and large payers [would] be predisposed to provide [redacted]" to Auvi-Q and EpiPen. 51-SJA-11367-68. If left to "fight it out" on the merits, 54-SJA-12239, 54-SJA-12262, Mylan knew Auvi-Q would quickly capture ~[redacted]% of EpiPen's monopoly, *supra* at 10.

In late 2011, Mylan formulated a comprehensive scheme (a "revised contract strategy") to "pre-empt" Auvi-Q and "[redacted]." SJ-Op.23-24 (12-JA-2613-14), 37-SJA-8351, 51-SJA-11498, 36-SJA-7975, 50-SJA-11317. Mylan would "restructure [its existing] contracts for exclusivity," requiring payors to block Auvi-Q in order to access deeper rebates on EpiPen's monopoly volume. SJ-Op.24 (12-JA-2614), 51-SJA-11509, 56-SJA-12594, 37-SJA-8351, 51-SJA-11515, 54-SJA-12167.

Mylan knew its near-100% share would put "[redacted]." 37-SJA-8182. Once Mylan instigated a battle for exclusivity, it could easily leverage its entrenched monopoly volume to block Auvi-Q from the formulary, despite inferior rebate offers. "[redacted]" to even merit consideration. 51-SJA-11368 (Mylan consultant), 54-

SJA-12127-28, 54-SJA-12131-34. Even if Sanofi offered "a significantly lower net price," 16-JA-2503, Auvi-Q would still need to capture 30-50% of the EAI market before payors would consider granting it "advantageous formulary access over EpiPen." 55-SJA-12393.

Mylan understood "how valuable it was to *hammer Sanofi at launch*" before it could accumulate enough market share to level the playing field, 51-SJA-11489: "if we don't begin our 'war game' scenarios *now* and begin to restructure contracts *now* we may be too late to do it after [Auvi-Q] gets momentum." SJ-Op.24 (12-JA-2614), 51-SJA-11509 (Mylan email). Mylan resolved to crush the innovator at inception. The only question was how to get payors to block patients from accessing Auvi-Q's novel, life-saving technology, when prevailing norms so heavily favored patient access.

1. Mylan pushes payors to block Auvi-Q with price escalation and exclusionary rebates.

In 2012, Mylan sped up its aggressive price escalation to anticipate Auvi-Q's "launch timing." 50-SJA-11332, SJ-Op.19, 24 (12-JA-2609, 2614); 37-SJA-8272. It was "uncommon" for pharmaceutical companies to increase list prices "twice a year," 9-JA-1785; but Mylan raised EpiPen's price three times and by an [redacted] 30% in the lead-up to Auvi-Q's launch. 51-SJA-11362. Mylan continued to raise the list price by 25-30% each year that Auvi-Q was on the market, from $181 at the start of 2012 to $529 by the end of 2015. 37-SJA-8242.

Mylan believed price escalation would directly "support" its "revised contract strategy" by ratcheting up financial pressure on payors to exclude Auvi-Q. 50-SJA-11317 (Mylan presentation); 35-SJA-7790. Mylan would offer to partly offset its aggressive pricing with increased rebates and price protection—but *only* if payors agreed to block Auvi-Q. 55-SJA-12279, 28-SJA-6295, 52-SJA-11629, 55-SJA-12405-06, 54-SJA-12186, 57-SJA-12909, 36-SJA-7980-91, 50-SJA-11205. Mylan knew PBMs would be "heavily impacted if they work[ed] against [Mylan]," and that the threat of "**lost rebate $'s**" would keep Auvi-Q off formulary. 52-SJA-11602 (Mylan presentation) (emphasis in original), 35-SJA-7790, SJ-Op.24-25 (12-JA-2614-15), 37-SJA-8351.

Restrictions were the key to Mylan's scheme. As one Mylan employee put it: "We will only pay [EpiPen] rebates if a client is willing to exclude Auvi-Q." 5-JA-983. Mylan's method was "so egregious that it turned managed care plans to say, 'We're only going to offer one lifesaving product on the market.'" 16-JA-3356.

2. Mylan could leverage its monopoly volume and substantial entrenched share to prevent meaningful price competition.

Mylan was warned that its extraordinary price hikes could backfire, prompting payors to try shifting share to Auvi-Q. 51-SJA-11362, 35-SJA-7790, 57-SJA-12953, 35-SJA-7759. But for three reasons, Mylan knew that would never happen.

First, Mylan's position was "[redacted]." 16-JA-3433. Steering share to Auvi-Q would mean

foregoing the steep EpiPen rebate off a high list price, multiplied by EpiPen's high utilization. To make those numbers work, payors would need to move a massive share of the market to Auvi-Q ("[redacted]"), and they knew "[redacted]." 56-SJA-12516, 16-JA-3451, 36-SJA-7962, 54-SJA-12262, 55-SJA-12368-69. For each patient that remained with EpiPen, payors would be forced to "pay full price for EpiPen," without recourse to Mylan's rebates or price protection. 36-SJA-8005, 36-SJA-8101 (internal Mylan email). Mylan knew its [redacted] price increases would have "[redacted]" on EpiPen's formulary placement precisely because payors were unlikely to "[redacted]" on its entrenched monopoly. 51-SJA-11365-67 (Mylan consultant). In the words of one payor: "I have a product that has 100% market share in T2, you have 0% market share and you want me to displace EpiPen??" 54-SJA-12262.

Mylan knew its monopoly volume would impact PBMs, too. 37-SJA-8351, 50-SJA-11306. PBMs not only retain 10% of the rebate for themselves, 18-JA-3951, but also pocket a fixed "administrative fee" (up to 4.375% of the list price) on every prescription filled, 54-SJA-12166, 52-SJA-11650, SJ-Op.30 (12-JA-2620); *see, e.g.*, 28-SJA-6267, 28-SJA-6259. And because administrative fees depend only on list price and utilization (not the proposed rebate), 56-SJA-12703, 26-SJA-5726, Mylan knew the larger PBMs would never forgo the "$[redacted] in EpiPen admin

fees," regardless of how deeply Sanofi was willing to rebate. 37-SJA-8351 (Mylan presentation); 50-SJA-11306.

Second, restrictions on EpiPen would cause, in Mylan's words, "[redacted]." 27-SJA-6096, 35-SJA-7837. Payors considering more aggressive management weigh the "balance between disruption" of forcing patients to a new product "and savings" from the restriction. 13-JA-2872, 27-SJA-6096. In EpiPen's case, Mylan knew a block would create such "[redacted]" that even the most aggressive payors would not "[redacted]." 27-SJA-6096. As Mylan has explained, EAIs "are not typical drug devices": they are "*emergency use products* that differ in important ways." 4-JA-771. Once a patient or caregiver is trained to administer the device "in a life-threatening situation," they are "logically" reluctant to switch away from what they know. Mylan's Opp. to Motion to Strike Blaiss Testimony, *In re EpiPen*, No. 17-md-02785 (D. Kan. Dec. 17, 2020), ECF No. 1623 at 6; 13-JA-2889-90, 37-SJA-8180; *In re EpiPen*, No. 17-md-2785, 2020 WL 1164869, at *4 (D. Kan. March 10, 2020) (*Mylan's* medical expert: "patients are likely to stick with EpiPen instead of having to learn how to use another product."). Mylan has sworn in court filings that "substitution" away from EpiPen "presents a distinct concern for patient safety." 4-JA-809. And with 30 years of market dominance, EpiPen had cultivated a "network" of teachers, neighbors, and school nurses trained exclusively to swing and jab. 13-JA-2890, 4-JA-804, 4-JA-

826. That network makes patients and parents even more "reluctant to switch" away from the incumbent product. Mylan's Opp. to Motion to Strike Blaiss Testimony, *In re EpiPen*, No. 17-md-02785 (D. Kan. Dec. 17, 2020), ECF No. 1623 at 3, 7; 13-JA-2889-90. Unsurprisingly, payors widely reported that excluding EpiPen was simply "[n]ot worth the disruption." 54-SJA-12262. Mylan could leverage the threat of "disruption" against the major payors to prevail over Sanofi, even with rising prices and inferior rebate offers. *See, e.g.*, 36-SJA-8100-01, 36-SJA-7945 & n.89 (MedImpact); 5-JA-902 (MedImpact: "the potential for disruption"); 27-SJA-6096 (Optum/United: "[redacted]" and "[redacted]"); 23-SJA-5193 ([redacted]: "quite a bit of patient disruption"); 52-SJA-11613 ([redacted]: "When you have a high market share, … it's important that they don't have disruption.").

Third, if any payors were "[redacted]" to try forcing patients off EpiPen, Mylan knew they would fail. 36-SJA-8100. No commercial payor had previously threatened Mylan with a restriction because, in Mylan's words, they knew "[redacted]." 57-SJA-12741, 52-SJA-11612-13. United came closest in 2008, when it placed EpiPen on the non-preferred tier. 60-SJA-13548. But that effort was a total "[redacted]," as "[redacted]." 23-SJA-5084 (United), 27-SJA-6096 (internal Mylan email), 52-SJA-11713, 20-JA-4495-96. Even when EpiPen was excluded from Medicaid formularies, Mylan reported that it "maintained 40% - 70% market share."

36-SJA-8100-01, Daubert-Op.73-75 (12-JA-2543-45), 51-SJA-11419. Later, when West Virginia tried to exclude EpiPen from its Medicaid formulary, Mylan warned that, "rather than switch to Auvi-Q, some current users of EpiPen will [simply] ask their medical providers to seek prior authorization." 4-JA-786. Consistent with these data and Mylan's own statements, Dr. Fiona Scott Morton—Sanofi's expert and the former Deputy Assistant Attorney General for Antitrust—"reliabl[y]" measured EpiPen's entrenched share at 50-70% when Auvi-Q entered the market. Daubert-Op.77 (12-JA-2547), 51-SJA-11414-20, 51-SJA-11425-29.

E. Mylan Blocks Auvi-Q Within a Year of Launch

Auvi-Q launched in 2013 and, by mid-year, was performing "significantly above forecast predictions." 57-SJA-12762, 57-SJA-12781. Mylan worried it had "underestimated the speed of [Auvi-Q's market] penetration," 18-JA-3814-19, and knew that "[redacted]." 57-SJA-12830.

But Mylan had the monopoly power to stop Auvi-Q in its tracks: "our friends at Sanofi have had their six months of launch. Now it's time to *flex our muscle*." 17-JA-3637. By year's end, Mylan restricted Auvi-Q at more than half of the largest payors. *Infra* at 23-29. Sanofi competed aggressively on price, but it was not enough: even "[redacted]" could not surmount Mylan's entrenched monopoly share. 35-SJA-7720 (Mylan consultant). Mylan would "[redacted]," 52-SJA-11663,

updating senior leadership on the millions of Americans denied access to Auvi-Q's life-saving technology. 7-JA-1371 (September 2013: "Four big wins accounting for almost 19% of the US population"); 50-SJA-11146 (October 2013: "Major wins resulted in Auvi-Q not being covered … in almost 24% (73 million) of the US Population"); 50-SJA-11155 (November 2013: "29% (87 million) of the US population"); 53-SJA-11883 (December 2013: "Major wins" meant no Auvi-Q for "31% (93 million) of the US population").

1. Express Scripts ("ESI")

Mylan paid ESI a ~[redacted]% access rebate before Auvi-Q's launch. 54-SJA-12167. In March 2013, ESI solicited bids from Mylan and Sanofi through its standard-form bid grid. 10-JA-2097-2109, 27-SJA-6112.[5] Mylan returned a grid "heavily weighted" to exclusivity, with [redacted]% rebates for nonexclusive positions and [redacted]% rebates to block Auvi-Q. 55-SJA-12405, 54-SJA-12275 (Mylan: "this does not include admin fees!").[6] Mylan added [redacted]% price protection, but only if Auvi-Q

[5] In early 2013, before ESI even circulated its bid grid, Mylan proposed unilaterally to double its rebate in exchange for a block on Auvi-Q. 58-SJA-13094, 50-SJA-11207, 37-SJA-8351.

[6] Rebate percentages do not include ESI's substantial 4.375% administrative fee. 41-SJA-9071, SJ-Op.30 (12-JA-2620).

was excluded.[7] 54-SJA-12275, 55-SJA-12405, 50-SJA-11205. Mylan knew it would *lose* [redacted] from this lopsided offer, but it was willing to sacrifice profits to block Auvi-Q at the largest payor and suppress its market share below critical mass. 36-SJA-8019-20, 58-SJA-13095-96.

Sanofi offered a substantially *deeper* discount ([redacted]% v. [redacted]%) and on *less* restrictive terms. 28-SJA-6159. But EpiPen "had almost all the market share," 23-SJA-5191-92, and ESI simply "couldn't refuse" the rebate and administrative fees on all the volume, 4-SJA-736. Even with Sanofi's deeper rebate, ESI would still face a higher "[redacted]" if it permitted patients to access Auvi-Q. 24-SJA-5212, 27-SJA-6090.

So Sanofi sweetened the offer even more, adding rebates on its leading insulin drug, Lantus—over $18 million in value and more than ESI's entire "book of business" for Auvi-Q—just to keep Auvi-Q on the formulary. 25-SJA-5646; 36-SJA-7983; 51-SJA-11461-62; 56-SJA-12607. But even those enhanced rebates were not enough to access the market.

As Sanofi improved its offer, Mylan did the opposite. Shortly after ESI announced the Auvi-Q exclusion, Mylan raised EpiPen's price by 15%. 55-SJA-

[7] Mylan's and Sanofi's internal documents value [redacted]% non-resetting price protection at roughly [redacted]% additional rebate. 56-SJA-12523, 30-SJA-6705.

12401.[8] ESI was [redacted] 25-SJA-5646), but the largest PBM was powerless to resist. After "[redacted], 25-SJA-5646, ESI concluded that even $18 million in Lantus points was insufficient to surmount Mylan's rebate, considering "patient disruption." 23-SJA-5193-94. With prices up and Sanofi out, Mylan celebrated the "Great news": "approximately 1 out of every 10" Americans would lack access to Auvi-Q. 17-JA-3679.

2. OptumRX/United Healthcare

In early 2012, Mylan provided United a [redacted]% access rebate. 56-SJA-12689. Mylan planned to restructure that contract as a "proactive response" to Auvi-Q, 55-SJA-12441, and it knew price escalation "would [redacted]" by the payor. 35-SJA-7793 (Mylan presentation).

In late 2012, United told Mylan right on cue that it was "[redacted]" on EpiPen, 27-SJA-6097, and that these significant price increases had "[redacted]" a review of the drug class, 52-SJA-11715. But Mylan knew it had a "[redacted]": it had all "[redacted]," 27-SJA-6100 (Mylan email), and United conceded that its prior efforts to disadvantage EpiPen were a "[redacted]

[8] At this stage, Auvi-Q's list price was $[redacted], and EpiPen's was $[redacted]. Factoring in the respective rebate terms, Auvi-Q's net price would have been $[redacted] and EpiPen's would have been $[redacted]. 37-SJA-8242, 55-SJA-12401, 28-SJA-6149-62; *supra* at 24 n.7.

[redacted]." 52-SJA-11713. Mylan knew United would "[redacted]," and avoid the "[redacted]" from an EpiPen exclusion. 27-SJA-6096, 562-SJA-11712.

Sanofi never stood a chance. In 2013, when both sides offered the same 22% rebate, 28-SJA-6248, 28-SJA-6258, United dismissed Sanofi's bid as "not close to what is needed," given Mylan's price protection and the "*extreme difference in utilization*" between EpiPen and Auvi-Q. 28-SJA-6261, 28-SJA-6251.[9] Sanofi refused to stand down. It came back with an even more "aggressive" [redacted]% rebate and 9% price protection. 28-SJA-6264.[10] But it was "too late." 28-SJA-6247, 28-SJA-6271. After tolerating a "[redacted]" from Mylan for a marginal rebate increase, 28-SJA-6238, United refused to consider Sanofi's superior offer. 28-SJA-6271. Meanwhile, more than two months passed before the parties executed their agreement to block Auvi-Q "[redacted]," 36-SJA-8093 (Mylan email). 26-SJA-5731. Despite an inferior rebate offer, Mylan could leverage its monopoly

[9] Rebate percentages do not include a [redacted]% administrative fee. 28-SJA-6247, 28-SJA-6259.

[10] In July 2013, when United made its decision, Auvi-Q's list price was $[redacted] and EpiPen's was $[redacted]. 37-SJA-8242. Factoring in the respective rebates, Auvi-Q's net price would have been $[redacted] and EpiPen $[redacted]. 37-SJA-8242, 28-SJA-6248, 28-SJA-6264. The parties offered substantially similar price protection terms (8% v. 9%). 28-SJA-6264.

volume to secure another "major win[]" and block [redacted] million Americans from accessing Auvi-Q. 15-JA-3238, 28-SJA-6277.

3. MedImpact

In 2012, Mylan provided MedImpact a 5% access rebate. 28-SJA-6320. Though Mylan wished to "[redacted]" contracts like this one, it knew that broaching exclusivity "[redacted]." 28-SJA-6325, 36-SJA-7976-77. So Mylan prompted MedImpact to start the conversation: it offered to double its existing rebate (5% to 10%) if MedImpact would "disadvantage Auvi-Q" on the highest tier. 28-SJA-6324. Predictably, and as "[redacted]," MedImpact inquired whether Mylan might raise the rebate even more in exchange for a step edit against Auvi-Q. 28-SJA-6324.

In early 2013, after Sanofi submitted the superior rebate bid, 28-SJA-6343, 55-SJA-12467, MedImpact told Mylan—*but not Sanofi*—that it was supposedly "going with Auvi-Q." 28-SJA-6348, 32-SJA-7129-30. But MedImpact acknowledged "[redacted]," 28-SJA-6325, and Mylan was skeptical that even the most aggressive payors would "[redacted]." 52-SJA-11712. So it warned MedImpact "[redacted]," 36-SJA-7945, and that "[redacted]," EpiPen would still "maintain[] 40% - 70% market share." 36-SJA-8101. In the event MedImpact was still "[redacted] to go

through with the exclusion, Mylan would "terminate its current contract," and require MedImpact's [redacted] members to buy EpiPen at [redacted]. SJ-Op.37 (12-JA-2627), 36-SJA-8100-01, 57-SJA-12915, 36-SJA-7990-91.

Mylan and MedImpact quickly agreed to a 22% rebate in exchange for a step edit against Auvi-Q. SJ-Op.38 (12-JA-2628), 29-SJA-6354, 26-SJA-5690. Once Sanofi received this "surprising news," 5-JA-902, it went to MedImpact *that very same day* and asked for "an opportunity to enhance the offer." SJ-Op.39 (12-JA-2629), 29-SJA-6429. But the "decision ha[d] been made"—MedImpact was "moving on," no matter Sanofi's terms. SJ-Op.39 (12-JA-2629), 29-SJA-6429. Indeed, excluding Auvi-Q was never about the per-unit rebate. MedImpact explained that its decision was "[b]ased on … the potential for disruption, [and] observation of market adoption rates." 5-JA-902. Once Mylan instigated a battle for exclusivity, it was "[redacted]"—Sanofi could never out-rebate Mylan's monopoly advantages. 52-SJA-11799.

4. Aetna

Mylan paid Aetna an [redacted]% rebate for access in 2011. 46-SJA-10249. By late 2012, Mylan had already "[redacted]" about "[redacted]." 57-SJA-12953. Whereas Sanofi offered Aetna a [redacted]% rebate for copreference, 29-SJA-6462, Mylan offered 15% to block Auvi-Q with a step edit.

29-SJA-6456, SJ-Op.40 (12-JA-2630), 4-JA-744. Aetna never sought a further bid from Sanofi "[redacted]." 35-SJA-7720. In May 2013, Aetna declared internally that it would step edit Auvi-Q, 10-JA-2196, and told Mylan it would accept its "[redacted]" offer. 29-SJA-6456. Only patients "with severe visual impairment" or illiteracy could access Auvi-Q. 30-SJA-6705. For Mylan, that was "very exciting" news. 4-JA-744, 52-SJA-11753, 52-SJA-11755-56.

5. Humana

Prior to Auvi-Q's launch, Mylan paid Humana a [redacted]% access rebate. 52-SJA-11666-68. In late 2012, Mylan began to press Humana for "restrictions" on Auvi-Q: "[redacted]." 52-SJA-11666, SJ-Op.42 (12-JA-2632). Mylan convinced Humana to block Auvi-Q on its Medicare formularies (80% of its business) by [redacted] its rebate offer (from [redacted]% to [redacted]%). 30-SJA-6637, 55-SJA-12298.

In mid-2013, as Auvi-Q outperformed expectations, Humana requested a "[redacted]" offer for 2014. 52-SJA-11677. Mylan refused, and instead offered an additional [redacted] percentage points to "[redacted]." 52-SJA-11675, 38-SJA-8410. As Humana stood its ground, Mylan became increasingly aggressive: "Am I wasting my time trying to get you to commit to an exclusive agreement for EpiPen? [redacted]."

14-JA-3069, 52-SJA-11673. Humana predictably capitulated and kept Auvi-Q excluded from its Medicare formularies. 37-SJA-8230, 36-SJA-7901, 52-SJA-11613.

6. CVS/Caremark

In early 2012, Mylan had already begun to restructure its contract with CVS, offering [redacted] the rebate ([redacted]% vs. [redacted]%) for "exclusive" position on the formulary. 46-SJA-10261. In November, CVS sent both manufacturers a standard "Bid Sheet" that permitted "incremental rebate[] [offers] for additional controls." 10-JA-2111-15 (caps omitted). In June 2013, as Auvi-Q exceeded market expectations, Mylan began to hound CVS for the opportunity to block Auvi-Q. 55-SJA-12412. At that point, CVS had already decided to place EpiPen on T2 in exchange for a [redacted]% rebate and Auvi-Q on *disadvantaged* tier (T3) for a *higher* rebate ([redacted]%), starting July 2013. 23-SJA-4988, 26-SJA-5724, 28-SJA-6199.[11]

7. Prime

Prior to Auvi-Q's launch, Mylan paid Prime a [redacted]% access rebate. 58-SJA-13082. In January 2013, Mylan more than doubled the rebate (12%) to keep Auvi-Q off T2. 26-SJA-5669.[12] When Sanofi offered [redacted]% for mere *access*,

[11] Figures do not include a 3% administrative fee for Auvi-Q and 4% for EpiPen. 26-SJA-5726, 28-SJA-6208.

[12] Figures do not include Prime's [redacted]% administrative fee. 28-SJA-6312.

Prime rejected the offer out of hand, 28-SJA-6285, 28-SJA-6312, and candidly explained there was no way Sanofi could overcome Mylan's monopoly volume: "Please understand that plans can earn incremental rebates on basically all of the current spend in this class. It's an uphill battle to overcome the incremental dollars [from EpiPen] until Auvi[-]Q builds share." 54-SJA-12128.

In November 2013, Mylan capitalized on its "recent price increase" to press again for a step edit. 57-SJA-12898 (Mylan email). Mylan explained that Prime would receive "[redacted]" ("[redacted]") and price protection, but only if it restricted Auvi-Q. 52-SJA-11660, 54-SJA-12186, 56-SJA-12523, 28-SJA-6309. Prime demurred. It had explained to Mylan "*more than once*" that it would not step edit Auvi-Q. 55-SJA-12462, 57-SJA-12902, 54-SJA-12127. So Mylan did the next best thing and blocked Auvi-Q from T2 with a subpar rebate offer. In early 2014, even when Sanofi outbid Mylan for T2 (17% for co-preference v. 14% for exclusivity), 28-SJA-6309, 57-SJA-12866, Prime still felt compelled to accept Mylan's inferior and more restrictive offer because it knew Mylan would "[redacted]" on its EpiPen volume. 57-SJA-12901.

Even when Mylan could not exclude Auvi-Q, it still managed to notch a "big win" in its broader campaign to suppress Auvi-Q below a critical mass. 55-SJA-12464. Mylan reported internally that blocking Auvi-Q from T2 would not only

"[redacted]" at Prime, "but will also impact physician prescribing in general" by undermining any "[redacted]" of Auvi-Q's "[redacted]" 36-SJA-7994, 28-SJA-6302. Each of Mylan's decisions fit within its broader scheme to "drive [Auvi-Q] to 0." 5-JA-927, 51-SJA-11509.

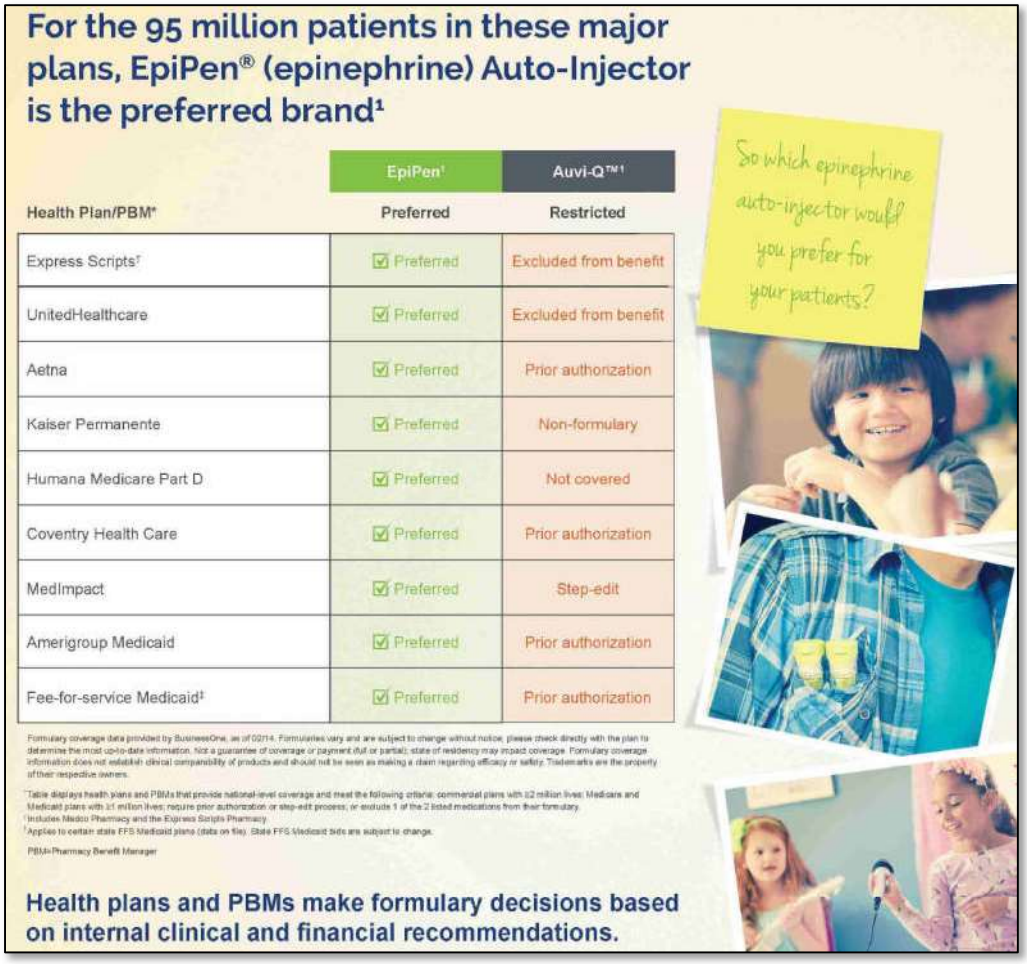
F. Spillover Forecloses Auvi-Q from More Than Half the Market

Mylan's exclusive contracts covered "1/3 of the US population." Daubert-Op.57 (12-JA-2527), 17-JA-3631, 51-SJA-11425-26. In practice, the exclusions swept even broader by virtue of what Mylan called the *spillover effect*. 53-SJA-11848.

Mylan knew that, since doctors see patients covered by many different insurance plans, they default to the product that most insurers cover. 15-JA-3270, 50-SJA-11207, SJ-Op.43-44 (12-JA-2633-2634). Mylan's exclusive contracts were so pervasive that, for any given patient almost anywhere in the country, there was a substantial risk the patient would be unable to fill an Auvi-Q prescription. Mylan's research confirmed Auvi-Q would need "[redacted]" before doctors would consider prescribing Auvi-Q on a regular basis. 52-SJA-11810. Mylan sacrificed profits for exclusions because it knew exclusions would have a massive "spillover effect on the perception of coverage for … all plans," 52-SJA-11719, and "cause coverage concerns from Physician[s] across the US," 27-SJA-6093, 52-SJA-11712, 14-JA-2949, 36-SJA-8019, 52-SJA-11743, 32-SJA-7143.

Mylan knew the coverage disparity was its "[redacted]" and "[redacted]" 38-SJA-8544, 55-SJA-12415. So it devised a comprehensive marketing plan to amplify spillover "and put Sanofi out of business!" 52-SJA-11750. In a presentation titled "Understanding the 'spill over' effect," Mylan's Vice President of EpiPen Marketing directed her team to "**QUANTIFY**" the "gap in coverage" and warn doctors that "[redacted] patients will experience an issue" trying to fill their Auvi-Q prescriptions. SJ-Op.44 (12-JA-2634), 53-SJA-11848, 34-SJA-7635, 52-SJA-11609, 52-SJA-11719, 52-SJA-11774. Because Auvi-Q was the better device, Mylan's team viewed EpiPen as affirmatively "[redacted]." 55-SJA-12415.

Mylan's marketing materials perfectly encapsulated this strategy. While Sanofi promoted Auvi-Q's features, 7-JA-1394-98, Mylan stressed the barriers to access:



53-SJA-11830. Mylan knew the exclusions would cause some doctors to "*erroneously* presume [EpiPen] is safer or more effective than [Auvi-Q]." 4-JA-816. Mylan fostered that misimpression by stating in boldface that payors exclude products for both "*clinical* and financial" reasons—even though there was no clinical basis for the Auvi-Q exclusions. SJ-Op.45 (12-JA-2635), 53-SJA-11829-11840, 15-JA-3333. Senior management instructed sales teams to "[e]mphasize [that] formulary decisions are made based on clinical criteria," and that "*[f]rom a clinical perspective the plans* have 'spoken' by selecting EpiPen over

Auvi-[Q]." 53-SJA-11834, 15-JA-3337, 52-SJA-11722. While Mylan could not "[redacted], 50-SJA-11230, it knew the coverage disparity was a "[redacted]," 38-SJA-8544. Even with greater per-unit marketing expenses, Sanofi could not dispute that Auvi-Q was blocked from half the major formularies. 14-JA-2943, 14-JA-3091, 51-SJA-11403, 52-SJA-11799.

Mylan's spillover strategy worked: "where Mylan was able to restrict access to Auvi-Q at the leading PBMs in the state, the Auvi-Q share fell on average across PBMs in the state." 14-JA-2925. Between contractual exclusions, spillover, and deceptive advertising, Mylan foreclosed Auvi-Q from "more than half the market" and suppressed its growth to less than half of its pre-market projections. 16-JA-3446, 36-SJA-8031.

In sum, Mylan knew it could not compete with Auvi-Q head-to-head. So, instead, Mylan leveraged its massive monopoly volume and unprecedented price escalation against payors to exclude Auvi-Q from more than half the largest formularies. It then amplified the foreclosure by lying to doctors and claiming Auvi-Q was restricted for "clinical" reasons.

G. Mylan Takes Steps to Cement and Subsidize the Exclusions

EpiPens4Schools. In fall 2012, as Auvi-Q was preparing to launch, Mylan devised an additional strategy to entrench the network of users trained exclusively on EpiPen. Through what it termed "EpiPens4Schools," Mylan would place devices

in schools across the country to "[redacted]." 60-SJA-13576. If Mylan could stock schools with EpiPens "prior to [Auvi-Q's] launch," it could prevent Auvi-Q from amassing the volume it needed to compete. 53-SJA-11851, 53-SJA-11875. As the President of Mylan Specialty explained: "[redacted]." 53-SJA-11852, 53-SJA-11877.

In August 2012, the day after Sanofi announced Auvi-Q's FDA approval, Mylan rolled out EpiPens4Schools. 14-JA-2931. The program offered (1) four "free" EpiPens to schools that pledged to provide swing-and-jab "training" to school personnel, 15-JA-3284, and (2) substantial discounts (below the school rate) to schools that pledged not to buy Auvi-Q for at least a year, 53-SJA-11888, 50-SJA-11139, 15-JA-3290. Before Auvi-Q had even come to market, Mylan placed [redacted] EpiPens into schools across the country, with school nurses ready-trained to swing and jab. 58-SJA-13133.

Mylan measured the program's success by its quantifiable ability to suppress Auvi-Q below critical mass. 53-SJA-11851-52, 53-SJA-11875, 53-SJA-11883, 53-SJA-11896, 56-SJA-12639-40. Mylan then brandished the program in rebate negotiations as proof that EpiPen could not be challenged. With MedImpact, Mylan

emphasized that [redacted] 36-SJA-7945, 36-SJA-8101. In another case, Mylan sought an *injunction* to keep EpiPen on West Virginia's Medicaid formulary, arguing that children across the state would be *harmed irreparably* if the state were to exclude the device school nurses were already trained on. 4-JA-769-838, 5-JA-839-60.

Medicaid Misclassification. When Mylan inflated EpiPen's price to exclude Auvi-Q, it should have paid a corresponding rebate back to the state Medicaid formularies under the Medicaid Drug Rebate Program. 4-JA-754-55. But Mylan never paid. Instead, it misclassified EpiPen as a "generic" (with a flat 13% rebate), leaving taxpayers to subsidize its exclusionary scheme. 4-JA-754, 53-SJA-11899 (Payor: "[e]very data point we have suggest the Epipen is a brand (because it is); however; [Mylan has] been paying federal rebates at 13% … as if it was a generic.").

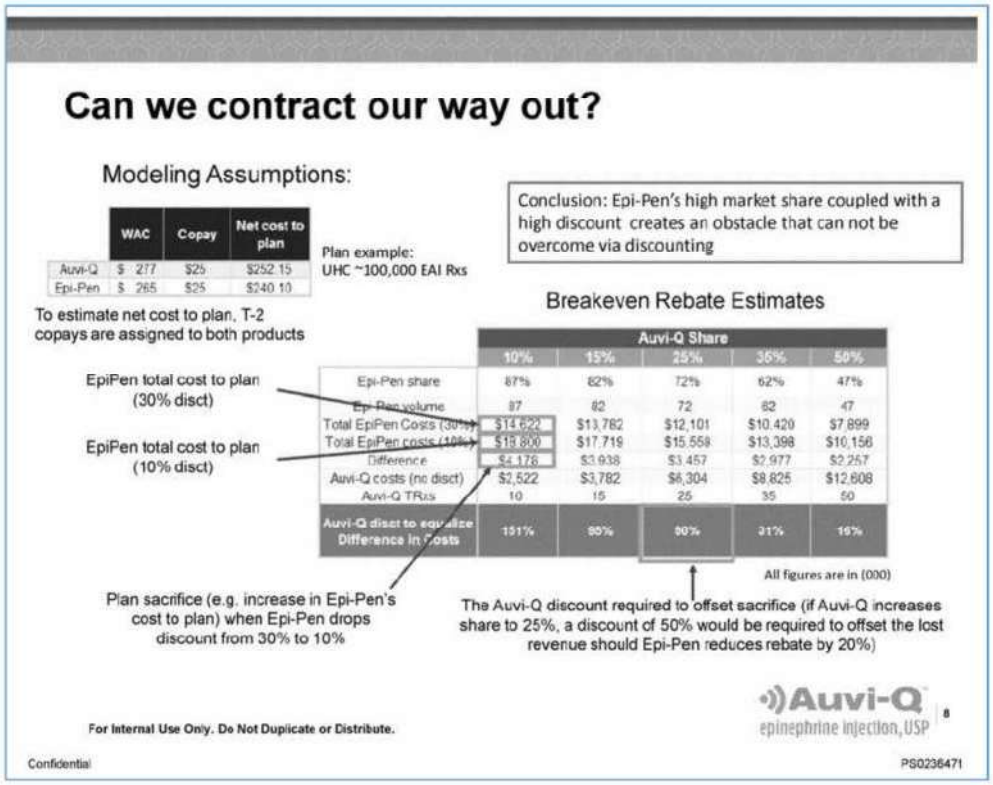
In 2017, following Sanofi's whistleblower complaint, the Justice Department brought Mylan to heel with a *$465 million* False Claims Act settlement. 4-JA-754. By the Department's account, Mylan had leveraged its monopoly power "to demand massive price increases in the private market while avoiding its corresponding rebate obligations to Medicaid." 4-JA-754. The settlement was designed to "level the playing field." 4-JA-754. But in Sanofi's case, the damage was done. 15-JA-3340. In Mylan's words, if it had to pay full Medicaid rebates it "could not have rebated

the product [during competition with Auvi-Q] as we have done because it would have been unprofitable." 53-SJA-11902.

H. Sanofi's Desperate Efforts to Regain Market Access

Mylan's scheme crushed Auvi-Q's momentum. 16-JA-3445. After capturing roughly 12% of the market in 2013, Auvi-Q's share fell precipitously in January 2014 and flatlined from the restrictions. 51-SJA-11663, 37-SJA-8299, 30-SJA-6682, 14-JA-2942, 54-SJA-12093. Mylan knew its success in holding "[redacted]" to only [redacted]" was practically "[redacted]" in all of "[redacted]." 52-SJA-11798; 16-JA-3419.

In late 2013, Sanofi hosted a strategy conference on what it would "take to equalize Mylan [incremental] rebate offers." 27-SJA-5934. The answer: even with a better product, Sanofi could not compete by offering a better price. "Epi-Pen's high market share coupled with a high discount create[d] an obstacle that [simply could] not be overcome via discounting." 54-SJA-12097. As long as Mylan retained its lock on market share, payors would block Auvi-Q in exchange for "easy money" on Mylan's monopoly volume. 16-JA-3397. Sanofi recognized that it could not "contract [its] way out" of Mylan's exclusions:



54-SJA-12097. Sanofi knew it could not grow share in a market it could not access. So, in early 2014, Sanofi began to "explore[] every possible contracting, pricing and financial strategy" to regain access, even if that meant trying to disadvantage EpiPen. 16-JA-3399. Mylan recognized Sanofi was "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*." 5-JA-905. Mylan knew that, even with "[redacted]," payors would be unable to force enough people off EpiPen to level the competitive playing field. 35-SJA-7720, 16-JA-3501; *supra* 21-22. Payors might experiment at the margins, excluding EpiPen from their smallest and most highly managed formularies. 14-JA-2933. But none would dare block EpiPen

from a major formulary. In Mylan's words, Sanofi "[redacted] [redacted][] by offering ridiculous pricing," but still "[redacted]." 56-SJA-12535.

1. Sanofi's "wins"

ESI. In mid-2014, ESI informed Sanofi that *no amount* of Auvi-Q rebates (not even 100%) could overcome Mylan's exclusionary contracts. 16-JA-3577, 56-SJA-12547. Sanofi would need to "write a check" on other, more established products—*$36 million* in Lantus rebate points ("very desperate move")—just to restore *access*. 16-JA-3577, 14-JA-3108-09, 51-SJA-11462-63, 57-SJA-12888. Mylan knew Sanofi was forced to make this "[redacted]" because Mylan had done such an "[redacted]." 55-SJA-12462, 52-SJA-11663.

But forgoing profits in other markets was not a viable long-run strategy (indeed, a nonstarter for almost any other competitor). 16-JA-3577, 31-SJA-6880. So Sanofi took the fight to Mylan and offered ESI a [redacted]% rebate to [redacted]. 30-SJA-6699. The rebate would render Auvi-Q unprofitable, 8-JA-1541; but it was the only way to try to shift utilization, without continuing to sacrifice millions of dollars from Lantus. 17-JA-3654, 30-SJA-6694.

Mylan's offer was substantially worse: 40.625% for copreference and [redacted]. 46-SJA-10227. But [redacted], ESI still determined it would *lose $1.6 million in rebates* if it went with Auvi-

Q. 30-SJA-6702, 23-SJA-5198. So ESI accepted Sanofi's exclusive offer only for its High Performance Formulary—its "most restrictive and least utilized formulary" that specifically selected for clients willing to tolerate disruption in exchange for savings. 14-JA-3062, 25-SJA-5650, 16-JA-3574, 23-SJA-5194-98, 8-JA-1638, 8-JA-1658. Even then, EpiPen maintained [redacted]% overall market share on the formulary—"[redacted]" 36-SJA-7962, 32-SJA-7165, Daubert-Op.75-76 (12-JA-2545-46). Mylan forced Sanofi to pay an enormous tax to compete, but Sanofi could not fight back.

CVS. Sanofi knew it could not afford to lose CVS. 30-SJA-6687. In April 2014, it offered a 61% rebate to exclude EpiPen. 30-SJA-6755.[13] But, like ESI, CVS knew it could not shift sufficient volume on its main formularies to level the playing field. So it granted Auvi-Q exclusivity only on its newest and smallest formularies—the Value and Advanced Control formularies—designed to "maximize[] generic savings." 16-JA-3544. When Mylan delivered a last-minute [redacted]% offer ([redacted] points worse than Sanofi's exclusive offer), CVS rejected Sanofi's mega-rebate: "[redacted]" 30-SJA-6797.

By mid-2015, CVS offered Mylan a mixed report on its "trial balloon" of exclusions: though EpiPen had ceded ground on Advanced Control, it was "still

[13] Figures do not include 4% admin fee. 30-SJA-6756.

holding share" on the Value Formulary. 5-JA-911. Either way, Mylan was unfazed. It knew these formularies were a "[redacted]" of CVS's business and "[redacted]" 30-SJA-6792. [redacted] Sanofi was offering a mega-rebate for exclusivity on these small formularies, 31-SJA-6817-18; but Mylan was so confident in its monopoly power that it offered [redacted] to reverse the exclusion, 31-SJA-6820-21.

Aetna. In early 2014, Aetna told Sanofi it would need to offer substantially more than Mylan ([redacted]% vs. 15%) just to secure "Non-preferred" positioning. 11-JA-2287, 29-SJA-6481. So Sanofi took "aggressive" action and offered a *65%* rebate to block EpiPen and chip away at Mylan's volume advantage. 30-SJA-6705, 11-JA-2287, 29-SJA-6481, 34-SJA-7627.

Aetna initially told Sanofi it would make Auvi-Q exclusive on its "[redacted]" Value Formulary—the less entrenched portion of its business. 30-SJA-6713. But that was apparently a ploy. In the end, Aetna (like the rest) capitulated to Mylan's inferior rebate (45% vs. Sanofi's 65%) and refused to exclude EpiPen. 30-SJA-6710, 30-SJA-6715-16. Afterward, Aetna continued to grumble about Mylan's monopoly price hikes ("488 percent in the last four years"). 37-SJA-8276. But no major payor would put Mylan's entrenched share to the test.

2. Sanofi's losses

OptumRX/United. In late 2014, Mylan paid United a [redacted]% rebate to block Auvi-Q. 26-SJA-5735. Yet, United told Sanofi it would need to offer a *60% rebate and 6% price protection* to merit consideration. 31-SJA-6856. Given EpiPen's entrenched position, United still refused to "[redacted]" even if Sanofi hit that absurd target, and advised that Sanofi consider "[redacted]" 31-SJA-6856.

MedImpact. Like United, MedImpact acknowledged "[i]t would be *very difficult* for Sanofi to neutralize th[e] savings advantage given the current share … [Sanofi] would need to offer a discount in the upper 30s to low 40s with Price Protection to even open the conversation." 31-SJA-6880. Mylan's offer at the time was for half that amount, and didn't include price protection. 29-SJA-6352-54, 29-SJA-6374. Sanofi's only path forward with MedImpact would have been "[redacted]." 31-SJA-6880.

Prime. Sanofi continued to up its bid at Prime for access on T2 ([redacted]% rebate and [redacted]% price protection). 31-SJA-6889. Yet, Prime stayed with Mylan's inferior and more restrictive offer [redacted]. 31-SJA-6898, 26-SJA-5742, 51-SJA-11663, 57-SJA-12901-03. Prime would gripe about Mylan's monopoly pricing ("over 350%"), but was powerless to resist. 31-SJA-6898.

I. Mylan's Scheme Renders Auvi-Q Unsustainable

Sanofi lost money on Auvi-Q every year it competed with EpiPen. 38-SJA-8549-50. Between Mylan's "aggressive tactics" and "the managed care response," the situation had become "unsustainable." 54-SJA-12062, 31-SJA-6880, 8-JA-1541, 24-SJA-5253, 55-SJA-12328, 8-JA-1706, 53-SJA-11961, 14-JA-2962-63. By the end of 2014, Sanofi considered "walk[ing] away" and returning its rights to the inventors. 54-SJA-12060.

1. Sanofi's short-run losses (2013-2015)

When Auvi-Q launched, Sanofi and Mylan both projected it would capture ~[redacted]% of the market by 2015. *Supra* at 10; 53-SJA-11955-56. That would have translated into $225 million in profits. 53-SJA-11961, 14-JA-2963. Instead, Mylan cut Auvi-Q's share to less than half that amount, 36-SJA-8031, and inflicted $103 million in losses on Sanofi, 53-SJA-11961 51-SJA-11468, 14-JA-2963.

If not for Mylan's anticompetitive conduct, the parties' joint ~[redacted]% share prediction was on target, as shown by select regions in which Sanofi was permitted to compete: Canada, Horizon Blue Cross Blue Shield of New Jersey, and University of Michigan. 36-SJA-8025-33, 14-JA-3104-06, 38-SJA-8458-64, 51-SJA-11495, 58-SJA-13184-86, 53-SJA-11955-57. In these situations, Auvi-Q easily reached ~35% market share. 36-SJA-8025-33 & Fig. 14; 15-JA-3348-49. With patent protection through 2029, Auvi-Q would have become a "long-term growth driver"

for Sanofi. Daubert-Op.61-62 (12-JA-2531-32), 53-SJA-11971, 53-SJA-12026, 16-JA-3361-62, 53-SJA-12041, 53-SJA-12044, 53-SJA-12047-48, 16-JA-3377-78.

2. Sanofi's long-run losses (2015-2029)

In late 2015, as Auvi-Q was hemorrhaging cash, Sanofi received reports of a "potential inaccurate dosage delivery."[14] Though none had "been confirmed," and "no fatal outcomes" reported,[15] Sanofi initiated a voluntary recall of the million units on the market. 22-JA-4838.

Sanofi could have "easily overcome any challenges" related to the recall. 22-JA-4845-49. Such drug-device recalls are "commonplace," with over 150 occurring during the three years Auvi-Q was on the market. 22-JA-4836-37. Indeed, Mylan's "EpiPen has undergone similar recalls, but it hasn't affected its marketability." Daubert-Op.66 (12-JA-2536), 51-SJA-11450-51, 22-JA-4838. Absent Mylan's anticompetitive scheme, Sanofi would have had every reason to "retain [its] rights" and ample profits to cover the costs of a quick relaunch. 51-SJA-11449-50.

But in the real world, "Mylan would continue to … make it very difficult for payers to put Auvi-Q on formulary." 16-JA-3382. Considering "the level of

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[14] *Sanofi US Issues Voluntary Nationwide Recall of All Auvi-Q® Due to Potential Inaccurate Dosage Delivery, Sanofi, Oct. 30, 2015*, https://bit.ly/1OZMo3f.

[15] *Id.*

investment that would be required" to surmount Mylan's barriers, Sanofi returned Auvi-Q to its inventor company, kaléo, in February 2016. 16-JA-3380-81; 53-SJA-12045; 13-JA-2859.

3. The kaléo relaunch

A year later, kaléo relaunched Auvi-Q as a "niche product" at $4,500 per device. 14-JA-3036-37, 14-JA-3099, 36-SJA-8037, 40-SJA-8884. Kaléo had learned from the Sanofi saga that Mylan would crush any threat to EpiPen. 14-JA-3036-37. So kaléo followed a "deliberate high-price, low-volume strategy" to evade Mylan's ire. 36-SJA-8037, 40-SJA-8884, 14-JA-3036-37, V14-JA-3099. With Auvi-Q now at "miniscule" utilization, 14-JA-3036, Mylan had succeeded in eliminating the "competitive threat." 6-JA-1286.

II. PROCEDURAL HISTORY

In 2017, Sanofi sued under Section 2 of the Sherman Act, charging Mylan with a scheme to monopolize, and exclusive dealing and deception in furtherance of the scheme. 2-JA-430-35. Sanofi filed in the District of New Jersey, and the Judicial Panel on Multidistrict Litigation transferred the case to the District of Kansas for coordinated discovery with a related consumer class action.[16]

[16] Mylan counterclaimed for commercial disparagement and common-law unfair competition. SJ-Op.2 (12-JA-2592). The district court granted summary judgment to Sanofi on those claims, SJ-Op.157 (13-JA-2747), and Mylan declined to cross-appeal. *Johnson v. Spencer*, 950 F.3d 680, 722-23 (10th Cir. 2020).

The parties cross-moved for summary judgment on the two elements of Sanofi's claims: (1) possession of monopoly power and (2) maintenance of that power through exclusionary conduct. *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966). Sanofi moved on the first element, Mylan on the second. SJ-Op.2 (12-JA-2592). The district court disposed of the case without oral argument, granting Mylan's motion and denying Sanofi's as moot. SJ-Op.157 (13-JA-2747). The court held that Mylan did not engage in exclusionary conduct and that Sanofi never suffered antitrust injury. SJ-Op.76 (13-JA-2666). Along with its summary judgment decision, the court issued a 120-page *Daubert* opinion confirming that Sanofi's expert economist "provided a reliable basis for considering each piece of evidence to reach her conclusion that Mylan had an entrenched share of 50–70%." Daubert-Op.77 (12-JA-2547). And she "adequately explain[ed]" why "the difference between [Sanofi's] forecast and Auvi-Q's actual performance" was fully attributable "to Mylan's conduct." Daubert-Op.50-67 (12-JA-2520-37). In addition, Sanofi's medical expert offered "reliable" testimony that "choice increases the likelihood that … patient will carry" EAIs, and "patients were harmed by not having access to Auvi-Q" during the 2018 EpiPen shortages. Daubert-Op.86-87, 92-93 (12-JA-2556-57, 12-JA-2562-63). The district court confirmed this was "supported by the record evidence." Daubert-Op.87 (12-JA-2557). "Mylan's disagreements" were "questions for the jury." Daubert-Op.63 (12-JA-2533). This appeal followed. 13-JA-2748-49.

SUMMARY OF ARGUMENT

I. Mylan leveraged its monopoly volume to block the most "significant threat to [its] EpiPen business." First, it escalated prices dramatically and conditioned rebates on EpiPen's exclusivity; then, it misled doctors about those exclusions to maximize spillover. It cemented its entrenched share through EpiPens4Schools, and subsidized the scheme through broad-scale Medicaid misclassification. None of that was competition on the merits, and it foreclosed Sanofi from more than half the EAI market.

The district court thought otherwise, but only because it failed to grasp that the value of rebates and administrative fees depend more on overall utilization than net price. Mylan's percentage rebates would always go farther because EpiPen had all the volume—and Mylan's exclusionary contracts kept it that way. The court believed Mylan was just offering lower prices; but payors repeatedly rejected Sanofi's superior offers and denied it the opportunity to outbid Mylan. The court believed Sanofi was not foreclosed because Mylan's exclusionary contracts were, in its view, short, terminable, and (therefore) surmountable. But Mylan's monopoly power had no termination date, and no amount of rebating in the EAI market could beat the EpiPen monopoly. Had the court grappled with the broader anticompetitive plan to restrict Auvi-Q and maximize spillover, as reflected clearly in Mylan's internal documents, it would surely have sent the case to a jury.

II. Mylan inflicted antitrust injury on Sanofi and harmed competition in myriad ways, raising prices, stunting output, and stymying innovation. All of that was a predictable consequence of Mylan's successful efforts to exclude its only significant competitor. The district court could reach a different view only by inflating Sanofi's burden and resolving contested fact issues in Mylan's favor.

STANDARD OF REVIEW[17]

Summary judgment is appropriate only "[w]here the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party." *Matsushita Elect. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). "Because [Sanofi] is the nonmoving party, its evidence is to be believed; all justifiable inferences are to be drawn in its favor; [and] its nonconclusory version of any disputed issue of fact is assumed to be correct." *Multistate Legal Stud., Inc. v. Harcourt Brace Jovanovich Legal and Pro. Publ'n, Inc.*, 63 F.3d 1540, 1545 (10th Cir. 1995) (citing *Eastman Kodak v. Image Tech. Servs. Inc.*, 504 U.S. 451, 456 (1992)). Mylan "must identify portions of the record that demonstrate the absence of a genuine issue of material fact." *Lenox MacLaren Surgical Corp. v. Medtronic, Inc.*, 762 F.3d 1114, 1118 (10th Cir. 2014). This Court reviews the grant of summary judgment de novo. *Id.*

[17] In this multidistrict litigation, Tenth Circuit precedent has "stare decisis effect," and Third Circuit law "merits close consideration." *In re Korean Air Lines Disaster of Sept. 1, 1983*, 829 F.2d 1171, 1176 (D.C. Cir. 1987) (R. Ginsburg, J.); SJ-Op.78 n.16 (13-JA-2669).

"Summary judgment in antitrust cases should be used sparingly," *Green Country Food Market, Inc. v. Bottling Group, LLC*, 371 F.3d 1275, 1278 n.1 (10th Cir. 2004), and "on a case-by-case basis, focusing on the particular facts disclosed by the [entire] record," *Eastman Kodak*, 504 U.S. at 467. Where an "expert provides a reliable and reasonable opinion with factual support, summary judgment is inappropriate." *Spirit Airlines, Inc. v. Northwest Airlines, Inc.*, 431 F.3d 917, 931 (6th Cir. 2005); *Lenox*, 762 F.3d at 1119.

ARGUMENT

Sanofi's monopolization claims have two elements: (1) possession of monopoly power and (2) willful maintenance of that power through exclusionary conduct. *Grinnell*, 384 U.S. at 570-71. To recover damages, Sanofi must also demonstrate "antitrust injury." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977). There is undisputedly at least a triable question on monopoly power, which is why Mylan never moved on the issue.[18] Because there is also, at a minimum, a triable question on exclusionary conduct and antitrust injury, the order granting summary judgment should be reversed.

[18] Sanofi, on the other hand, did move for summary judgment on monopoly power. And though the district court recognized that "Mylan had significant—one even could say, dominant—market share," it believed, mistakenly, that it could set that dominance aside as a box that had been checked in deciding whether Mylan's conduct was exclusionary. SJ-Op.87 (13-JA-2677); *supra* at 62.

I. THERE IS A TRIABLE QUESTION WHETHER MYLAN ENGAGED IN EXCLUSIONARY CONDUCT TO MAINTAIN ITS MONOPOLY

A. The Law Governing Exclusive Dealing

Exclusive dealing is analyzed under the "rule of reason." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 268 (3d Cir. 2012). That holistic inquiry "weighs all of the circumstances of a case," *Cont'l T.V., Inc. v. GTE Sylvania, Inc.*, 433 U.S. 36, 49 (1977), to determine whether a monopolist has excluded competition "on some basis other than efficiency," *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 605 (1985); *Grinnell*, 384 U.S. at 570-71. Though a defendant's isolated acts "standing alone [may] not be sufficient to sustain a claim," they may still be deemed exclusionary "when considered with the entire monopolistic scheme." *Kobe, Inc. v. Dempsey Pump Co.*, 198 F.2d 416, 425 (10th Cir. 1952); *Aspen Highlands Skiing Corp. v. Aspen Skiing Co.*, 738 F.2d 1509, 1522 n.18 (10th Cir. 1984).

Under *Tampa Electric v. Nashville Coal*, exclusive dealing is impermissible when the "probable effect" is to "foreclose competition in a substantial share" of the market. 365 U.S. 320, 326 (1961). "Substantiality" is a "practical" concept defined by the "probable effect of the contract on the relevant area of effective competition." *Id.* at 326, 329. "[T]he test is not total foreclosure, but whether the challenged practices … severely restrict the market's ambit." *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005). Lower courts have generated a litany of

factors to guide that inquiry, but there is "no set formula" and none is a prerequisite for foreclosure. *ZF Meritor*, 696 F.3d at 271; *Dentsply*, 399 F.3d at 192-95.

"Exclusive dealing arrangements are of special concern when imposed by a monopolist." *ZF Meritor*, 696 F.3d at 271. Dominant firms can deploy a "set of strategically planned exclusive-dealing contracts" to destroy competition by "keeping [rivals'] sales … below the critical level necessary … to pose a real threat to [the monopolist's] market share." *Dentsply*, 399 F.3d at 191-92. These strategic agreements harm "competition in general" by "prevent[ing] … competitors from gaining a foothold in the market." *LePage's*, 324 F.3d at 159.

In this respect, Section 2 violations involving monopolists (this case) differ from Section 1 concerted-activity violations (not this case): "a monopolist's use of exclusive contracts … may give rise to a §2 violation even though the contracts foreclose less than the roughly 40% or 50% share usually required in order to establish a §1 violation." *United States v. Microsoft Corp.*, 253 F.3d 34, 70 (D.C. Cir. 2001) (en banc); *LePage's*, 324 F.3d at 159.[19] "Behavior that otherwise might

[19] This was a holding in *Microsoft*. *Contra* SJ-Op.104 (13-JA-2694). The district court in that case dismissed the Section 1 claim because the government had not demonstrated Microsoft excluded Netscape "from access to forty percent of the browser market." *United States v. Microsoft Corp.*, 87 F. Supp. 2d 30, 52-53 (D.D.C. 2000). The D.C. Circuit, in affirming the Section 2 claim, necessarily held a monopolist can violate the antitrust laws without crossing a foreclosure threshold. *Microsoft*, 253 F.3d at 70; *LePage's*, 324 F.3d at 159; *McWane*, 783 F.3d at 837.

comply with antitrust law may be impermissibly exclusionary when practiced by a monopolist." *Dentsply Int'l*, 399 F.3d at 187 (citing *Eastman Kodak*, 504 U.S. at 488 (Scalia, J., dissenting)); *McWane, Inc. v. FTC*, 783 F.3d 814, 836 (11th Cir. 2015). Even when monopolists do not cross a particular foreclosure threshold, they can still use exclusive dealing to "disproportionately raise [a rival's] costs" and harm competition. *Multistate*, 63 F.3d at 1553 n.12; *see, e.g.*, *Microsoft*, 253 F.3d at 70; *Dentsply*, 399 F.3d at 191-92. In *Microsoft*, "Netscape was not 'foreclosed' at all [because it] could reach all consumers through free Internet downloads," but under *Tampa Electric*'s qualitative inquiry, that was no barrier to liability. Jonathan M. Jacobson, *Exclusive Dealing, "Foreclosure," and Consumer Harm*, 70 Antitrust L.J. 311, 362-63 (2002) ("Courts have found liability in some cases even when the amount of 'foreclosure' is zero … if price, output, quality, choice, or innovation have been harmed."); *see McWane*, 783 F.3d at 838 ("[T]he Commission did not place an exact number on the percentage foreclosed[.]").

B. Mylan Engaged in Exclusionary Conduct

The record easily reveals a genuine dispute whether Mylan competed "on some basis other than the merits." *LePage's*, 324 F.3d at 158. Mylan's internal documents reflect "clear expressions of a plan to maintain [its] monopolistic power." *Dentsply*, 399 F.3d at 190. First, Mylan inflated EpiPen's price dramatically, knowing its utilization rate would magnify the impact of any price movement. *Supra*

at 17-18. It then launched an aggressive campaign to block Auvi-Q with exclusionary rebates that only partly offset its monopoly price escalation. *Supra* at 16-18. Mylan knew PBMs would be "heavily impacted" if they turned away these offers. 37-SJA-8351; 51-SJA-11419-20. Holdouts would face "[redacted]," 27-SJA-6096, and be forced to internalize EpiPen's ever-rising list price, multiplied by its dominant market share. *Supra* at 18-22.

Mylan could deploy that power to foreclose Auvi-Q "even after [Sanofi offered] a more generous rebate." *McWane*, 783 F.3d at 821. At ESI, the largest PBM, Sanofi offered a lower per-unit price on a better mousetrap, *supra* at 23-25; but Mylan's bid was so [redacted] that ESI simply "couldn't refuse" the rebate on EpiPen's entrenched volume. 54-SJA-12275, 4-JA-735-36. At United, Sanofi made a more "aggressive" offer than Mylan; but United "[redacted]" given the "extreme difference in utilization" between the two products. 28-SJA-6246-49, 28-SJA-6261. And MedImpact would not even consider a superior offer from Sanofi (the "decision ha[d] been made" and it was "moving on"), because of the "potential for disruption." 29-SJA-6429-30; 5-JA-902-03. When Humana asked Mylan for a bid for copreference, Mylan refused and demanded that Auvi-Q remain blocked. 52-SJA-11675-78; 38-SJA-8409-12. In the words of one payor: "the makers of EpiPen … [redacted]." 56-SJA-12517-18. And, once Mylan's price

escalation prompted Medimpact to "have only one product in the category," 11-JA-2212, 28-SJA-6324-26, Mylan threatened to "terminate its current contract" and withdraw all rebates if MedImpact dared to go with Auvi-Q, rather than EpiPen. 36-SJA-8100-01; *see also* 53-SJA-11902. The "goal" was never to sever ties, but to "dissuade [PBMs] from leaving [EpiPen] in the first place." *McWane*, 783 F.3d at 821 n.3.

Mylan cemented these exclusive contracts with parallel strategies that worked in "synerg[y]" to further lock Sanofi out of the market. *LePage's*, 324 F.3d at 162.

First, Mylan developed a deceptive marketing program to augment the spillover effects of its contracts. *Supra* at 33-35. Mylan knew the coverage disparity was its "[redacted]" and "the only clear reason" to prescribe EpiPen over Auvi-Q. 38-SJA-8544. So Mylan tied up the key payors, then trained its salesforce to "drive home the message that Auvi-Q will be a difficult product … to obtain." 52-SJA-11742-43. Even worse, it misleadingly suggested Auvi-Q was excluded for "clinical" reasons, 53-SJA-11834, 15-JA-3333, 53-SJA-11848; *Conwood Co., L.P. v. U.S. Tobacco Co.*, 290 F.3d 768, 787-88 (6th Cir. 2002) (unlawful to couple "exclusive agreements with … misrepresentations").

Second, Mylan fortified its entrenched network by extracting pledges from schools to train on EpiPen and not to buy Auvi-Q. *Supra* at 35-37. Mylan's internal documents make clear the program was "designed primarily to further [its]

domination of the relevant market" by strengthening network effects and solidifying its entrenched share. *Aspen*, 472 U.S. at 597; 60-SJA-13576, 53-SJA-11850-52, 53-SJA-11875, 53-SJA-11880-83. Though giveaway programs may be "procompetitive" in some contexts, this one "t[ook] on exclusionary connotations," *Eastman Kodak*, 504 U.S. at 488 (Scalia, J., dissenting), when Mylan deployed it as a weapon in commercial negotiations. 36-SJA-7944-45, 36-SJA-8101-02; *see also Multistate*, 63 F.3d at 1551.

Third, Mylan misclassified EpiPen as a generic drug to evade hundreds of millions of dollars in government rebates triggered by its strategic price escalation. *Supra* at 37-38. This misclassification allowed Mylan to "demand massive price increases in the private market while avoiding its corresponding rebate obligations to Medicaid." 4-JA-754. Even Mylan's own emails confirm that misclassification had a direct impact on its rebating capacity. 53-SJA-11902.

A jury could easily conclude that Mylan engaged in an unlawful "monopolistic scheme" to exclude its only serious rival. *Kobe*, 198 F.2d at 425; *W. Penn Allegheny Health Sys.* v. *UPMC*, 627 F.3d 85, 109 n.14 (3d Cir. 2010); *Caldera, Inc. v. Microsoft Corp.,* 87 F. Supp. 2d 1244, 1249 (D. Utah 1999).

C. The Probable Effect of Mylan's Conduct Was to Foreclose Auvi-Q from a Substantial Share of the EAI Market

A reasonable jury could likewise conclude that Mylan's anticompetitive conduct culminated in substantial foreclosure.

1. *Mylan blocked Auvi-Q from more than half the market.*

Mylan did not need to exclude Sanofi with every major payor to suppress Auvi-Q below critical mass. EpiPen was so dominant that doctors would write prescriptions for it "automatically" because it was "the first thing that comes to mind," even when "EpiPen wasn't on formulary." 20-JA-4496. Mylan's physician research confirmed Auvi-Q would need "[redacted]" before doctors would consider defaulting to the new device. 52-SJA-11810. Mylan thus understood that a set of "strategically planned exclusive-dealing contracts" could produce enough spillover to keep Auvi-Q "below the critical level necessary … to pose a real threat to [EpiPen's] market share." *ZF Meritor*, 696 F.3d at 277. "The reality [was] that the firm that ties up the key dealers rules the market." *Dentsply*, 399 F.3d at 190. That is why Mylan knowingly sacrificed millions in short-term profits for exclusivity at ESI. 36-SJA-8018-20; *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004) (profit sacrifice "reveal[s] a distinctly anticompetitive bent"),

Mylan's exclusive contracts covered more than half the largest payors and close to 100 million people (1/3 of the U.S. population). 53-SJA-11883, 56-SJA-12637, 17-JA-3631. Together with spillover, those contracts foreclosed Sanofi from "more than half the market," 16-JA-3446, and suppressed Auvi-Q's share to *less than half of pre-market projections*, 36-SJA-8031 & fig.14; *see McWane*, 783 F.3d

at 838 (inferring foreclosure from the fact that plaintiff "gained market share—but [far] less than it likely would have absent the [exclusionary] conduct").

2. *Mylan's lockouts had enduring anticompetitive effects.*

Sanofi fought to reverse the lockouts. But ESI made clear that no amount of Auvi-Q discounting could surmount Mylan's monopoly power. *Dentsply*, 399 F.3d at 195; *supra* at 40. Sanofi would need to "write a check" for $36 million in Lantus points (a different product) merely to *access* the EAI market. *Supra* at 40. But paying $36 million rebates in a *different market* is not a sustainable strategy, and Mylan's scheme to "disproportionately raise [Sanofi's] costs … qualif[ies] as anticompetitive conduct." *Multistate*, 63 F.3d at 1553 n.12. United and MedImpact were no different: United advised that Sanofi "[redacted]," 31-SJA-6856, while MedImpact demanded that Sanofi double Mylan's rebate to "even open the conversation." *Supra* at 43. Sanofi had a product "with significant customer demand," but Mylan leveraged its monopoly power to deny Sanofi a meaningful "opportunity to compete." *ZF Meritor,* 696 F.3d at 281.

Sanofi was desperate to regain access and, eventually, began to make exclusive offers of its own. 28-SJA-6261; *supra* at 38-42. But no major payor was willing to test Mylan's entrenched share. ESI calculated that an exclusion against EpiPen would cost $1.6 million in net rebates, even with Sanofi's mega-rebate offer.

30-SJA-6702, 56-SJA-12535. Mylan knew Sanofi could never "provide dealers with a comparable economic incentive to switch" away. *Dentsply*, 399 F.3d at 195.

By 2015, Mylan had rendered Auvi-Q "unsustainable," 54-SJA-12063: Sanofi was paying a steep access tax at ESI, 56-SJA-12547, 51-SJA-11461-62, 57-SJA-12888-94; it remained excluded from several of the largest payors, *supra* at 43; and it had captured less than half of its projected market share, 36-SJA-8031. By the time Sanofi recalled the product, it was clear Mylan would do whatever it took to restrict Auvi-Q in perpetuity. 16-JA-3380-82, 53-SJA-12045.

3. *Mylan's clear plan confirms Sanofi's substantial foreclosure.*

"Summary judgment in antitrust cases should be used sparingly because motive and intent play leading roles in the analysis." *Green Country Food*, 371 F.3d at 1278 n.1. Clear evidence of intent can "help the [C]ourt to interpret facts and to *predict consequences*." *Microsoft*, 253 F.3d at 59 (quoting *Bd. of Trade of City of Chi. v. United States*, 246 U.S. 231, 238 (1918)).[20]

[20] *See Aspen Skiing*, 472 U.S. at 602, 602 ("[E]vidence of intent is … relevant to the question whether the challenged conduct is fairly characterized as 'exclusionary'"); *Broad. Music, Inc. v. Columbia Broad. Sys.*, 441 U.S. 1, 19-20 (1979) ("purpose" of restraint "tends to show [its] effect"); *Nat'l Soc'y of Pro. Eng'rs v. United States*, 435 U.S. 679, 692 (1978) (considering "reasons why" defendant hatched their plan); *LePage's*, 324 F.3d at 163 ("The Supreme Court has made clear that intent is relevant to proving monopolization.").

Here, Mylan's comprehensive plan to block Auvi-Q further confirms Sanofi's foreclosure. *Dentsply*, 399 F.3d at 190. Mylan recognized that Auvi-Q posed "a significant threat." 38-SJA-8435.[21] After trying and failing to license or copy the device, *supra* at 9-10, Mylan formulated a multipronged plan to "pre-empt Auvi-Q" and "[redacted]." SJ-Op.23-24 (12-JA-2613-14), 37-SJA-8353, 51-SJA-11504, 51-SJA-11498, 51-SJA-11522, 50-SJA-11317. Mylan knew it had "[redacted]": it had "[redacted]," 27-SJA-6100, and payors would want to "[redacted]" to avoid the "[redacted]" from an EpiPen exclusion. 27-SJA-6096, 52-SJA-11712. Mylan also knew that, [redacted] EpiPen would still "maintain[] 40% - 70% market share." 36-SJA-8101, SJ-Op.113 (13-JA-2703). And Mylan understood "just how valuable it was to hammer Sanofi at launch" before Auvi-Q could accumulate the "momentum" and market share necessary to neutralize its monopoly advantages. 51-SJA-11489, 51-SJA-11509.

Mylan then devised an entire advertising strategy to broadcast its "[redacted]": that, for "clinical" reasons, "[redacted]." 38-SJA-8544, 52-SJA-11743, 53-SJA-11830, 15-JA-3333, 53-SJA-11848. According to Mylan, Sanofi's "desperate" efforts to regain

[21] All quotes in this paragraph come directly from the internal documents of Mylan and its affiliates.

access "[r]eally demonstrate[] what a good job we've done *locking them out*." 5-JA-905.

Taken together, Mylan's "[i]nternal documents reveal that [its] express purpose was to raise [Sanofi's] costs and impede it from becoming a viable competitor." *McWane*, 783 F.3d at 821. That purpose further confirms the "probable [foreclosure] effect" of Mylan's exclusionary scheme. *Id.* at 836.[22]

D. The District Court Erred in Granting Summary Judgment

1. *Mylan did not compete on the merits.*

The district court believed Mylan was engaged in run-of-the-mill price competition. SJ-Op.97-100 (13-JA-2687-90). But that "makes no economic sense," and "the factual context renders [it] implausible." *Matsushita*, 475 U.S. at 587. PBMs collect administrative fees and rebates on every prescription filled, and Mylan had all the volume. So, as a matter of basic "math," a price concession by Sanofi would not go nearly as far as the same concession by Mylan. 16-JA-3356, 37-SJA-8351. And Mylan made its impossible-to-beat rebates conditional on excluding Auvi-Q, to ensure Auvi-Q would never build up the market share necessary to

[22] There are many reasons why a *seller* might prefer exclusivity. *See, e.g.*, *ZF Meritor*, 696 F.3d at 270 (exclusivity "may reduce expenses, provide protection against price fluctuations, and offer the possibility of a predictable market."). Mylan has never even attempted to explain its anticompetitive scheme by reference to these procompetitive aims.

compete. *Supra* at 26-28. Of course, payors *could* try restricting EpiPen as a means of shifting share to Auvi-Q. But they would suffer "[redacted]," 27-SJA-6096, and run the real risk that a substantial entrenched share would remain loyal to EpiPen. *Supra* at 18-22. Payors would then be forced to purchase EpiPen at a much higher cost and PBMs would lose administrative fees. *Supra* at 21-22. The district court failed to appreciate these basic market realities.

a. Mylan leveraged its monopoly volume against Sanofi.

EpiPen's market share put Sanofi in a "[redacted]." 37-SJA-8182. PBMs widely reported that excluding EpiPen was "[n]ot worth the disruption." 54-SJA-12262. Virtually every payor invoked the "extreme difference in utilization" and patient disruption as reason for turning Auvi-Q away. 28-SJA-6261 (United); 5-JA-902, 31-SJA-6880-81 (MedImpact); 23-SJA-5198 (ESI: "[redacted]"); 52-SJA-11613 (Humana: "[redacted]"). Yet, the district court's opinion never once acknowledges that the value of a rebate turns as much—or more—on volume as it does on per-unit price.

b. Mylan had substantial entrenched share.

Mylan knew it could instigate battles for access without risk of exclusion because it had entrenched market share. *Supra* at 18-22. United's attempt to disadvantage EpiPen had failed badly, 27-SJA-6097; Mylan retained 40%-70%

market share even with exclusions in the Medicaid space, Daubert-Op.74-75 (12-JA-2544-45); and, according to Mylan, even an exact "generic" copy would need a "period of years" to build the "brand equity" necessary to challenge EpiPen, 7-JA-1322. Payors knew "[redacted]," which is why they (1) presented Mylan and Sanofi with asymmetric bid targets, (2) denied Sanofi the opportunity to outbid Mylan on price, and (3) rejected Sanofi's superior rebate offers outright. *Supra* at 23-32, 40-44.

1. The district court recognized as much in its *Daubert* opinion. "[A]fter reviewing the evidence that Dr. Scott Morton relied on to form her entrenched share opinion," the court found that she "provided a reliable basis for considering each piece of evidence to reach her conclusion that Mylan had an entrenched share of 50–70%." Daubert-Op.77 (12-JA-2547). The court cited Mylan's internal emails that EpiPen maintained 40-70% share when it was excluded from Medicaid plans in favor Adrenaclick; it ratified the document as "a reliable data point"; and it accepted as reasonable Sanofi's view that "the entrenched share for commercial payers should be higher than it is for Medicaid customers." Daubert-Op.74-75 (12-JA-2544-45). The court then walked carefully through the handful of small, high-control formularies on which EpiPen was excluded and found, once again, that Sanofi's expert had "adequately explain[ed]" the data in each case. Daubert-Op.75-77 (12-JA-2545-47). That analysis deserves deference, *United States v. Foust*, 989 F.3d

842, 845 (10th Cir. 2021), and shows there is at least a triable issue as to EpiPen's entrenched share, *Spirit Airlines*, 431 F.3d at 931; *Lenox*, 762 F.3d at 1119.

2. Yet, the district court reached the startling summary-judgment conclusion that *no reasonable jury could believe Sanofi's expert*. SJ-Op.111-14 (13-JA-2701-04). The court stressed that (1) Sanofi "took market share from EpiPen" on two small, high-control formularies; and (2) "[s]everal payors testified that they *could have* excluded EpiPen." SJ-Op.111-12 (13-JA-2701-02). That analysis ignores conflicting evidence and completely misses the bigger picture.

High-control formularies. The district court's singular focus on a few "small, highly managed" formularies proves that Mylan's share *was* entrenched. 36-SJA-8003. The only truly undisputed fact in this area is that no major payor excluded EpiPen from their main commercial formularies, despite aggressive—even "desperate"—offers from Sanofi. 5-JA-905, 36-SJA-7992-93, 36-SJA-7996. When PBMs blocked EpiPen, it was only as "a trial balloon" on small, select formularies where demand was most likely to move. 5-JA-911. Mylan knew these gerrymandered exclusions were "[redacted]," and in no way undermined EpiPen's entrenched position. 30-SJA-6792, 36-SJA-8003. "The record taken as a whole could" could easily lead a "rational trier of fact to find for [Sanofi]." *Matsushita*, 475 U.S. at 587.

In addition, the court's summary-judgment analysis *ignores* the explanations from Sanofi's expert that the court's own *Daubert* opinion had already credited as "reliable." *Compare* Daubert-Op.75-77 (12-JA-2545-47), *with* SJ-Op.112-13 (13-JA-2702-03); *see* 51-SJA-11415-18. That was indefensible.

Payor testimony. The contemporaneous evidence shows that no major payor was willing to test Mylan's entrenched position on the major formularies. *Supra* at 40-44. Even with Sanofi's unprecedented mega-rebate offer, ESI determined it would still lose $1.6 million from an EpiPen exclusion. 30-SJA-6702, 56-SJA-12535. PBMs' *self-serving*,[23] *retrospective* testimony that "they *could have* excluded EpiPen" is beside the point. SJ-Op.111-12 (13-JA-2701-02).

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[23] *See, e.g.*, *In re EpiPen*, No. 17-md-2785, 2018 WL 263239, at *2 (D. Kan. Jan. 2, 2018) (consumer class actions against the major payors alleging Mylan "artificially inflated prices" on EpiPen to pay kickbacks to PBMs); 36-SJA-7976 (ESI to Mylan: [redacted]"); *see also* Robin Feldman, *Perverse Incentives: Why Everyone Prefers High Drug Prices—Except for Those Who Pay the Bills*, 57 Harv. J. Leg. 303, 326-27 (2020) (explaining why PBM "incentives operate to drive prices higher"). The payors' incentives distinguish this case from *Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57 (3d Cir. 2010). *Race Tires* sanctioned an exclusive supply arrangement between "a tire supplier competitor and a motorsports sanctioning body," *id.* at 62, on the theory that uniformity (i.e., the constriction of consumer *choice*) is often an essential element of league sports and that "sports-related bodies should [therefore] be given leeway with respect to their adoption of equipment requirements," *id.* at 80. Here, by contrast, market realities and all of the relevant incentives cut in the exact opposite direction.

EpiPen's history of entrenchment. Everyone—Mylan, United, and even Sanofi—knew that United's move against EpiPen in 2008 was a complete failure, 27-SJA-6097, 13-JA-2703; and Mylan knew it retained 40%-70% of Medicaid patients even with restrictions, SJ-Op.113 (13-JA-2703). Yet, the district court ignored the United example and dismissed the Medicaid evidence as just "one reference to another [EAI's] performance (which one payor testified had supply problems) on a Medicaid formulary." SJ-Op.113 (13-JA-2703).[24] But this "one reference" was in Mylan's own *internal documents*, Daubert-Op.74 (12-JA-2544); and Sanofi's expert provided "reliable" explanations for why EpiPen would be *more entrenched* on commercial, as opposed to Medicaid, formularies, and *less entrenched* vis-à-vis Adrenaclick (another swing-and-jab device). Daubert-Op.74-75 (12-JA-2544-45), 51-SJA-11418-19. "[V]igorous cross-examination" at trial was the "appropriate means of attacking" the reliable opinion of Sanofi's expert. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 596 (1993); *Spirit Airlines*, 431 F.3d at 931; *Lenox*, 762 F.3d at 1119.[25] The district court was wrong to act as a

[24] The payor testimony about supposed supply problems was farcical—it came from a *different payor* and concerned a *different product*. 20-JA-4496-97.

[25] The court could have avoided this error by entertaining Sanofi's affirmative motion to define the relevant market as *all* "U.S. EAI Drug Devices"—commercial insurance, Medicare, and Medicaid. 13-JA-2765; *Ohio v. American Express Co.*, 138 S. Ct. 2274, 2285 (2018) ("[C]ourts usually cannot properly apply the rule of reason without an accurate definition of the relevant market.").

juror and dismiss an internal Mylan document confirming EpiPen's entrenched position.

c. Mylan exercised coercive power.

1. The district court thought coercion was necessary and that Mylan did not "coerce" PBMs into exclusive agreements. SJ-Op.93-100 (13-JA-2683-90). It was wrong on both counts. "[I]t is well established that no coercion is necessary to effect an anticompetitive exclusive dealing scheme." Sean P. Gates, *Antitrust by Analogy: Developing Rules for Loyalty Rebates and Bundled Discounts*, 79 Antitrust L.J. 99, 132 (2013). Under *Tampa Electric,* "[t]he real question … is not whether buyers are 'coerced' by the rebate scheme," but "whether the 'practical effect' of the scheme is to sufficiently exclude [competitors] so as to protect or enhance the incumbent's market power." *Id.* (citing *Tampa Elec. Co.*, 365 U.S. at 327).

That said, Mylan's coercive conduct is yet another way of showing Sanofi was excluded "on some basis other than the merits." *LePage's*, 324 F.3d at 147. Coercion, in this context, flows from "monopoly power"—a defendant's "substantial" ability "to force a purchaser to do something that he would not do in a competitive market." *Suture Express, Inc. v. Owens & Minor Distrib., Inc.*, 851 F.3d 1029, 1037 (10th Cir. 2017) (defining market power); *Reazin v. Blue Cross & Blue Shield of Kan., Inc.,* 899 F.2d 951, 967 (10th Cir. 1990) (monopoly power is "'substantial' market power"). Exclusive dealing thus reflects "some element of

coercion," *ZF Meritor*, 696 F.3d at 284, when the monopolist leverages its power to exclude rivals by threatening substantial penalties against holdouts.[26]

2. The record discloses coercion in the relevant sense. Mylan knew PBMs would be "heavily impacted" if they turned down its exclusive offers. 37-SJA-8351; 51-SJA-11420. Holdouts would face the penalty of EpiPen's ever-rising list price multiplied by Mylan's dominant share, without the safeguard of price protection, and barely offset by a small EpiPen access rebate. *Supra* at 21-22, 27-28.

Mylan's leverage was substantial. ESI "couldn't refuse" Mylan's advances, despite a superior offer from Sanofi, 4-JA-736; United was forced to accept Mylan's inferior offer because of the "extreme difference in utilization," 28-SJA-6261; Mylan successfully threatened to "terminate its current contract" and withdraw all rebates if MedImpact excluded EpiPen rather than Auvi-Q, 12-JA-2627, 36-SJA-8101; Mylan refused Humana's request for a copreference bid and demanded that

[26] *See Dentsply*, 399 F.3d at 194 (coercion manifests as "strong economic incentive"); *LePage's*, 324 F.3d at 173 (bundled discount was "a 'penalty'"); 10 Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 1752e (4th ed. 2018); *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 654 (2d Cir. 2015) (distinguishing between effort "to coerce consumers" and effort to "persuade them on the merits"); *compare* Kenneth L. Glazer & Brian R. Henry, *Coercive vs. Incentivizing Conduct: A Way out of the Section 2 Impasse*, 18 Antitrust 45, 46 (2003) ("penalty" is "coercive" when "the [exclusivity] 'discount' is no discount at all, but merely returns customers to the original price"), *with* 50-SJA-11324 (Mylan: [redacted].").

Auvi-Q remain off formulary, 52-SJA-11675-77, 52-SJA-11673, 38-SJA-8410; and at least one payor reported being held "hostage" by Mylan's exclusionary offers. 56-SJA-12518. And it wasn't just the payors who Mylan coerced: *patients* were denied "the freedom … to choose" and forced to use EpiPen even if they or their doctor believed Auvi-Q was better for them. *Perington Wholesale v. Burger King Corp.*, 631 F.2d 1369, 1374 (10th Cir. 1979); 5-JA-999.

3. The district court believed "coercion" exists only when "defendants threaten[] to stop supplying their products" or "cut off discounts … *entirely*." SJ-Op.95-97 (13-JA-2685-87). But antitrust law disfavors "formalistic distinctions," *Eastman Kodak*, 504 U.S. at 466-67, and it would exalt form over substance if Mylan could evade liability merely by leaving a modest access rebate on the table while pressing aggressively for exclusions.

Next, the court thought "Mylan motivated payors [simply] by offering them higher discounts," and that offering a lower price isn't coercion. SJ-Op.97, 99-100 (13-JA-2687, 13-JA-2689-90). Wrong again. Mylan leveraged its monopoly power, not lower prices, to prevail over Sanofi: (1) United, MedImpact, and Aetna all demanded that Sanofi offer *deeper* rebates than Mylan to compete for *inferior* formulary position; (2) United, ESI, and Prime flatly rejected Sanofi's superior per-unit offers; and (3) MedImpact, Aetna, and Humana did not even bother offering Sanofi a meaningful opportunity to beat Mylan's offer because the rebate value

across EpiPen's entrenched monopoly volume was insurmountable. *Supra* at 23-32, 40-44. Unlike in *Eisai v. Sanofi Aventis U.S*, "the record [here easily] indicates that an equally efficient competitor was unable to compete." 821 F.3d 394, 406 (3d Cir. 2016). Whereas the plaintiffs in *Eisai* rested exclusively on "hypothetical assumptions" untethered to "the record," 821 F.3d at 406 & n.36, Sanofi's claims are supported by a mountain of evidence, and, importantly, its expert "provided a reliable basis for considering each piece … to reach her conclusion[s]." Daubert-Op.77 (12-JA-2547).

The district court claimed not to see coercion because some payors "solicited exclusive offers from both Mylan and Sanofi." SJ-Op.100 (13-JA-2690). But that ignores Mylan's multiple strategies for securing exclusions. At the payor level, Mylan sometimes lobbied aggressively to block Auvi-Q (ESI, Humana, Aetna); other times, it took a more subtle approach (MedImpact). Either way, Mylan knew its price escalation alone "would [redacted]" (United). 35-SJA-7793; 26-SJA-5876 (CVS Whitepaper: "high product price inflation" leads to aggressive management). Mylan's strategies "c[a]me in too many different forms" to accommodate the illusion of payor-instigated price competition. *Caribbean Broad. Sys., Ltd. v. Cable & Wireless PLC*, 148 F.3d 1080, 1087 (D.C. Cir. 1998).[27] And,

[27] Consider the Cigna story. In late 2012, Mylan reached out to Cigna about "[redacted]," *i.e.*, excluding Auvi-Q. 29-SJA-6494, 12-JA-2631. Mylan spoke with Cigna and, a week later, asked in writing for "information

even assuming PBMs wanted exclusivity, Mylan "would [still] be liable" for its "acce[ssion] to th[ose] demands," *Perington Wholesale*, 631 F.2d at 1374, especially because excluding Auvi-Q was Mylan's goal from the start.

Finally, the district court stressed that some payors balked at the notion of excluding a novel, life-saving device. SJ-Op.93-95 (13-JA-2683-85). But that hardly shows an absence of coercion. Monopoly power need only be "substantial," *Reazin*, 899 F.2d at 967; it is virtually never absolute, *McWane*, 783 F.3d at 822, 831. Even if Mylan's relationship with the PBMs was "not totally one-sided," that leaves a fact question whether Mylan's power was substantial enough to constitute coercion. *ZF Meritor*, 696 F.3d at 285 n.17. A reasonable jury could easily say yes.

d. Mylan moved the EAI market toward exclusions.

The district court excused Mylan's exclusive offers because it thought Sanofi did the same for Auvi-Q. SJ-Op.100-02 (13-JA-2690-92). That is wrong: "The fact that [the plaintiff] had itself signed such an [exclusive] agreement [does] not preclude it from suing on the antitrust violation." *Perington Wholesale*, 631 F.2d at 1375. While prevailing norms can help set a baseline, *ZF Meritor*, 696 F.3d at 272,

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on … [redacted] for the commercial formulary." 29-SJA-6492. Within *fifteen minutes* of receiving that email, Cigna responded that it wanted "an offer for exclusive epinephrine positioning for Epipen" and that "[redacted]." 29-SJA-6491; *accord* 57-SJA-12953 (Mylan: "I … intend to offer [exclusivity] to Cigna"); 25-SJA-5642 ("Mylan has approached Cigna with an exclusive position for Epi-Pen[.]").

the equal-access standards that prevailed prior to Mylan's scheme cut decisively in favor of liability. *Supra* at 14-16. Sanofi began pressing for exclusivity in 2014 *only after Mylan foreclosed Auvi-Q from more than half market*. *Supra* at 38-40. Sanofi's desperate, procompetitive effort "to establish a foothold against the counterattacks of [an] entrenched" monopolist cannot excuse Mylan's exclusionary scheme. *Standard Oil Co v. United States*, 337 U.S. 293, 307 (1949).

e. Mylan fortified its exclusive dealing with additional misconduct.

Mylan coupled its exclusive contracts with deceptive advertising, the schools program, and Medicaid misclassification. Sanofi should have received "the full benefit of [all that] proof without tightly compartmentalizing the various factual components." *Cont'l Ore v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962). Instead, the district court took a divide-and-conquer approach that missed the forest for the trees.

Deceptive advertising. The district court, applying yet another multi-factor test, dismissed Mylan's marketing campaign as not "clearly false" and amenable to neutralization. SJ-Op.114-20 (13-JA-2704-10). That box-checking exercise was unnecessary and illogical, given that Mylan's advertising was part and parcel of a broader anticompetitive scheme. *See Allegheny Health*, 627 F.3d at 109 n.14.[28]

[28] *Ayaya Inc., RP v. Telecom Labs, Inc.*, 838 F.3d 354, 420 n.7 (3d Cir. 2016) (Third Circuit "not among those that have adopted" the multifactor test); *Caldera*,

Whether or not the advertisements were "clearly" false, Mylan knew they would cause doctors to believe mistakenly that EpiPen is safer or more effective than Auvi-Q. 4-JA-816. That was the whole point of using its "[redacted]." 38-SJA-8544.

EpiPens4Schools. The district court dismissed EpiPens4Schools as a typical exercise in "reputation building." SJ-Op.121 (13-JA-2711). That sanitized account ignores that the purpose was to "[redacted]": Mylan designed the program to entrench the network of nurses and teachers trained exclusively on EpiPen *before Auvi-Q's launch*, 60-SJA-13576, 53-SJA-11850, and leveraged its success to keep Auvi-Q off formulary, 36-SJA-7945, 36-SJA-8100, 4-JA-816.

Medicare misclassification. The district court ignored Mylan's misclassification because it believed Mylan might still have "offered significant rebates" even if "it had[n't] misclassified the EpiPen." SJ-Op.95 n.21 (13-JA-2685). But that sets the bar too high. Regardless of whether it was a necessary condition, Mylan's misclassification efforts still "g[a]ve effect" to its broader plan by defraying the costs of its aggressive price escalation. *Kobe*, 198 F.2d at 425. As Mylan explained, it "could not have rebated" against Auvi-Q with the proper classification "because it would have been unprofitable." 53-SJA-11902. Inexplicably, the district

87 F.Supp.2d at 1249; *see also Lenox*, 762 F.3d at 1128 & n.9; *Kobe*, 198 F.2d at 425.

court ignored the conclusions of leading government agencies that Mylan's misclassification allowed it to "demand massive price increases in the private market while avoiding its corresponding rebate obligations to Medicaid." 4-JA-754. A reasonable jury could reach the same conclusion.

2. *Sanofi was substantially foreclosed from the EAI market.*

The district court believed that, despite Mylan's best efforts, Sanofi wasn't foreclosed from the market because (1) spillover doesn't count as foreclosure; (2) forcing Sanofi to pay an access tax through rebates *in a different market* was procompetitive; (3) duration and terminability are dispositive; and (4) intent evidence is irrelevant. SJ-Op.101-07 (13-JA-2691-97). All of that was wrong.

a. Spillover counts as foreclosure.

The district court claimed spillover should not count as foreclosure because "a patient whose PBM or payor covered Auvi-Q wasn't prevented from accessing Auvi-Q." SJ-Op.107 (13-JA-2697). But theoretical access isn't the test. *Tampa Electric* directs courts to the "practical" consequences of a contract and its "probable effect … on the relevant area of effective competition." 365 U.S. at 326, 329; *LePage's*, 324 F.3d at 157-58; *Microsoft*, 253 F.3d at 69-71. Mylan planned for spillover: it forwent millions in profits to secure Auvi-Q's exclusion at ESI, 36-SJA-8018-20; *Trinko*, 540 U.S. at 409, and devised an entire advertising campaign ("[redacted]") to amplify the intended foreclosure, 53-SJA-

11848, 34-SJA-7635, 52-SJA-11606, 11719, 11774, 55-SJA-12415. The district court had no mandate to ignore those "real world" effects. *ZF Meritor*, 696 F.3d at 270.

The district court faulted Sanofi for not "quantif[ying]" spillover to its satisfaction. SJ-Op.106 (13-JA-2696). But Sanofi did quantify spillover: Dr. Scott Morton ran an admissible regression analysis that showed a quantifiable relationship between Auvi-Q's market access and share on a given plan. 36-SJA-7994-95, 29-SJA-6525, 52-SJA-11799, 36-SJA-7995 (a ten percent increase in Auvi-Q's state-wide access "generate[d] around a 6 to 9 percentage point increase in plan-level Auvi-Q shares"). Between contractual exclusions and spillover, Mylan foreclosed Sanofi from "more than half the market." 54-SJA-12134; *McWane*, 783 F.3d at 838.

In any event, Sanofi had no obligation to quantify spillover. *Tampa Electric* disposed of a quantitative approach and instead adopted a "qualitative" view of substantiality that focuses on competitive impact. *McWane*, 783 F.3d at 836. That is why a monopolist can violate Section 2 without crossing any particular foreclosure threshold. *Microsoft*, 253 F.3d at 70; *supra* at 52-53. Quantification is not required.[29]

[29] In addition, any ambiguity about quantification arose only because Mylan's scheme "rendere[d] more exact proof … impossible." *Spray-Rite Serv. Corp. v. Monsanto Co.*, 684 F.2d 1226, 1243 (7th Cir. 1982), *aff'd*, 465 U.S. 752 (1984). Mylan's deceptive marketing may have made it difficult to trace the spillover attributable to contractual exclusions rather than Mylan's amplifications. But Mylan,

b. The Lantus payments exemplify foreclosure.

The district court surmised that Sanofi was not foreclosed because it reversed the ESI exclusion and regained "80% market access." SJ-Op.92-93, 108 (13-JA-2682-83, 13-JA-2698). But the fact that Sanofi was "able to enter and grow despite" Mylan's scheme does not end the analysis. *See McWane*, 783 F.3d at 840. Sanofi overcame that exclusion only by paying a *$36 million access tax* on Lantus. 56-SJA-12547, 51-SJA-11462. That Mylan could erect such a massive barrier to entry only *underscores* Sanofi's foreclosure. *McWane*, 783 F.3d at 840; *Multistate*, 63 F.3d at 1553 n.12.

The district court, in a footnote, dismissed the fact that Sanofi had to "write a check" with Lantus because those additional rebates "provided consumers greater discounts." SJ-Op.101 n.22 (13-JA-2691). That speculation misses the point: in the *relevant product market*—where Mylan was a monopolist and Sanofi had the "better mousetrap"—no amount of Auvi-Q discounting (even 100%) would be enough even to gain access. Few companies have the resources to divert tens of millions of dollars in profits from a different product market just for the privilege of competing head-to-head. 56-SJA-12547. And no company can be compelled to do so. Sanofi was not "obliged to pursue any imaginable alternative, regardless of cost or efficiency,

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not Sanofi, must "suffer the uncertain consequences of its own undesirable conduct." *Microsoft*, 253 F.3d at 79.

before it can complain that [Mylan] restrained competition." *Buffalo Broad. Co. v. Am. Soc'y of Composers, Authors & Publishers*, 744 F.2d 917, 925 (2d Cir. 1984). To the contrary, it was Mylan's burden to present a *"nonpretextual claim* that its conduct [was] a form of competition on the merits." *Microsoft*, 253 F.3d at 355 (emphasis added). But Mylan's "stated exclusive purpose [was] to eliminate [EpiPen's] competition," 7 Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 1506 (4th ed. 2017), not stimulate competition in a different product market, *United States v. Topco Assocs., Inc.*, 405 U.S. 596, 611-12 (1972). The Lantus tax thus confirms that Mylan "use[d] its [monopoly] power to break the competitive mechanism" in the EAI market, *ZF Meritor*, 696 F.3d at 285, the only market properly before the court, *Topco*, 405 U.S. at 611-12; *Times-Picayune Publ'g Co. v. United States*, 345 U.S. 594, 610 (1953).

c. Mylan's monopoly made its lockouts durable.

Mylan's contracts generally ranged from two to three years in length and often contained automatic renewal provisions. 57-SJA-12926 (Mylan-MedImpact 2.5 year agreement), 26-SJA-5716 (Mylan-[redacted] three-year agreement with automatic three-year renewals). Termination rules varied by payor: the agreement with MedImpact required 90 days' notice before termination, 26-SJA-5681, whereas [redacted] policy required six-months' notice before excluding a product on the formulary, 24-SJA-5287 ("Sanofi offer couldn't have started earlier").

The district court believed these contracts were "short-term and easily terminable," and that this somehow "negated" their foreclosing effects. SJ-Op.88-93, 105-07 (13-JA-2678-83, 13-JA-2695-97). Setting aside what counts as "short," the court's analysis ignores the monopoly power that gave rise to these deals in the first place.

Under *Tampa Electric*, the key "practical" question is whether "dealers have a strong economic incentive to continue" excluding competitors beyond the stated terms. *Dentsply,* 399 F.3d at 189, 194; *McWane*, 783 F.3d at 833-34.[30] Duration and terminability can sometimes "negate" foreclosure, SJ-Op.90 (13-JA-2680), but *only* if the defendant lacks the monopoly power to perpetuate the exclusion beyond the contract's term. *See, e.g.*, *Omega Envtl., Inc. v. Gilbarco*, *Inc.*, 127 F.3d 1157, 1164 (9th Cir. 1997) (when manufacturer has only 55% market share, "a competing manufacturer need only offer a better product or a better deal to acquire their services"); *compare FTC v. Brown Shoe Co.*, 384 U.S. 316, 318-19 & n.13 (1966)

[30] *See also FTC v. Surescripts, LLC*, 424 F.Supp.3d 92, 104 (D.D.C. 2020) (monopolist's agreements could have "the effect of foreclosing large parts" of the relevant market "[e]ven if the contracts were short term and easily terminable"); *Minn. Mining & Mfg. Co. v. Appleton Papers, Inc.*, 35 F. Supp. 2d 1138, 1144 (D. Minn. 1999) (similar); *United States v. Microsoft Corp.*, No. CIV. A. 98-1232, 1998 WL 614485, at *20 (D.D.C. Sept. 14, 1998) (duration is "only one among many factors the Court will consider and does not admit of, much less compel summary judgment"); Jacobson, *Exclusive Dealing*, at 352 ("[T]he agreements in [*Microsoft*] were generally not of long duration.").

(condemning exclusionary agreement even though buyers could "voluntarily withdraw" at any time).

The record easily raises a fact question of whether Mylan's monopoly power made it "economically infeasible for [PBMs] to switch" away from EpiPen. *McWane*, 783 F.3d at 833-34. ESI made clear that no amount of Auvi-Q discounting could overcome Mylan's monopoly volume and substantial entrenched share, 56-SJA-12547; MedImpact explained Sanofi would have to double the Mylan rebate to "even open the conversation," 31-SJA-6880; and [redacted] flatly advised that Sanofi "dedicate their resources elsewhere," 31-SJA-6856. "The District Court's theory that any new or existing manufacturer may 'steal' a [Mylan] dealer by offering a superior product at a lower price … simply has not proved to be realistic." *Denstply*, 399 F.3d at 194; 51-SJA-11427. Mylan's monopoly power locked Auvi-Q out of the market, and that power had no termination date.

The practical "realities" of the EAI market further entrenched Mylan's position. *Eastman Kodak Co.*, 504 U.S. at 466-67. After winning the initial battles for exclusivity, Mylan knew payors would not turn around and block EpiPen the following year, forcing massive numbers of patients to retrain on a new life-saving device. 57-SJA-12953 (Internal Mylan email: "[redacted]"). This aversion to ping-ponging produced a "[redacted]," 36-SJA-

8093, 28-SJA-6238, and it is why Mylan fought so hard for these exclusions in the first place. The district court never engaged with these market realities.

d. Mylan's intent confirms that Sanofi was foreclosed.

The district court believed it could ignore the contemporaneous evidence of Mylan's company-wide plan to maintain its monopoly and, instead, "proceed to" the "ultimate issue whether Mylan's rebate contracts substantially foreclosed competition." SJ-Op.103 (13-SJA-2693). That was error. The rule of reason compels an inquiry into "all of the circumstances of a case," *Cont'l T.V.*, 433 U.S. at 49, including the defendant's state of mind, *supra* at 59 & n.20; Areeda & Hovenkamp, ¶ 1506 ("intent" reveals "defendants' belief that their conduct … restrains competition"). Even if intent *alone* is not sufficient for liability for a Section 1 claim, *U.S. Healthcare, Inc. v. Healthsource, Inc.*, 986 F.2d 589, 594-95 (1st Cir. 1993), the district court was still wrong to ignore such "clear expressions of [Mylan's] plan to maintain [its] monopolistic power" under Section 2. *Dentsply*, 399 F.3d at 190; *McWane*, 783 F.3d at 840; *Microsoft*, 253 F.3d at 76; *Green Country Food*, 371 F.3d at 1278 n.1.

II. THERE IS A TRIABLE QUESTION WHETHER MYLAN CAUSED ANTITRUST INJURY

Antitrust injury requires that the plaintiff suffer an "injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful." *Brunswick*, 429 U.S. at 489; *Lenox*, 762 F.3d at 1119 &

n.3. Sanofi suffered antitrust injury when it was foreclosed as a result of Mylan's anticompetitive scheme. *Viamedia, Inc. v. Comcast Corp.*, 951 F.3d 429, 467 (7th Cir. 2020).

A. Mylan Harmed Competition

Exclusive dealing can harm competition by enabling the monopolist to "increase prices, restrict output, reduce quality, slow innovation, or otherwise harm consumers." Jacobson, *Exclusive Dealing*, at 328.[31] Sanofi was not required to produce "'clear evidence' or definitive proof of anticompetitive harm, but [only a] 'probable effect'" of competitive harm. *McWane*, 783 F.3d at 836 (citing *Tampa Elec.*, 365 U.S. at 329). The "still-authoritative" test is whether Mylan's scheme had an "actual *or probable*" adverse effect on competition. *Westman Comn'n Co. v. Hobart Int'l. Inc.*, 796 F.2d 1216, 1227-28 (10th Cir. 1986). If Mylan's foreclosure campaign could "be reasonably expected to restrain output or increase price," that was enough to discharge Sanofi's burden, even "without evidence of an actual output restraint or price increase." Herbert Hovenkamp, *The Rule of Reason*, 70 Fla. L. Rev.

[31] The district court treated "harm to competition" as an element of antitrust injury rather than the substantive Sherman Act violation. SJ-Op.124 (13-JA-2714). That was wrong: "To say that the plaintiff has not shown any injury to competition is to conclude that the antitrust laws have not been violated at all." 2A Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 337a (4th ed. 2014); *cf.* SJ-Op.99 (13-JA-2689). In any event, the inquiry is the same. *Lenox*, 762 F.3d at 1119 & n.3.

81, 107 (2018). Applying these standards, a reasonable jury could readily discern harm to competition.

Mylan raised prices. When "a new innovative product" enters a competitive market, incumbents generally respond by *lowering* prices to preserve market share. 36-SJA-8017. But this was not a competitive market.

Between 2009 and 2016, Mylan *raised* the list price of EpiPen by over 500% to maximize monopoly profits and hammer Auvi-Q with exclusionary rebates. SJ.Op18-19, 124 (12-JA-2608-09, 13-JA-2714), 37-SJA-8263. In 2012, Mylan raised EpiPen's price three times by an "[redacted]" 30%, and continued to do so every year Auvi-Q was on the market. SJ-Op.18-19 (12-JA-2608-09), 37-SJA-8263, 50-SJA-11332. As Aetna observed, "EpiPen's price has jumped 488 percent in the last four years despite the fact that epinephrine is not a new drug." SJ-Op.19 (12-JA-2609), 37-SJA-8276. Mylan acknowledged internally that millions of Americans who [redacted]." 50-SJA-11317, 5-JA-996.

And it was not just the sticker price that Mylan hiked up. The rebates were a sideshow: EpiPen's average *net* price went from $111 in early 2013 to $150 in late 2015; the net price rose *for every major payor* relative to 2012, the pre-Auvi-Q baseline; and Mylan's profits per pen in 2013-2015 far exceeded 2012 levels. SJ-

Op.19-20 (12-JA-2609-10), 36-SJA-7966-67, 36-SJA-8018, 51-SJA-11398, 37-SJA-8316.

After Auvi-Q's recall, Mylan ratcheted up the price even more, with another 14% increase on EpiPen, now "[redacted]." 38-SJA-8396, 38-SJA-8387, 38-SJA-8392. At the same time, Mylan's senior most executives told all managed-care personnel to revoke existing offers and lower the rebates on EpiPen. 38-SJA-8407, 38-SJA-8387, 37-SJA-8208-09, 7-JA-1377, 54-SJA-12190, 36-SJA-7969 & n.170, 36-SJA-8024 & n.386. With prices climbing and rebates disappearing, Mylan's manufacturer began to raise "concerns" about the "reputational impact" of Mylan's unprecedented escalation. 37-SJA-8278, 7-JA-1366, 37-SJA-8290. Congress shared the sentiment and summoned CEO Heather Bresch to answer for Mylan's misdeeds. 7-JA-1436-38. All of this was sufficient to show harm to competition. *Lenox*, 762 F.3d at 1129.

Mylan stunted output. Mylan knew Auvi-Q's improved technology would grow the market by satisfying an "unmet medical need" for a more portable device. SJ-Op.9-10 (12-JA-2599-10), 38-SJA-8417, 37-SJA-8135, 54-SJA-12112. As Auvi-Q prepared to launch, Mylan projected the market would grow from ~[redacted] million prescriptions in 2012 to almost [redacted] million prescriptions in 2015. 46-SJA-10265, 46-SJA-10267, 37-SJA-8135. As Mylan's CEO acknowledged, there was clearly "room in the market for competitors" when Auvi-Q launched. 54-SJA-12112.

But the "probable effect" of Mylan's scheme was to constrain output. *Tampa Elec.*, 365 U.S. at 329. By 2015, the market barely exceeded 4 million prescriptions. 36-SJA-7932-33; *Conwood Co.*, 290 F.3d at 789; *McWane*, 783 F.3d at 838. And Mylan capped long-run growth by forcing Auvi-Q to rebrand as a "niche" product with "miniscule" market share. 51-SJA-11389, 36-SJA-8037. Patients paid the price. During the protracted EpiPen "shortages" of 2018 and 2019, many "were harmed by not having access to Auvi-Q." Daubert-Op.93 (12-JA-2563); 15-JA-3219-21; *see Lenox*, 762 F.3d at 1129.

Mylan restricted choice and reduced quality. "Choice increases the likelihood that … patients will carry their EAI device consistently and have it readily accessible in the event of an anaphylactic reaction." Daubert-Op.87 (12-JA-2557). But Mylan deprived more than half the country of meaningful choice for a [redacted]" by blocking Auvi-Q and consigning it to a "niche" status. 51-SJA-11389, 36-SJA-8037. In the words of one patient: Auvi-Q "wasn't covered. I asked for it and I couldn't get it." 5-JA-999, 5-JA-996.

Mylan stymied innovation. Stunting innovation is a well-recognized form of harm to competition. *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 radio competitor).[32] When Mylan blocked Auvi-Q, it never had to improve its dated swing-and-jab technology or invest in a smaller EpiPen. *Supra* at 10. Today, Auvi-Q is the "first and only FDA-approved [EAI] for infant and toddlers" weighing less than thirty-three pounds.[33] Had Mylan not foreclosed Sanofi, this innovation—and others like it—could well have achieved greater market penetration and been better able to serve the most vulnerable members of society. 36-SJA-8016.

B. The District Court's Contrary View Is Wrong

Price. The district court credited Mylan's view that "'but-for' Mylan's exclusive rebate offers, EpiPen prices would have been higher than they actually were in 2013, 2014, and 2015." SJ-Op.125 (13-JA-3715). But that gerrymandered account ignores that Mylan's price escalations and exclusionary rebates *together* enabled it to restrict Auvi-Q, while simultaneously *raising* EpiPen's net price. 36-SJA-7964, 36-SJA-8018. At the very least, the dueling expert reports raise a fact question for the jury. *Spirit Airlines*, 431 F.3d at 931; *Lenox*, 762 F.3d at 1119.

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[32] *See also Broadcom Corp. v. Qualcomm Inc.,* 501 F.3d 297, 318 (3d Cir. 2007); *United States v. Visa U.S.A., Inc.*, 344 F.3d 229, 241 (2d Cir. 2003).

[33] *Auvi-Q: Meet the Family*, Auvi-Q, https://www.auvi-q.com/about-auvi-q (last visited May 25, 2021).

In addition, the court condoned Mylan's *+500% price escalation* (<$100 in 2008 to >$500 in 2016) because it believed there was one quarter in one year (Q1 2015) where net prices dropped briefly. SJ-Op.125 (13-JA-3715). But antitrust law focuses "on the long-term impact of firm conduct on prices, even when the short-term effects might appear (at first blush) to be beneficial to consumers." *JetAway Aviation, LLC v. Bd. of Cnty. Comm'rs*, 754 F.3d 824, 842 (10th Cir. 2014) (Holmes, J., concurring). The evidence was undisputed that Mylan took consistent price increases before, during, and after Sanofi's foray into the EAI market. *Supra* at 7; *Lenox*, 762 F.3d at 1129. And even the short-term effects show harm to consumers: the district court ignored that Mylan raised net prices at ESI by [redacted]% while excluding Auvi-Q. *Supra* at 24-25; 55-SJA-12401; 37-SJA-8273; 36-SJA-7964, 36-SJA-8018.

Output. The district court thought Mylan's scheme did not reduce output. SJ-Op.126 (13-JA-2716). But the court ignored that (1) between 2012 and 2015, actual growth fell below Mylan's pre-market projections; and (2) Auvi-Q was forced to rebrand as a "niche" product with limited distribution. 51-SJA-11389, 36-SJA-8037. The court dismissed Dr. Scott Morton's opinion because she did not "quantify" hypothetical output but for Mylan's scheme. SJ-Op.126 (13-JA-2716). That standard is "virtually impossible to meet," *Standard Oil*, 337 U.S. at 309-10, which is why "[q]uantification … is *not required* by the leading cases," Andrew I. Gavil & Steven C. Salop, *Probability, Presumptions, and Evidentiary Burdens in Antitrust Analysis*,

168 U. Pa. L. Rev. 2107, 2132 (2020) (emphasis added); Hovenkamp, *Rule of Reason*, at 107 (same); *see, e.g.*, *McWane*, 783 F.3d at 836; *Microsoft*, 253 F.3d at 79.

Choice. The district court believed consumers were never deprived of Auvi-Q because they were not "wholly prohibited" from buying it—in other words, they could still pay *out of pocket without insurance*. SJ-Op.127 (13-JA-2717). But, again, "*the practical effect*" of Mylan's exclusions was to prevent access. *Tampa Electric*, 365 U.S. at 326 (emphasis added); *Microsoft*, 253 F.3d at 64. Mylan pushed for exclusivity because it knew that an overwhelming majority of Americans could not realistically afford an EAI that was excluded from the formulary and not covered by insurers. *Supra* at 32-33.

Quality. The district court dismissed Auvi-Q's innovations on the theory that "*payors* … viewed the two product as interchangeable." SJ-Op.127 (13-JA-2717). But even Mylan has conceded that antitrust law protects *patients* ("the ultimate consumers," 17-JA-3660-61), not corporate intermediaries. PBM policy is no substitute for consumer welfare. 55-SJA-12391 (PBM: "[redacted]."); *supra* at 65 n.23. The district court also claimed Auvi-Q wasn't better because it was subject to a recall. SJ-Op.127 (13-JA-2717). That is wrong and, in any event, a fact question for the jury. EpiPen was also subject to

significant recalls, and the manufacturing issues with Auvi-Q were easily surmountable. 22-JA-4845-48.

Innovation. Finally, the district court ignored Mylan's failure to innovate a smaller EpiPen, with audio instruction and no swing-and-jab. That was indefensible.

* * *

When Mylan pressed its "foot on [Auvi-Q's] throat," the entire anaphylaxis community paid the price. 4-JA-738. As this Court has explained, "foreclosure of *even a single significant competitor* can led to higher prices and reduced output," *Lenox*, 762 F.3d at 1129 (emphasis added), especially in "a concentrated market with very high barriers to entry," *McWane*, 783 F.3d at 836. A reasonable jury could thus conclude that Mylan harmed competition through its scheme to "[redacted]." 51-SJA-11498.

CONCLUSION

For the foregoing reasons, the Court should reverse and remand.

STATEMENT IN SUPPORT OF ORAL ARGUMENT

Sanofi respectfully requests oral argument in order to assist this Court in understanding the complex legal issues and the detailed summary judgment record presented in this appeal.

Date: May 28, 2021

Respectfully submitted,

/s/ *Gregory Silbert*

Gregory Silbert
Yehudah L. Buchweitz
Eric S. Hochstadt
WEIL, GOTSHAL & MANGES LLP
767 Fifth Avenue
New York, New York 10153
Telephone: (212) 310-8000
gregory.silbert@weil.com

Joshua Halpern
WEIL, GOTSHAL & MANGES LLP
2001 M Street NW #600
Washington, DC 20036
Telephone: (202) 682-7000

Counsel for Plaintiff-Appellant

CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitation in this Court's May 13, 2021 Order because it contains 18,600 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f); and that this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the typestyle requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point font.

Dated: May 28, 2021

/s/ *Gregory Silbert*
Gregory Silbert

CERTIFICATE OF DIGITAL SUBMISSION

I hereby certify that all required privacy redactions have been made in accordance with Circuit Rule 25.5; any hard copies submitted to the clerk are exact copies of the ECF submission; and the digital submissions have been scanned for viruses with the most recent version of a commercial virus-scanning program, and according to the program are free of viruses.

Dated: May 28, 2021

/s/ *Gregory Silbert*
Gregory Silbert

CERTIFICATE OF SERVICE

I hereby certify that on May 28, 2021, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Tenth Circuit by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

Dated: May 28, 2021

/s/ *Gregory Silbert*
Gregory Silbert