No. 21-3005

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 L.P.,

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

BRIEF OF APPELLEES MYLAN INC. AND MYLAN SPECIALTY L.P.
(Public, Redacted)
Oral Argument Requested

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Defendants-Appellees Mylan Inc. and Mylan Specialty L.P. certify that they are wholly owned, indirect subsidiaries of Viatris Inc., and that no publicly held company owns 10% or more of Viatris's stock.

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GLOSSARY

Auvi-Q – Auvi-Q®

EAI – Epinephrine Auto-Injector

EEB – Effective Entrant Burden

EpiPen – EpiPen® and EpiPen Jr.® Auto-Injectors

ESI – Express Scripts Holding Company

NC – Not Covered

PA – Prior Authorization

PBM – Pharmacy Benefit Manager

SE – Step Edit

UM – Utilization Management

United – United Healthcare Services, Inc.

T2 – Tier 2 of a PBM's Formulary

T3 – Tier 3 of a PBM's Formulary

WAC – Wholesale Acquisition Cost

STATEMENT OF PRIOR OR RELATED APPEALS

Pursuant to Circuit Rule 28.2(C)(3), Mylan Inc. and Mylan Specialty L.P. state that there are no prior or related appeals.

PRELIMINARY STATEMENT

Plaintiff-Appellant Sanofi-Aventis U.S., LLC (Sanofi) has only itself to blame for the failure of its Auvi-Q epinephrine auto-injector. When Sanofi launched Auvi-Q, it *chose not to compete on price*. Its then-CEO Christopher Viehbacher testified:

> *[W]hen you're marketing a drug, you know, the whole point of marketing is that you don't use price, right?* Otherwise you become a commodity. And if you believe your product is better, and Sanofi at that time believed, and probably still does, that Auvi-Q was a better drug, then there shouldn't really be a necessity to have a deep discount. *What you . . . may not actually want [is] to set off a whole cascade of price discounts*.

9-JA-1812-13 (emphasis added).[1] Once Sanofi changed its approach on price competition, it did very well. Then its product was recalled because it was a danger to patients' health. That is the whole story of its failure.

After Sanofi's product launch failed economically thanks to its do-not-compete-on-price strategy, Sanofi changed its strategy. Unsurprisingly, when Sanofi began to compete on price it rapidly started taking away sales from the rival product, Mylan's EpiPen. The "cascade of price discounts" that Viehbacher warned about became a reality, to the tremendous benefit of consumers.

[1] This brief cites the Joint Appendix using both volume and page range (*e.g.*, Volume Number-(Sealed) Joint Appendix-Page Range). References to the Supplemental Appendix filed with this brief are in the same form.

Even after it became serious about competing, however, Sanofi did not win every sale. But *every time* it was excluded from a PBM's formulary, the reason was price. "[W]hen payors [such as ESI, OptumRx, MedImpact, and Aetna] agreed to exclude Auvi-Q, Mylan *had offered a lower price* on EpiPen." SJ-Op.97 (13-JA-2687) (emphasis added).

Lowering prices to compete for favorable formulary placement is standard practice for the branded-pharmaceutical industry. As Sanofi's expert has pointed out in Congressional testimony, "the way" buyers "get low prices in the pharmaceutical industry is by the ability to exclude drugs. . . . When you can do that, you force price competition." 9-JA-1920. For its blockbuster insulin drug Lantus, and for Auvi-Q itself, Sanofi used the same array of rebating techniques, including offering rebates for exclusivity, that Mylan did.

Moreover, Auvi-Q endangered patient health because it *did not work properly*, forcing Sanofi to completely recall it in 2015. Sanofi did not then fix the product and resume selling it (which would have benefited consumers). Instead, it gave rights to the product back to the inventor and went all in on blaming Mylan.

Sanofi called Mylan's aggressive price-cutting—exactly the competition the antitrust laws encourage—an anticompetitive practice supposedly causing Sanofi's downfall. In Sanofi's telling, price reductions became "exclusion" and Mylan's decision to *give away* free EpiPens to schools became part of a broth of tactics

supposedly designed, in combination, to drive a new entrant from the market. Sanofi has chosen to pursue substantial treble damages since it could not prevail in marketplace competition.

The district court saw through this deeply cynical, hypocritical lawsuit and entered summary judgment in Mylan's favor on two grounds, each independently sufficient. This Court can affirm on either ground alone, but both are correct.

Largely ignoring the legal basis of Judge Crabtree's 157-page, factually detailed, and well-reasoned opinion, Sanofi spends dozens of pages discussing—and misrepresenting—facts that are immaterial to his ruling. As for Judge Crabtree's first ground, the legal test for exclusive dealing is well settled, and the relatively few facts necessary to rule in Mylan's favor are undisputed. In lieu of the settled law and undisputed facts, Sanofi instead advances a novel legal theory of "entrenched market share" that neither this Court nor any other has adopted. As for the second ground, the undisputed facts show no increase in price or reduction in output that could provide a basis for antitrust injury to Sanofi. As Judge Crabtree recognized, the antitrust laws exist to promote—not punish—vigorous competition. This Court should affirm.

ISSUES PRESENTED

1. Whether the district court erred in granting Mylan summary judgment because there was no triable issue whether Mylan had acted anticompetitively.

2. Whether the district court erred in granting Mylan summary judgment because the undisputed facts failed to show that Sanofi suffered antitrust injury.

STATEMENT

I. UNDISPUTED FACTS RELEVANT TO THE ISSUES PRESENTED

This case was resolved on summary judgment. Under the applicable Local Rules, the movant submits a Statement of Undisputed Material Facts (SUMF) to which the opposing party responds. D. Kan. Local Rule 56.1. Judge Crabtree's opinion relies *entirely* on a narrow set of facts that Sanofi either admitted or did not genuinely dispute.[2] This brief does the same.

Sanofi's brief takes a different tack: obscuring the truth. As the party opposing summary judgment, Sanofi is entitled to construe disputed facts in its favor and to benefit from reasonable inferences. But Sanofi's brief goes way beyond that. Sanofi cites the 61-volume joint appendix indiscriminately, rarely identifying what documents it cites or quotes. The district court relied on what *actually happened* in negotiations, not on abstract theory or speculative predictions that proved wrong. The record shows the following facts beyond genuine dispute.

[2] In many instances, Sanofi purported to "den[y]" or "den[y] in part" a paragraph of Mylan's SUMF but then did not contradict what Mylan had written, instead just making additional factual assertions. *See* Mylan's SUMF (34-SJA-7445-95), Sanofi's Response (RSUMF) (49-SJA-11047-74), and Mylan's Reply (61-SJA-13647-56). The district court was entitled to treat uncontradicted paragraphs of the SUMF as not being in genuine dispute.

A. Anaphylaxis And Its Treatment

Anaphylaxis is a severe allergic reaction—for example, the throat closure that an allergic person can experience after accidentally eating peanut butter. For more than 30 years, the leading drug for treatment of anaphylactic reactions has been the EpiPen, which Defendants-Appellees Mylan Inc. and Mylan Specialty L.P. (collectively, Mylan) sell. SJ-Op.5-6 (12-JA-2595-96).[3]

EpiPen had competition from other EAIs[4] (such as Adrenaclick) before 2013, but that year global pharmaceutical giant Sanofi brought to market another EAI called Auvi-Q, which it licensed from the original inventor. SJ-Op.6-8 (12-JA-2596-98). Sanofi and Mylan competed to sell their EAIs to patients and negotiate with PBMs and health insurance plans (collectively, payors) to have their EAIs covered by patients' insurance. SJ-Op.21-29 (12-JA-2611-19).

Payors create lists of drugs—called formularies—that are eligible for insurance coverage. SJ-Op.12 (12-JA-2602), SUMF¶18 (34-SJA-7450). If a payor excludes a drug from formulary, patients must pay the full list price to acquire it. SJ-Op.15 (12-JA-2605). If a drug is on formulary, then insurance plans will pay for it, and patients usually pay only a small co-pay. SJ-Op.14 (12-JA-2604). For many

[3] Mylan's parent company merged with another company during this litigation, which resulted in the creation of a new parent company named Viatris.

[4] "EAI" and other acronyms and abbreviations not in common use that are used in this brief are defined in the Glossary at p. xi, *supra*.

payors, that co-pay varies based on what formulary tier a drug is on; drugs on T2, for example, will have lower co-pays than drugs on T3. *Id.* As detailed below, payors leverage the threat of being off formulary to force manufacturers to compete on price. SJ-Op.15-16 (12-JA-2505-06), SUMF¶¶29-31, 42-44 (34-SJA-7453-54).

B. Commercial Health Plans, Prescription Drug Formularies, And PBMs

A health insurance plan need not cover *all* available prescription drugs in a therapeutic class. SJ-Op.12 (12-JA-2602), SUMF¶19 (34-SJA-7450). "Managed care" health plans—which control (or "manage") patients' access to medicine to reduce costs—are the most common form of commercial health insurance in the United States. SJ-Op.11 (12-JA-2601), SUMF¶13 (34-SJA-7449). Some large health plans manage their own prescription drug benefits; most retain PBMs to do so on their behalf. SJ-Op.12 (12-JA-2602), SUMF¶15 (34-SJA-7449).[5]

Sanofi's brief barely acknowledges the health plan clients served by PBMs. But PBMs maintain hundreds or thousands of different formularies to meet their health plan clients' needs, including template formularies that clients may select and custom formularies for larger clients. SJ-Op.12-13 (12-JA-2602-03), SUMF¶¶20-22

[5] Although some patients access prescription drug benefits through government-sponsored programs such as Medicaid and Medicare, Sanofi's Complaint did not allege that Mylan engaged in exclusive dealing with respect to Medicare formularies, and the district court, in a ruling Sanofi has not appealed, dismissed Sanofi's claims based on Medicaid discounts. 2-SA-440-43. This appeal pertains only to commercial prescription drug benefits.

(34-SJA-7450-51). Some formularies cover multiple drugs that treat the same condition. *Id.* However, to facilitate cost savings, others restrict choice. *Id.* As Sanofi's then-CEO who launched Auvi-Q acknowledged, "the tighter the access to any given formulary, the more [a payor has] control over price." SJ-Op.13 (12-JA-2603), 9-JA-1810 (Viehbacher Depo.).

When developing formularies, PBMs and health plans employ UM techniques—such as co-pay tiers, SEs, PA requirements, and benefit exclusion—to steer patients to preferred drugs. SJ-Op.13-15 (12-JA-2603-05), SUMF¶¶23-28 (34-SJA-7451-53). They do so to encourage patients to use more cost-effective products and to negotiate better pricing from manufacturers. SJ-Op.13 (12-JA-2603), SUMF¶23 (34-SJA-7451-52).

Payors' ability to drive patients toward preferred products on the formulary gives them leverage to extract price concessions, in the form of rebates, for preferred placement. SJ-Op.15-16 (12-JA-2605-06), SUMF¶29 (34-SJA-7453-54). In a lawsuit *defending* its own rebating practices for Lantus, Sanofi emphasized that "[t]he use of formularies thus gives the PBMs enormous power to extract rebates from manufacturers" "in exchange for having their products appear on formularies that insurers use to make coverage decisions for the vast majority of patients." 10-JA-2036; -47 (Sanofi Brief, *In re Insulin Pricing Litigation*).

On appeal Sanofi labels certain UM techniques "drastic," Br.12, but the record establishes that payors commonly deploy them to negotiate lower prices from manufacturers in return for favorable coverage, SUMF¶¶23-31 (34-SJA-7451-54). As Sanofi has acknowledged, this is "*how the entire branded pharmaceutical industry functions*." 10-JA-2037 (Sanofi Brief, *In re Insulin Pricing Litigation*) (emphasis added).

C. Prescription Drug Rebate Agreements

PBMs and health insurers solicit from brand manufacturers rebates that align with their benefit-design goals. A large PBM that develops hundreds or thousands of formularies for health-plan clients might seek a menu of rebate options for different formulary positions, including one for "equal access" (T2 coverage alongside alternative branded products), another to be the only branded product on T2 (with other branded products covered at a higher co-pay on T3), and yet another for more restrictive formulary coverage, with other products either excluded from formulary or restricted by an SE or PA protocol requiring additional steps before those products are covered. SJ-Op.16-17 (12-JA-2606-07), SUMF¶33 (34-SJA-7455). In contrast, a health plan that decides to cover only one product in a therapeutic class might request only one rebate offer for that exclusive formulary coverage. *Id.*

Another way that payors reduce price is through price protection, a contractual term providing that, if a manufacturer increases a drug's list price—the WAC—beyond negotiated limits, the payor receives a rebate. SJ-Op.16 (12-JA-2606), SUMF¶32 (34-SJA-7455). Price protection sets a limit on the amount WAC price can increase before triggering an additional rebate: The lower the percentage limit, the more protection it provides. 23-SJA-5148 (Prime Depo.). And "cumulative" price protection, which applies the limit over the duration of a contract, is more valuable than price protection that resets the WAC baseline annually. 39-SJA-8780 (Navarro Report).

After negotiations, payors and manufacturers sign agreements memorializing the conditions on which manufacturers will pay rebates. Those agreements are central to this case, yet Sanofi barely mentions them. The record contains more than three dozen rebate agreements (*e.g.*, 26-SJA-5662-5805, 28-SJA-6148, 28-SJA-6316, 29-SJA-6360, 29-SJA-6445, 29-SJA-6468) establishing the following unrefuted facts.

First, rebate agreements often include an entire menu of rebate options, not just one. SJ-Op.17 (12-JA-2607), SUMF¶36 (34-SJA-7456). PBMs often request that manufacturers provide a rebate offer for each level of formulary restriction (including exclusivity) by submitting a "bid grid" for the manufacturer to complete. SJ-Op.16 (12-JA-2606), SUMF¶34 (34-SJA-7456). Mylan would fill out those bid

grids, offering a menu of rebate options for PBMs and their clients to choose from. An example menu is below (26-SJA-5688):

Mylan-MedImpact 2014 Rebate Agreement

Health plans select or customize formularies with their desired level of control, and payors collect rebates based on the number of prescriptions filled by patients whose health plan fits a particular rebate category. SJ-Op.17 (12-JA-2607), SUMF¶36 (34-SJA-7456).

When a PBM "excludes" a drug from a template formulary, it does not follow that all patients with insurance benefits managed by that PBM lack access to the drug, as Sanofi suggests, Br.22-23. For example, as Sanofi conceded below, when ESI excluded Auvi-Q from its 2014 National Preferred and High Performance formularies, many ESI clients did not adopt those formularies. ESI's exclusion of Auvi-Q affected only about "35% of ESI commercial lives." SJ-Op.31 (12-JA-2621), SUMF¶81 (34-SJA-7472), RSUMF¶81 (49-SJA-11047).

Second, "rebate agreements typically don't require the payor to make specific drug choices or formulary decisions." SJ-Op.17 (12-JA-2607), SUMF¶¶38-39 (34-

SJA-7457). They require only the rebate for the coverage the payor or client *selects* from the grid. *Id.* Mylan's agreements with payors generally contained a variation of this provision: [redacted] SUMF¶39 (34-SJA-7457). Payors therefore could—and did—change their formularies *at any time*. *See infra* at 21-31.

Third, Mylan's rebate agreements generally had "terms of 2.5 years or less" and could be terminated without cause "on 90 days' written notice or less." SJ-Op.89 (13-JA-2679), SUMF¶¶40-41 (34-SJA-7457-58). Payors exercised those termination provisions with regard to EAIs: nearly all major payors forced Mylan to renegotiate for formulary coverage on a yearly or even more frequent basis. *See infra* at 21-31.

D. Payors' Use Of Formulary Exclusions

Beginning in 2012, payors increasingly excluded drugs from coverage to reduce costs, sometimes covering only one branded product per therapeutic class. SJ-Op.21-22 (12-JA-2611-12). As Sanofi's former Vice President of Strategic Pricing and Contracts explained, "[a]n exclusive formulary would typically be *pursued by a PBM* at the request of . . . client plans that are looking for a more

restrictive and potentially . . . *a less costly option for their clients*." 7-JA-1494 (Borneman Depo.) (emphasis added).

An internal Sanofi white paper recognized the industrywide shift towards tighter formulary control occurring around the time of Auvi-Q's launch:

[redacted]

25-SJA-5649, *cited at* SJ-Op.21-22 (12-JA-2611-12). At that time, payors also increasingly demanded "price protection" terms. SJ-Op.22 (12-JA-2612), SUMF¶51 (34-SJA-7462).

The district court highlighted this industry shift. SJ-Op.21-22 (12-JA-2611-12), SUMF¶¶45-51 (34-SJA-7459-62). Yet Sanofi's appellate brief pretends that, when Auvi-Q launched in 2013, only Mylan's alleged conduct could explain any payor's decision to cover just one product in the EAI class.

Sanofi, however, is no stranger to payors' use of formulary exclusions to control costs. Around the time of Auvi-Q's launch, Sanofi's market-leading insulin drug, Lantus, faced a new competitor. SUMF¶¶139-141 (34-SJA-7492-93). [redacted]

[redacted]. *Id.* Mylan responded to the same market forces in the same way—rebates on the EpiPen—yet Sanofi's appellate brief reads as if Mylan engaged in unheard-of conduct.

Even within the EAI product space, Mylan and Sanofi alike offered payors rebates conditioned on exclusive coverage for their respective products. Sanofi began offering rebates conditioned on exclusivity for Auvi-Q [redacted]. SJ-Op.101 (13-JA-2691), SUMF¶¶138, 117-19 (34-SJA-7492, 83-85).

E. Sanofi's Launch Of Auvi-Q

Sanofi launched Auvi-Q in 2013. Auvi-Q treats the same condition as EpiPen (anaphylaxis) injecting the same active ingredient (epinephrine) through the same basic method (an auto-injector device). SJ-Op.7 (12-JA-2597), SUMF¶¶8-9 (34-SJA-7447-48). No clinical study ever showed that Auvi-Q was safer or more effective than EpiPen in treating anaphylaxis. *Id.*

1. The Impact Of Competition On Payors' Treatment Of EAIs

Before Auvi-Q's launch, payors generally did not exclude EAIs from coverage. SJ-Op.22 (12-JA-2612). But the launch of a new product changed things.

Many payors—[redacted]—"viewed Auvi-Q to deliver a treatment that was similar to or interchangeable with EpiPen," SJ-Op.27 (12-JA-2617), SUMF¶61 (34-SJA-7465-66) (collecting payor testimony).

Therefore, if any of those payors opted to cover *only one* of the two products, patient health would not suffer because one of the two devices was covered. *Id.*

Accordingly, "some payors viewed Auvi-Q's introduction as an opportunity to manage the EAI class and push for more competitive pricing." SJ-Op.28 (12-JA-2618), SUMF¶61 (34-SJA-7465-66). Indeed, "[s]everal payors have testified that competition in a therapeutic drug class encourages manufacturers to offer more favorable pricing and rebates in exchange for better placement." SJ-Op.17 (12-JA-2607), SUMF¶43 (34-SJA-7459) (collecting payor testimony). Payors told both Sanofi and Mylan that they were looking to cover only one EAI and might exclude all others, and payors encouraged price competition. SJ-Op.28-29 (12-JA-2618-19), SUMF¶¶62-63 (34-SJA-7466-67) (collecting payor testimony).

Sanofi addresses *none of this evidence*. Instead, Sanofi strings together quotes from *pre-launch* research *predicting* that payors would continue after Auvi-Q's launch to provide "open access" to all EAIs. Br.15 (citing pre-launch presentations 16-JA-3501, 16-JA-3535, 51-SJA-11368, 55-SJA-12372). But the uncontroverted facts in the record show that, whatever anyone might have anticipated, many payors responded by choosing to manage the class. SJ-Op.28-29 (12-JA-2618-19).

2. Mylan's Competitive Response To Auvi-Q's Launch

Sanofi devotes considerable effort to establishing that Mylan viewed Auvi-Q as a competitive threat. Br.7-10. But that fact is undisputed. SJ-Op.8-9 (12-JA-2598-99).

Mylan found itself confronted with a rival product backed by Sanofi, "one of the world's largest pharmaceutical companies." SJ-Op.6 (12-JA-2596), SUMF¶6 (34-SJA-7446-47). Payors told Mylan "about the need to compete on price after Auvi-Q entered the market." SJ-Op.29 (12-JA-2619), SUMF¶63 (34-SJA-7467). So Mylan competed on price.

Specifically, Mylan's rebates for EpiPen increased after Auvi-Q's launch. SJ-Op.25 (12-JA-2615). When payors sought higher rebates, Mylan offered them.[6] When payors sought rebates for exclusive coverage, Mylan offered them.[7] Mylan offered price protection.[8] And Mylan sometimes took the initiative to submit offers that included higher rebates for preferred or exclusive formulary positions.[9]

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[6] SJ-Op.36, 41 (12-JA-2626, -31), SUMF¶¶96, 111 (34-SJA-7476, -80-81) (Prime, Cigna).

[7] SJ-Op.32-33, 37-38 (12-JA-2622-23, -27-28), SUMF¶¶85, 100-102 (34-SJA-7473, -78-79) (OptumRx, MedImpact).

[8] SJ-Op.30, 33, 35-36, 40 (12-JA-2620, -23, -25-26, -30), SUMF¶¶ 78, 87, 95, 107 (34-SJA-7471, -74, -76, -79) (ESI, OptumRx, Prime, Aetna).

[9] SJ-Op.36, 42 (12-JA-2626, -32), SUMF¶¶95, 113 (34-SJA-7476, -81-82) (Prime, Humana).

Sanofi's assertion that Mylan threatened to pay rebates *only* if clients excluded Auvi-Q, Br.18, is pure fiction. The uncontroverted evidence of Mylan's rebate negotiations, and the dozens of agreements in the record, establish beyond dispute that Mylan offered payors many rebate options to choose from, for various formulary positions.[10] Mylan still paid rebates to payors who covered Auvi-Q. SUMF¶68 (34-SJA-7468-69).

Sanofi cites *no actual rebate offers* to support its contrary assertion. Sanofi instead quotes an *internal* Mylan email discussing one potential offer to a single payor (ESI client Wellpoint), Br.18 (citing 5-JA-983), and the self-serving testimony of a Sanofi witness *speculating* about Mylan's offers, Br.18 (citing 16-JA-3356). Mylan *actually* offered Wellpoint a substantial rebate *not* conditioned on Auvi-Q's exclusion. SJ-Op.97 (13-JA-2687). "In sum, Sanofi has adduced no evidence that Mylan refused to pay rebates on EpiPen altogether unless payors excluded Auvi-Q from their formularies." *Id.*

3. Sanofi's Pricing Strategy For Auvi-Q In 2013

Sanofi *chose* not to compete on price when it launched Auvi-Q. Sanofi's central assertion on appeal that it "competed aggressively" on price, Br.22, is refuted by the record and facts Sanofi admitted below.

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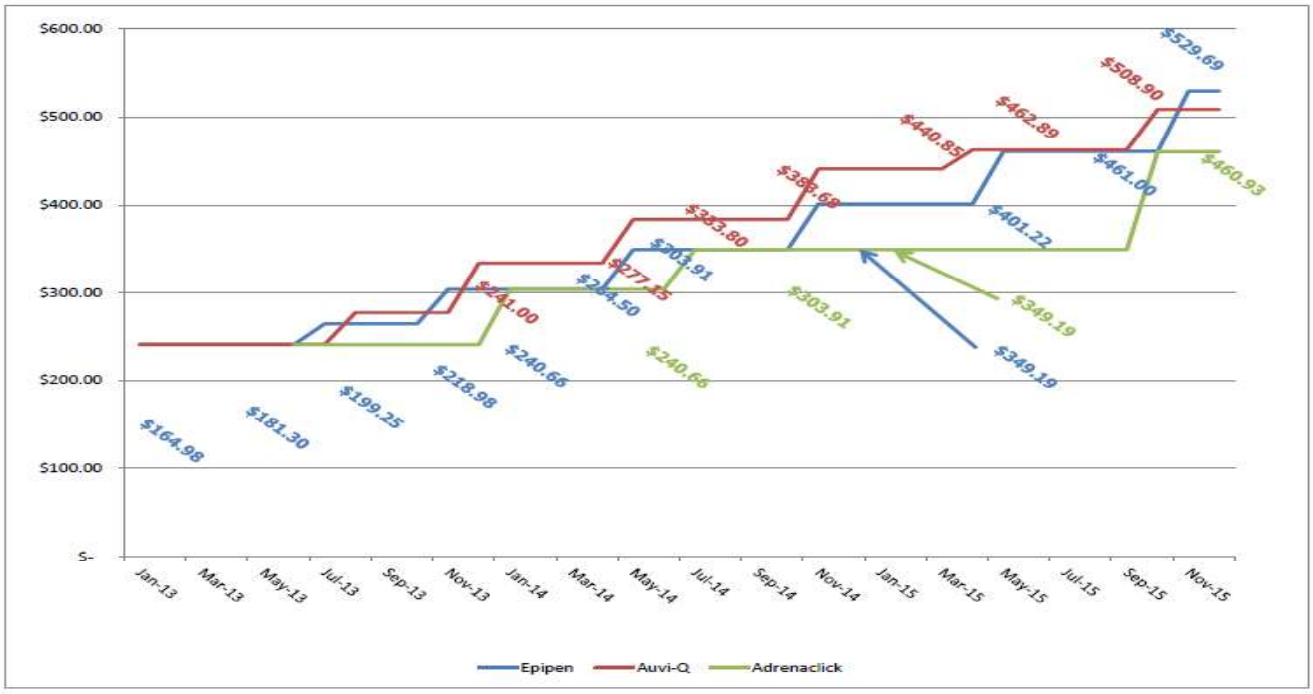
[10] *E.g.*, SJ-Op.30-33 (12-JA-2620-24), SUMF¶¶76-91 (34-SJA-7470-75) (describing Mylan's rebate offers to ESI, CVS, United).

Sanofi criticizes Mylan's EpiPen pricing but relegates the list price (WAC) *of its own product* to footnotes. Br.25 n.8, 26 n.10. Sanofi conceded below that its pricing strategy for Auvi-Q was to launch at the *same price* as EpiPen and then establish a price *premium*. SUMF¶52 (34-SJA-7462), RSUMF¶52 (49-SJA-11047). As shown below, Sanofi increased its WAC six times during the 33 months Auvi-Q was on the market, maintaining a premium over EpiPen for most of that time. SUMF¶53 (34-SJA-7462-63), RSUMF¶53 (49-SJA-11047):

Auvi-Q® and EpiPen® WAC



Sanofi also chose initially *not* to compete with aggressive rebates. Thinking it had a better product, Sanofi did not match Mylan's rebates in 2013. SJ-Op.27 (12-JA-2617), 9-JA-1816 (Viehbacher Depo.). Because Auvi-Q had high manufacturing costs and royalty payments, SJ-Op.6 (12-JA-2596), SUMF¶¶7, 58 (34-SJA-

7447, -64-65), paying substantial rebates also would "put pressure" on Sanofi's bottom line, SJ-Op.26 (12-JA-2616), 54-SJA-12053 (Barry Depo. 31-32).

As Sanofi's then-CEO tellingly explained, Sanofi was not interested in offering aggressive rebates in Auvi-Q's first year because it did not "want to set off a whole cascade of price discounts." SJ-Op.23 (12-JA-2613), 9-JA-1813 (Viehbacher Depo.). In Sanofi's view, there would be "no winners in a price war." 27-SJA-5936 (Auvi-Q Strategy Discussion). Apparently unimpressed with Sanofi's claim to have a better product that should command a premium price, payors deemed Sanofi's early rebate offers for Auvi-Q "inadequate," "not competitive," and "laughable." 27-SJA-5917 (United); 27-SJA-5919 (MedImpact); 27-SJA-5923 (Coventry).

Sanofi conceded below that, because it wanted to compete on attributes *other than* price, it was "not planning for a lot of tier two access." SUMF¶56 (34-SJA-7464), RSUMF¶56 (49-SJA-11047). Instead, Sanofi hoped to secure T3 coverage for Auvi-Q without paying rebates. SJ-Op.23 (12-JA-2613), SUMF¶¶55-57 (34-SJA-7463-64).

F. Rebate Negotiations And Coverage Determinations For Auvi-Q For 2014

At launch, many payors covered Auvi-Q on T3 by default while their clinical and financial committees evaluated it. SJ-Op.29 (12-JA-2619), SUMF¶65 (34-SJA-

7467-68). Mylan and Sanofi then negotiated rebate agreements with payors for 2014 formulary coverage.

Payors made varying coverage determinations for Auvi-Q. The following chart depicts Auvi-Q's coverage for 2013-2015 on the seven largest payors' primary national formularies:

SUMF¶72 (34-SJA-7469-70), RSUMF¶72 (49-SJA-11062).[11] These payors and others made their formulary coverage determinations for the EAI class after giving *both* Mylan and Sanofi the opportunity to compete through rebates and price protection. SUMF¶¶65-113 (34-SJA-7467-82) (describing negotiations for 2014 coverage).

Three of these payors (Prime, CVS, Cigna) *never* restricted or excluded Auvi-Q, always covering it on T2 or T3 without restriction. Sanofi conceded below that it was "content with T3 placement for Auvi-Q." SUMF¶74 (34-SJA-7470),

[11] OptumRx—a PBM owned by the same parent company as United—provides services to United and other plans.

RSUMF¶74 (49-SJA-11047). Indeed, Sanofi's stated *goal* at Auvi-Q's launch was to secure a mix of T2 and T3 access. SUMF¶56 (34-SJA-7464), RSUMF¶56 (49-SJA-11047). Sanofi now advances a different position on appeal, complaining that it was "disadvantaged" on T3 at CVS and "blocked" from T2 at Prime. Br.30-31.

Four of these payors (ESI, Aetna, OptumRx, MedImpact) excluded or restricted Auvi-Q in 2014 on their template formularies (but not all their formularies, *see supra* at 10). Sanofi *does not cite a single rebate offer or agreement* to support the assertion that it "competed aggressively on price" in its negotiations with these payors, Br.22, instead quoting hearsay from a market research firm [redacted], 35-SJA-7720.

Rather than rely on rumors of Sanofi's pricing, the district court analyzed uncontroverted evidence of Mylan's and Sanofi's 2014 negotiations and agreements with the seven largest payors. SJ-Op.29-42 (12-JA-2619-32). As explained below, Sanofi egregiously mischaracterizes those negotiations on appeal.

Sanofi's repeated assertion that payors rejected Sanofi's "superior" offers, Br.26-27, 48, 54, 68-69, similarly contradicts the undisputed material facts. Neither Sanofi's expert economist nor its executives could identify *one instance* when Auvi-Q was excluded or restricted when Sanofi offered a better per-unit net price. 24-SJA-5302 (Scott Morton Depo.), 8-JA-1541-42 (Downey Depo.), 23-SJA-5122 (Guenter Depo.). Instead, as the district court acknowledged, and the uncontroverted facts

discussed in more detail below show, "when payors [such as ESI, OptumRx, MedImpact, and Aetna] agreed to exclude Auvi-Q, Mylan *had offered a lower price* on EpiPen." SJ-Op.97 (13-JA-2687) (emphasis added). That price competition is what Sanofi's antitrust lawsuit seeks to punish.

ESI. Sanofi and Mylan each filled out ESI's "rebate matrix" for 2014-2015, offering a range of rebates for various formulary positions. SJ-Op.30 (12-JA-2620), SUMF¶¶76-78 (34-SJA-7470-71). Mylan's highest rebate offer, applicable to plans that made EpiPen the exclusive EAI device on formulary, was 23% (inclusive of ESI's admin fee), plus [redacted]% price protection. *Id.* Sanofi's own expert placed "the overall value of the Mylan discounts (rebate, plus price protection of [redacted]%)" at [redacted] 36-SJA-8010 (Scott Morton Report).

Sanofi's highest rebate offer, for plans that made Auvi-Q exclusive, was 30%. SJ-Op.30 (12-JA-2620). But Sanofi's starting WAC was higher. 41-SJA-9071 (Willig Report).[12] And Sanofi offered ESI *no* price protection. SJ-Op.30 (12-JA-2620), SUMF¶77 (34-SJA-7470-71). After comparing the offers, ESI chose not to cover Auvi-Q on its National Preferred and High Performance formularies (accounting for 35% of ESI commercial lives, *see supra* at 10).

[12] Sanofi notes that Mylan raised EpiPen's list price to $[redacted] *after* Auvi-Q was "excluded," Br.24, 25 n.8, but Sanofi itself took a [redacted] price increase one month later to $333.80, 10-JA-2162 (Sanofi spreadsheet depicting prices). If ESI was [redacted] as Sanofi claims, Br.25, about Mylan's price increase, it was free to renegotiate rebates and alter coverage determinations—and it did so in 2015.

Sanofi claims it was "exclude[d]" despite offering the "deeper discount." Br.24. But ESI's representative testified unequivocally that ESI chose EpiPen over Auvi-Q for its 2014 national formulary because it was "able to get a lower net cost for our plans" ([redacted]). SJ-Op.31 (12-JA-2621), 23-SJA-5191 (ESI Depo.). And Mylan's expert economist, Dr. Willig, showed—in an analysis that Sanofi never challenged—that ESI chose the lower-priced product. 41-SJA-9071 (Willig Report).

Sanofi also misleads the Court by asserting that ESI rejected an "enhanced" offer for Auvi-Q coverage that also included $18 million in Lantus rebates as "not enough." Br.24-25. The cited Sanofi white paper states that ESI rejected this offer *not*, as Sanofi claims, because it was "insufficient to surmount Mylan's rebate," but because Sanofi's offer [redacted]. 25-SJA-5646. [redacted]. *Id.*; SJ-Op.31 (12-JA-2621). According to Sanofi's own document, ESI [redacted] 25-SJA-5646.

OptumRx/UnitedHealthcare. Sanofi falsely claims it "never stood a chance" at OptumRx. Br.26. But Sanofi omits the key undisputed facts.

OptumRx decided to choose only one EAI for its formularies and pushed *both* manufacturers to increase their rebate offers. SJ-Op.32-34 (12-JA-2622-24), SUMF¶¶85-86 (34-SJA-7473-74). Mylan offered OptumRx a 17% rebate for

exclusive coverage, but OptumRx responded that, "if Mylan did not offer a better rebate for EpiPen, the product would be placed into a benefit exclusion." SJ-Op.33 (12-JA-2622); [redacted]. OptumRx similarly pushed Sanofi to improve its initial rebate offers. SJ-Op.33 (12-JA-2622-23), SUMF¶86 (34-SJA-7474).

Ultimately, *both* manufacturers submitted higher rebates for exclusive formulary coverage. SJ-Op.33-34 (12-JA-2623-24), SUMF¶¶87-88 (34-SJA-7474). Sanofi again takes liberties when it asserts that "both sides offered the same 22% rebate." Br.26. OptumRx's corporate designee testified, without contradiction in the record, that Mylan's offer was better for several reasons. SJ-Op.34 (12-JA-2624), 24-SJA-5287 (OptumRx Depo.). First, Sanofi offered 9% price protection, while Mylan offered a superior 8% based on an earlier list price. *Id.* Second, Mylan's price protection was cumulative, whereas Sanofi's reset each year, which lowered its value. *Id.* Third, Mylan's rebates started six months earlier. *Id.*

Sanofi emphasizes that—weeks after OptumRx's deadline had passed—Sanofi submitted a revised rebate offer of [redacted]%. Br.26. Sanofi now dubs its [redacted] offer "superior" but conceded below that [redacted] SUMF¶90 (34-SJA-7475), RSUMF¶90 (49-SJA-11064). [redacted], OptumRx rejected it. *Id.*; SJ-Op.34 (12-JA-2624).

MedImpact. Sanofi's assertion that Mylan "instigated" a battle for exclusivity at MedImpact, Br.28, is refuted by the uncontroverted facts. MedImpact *solicited* rebate offers for exclusive coverage from both Mylan and Sanofi, deliberately pitting the competitors against one another as a "negotiation technique," SJ-Op.37 (12-JA-2627), 23-SJA-5022-23 (MedImpact Depo.). MedImpact told Sanofi it would cover only one EAI device. SJ-Op.37 (12-JA-2627), SUMF¶101 (34-SJA-7478).

MedImpact later told Mylan it was selecting Auvi-Q, prompting Mylan to increase its rebate offer. SJ-Op.38 (12-JA-2628), SUMF¶103 (34-SJA-7478). *Both* manufacturers offered menus of rebates, including higher rebates conditioned on step-editing competitors. SUMF¶102 (34-SJA-7478). Ultimately, once all offers were received, MedImpact elected to cover EpiPen at a "better price, net of rebate," at $113 per device compared to Auvi-Q's $145. 29-SJA-6401 (MedImpact Formulary Committee Minutes), SJ-Op.39 (12-JA-2629).

Sanofi declares that "excluding Auvi-Q was never about the per-unit rebate," and selectively quotes MedImpact's email communicating its final decision to Sanofi. Br.28. In the *omitted* portion of the email, however, MedImpact informed Sanofi that it was "a competitive bidding situation" and that MedImpact made its decision by "analy[zing] . . . the offers from both companies." 5-JA-902.

MedImpact's "exclusion" of Auvi-Q did not even extend to all MedImpact clients. MedImpact's custom clients remained eligible for Sanofi rebates if they chose to cover Auvi-Q, which some did. SJ-Op.39 (12-JA-2629), SUMF¶106 (34-SJA-7479). In addition, Sanofi conceded below that [redacted] of MedImpact's clients selected open formularies where Auvi-Q was covered on T2 alongside EpiPen. SUMF¶106 (34-SJA-7479), RSUMF¶106 (49-SJA-11065).

Aetna. Sanofi asserts that Mylan [redacted] in 2012 but quotes an email [redacted]. Br.28. Aetna initiated its own "Initiative Feasibility Summary" in May 2013 suggesting a "revenue opportunity by placing [a PA or SE] on Auvi-Q" on its commercial formulary. SJ-Op.40 (12-JA-2630), SUMF¶107 (34-SJA-7479). Mylan offered Aetna a 15% rebate for T2 placement, with Auvi-Q on T3 with an SE. *Id.* Sanofi, by contrast, offered only a [redacted]% rebate for co-preferred coverage. SUMF¶¶108-09 (34-SJA-7480). Again, Aetna accepted Mylan's better offer. SJ-Op.40 (12-JA-2630).

Sanofi declares that Aetna would not give Sanofi an additional chance to improve its bid because of physician and member [redacted] to EpiPen. Br.29. But Sanofi quotes hearsay [redacted], 35-SJA-7720, [redacted] Aetna had, in fact, offered

to remove the restriction on Auvi-Q if Sanofi offered a larger rebate, SJ-Op.40 (12-JA-2630), SUMF¶109 (34-SJA-7480).

CVS. Sanofi conceded below that CVS expressly requested "incremental rebates for additional controls (exclusion opportunities)." SUMF¶82 (34-SJA-7482), RSUMF¶82 (49-SJA-11047). Mylan and Sanofi each filled out CVS's bid document in 2013. SJ-Op.32 (12-JA-2622), SUMF¶83 (34-SJA-7473). CVS covered both products in 2013, with EpiPen on T2 and Auvi-Q on T3. Sanofi now complains about T3 coverage, but it remains undisputed that CVS never excluded or restricted Auvi-Q. *Id.*

Prime. Prime covered Auvi-Q on T3 the entire time it was on the market. Sanofi now blames Mylan for its failure to obtain T2 coverage for Auvi-Q in 2013. Br.31. Besides telling the court below that its lawsuit did not challenge T3 formulary placement, *see supra* at 19-20, Sanofi conceded below that Prime told Sanofi in 2013 that its clients would consider placing Auvi-Q on T2 only if Sanofi offered price protection, which Sanofi refused. SUMF¶94 (34-SJA-7476), RSUMF¶94 (49-SJA-11047).

Sanofi emphasizes that, when Prime renegotiated with both manufacturers in 2014, Mylan offered Prime a higher rebate conditioned on restricting Auvi-Q through an SE. Br.31. True—but Prime *declined* the offer. SJ-Op.36 (12-JA-2626), SUMF¶96 (34-SJA-7476).

Instead, Prime demanded that Mylan increase its offer for sole T2 coverage with Auvi-Q covered on T3, which Mylan did. *Id*. Sanofi also misrepresents that it "outbid" Mylan: Mylan's highest rebate (14%) was for *sole* T2 coverage, but Sanofi did not make *any* competing offer for sole T2 coverage. SUMF¶97 (34-SJA-7477). In any event, Prime continued to cover Auvi-Q on T3 without restriction. *Id.*

Finally, Prime's clients (primarily Blue Cross Blue Shield plans) each make independent formulary decisions. For example, it is undisputed that Horizon Blue Cross Blue Shield of New Jersey—a Prime client—covered both Auvi-Q and EpiPen on T2 the entire time Auvi-Q was on the market. SUMF¶98 (34-SJA-7477), RSUMF¶98 (49-SJA-11047).

Cigna. Cigna never excluded or restricted Auvi-Q, covering it on T3 in 2014. SJ-Op.41 (12-JA-2631).

Other Payors. Other payors made various coverage decisions for Auvi-Q in 2014. SJ-Op.42 (12-JA-2632). Some covered EpiPen and Auvi-Q as co-preferred (*e.g.*, Blue Shield of California); others covered EpiPen on T2 and Auvi-Q on T3 (*e.g.*, Humana), or Auvi-Q on T2 and EpiPen on T3 (*e.g.*, Presbyterian Health), or put a PA on EpiPen (Geisinger Health Plan). SUMF¶113 (34-SJA-7481-82) (describing various coverage determinations). Others chose to cover only one product (*e.g.*, Kaiser Permanente). *Id.*

Sanofi devotes a section of its brief to one payor, Humana, to highlight the undisputed fact that Mylan sometimes offered payors a higher rebate for exclusive formulary coverage. Br.29. But Sanofi relies on documents concerning Mylan's coverage on Humana's *Medicare* formularies, which are irrelevant. *See* n.5, *supra.* As for Humana's *commercial* formularies, Sanofi conceded below that Humana *never excluded* Auvi-Q, covering it on T3 in 2014. SUMF¶113 (34-SJA-7481), RSUMF¶113 (49-SJA-11066).

G. Sanofi's Higher Rebate Offers And Commercial Coverage Of Auvi-Q In 2015

Sanofi got the chance to renegotiate with payors for the 2015 cycle. Sanofi's leaders decided to get "aggressive" with "significant discounting." SJ-Op.46 (12-JA-2636), 9-JA-1817-18 (Viehbacher Depo.), 30-SJA-6687 (Whitaker email). Sanofi thus "changed its contracting strategy" and "made deeper offers" to payors to secure formulary access. SJ-Op.46, 12-JA-2636. In short, Sanofi finally started competing by lowering its prices.

Sanofi's assertion that it could not access the market even with "ridiculous pricing," Br.39-40, is utterly counterfactual. With competitive pricing, Sanofi was able to secure T2 or T3 coverage on many of the largest formularies, including ESI, CVS, Prime, Aetna, and Cigna. *See supra* at 19 (chart of Auvi-Q coverage). In fact, *Sanofi conceded below that it was able to regain 80% commercial market access in 2015.* SJ-Op.50 (12-JA-2640), SUMF¶124 (34-SJA-7486-87), RSUMF¶124 (49-

SJA-11047). Sanofi's then-CEO wrote, "[f]ighting back . . . paid off." 11-JA-2317 (Viehbacher email).

Sanofi's contemporaneous documents celebrated these successes:

[redacted]

31-SJA-6832 ([redacted]). After seeing that Auvi-Q had regained 80% commercial access overall, Sanofi's new CEO asked for an "upside proposal" to drive further growth. SJ-Op.50 (12-JA-2640), SUMF¶124 (34-SJA-7486-87). Sanofi then increased its investment, planning for substantial budget increases. *Id.*

Now, Sanofi reframes its successes as losses, asserting that it was not enough for ESI, Aetna, and CVS to cover Auvi-Q on their primary formularies in 2015. Rather, says Sanofi (for the first time on appeal), Auvi-Q would not succeed unless these payors covered Auvi-Q *and excluded EpiPen*. Br.40-42.

ESI. ESI reversed its decision to exclude Auvi-Q from certain formularies, making Auvi-Q co-preferred on ESI's national formulary and giving Auvi-Q

exclusivity on ESI's High Performance Formulary. SJ-Op.47 (12-JA-2637). Sanofi nevertheless laments that it had to "sacrifice millions of dollars" in Lantus profits to secure this access. Br.40. But vigorous price competition on EAIs *and* lower prices on Lantus benefit competition and consumers.

And, even though ESI *excluded EpiPen* on its High Performance Formulary in 2015, Sanofi grumbles that ESI rejected Sanofi's offer for exclusive coverage on the national formulary. But ESI determined that it could "decrease the cost per [prescription] significantly" if it covered *both* products. 28-SJA-6164 (ESI email), SJ-Op.47 (12-JA-2637). As ESI testified, [redacted] 23-SJA-5192 (ESI Depo.).

Aetna. Aetna also reversed its exclusion of Auvi-Q in 2015, giving co-preferred coverage to EpiPen and Auvi-Q. SJ-Op.48 (12-JA-2638). Yet Sanofi complains that Aetna did not accept Sanofi's exclusive offer. Br.42.

What Aetna did instead benefited consumers in another way: it used Sanofi's offer as leverage to threaten to exclude EpiPen and to convince Mylan to pay a 45% rebate for co-preferred coverage. SJ-Op.47 (12-JA-2637), SUMF¶118 (34-SJA-7484). Sanofi ultimately paid a 30% rebate for co-preferred (T2) coverage, a *substantially smaller rebate* than Mylan paid for the same access. *Id.*

CVS. The pattern continues. By offering CVS greater rebates in 2015, Sanofi improved its coverage from T3 in 2014 to co-preferred (T2) coverage on CVS's national formulary, and obtained *exclusive* coverage on CVS's high-control formularies, with EpiPen excluded. SJ-Op.48 (12-JA-2638), SUMF¶119 (34-SJA-7484-85), RSUMF¶119 (49-SJA-11047). But Sanofi takes issue with CVS's decision [redacted] Br.41 (quoting 30-SJA-6797 but omitting the italics). Sanofi asserts that its better offer was "rejected" and compares its 61% offer for *exclusive* coverage to Mylan's [redacted]% offer for *co-preferred* coverage. But Sanofi, like Mylan, offered CVS a range of rebates, SUMF¶119 (34-SJA-7484-85), and Sanofi's offer was not "rejected"; rather, CVS decided it was in its best interests (and that of its members) to give Auvi-Q T2 coverage on its national formulary with a 40% rebate. *Id.*; SJ-Op.48 (12-JA-2638).

Other Payors. Sanofi failed to obtain T2 or T3 coverage for Auvi-Q in 2015 *only* when it failed to respond to payors' demands. For example, when United sought an exclusive offer from Sanofi and provided a rebate "target" of 60% plus 6% price protection, Br.43, Sanofi refused to make *any* offer for exclusive coverage, SJ-Op.49 (12-JA-2639), SUMF¶121 (34-SJA-7485-86). Similarly, when MedImpact told Sanofi what offer would "open the conversation," Br.43, Sanofi refused to offer the requested discount. SJ-Op.49-50 (12-JA-2639-40), SUMF¶122 (34-SJA-7486).

H. The Role Of Market Share In Coverage Determinations

Sanofi's central assertion—that, because of EpiPen's high market share, payors could not turn down Mylan's exclusive rebate offers to cover Auvi-Q—has no support in the record.

First, the unrefuted evidence establishes that payors *did* turn down offers for exclusive coverage. Sanofi cites Mylan *offers* of high rebates for exclusive coverage, Br.30 (CVS), Br.31 (Prime). But, as the district court observed, "Sanofi's argument ignores the outcome of Mylan's rebate negotiations. In many instances, payors *rejected* Mylan's exclusive offers and chose to cover Auvi-Q." SJ-Op.94 (13-JA-2684).

In the court below, Sanofi relied heavily on a list of 11 payors to which Mylan made exclusive rebate offers: [redacted]. SJ-Op.94 (13-JA-2684), Opp-Br.71-74 (49-SJA-11093-96). But only *three* of those payors (ESI, Aetna, and Anthem) *ever* excluded *or* restricted Auvi-Q.[13] And *two of those three* (ESI and Aetna) reversed course and covered Auvi-Q in 2015. SJ-Op.95 (13-JA-2685). Sanofi's assertion that PBMs were "powerless to resist" Mylan's offers, Br.43, is counterfactual in the extreme.

[13] *See* Mylan Reply at 9 n.9 (61-SJA-13653) (collecting evidence of coverage determinations made by the 11 payors).

Moreover, even when payors ultimately decided not to cover Auvi-Q—or decided to cover both EAIs—they leveraged the competition from Sanofi to extract lower prices from Mylan for EpiPen. For example, when Sanofi increased its rebate offer to Prime in 2014, Prime did not, as Sanofi asserts, simply "stay[] with Mylan's inferior . . . offer." Br.43. Rather, the document Sanofi cites shows that [redacted]. 52-SJA-11663, *see* SJ.Op.50 (12-JA-2640). And CVS and Aetna both used the threat of excluding EpiPen in 2015 to extract better prices from Mylan for co-preferred T2 coverage. *See supra* at 30-31; SJ-Op.47-48 (12-JA-2637-38), SUMF¶¶118-19 (34-SJA-7484-85).

Second, payors believed they *could* shift market share from EpiPen to Auvi-Q, and many *did*. As the district court emphasized, numerous payors "testified that they could have excluded EpiPen in favor of Auvi-Q because they could shift product use from EpiPen to Auvi-Q." SJ-Op.51 (12-JA-2641), SUMF¶127 (34-SJA-7487-88) (collecting testimony). Sanofi offered no contrary testimony below. Sanofi's market research consultant testified that payors were "willing to remove market leaders." 7-JA-1523 (Byrne Depo.), SJ-Op.51-52 (12-JA-2641-42). Indeed, ESI has excluded numerous blockbuster products from its formularies and "[redacted]." 24-SJA-5208-10 (ESI Depo.), SUMF¶128 (34-SJA-7488).

When two payors *did* exclude EpiPen—CVS on its Advanced Control Formulary (ACF) and ESI on its High Performance Formulary (HPF)—patients shifted in droves to Auvi-Q. SJ-Op.52-53 (12-JA-2642-43), SUMF¶130-131 (34-SJA-7489-90), 3-SSA-466-67 ([redacted]), 40-SJA-9020-21, 41-SJA-9079 (Willig Report, calculating EpiPen share drop on ESI HPF).

Yet Sanofi asserts that any payor who tried to exclude EpiPen "would fail." Br.21. Sanofi cites no actual marketplace results but instead (1) internal Mylan documents and testimony of Mylan witnesses [redacted], 57-SJA-12741, 52-SJA-11612-13; (2) [redacted]; and (3) internal Mylan talking points [redacted], 36-SJA-8100.

Sanofi cites *no testimony from any payor* suggesting that it could not shift share. And Sanofi cites *not a single instance* when a payor tried, but failed, to shift share on a commercial formulary from EpiPen to Auvi-Q.

I. The Recall Of Auvi-Q And The Return Of Rights

Sanofi sold Auvi-Q for less than three years. SJ-Op.7-8 (12-JA-2597-98). On October 28, 2015, Sanofi recalled every Auvi-Q due to a potentially fatal defect. *Id.*

The FDA determined that a Class I recall was appropriate, which (as Sanofi conceded below) is "a situation in which there is a reasonable probability that the use of a . . . product will cause serious adverse health consequences or death." SUMF¶143 (34-SJA-7494), RSUMF¶143 (49-SJA-11047). Sanofi never re-launched its product, instead deciding soon after the recall to return the rights to Auvi-Q's inventor. 7-JA-1484-88 (Barry Depo.).

II. PROCEDURAL HISTORY

A. Sanofi Files A Complaint Blaming Mylan For Its Lack Of Success Selling Auvi-Q

In 2017, two years after the return of rights, Sanofi sued Mylan in the District of New Jersey. Sanofi alleged that Mylan had violated Section 2 of the Sherman Act by using EpiPen's monopoly market share to "force" commercial and Medicaid payors to accept rebates conditioned on the exclusion or restriction of Auvi-Q on their formularies. 2-JA-408-410, -430-31. Additionally, Sanofi accused Mylan of advertising EpiPen deceptively and of signing exclusive agreements with schools to purchase only EpiPen. 2-JA-372-74, -432-34.

B. The District Court Partially Dismisses Sanofi's Complaint

The Judicial Panel on Multidistrict Litigation transferred Sanofi's case to the District of Kansas, where it was administered alongside a consolidated consumer class action. 2-SA-422. In December 2017, the district court granted in part and denied in part Mylan's motion to dismiss. 2-SA-461.

The district court dismissed Sanofi's claims based on the rebates Mylan offered for positions on Medicaid formularies. 2-SA-440-43. That ruling relied on the *Noerr-Pennington* doctrine, which exempts from antitrust liability legitimate uses of the political process. *Id.* The court, however, declined to dismiss Sanofi's other claims, permitting Sanofi to present evidence in support of its claims that Mylan monopolized the commercial EAI market. 2-SA-429-40; -43-60.

C. The District Court Grants Summary Judgment For Mylan

After discovery, the district court granted Mylan's motion for summary judgment and dismissed Sanofi's complaint in its entirety. 13-JA-2718.[14] The court's comprehensive opinion features more than 50 pages of undisputed facts (12-JA-2594-13-JA-2660). The Court granted Mylan summary judgment for two independent reasons.[15]

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[14] Sanofi filed a cross-motion for summary judgment on Mylan's counterclaims. The Court granted Sanofi's motion as well and dismissed the counterclaims. 13-JA-2747. Mylan does not appeal that decision.

[15] Mylan later moved for summary judgment in the MDL's consumer class action,

First, drawing on numerous precedents for exclusive dealing claims, the court held that no reasonable jury could find that Mylan engaged in anticompetitive conduct. 13-JA-2671-98. The district court found the following factors determinative in combination:

- *Contract Duration and Terminability.* It is undisputed that the agreements between Mylan and payors "never prevented payors from making formulary changes." 13-JA-2678-79. Because of the easy terminability of Mylan's agreements, Sanofi was able to regain coverage in 2015 on the formularies of two large payors that had previously excluded it. 13-JA-2682-83.
- *No Coercive Behavior.* Sanofi cited no evidence that Mylan coerced payors into excluding Auvi-Q. 13-JA-2683-90. Every time Sanofi was excluded from formulary, Mylan's price for EpiPen was lower than Sanofi's price for Auvi-Q. 13-JA-2687. Indeed, "[i]n many instances, payors *rejected* Mylan's exclusive offers and chose to cover Auvi-Q." 13-JA-2684-85. And the "record contain[ed] no evidence of any threats

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and, in a 182-page opinion, the district court entered summary judgment on all the claims related to Auvi-Q (though it did not do so on all class claims). As it did in the decision below, the court concluded that "Mylan's exclusive contracts . . . didn't foreclose Sanofi from competing in the EAI drug market." *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. and Antitrust Litig.*, 2021 WL 2585065, at *71 (D. Kan. June 23, 2021).

by Mylan to cut off payors' access to EpiPen" if they did not agree to exclusivity. 13-JA-2685-90.

- *Competitors' Use of Exclusive Contracts*. Sanofi had made exclusive offers for Auvi-Q, just as Mylan had for EpiPen, and some payors accepted Sanofi's offer and excluded EpiPen. 13-JA-2691-92. This was standard industry practice.
- *Foreclosure From the Market.* Sanofi identified no evidence that it was foreclosed from the market. 13-JA-2693-98. At the peak of its "foreclosure," approximately 70% of patients had access to Auvi-Q. 13-JA-2694-95. Once Sanofi competed on price for 2015, more than 80% of patients had Auvi-Q covered. 13-JA-2697.
- *Anticompetitive Effects of the Contracts.* The district court considered Sanofi's argument that internal emails showed that Mylan intended to exclude its rival. 13-JA-2692-93. But, the court explained, documents expressing a desire to win could not turn Mylan's "hypercompetitive" conduct into *anti*competitive conduct. 13-JA-2711 (citing *FTC v. Qualcomm, Inc.*, 969 F.3d 974 (9th Cir. 2020)).

The court concluded that Mylan's contracts "were relatively short in duration and easily terminable, they were not the product of any unlawful coercion on Mylan's part, and they didn't foreclose Sanofi from competing in the EAI drug

market." 13-JA-2698. Thus, Sanofi did not "present a triable issue whether Mylan's exclusive rebate contracts violated the Sherman Antitrust Act under a rule of reason analysis." 13-JA-2698.

The district court also considered Sanofi's novel legal theory that Mylan "leveraged its non-contestable demand for EpiPen to force payors to agree to cover EpiPen and exclude Auvi-Q from their EAI formularies." 13-JA-2698. Without deciding whether such a theory was legally viable, the court concluded that Sanofi had not developed a factual record to support it. 13-JA-2700-04.

Sanofi had pointed to the analysis of its expert witness, Professor Fiona Scott Morton, who presented a novel measurement—EEB—to determine the rebates that Sanofi supposedly would have had to offer to match the value of Mylan's offers given EpiPen's "entrenched" market share. The district court, however, concluded that Professor Scott Morton's EEB opinion was unreliable and inadmissible under *Daubert* because it was contradicted by the record *and* unsupported in the economic literature. 13-JA-2704 n.26; 12-JA-2537-43. Sanofi does not appeal that decision. Indeed, Sanofi's brief never mentions this important ruling, even though Sanofi relies heavily on Professor Scott Morton's analysis and selectively quotes the *Daubert* opinion.

The district court also rejected Sanofi's claims that some of Mylan's EpiPen marketing and the EpiPen4Schools program violated the Sherman Act. The record

showed "no triable issue about . . . the falsity of Mylan's statements," whether the statements "continued for prolonged periods," or whether they were "susceptible to neutralization" by Sanofi. 13-JA-2706-08. And Mylan's decision to offer a discount to schools was permissible reputation-building, 13-JA-2710-11, in addition to being inherently beneficial.

Second, as an independent ground for summary judgment, the district court determined that no reasonable jury could conclude that Mylan's conduct caused antitrust injury. 13-JA-2713-18.

SUMMARY OF ARGUMENT

Sanofi's lawsuit seeks treble damages to punish competition. Instead of directly confronting the district court's sound legal reasoning, Sanofi spends dozens of pages just recounting—and misrepresenting—the facts. But Sanofi's obfuscation cannot conceal the truth: Sanofi won business when it offered low prices for Auvi-Q and lost business when it insisted on high prices, just as one would expect in a competitive marketplace.

No reasonable jury could find that payors were coerced into buying EpiPen. The cases finding coercion all involved threats to cut off supply completely unless the buyer dealt exclusively with the dominant seller. In this case, the only consequence to payors of non-exclusivity was loss of a particular discount. Sanofi,

as a defendant, prevailed in a case in the Third Circuit for that exact reason. *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 403 (3d Cir. 2016).

In addition, payors could—and did—revise their formularies at virtually any time by renegotiation, which all the contracts at issue in this case permitted. No payor was locked into anything.

Exclusive deals are not something Mylan invented to "exclude" Auvi-Q. As Sanofi's expert testified to Congress, "the way you get low prices in the pharmaceutical industry is by the ability to exclude drugs. . . . When you can do that, you force price competition." 9-JA-1920. This procompetitive paradigm pervades the pharmaceutical industry. Sanofi, no less than Mylan, bid for exclusivity on EAIs—and sometimes won.

And no reasonable jury could find that Sanofi was "foreclose[d] [from] competition in a substantial share of the line of commerce affected." *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 327 (1961). The highest foreclosure Sanofi even *claimed*—without evidence—was 31% of the market, which is not enough. But, properly examined, this record shows *no foreclosure at all*.

Although the district court correctly entered summary judgment for those reasons, it could be affirmed on an alternative ground. Here, "price [wa]s the clearly predominant mechanism of exclusion," and when that is so, the challenged conduct

should be evaluated under a price-cost test that Sanofi did not attempt to meet. *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 275 (3d Cir. 2012).

Nor can Sanofi salvage its case by moving antitrust law into new realms. Sanofi offers no test to discern when conduct becomes anticompetitive. It ignores this Court's precedent on the minimal relevance of intent evidence in antitrust law, and the intent evidence it cites shows only vigorous competition. Sanofi's claim that Mylan leveraged "entrenched" demand for EpiPen is unsupported by evidence or by any reasonable extension of existing case law. And its attempt to shoehorn Mylan's other supposedly wrongful conduct into an antitrust paradigm is just a desperate attempt to get this Court to substitute Sanofi's dismay at Mylan's procompetitive conduct for reasoned antitrust analysis.

Sanofi's claims independently fail for another reason: no reasonable jury could find any injury to competition. The record does not connect Mylan's rebating to higher prices or reduced output.

STANDARD OF REVIEW

This Court "review[s] a grant of summary judgment de novo." *Yousuf v. Cohlmia*, 741 F.3d 31, 37 (10th Cir. 2014).

Summary judgment is not a "disfavored procedural shortcut." *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986). Instead, summary judgment has "*particular importance* in the area of antitrust law, because it helps to avoid wasteful trials and

prevent lengthy litigation that may have a chilling effect on pro-competitive market forces." *Major League Baseball Props., Inc. v. Salvino, Inc.*, 542 F.3d 290, 309 (2d Cir. 2008) (emphasis added).[16]

ARGUMENT

I. The District Court Correctly Held That No Reasonable Jury Could Find That Mylan Engaged In Anticompetitive Conduct

The district court evaluated Sanofi's claims using the correct legal standard and applied that standard unerringly. The novel approach that Sanofi proposes would condemn procompetitive price-cutting behavior. All established tests to assess exclusive dealing favor Mylan. This Court should affirm the district court's holding that Mylan did not act anticompetitively.

A. Mylan Did Not Violate The Sherman Act In Its Dealings With Payors

"Low prices benefit consumers regardless of how those prices are set." *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 340 (1990). Consumers benefit when companies try to beat each other by cutting prices, and that is so even when the main price-cutter is an incumbent firm with a popular and well-liked product. That may leave some new entrants out in the cold, but "[t]he antitrust laws . . . were enacted for the protection of competition not competitors." *Brunswick Corp. v.*

[16] All internal quotation and alteration marks, citations, and footnotes are omitted unless otherwise noted.

Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 488 (1977).

As the district court recognized, exclusive contracts are common and generally procompetitive. 13-JA-2672. For that reason, summary judgment can be especially appropriate in cases of alleged exclusive dealing because "[e]xclusive dealing agreements are often entered into for entirely procompetitive reasons, and generally pose little threat to competition." *ZF Meritor*, 696 F.3d at 270. "[I]n many circumstances [exclusive dealing agreements] may be highly efficient . . . and pose no competitive threat at all." *Eastern Food Servs., Inc. v. Pontifical Catholic Univ. Servs. Ass'n*, 357 F.3d 1, 8 (1st Cir. 2004).

Indeed, the antitrust laws promote competition for the contract, no less than competition for individual sales. And competition for an exclusive contract "is a vital form of rivalry, and often the most powerful one, which the antitrust laws encourage rather than suppress." *Menasha Corp. v. News Am. Mktg. In-Store, Inc.*, 354 F.3d 661, 663 (7th Cir. 2004); *accord Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 403 (3d Cir. 2016). Courts accordingly evaluate it under the rule of reason. The key question is whether the contracting at issue "foreclose[d] competition in a substantial share of the line of commerce affected." *Tampa Elec.*, 365 U.S. at 327.

The district court undertook that rule-of-reason analysis. It appropriately considered a series of factors most fully articulated in a Third Circuit case, *ZF Meritor*, 696 F.3d at 271-72: "(1) whether the defendant has significant market

power; (2) whether there is substantial market foreclosure; (3) whether the contract's duration is sufficient to prevent meaningful competition by rivals; (4) an analysis of likely or actual anticompetitive effects considered in light of any procompetitive effects; (5) whether [the] defendant engaged in coercive behavior; (6) the ability of customers to terminate the agreements; and (7) the use of exclusive dealing by competitors of the defendant." 13-JA-2674.

Five of those factors were most central to the district court's analysis—coercion, duration/terminability (two separate factors, treated here as one), use of exclusive dealing by competitors, and foreclosure. All show that no reasonable jury could conclude that Mylan's dealings with payors violated the antitrust laws.[17] Mylan chose to compete on price and won business; Sanofi chose not to until 2015, and it lost until it started competing.

1. Mylan Did Not Engage In Coercion That The Antitrust Laws Forbid

"Exclusive dealing will generally only be unlawful where the market is highly concentrated, the defendant possesses significant market power, and there is some element of coercion present." *ZF Meritor*, 696 F.3d at 284; *see also Race Tires Am.*

[17] As to the other two factors—the district court concluded that the "significant market power" factor favored Sanofi, and Mylan does not challenge that conclusion here, though it is debatable and would remain open to litigation on any possible remand. SJ-Op.87-88 (13-JA-2677-78). And the analysis of anticompetitive and procompetitive effects is subsumed in the discussion of the other five factors.

v. Hoosier Racing Tire Corp., 614 F.3d 57, 77 (3d Cir. 2010) (coercion "has played a key . . . role in the relevant case law, especially in the Section 2 context"). Applicable case law addressing what constitutes anticompetitive coercion demonstrates that Mylan engaged in no such behavior.

Three cases that Sanofi frequently cites exemplify anticompetitive coercion. *McWane, Inc. v. FTC*, 783 F.3d 814 (11th Cir. 2015); *ZF Meritor*, 696 F.3d 254; *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181 (3d Cir. 2005). Each defendant threatened to cut off access to necessary goods *entirely* unless the customers acceded to exclusivity.

The defendant in *McWane* "unilaterally imposed [exclusivity] by fiat upon all distributors" by threatening to "cut off [customers] from purchasing" its pipe fittings instead of offering any "discount . . . in exchange for exclusivity." 783 F.3d at 821, 834. In *ZF Meritor*, too, the customers had to agree to exclusivity to receive *any* truck transmissions. Customers testified that "many of the terms . . . were unfavorable . . . , but that [they] agreed to such terms because without Eaton's transmissions, [they] would be unable to satisfy customer demand." 696 F.3d at 285. And in *Dentsply* the defendant "threatened to sever access not only to its teeth, but to other dental products as well" to induce exclusivity. 399 F.3d at 190. The defendants in all three cases threatened to cut off access to their products if customers would not deal exclusively with them. *Unlike* Mylan, none merely offered

increasing *discounts* for exclusivity, much less responded to a customer *request* for such a discount.

Sanofi also relies on *LePage's, Inc. v. 3M*, 324 F.3d 141 (3d Cir. 2003) (en banc). But "*LePage's* . . . has been the subject of much criticism," as the Third Circuit itself has acknowledged. *Eisai*, 821 F.3d at 405 n.35. And that court has limited *LePage's* "to cases in which a single-product producer is excluded through a bundled rebate program offered by a producer of multiple products, which conditions the rebates on purchases across multiple different product lines." *ZF Meritor*, 696 F.3d at 274 n.11.

That is not the situation here. Furthermore, *LePage's* involved similar coercion to the cases cited above: "'all-or-nothing' discounts, leading customers to maximize their discounts by dealing exclusively with the dominant market player." 324 F.3d at 159. But Mylan offered customers various discount options for different levels of formulary control. *See, e.g.*, *supra* at 10.

By contrast, the Third Circuit years after *LePage's* found no coercion in *Eisai*, which is by far the closest case to this one. The plaintiff in *Eisai* accused Sanofi (there, the defendant) of using discounts to foreclose the anticoagulant market. Sanofi's Lovenox (like EpiPen here) was the incumbent product, and Eisai's Fragmin (like Auvi-Q) was new. *Eisai*, 821 F.3d at 399.

After Eisai's entry, Sanofi offered loyalty discounts on Lovenox ranging "from 9% to 30% of the wholesale price." *Id.* at 400. Customers received higher discounts if they purchased at least 75% of their products from Sanofi, with a customer who failed to reach that threshold receiving only a 1% base discount. *Id.* Eisai accused Sanofi of "bundling each customer's contestable demand for Lovenox . . . with the customer's incontestable demand for Lovenox," so that "customers occupying a certain spectrum of market share would not save money by partially switching to a rival drug, even if the rival drug was cheaper." *Id.* at 401.

Although "no court . . . ha[d] credited" Eisai's (now Sanofi's) theory, the Third Circuit did not need to decide its validity. *Id.* at 406. Instead, it stated that, "[e]ven if bundling of different types of demand for the same product could, in the abstract, foreclose competition, nothing in the record indicates that an equally efficient competitor was unable to compete" because the only consequence if customers did not meet the market-share targets was a lost discount. *Id.*; *see also* PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 1807d (2018) [hereinafter AREEDA & HOVENKAMP] ("the structural requirements for 'quasi' exclusive-dealing practices that fall short of actual exclusive dealing, including market-share and similar discounts where price is the engine of exclusion, should be strict").

"[T]he threat of a lost discount," the Third Circuit observed, was "a far cry from the anticompetitive conduct at issue in *ZF Meritor*." *Eisai*, 821 F.3d at 407. That threat left customers "free to switch to a different product," and thus no customers "were foreclosed from purchasing competing drugs as a result of Sanofi's conduct." *Id.* at 403, 407. There was, in other words, no coercion.[18]

This case is on all fours with *Eisai* in every relevant respect.[19] Here, Sanofi and Mylan both negotiated with payors for EAI formulary coverage in 2013, 2014, and 2015. Some payors approached Mylan to request exclusive offers; others provided "bid grids" that asked Mylan to offer a range of rebates, including one for excluding competitor products; and for others, Mylan introduced exclusivity as an option. *E.g.*, *supra* at 21-27. Sanofi's negotiations took the same forms. *Id.* Some payors covered only one EAI product; others covered both EpiPen and Auvi-Q. *Id.* Mylan never threatened to cut off supply or withdraw discounts entirely if payors refused to exclude Auvi-Q.

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[18] In the opinion below, the district court relied heavily on *Eisai* and discussed it at length. 13-JA-2687-89. But Sanofi mentions *Eisai* only once in its opening brief. Br.70.

[19] As the district court pointed out, 13-JA-2689, it makes no difference that the discounts in *Eisai* were market-share discounts instead of the formulary placement discounts here. "'[P]ure' exclusive dealing . . . is economically indistinguishable from the example in which the manufacturer offers a discount if the distributor buys 99 percent of its requirements from the manufacturer." Derek W. Moore & Joshua D. Wright, *Conditional Discounts and the Law of Exclusive Dealing*, 22 GEO. MASON L. REV. 1205, 1236 (2015).

Sanofi did not meaningfully dispute these case-dispositive facts below. It complained about Mylan's [redacted]. *See* RSUMF¶69 (49-SJA-11061). *But Sanofi did not identify a single instance where Mylan coerced a payor by threatening to withhold EpiPen products unless the payor agreed to exclusivity.*

Now, Sanofi offers various arguments that, it suggests, prove that Mylan did unlawfully coerce payors. None has merit.

First, Sanofi suggests that it is sufficient evidence of "coercion" if customers received a "superior" offer from Sanofi but instead chose exclusivity with Mylan. Br.68. Sanofi cites no legal support for this proposition because there is none. Moreover, the undisputed facts show that every time a major payor excluded Sanofi it was because Mylan simply offered a lower price. *See supra* at 20-21. Sanofi asserts that three payors (OptumRx/United, ESI, Prime) rejected *superior* per-unit rebate offers from Sanofi. Br.69. But that is a glaring mischaracterization of the record; as laid out above, Mylan's offers to OptumRx (*supra* at 22-23) and ESI (*supra* at 21-22) were better than Sanofi's,[20] and Prime never excluded Auvi-Q or "rejected" a

[20] Sanofi places Mylan's rebate offer at less than [redacted]% and thus argues that Sanofi offered ESI a better per-unit price. Br.23-24. But Sanofi has no basis for this argument, as it cites only an email [redacted] and an internal

superior offer from Sanofi for exclusive T2 coverage, as Sanofi never made one. *See supra* at 26-27.

Second, Sanofi accuses Mylan of leveraging its market share to coerce payors into accepting its exclusive offers. Br.68-69. But Sanofi nowhere addresses the unrefuted evidence (detailed by the district court, 13-JA-2684-85) that *many* payors rejected Mylan's exclusive offers and covered Auvi-Q on T2 or T3. *See supra* at 26-31. Indeed, two of the three large payors that allegedly "excluded" Auvi-Q in 2014 because they "couldn't refuse" Mylan's offers (ESI and Aetna), Br.68, *did refuse* Mylan's exclusive offers in 2015 and chose to cover Auvi-Q. *See supra* at 29-31.

Sanofi does not grapple with these facts, instead saying that it does not matter that *some* payors resisted Mylan's offers because monopoly power is "virtually never absolute." Br.71. But Sanofi fails to address the relevant question: If payors "couldn't refuse" Mylan's offers because of Mylan's monopoly power, what explains the ones who *did* refuse? And the record answers that question: Payors refused Mylan's offers *when Sanofi offered better prices*. Sanofi could and did beat Mylan in price competition when it chose to compete. But Sanofi's backward theory is that it should not have *had to* compete.

Sanofi document [redacted]. Neither addresses the value of the rebate and price protection that Mylan offered ESI for 2014, and neither was cited by Sanofi below as refuting the undisputed material facts.

Consistent with that theory, Sanofi attempts to minimize key undisputed facts—that both ESI and Aetna *covered* Auvi-Q in 2015—by claiming that the rebates Sanofi paid to regain that coverage were too expensive. Br.40-41. For example, Sanofi expresses outrage that it had to sacrifice profits on its blockbuster drug Lantus to gain access to ESI's national formulary. *Id.* But "[l]ow prices benefit consumers regardless of how those prices are set, and so long as they are above predatory levels"—which they undisputedly were here—"they do not threaten competition." *Atl. Richfield*, 495 U.S. at 340.[21]

Sanofi's theory threatens and punishes *competition itself*. And "mistaken inferences in cases such as this one are especially costly, because they chill the very conduct the antitrust laws are designed to protect. 'We must be concerned lest a rule or precedent that authorizes a search for a particular type of undesirable pricing behavior end up by discouraging legitimate price competition.'" *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986) (quoting *Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227, 234 (1st Cir. 1983) (Breyer, J.)).

Third, Sanofi argues that some payors demanded that it pay *deeper* rebates than Mylan to compete for *inferior* formulary positions, citing United, MedImpact,

[21] In any event, the Court should not take Sanofi's crying poverty seriously. Sanofi's own expert's calculations show that the average net price per pen for Auvi-Q [redacted]. 36-SJA-7967. Sanofi never claims prices in 2013 were ruinous.

and Aetna. Br.69. The record does not support that contention (newly minted on appeal).

For example, Sanofi asserts that in 2015 Aetna "capitulated to Mylan's inferior rebate (45% vs. Sanofi's 65%)." Br.42. But Sanofi is comparing apples and oranges; its 65% offer was for exclusivity, and the Mylan offer of 45% was *for T2 access*. Sanofi paid *30*% for T2 access in that same year. *See supra* at 30.

United and MedImpact did *try* to elicit sizable rebates from Sanofi in 2015 in exchange for covering Auvi-Q. But it is undisputed that Sanofi chose not to respond to those demands. *Id.* at 31.

Fourth, Sanofi repeatedly references Mylan's negotiations with Humana in 2014 as evidence of Mylan's successful attempts to block Auvi-Q. *E.g.*, Br.69-70. But the Humana offer concerned Medicare, which is not part of this case. *See supra* at 28. Humana never excluded or restricted Auvi-Q on its commercial formularies. *Id.*

Fifth, Sanofi also complains about occasions when it was placed on T3 with EpiPen on T2. But Sanofi's Auvi-Q brand lead testified that he did not "blame Mylan" for those instances. 23-SJA-5069. Mylan's Statement of Undisputed Material Facts stated flatly, "Sanofi does *not* challenge as anticompetitive Mylan rebates that led to EpiPen being placed on Tier 2, with Auvi-Q on Tier 3." SUMF¶74 n.148 (34-SJA-7470). Sanofi *did not dispute* that fact. RSUMFp.40 (49-SJA-11062).

Facts that are undisputed "must be deemed conceded." *Walker v. City of Orem*, 451 F.3d 1139, 1155 (10th Cir. 2006). And, because Sanofi conceded below that it was not challenging Auvi-Q's T3 placements, it has waived any claim to that effect. *See United States v. Teague*, 443 F.3d 1310, 1314-15 (10th Cir. 2006).

Sixth, unable to deny that many payors *solicited* exclusive offers from Mylan, Sanofi blames Mylan anyway, claiming that "Mylan knew its price escalation alone '[redacted].'" Br.70. But no admissible evidence supports that claim.

Sanofi cites only a Mylan presentation from October 2011—well before Auvi-Q launched—predicting that EpiPen price increases might [redacted] and a CVS whitepaper that there is no evidence anyone at Mylan ever saw. Br.70 (citing 35-SJA-7793, 26-SJA-5876). This type of gamesmanship with the facts pervades Sanofi's brief. And though Sanofi claims that Mylan sacrificed profits to exclude Auvi-Q by offering lower rebates than it otherwise would have without exclusions, *see* Br.57, the fact is that Mylan had to meet payors' demands for exclusivity to ensure that EpiPen was not the product excluded. That is called competition.

Finally, Sanofi contends that antitrust liability on exclusive-dealing grounds does not *always require* "coercion." Br.67. Mylan does not disagree, and neither did the district court. The absence of coercion is not always dispositive.

But it is highly *probative* when customers—the payors—seek exclusive deals and competitors complain. "That retailers and manufacturers *like* exclusive deals implies that they serve [their] interests." *Menasha Corp.*, 354 F.3d at 663. "[T]he most natural inference is that the complained-of practice promotes rather than undermines competition, for what helps consumers often harms other producers." *Id*. When Mylan offered better prices than Sanofi, it secured exclusive access if—and only if—a given payor chose to accept the lower price associated with an exclusive position. And, when Sanofi offered better prices, it was able to obtain access for its product. That is not coercion—it is competition.[22]

[22] Sanofi and some amici claim that the interests of payors and patients diverge, so payor preference for exclusivity is irrelevant. *See, e.g.*, Br.65 n.23 (claiming that payors, unlike patients, prefer prices to rise). But all Mylan could control were the discounts it offered payors; any divergence between the interests of payors and patients would come from payors not choosing to pass Mylan's discounts on to their patients, which is not something Mylan could influence. In any event, the undisputed record shows that "90% of total rebate dollars are passed on from PBMs to" their patients—meaning, *contra* Sanofi's counterintuitive view, that both payors and patients benefited from Mylan's discounts. 40-SJA-8996 (Willig Report); *see also Drug Pricing in America: A Prescription for Change, Part III: Hearing Before the Sen. Comm. on Fin.*, 116th Cong. 189 (2019), https://perma.cc/J6VK-2783 (responses of John M. Prince to questions from committee members) (noting that OptumRx "shares with its clients approximately 98 percent of the discounts it obtains from manufacturers"); *id.* at 132 (responses of Mike Kolar to questions from committee members) (Prime passes through "100 percent of the rebates to owner clients").

2. Mylan's Agreements Were Short, Were Easily Terminable, And Did Not Lock In Formulary Placements

Case law and leading commentators uniformly conclude that "the short duration and easy terminability of [exclusive dealing] agreements negate substantially their potential to foreclose competition." *Omega Env't, Inc. v. Gilbarco, Inc.*, 127 F.3d 1157, 1163 (9th Cir. 1997); *see also, e.g.*, *Methodist Health Servs. Corp. v. OSF Healthcare Sys.*, 859 F.3d 408, 410-11 (7th Cir. 2017); *ZF Meritor*, 696 F.3d at 286-87; *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1059 (8th Cir. 2000); *Barry Wright*, 724 F.2d at 237. As the leading antitrust treatise notes, "[d]iscounts conditioned on exclusivity in relatively short-term contracts *are rarely problematic*. . . . [A]ny above-cost discount can be matched by an equally efficient firm." AREEDA & HOVENKAMP ¶ 1807b1 (emphasis added); *see also id.* ¶ 1202g.

As the district court correctly held, the record undisputedly establishes that Mylan's contracts were easily terminable and frequently rebid. 13-JA-2679-80. The largest payors renegotiated contracts with Sanofi and Mylan at least yearly. *See supra* at 21-31. Sanofi benefited: though Auvi-Q was not covered on the main national formularies at ESI and Aetna in 2014, Sanofi obtained coverage on both formularies for 2015. *Id.* at 29-30. Other payors solicited offers from Sanofi outside the yearly rebidding schedule. *E.g.*, SJ-Op.40 (12-JA-2630).

Moreover, the agreements that Mylan reached with payors did not impose a legal obligation on any payor to put EpiPen (or Auvi-Q) in a given formulary position but merely offered a rebate if it did so. A payor could, for example, put EpiPen on T2 and exclude Auvi-Q from formulary for a given rebate, but if it elected to change course it could simply return Auvi-Q to formulary *at any time* and receive a lesser rebate from Mylan. *See supra* at 10-11. There is an important difference between a "[t]raditional . . . exclusive dealing" contract and a "discount conditioned on exclusivity," under which an "equally efficient rival should be able to steal the sale as long as the fully discounted price is above cost." AREEDA & HOVENKAMP ¶ 1807b2.[23]

Sanofi argues that, *in this case*, duration and terminability should not matter, because no payor would ever "block EpiPen." Br.79. But note Sanofi's not-so-subtle goalpost moving. Before the district court, Sanofi only wanted *access* to formularies (*i.e.*, unrestricted T2 or T3 coverage). 49-SJA-11089-91. Now, it claims Mylan's actions were somehow anticompetitive because PBMs would not *exclude EpiPen* in

[23] *Cf. Allied Orthopedic Appliances, Inc. v. Tyco Health Care Grp. LP*, 592 F.3d 991, 996 (9th Cir. 2010) (affirming summary judgment for defendant and finding it "significant that the . . . agreements . . . did not contractually obligate Tyco's customers to purchase anything from Tyco," instead "provid[ing] only for substantial discounts to customers that actually purchased a high percentage of their sensor requirements from Tyco").

favor of Auvi-Q. No authority suggests that a new entrant must be able to *exclude* an established competitor for that competitor to avoid violating the antitrust laws.

Sanofi also claims that the district court's orthodox view of short duration and easy terminability failed to "engage[] with these market realities" and "ignore[d] [Mylan's] monopoly power." Br.78, 80. Even though payors who received Mylan's exclusive rebates could call off exclusivity, Sanofi claims, none ever did. Br.79. And Sanofi cites the two payors, MedImpact and United, that excluded Auvi-Q from formularies in 2014 and 2015. *Id.*

But Sanofi relies on a tiny sliver of the record for these misleading assertions. As discussed above, Sanofi enjoyed great success in 2015, regaining coverage on large commercial formularies like ESI and Aetna, and improving coverage with CVS and others. *See supra* at 28-31. Mylan's "monopoly power" did not prevent Sanofi from regaining coverage through price competition, and the "market reality" is that the short duration and terminability of the agreements facilitated competition.

This was not a market where all the major players were signed up to long-term and unbreakable exclusive contracts, leaving Sanofi to fight over scraps. *Cf. Eastern Food Servs.*, 357 F.3d at 8 ("The best example of a possible threat to competition exists where a market is already heavily concentrated and long-term exclusive dealing contracts . . . foreclose so large a percentage of the available supply or outlets that entry into the concentrated market is unreasonably constricted.").

Sanofi had access to every customer the entire time; all it had to do was offer a compelling deal.

3. Exclusive Contracting Is Normal For EAIs Particularly And The Pharmaceutical Industry Generally

The next *ZF Meritor* factor was the "use of exclusive dealing by competitors of the defendant." 696 F.3d at 272. As Judge Crabtree pointed out, 13-JA-2691-92, Sanofi, like Mylan, made exclusive offers to payors for its EAI device. Thus, the record shows that such offers were "a normal competitive tool" for EAIs. *Concord Boat*, 207 F.3d at 1062.

Sanofi contends it made exclusive offers "only after Mylan foreclosed Auvi-Q from more than half [the] market." Br.72 (italics omitted). Not true—Sanofi began making exclusive offers in 2013, shortly after Auvi-Q's launch. SJ-Op.101 (13-JA-2691) (describing Sanofi's exclusive offers to OptumRx and MedImpact). It also claims that the fact that it made exclusive offers does not by itself preclude antitrust liability. Br.71 (citing *Perington Wholesale, Inc. v. Burger King Corp.*, 631 F.2d 1369, 1375 (10th Cir. 1979)). That is beside the point; what matters is that the widespread solicitation and use of exclusive offers for EAIs confirms that Mylan did nothing out of the ordinary. That fact combined with others demonstrates lawfulness beyond any genuine dispute.

This Court also should examine Mylan's actions in the context of the broader industry. "Acts which are ordinary business practices typical of those used in a

competitive market do not constitute anti-competitive conduct violative of Section 2." *Trace X Chem., Inc. v. Canadian Indus., Ltd.*, 738 F.2d 261, 266 (8th Cir. 1984); *see* Brief of Appellees Sanofi-Aventis U.S. LLC *et al.* at 54, *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, No. 14-2017 (3d Cir. Oct. 2, 2014) (making same argument).

Payors testified that they use formulary exclusions and restrictions to reduce costs to consumers by forcing procompetitive price decreases and driving utilization to the cheaper therapeutic alternative. *See supra* at 7-8. As Sanofi's own expert, Professor Fiona Scott Morton, testified before Congress, "the way [payors] get low prices in the pharmaceutical industry is by the ability to exclude drugs. . . . You identify a few therapeutic substitutes and you essentially hold an auction. . . . Whoever gives me the best price is the one I am going to buy from, and everybody else gets none of my business. When you can do that, you force price competition." 9-JA-1920.

It is undisputed, as the district court observed, that, *to reduce costs,* the pharmaceutical industry underwent a shift toward tighter formulary controls around the time Auvi-Q entered the market. *See supra* at 11-12. This industrywide shift greatly increased formulary exclusions, affecting many drug classes where Mylan did not have a product. *Id.* at 12-13.

Sanofi, like Mylan, responded by enlarging exclusive offers for its products, including its dominant insulin product Lantus. *Id.* at 12-13. Indeed, Sanofi felt compelled to make exclusive offers for Lantus, as otherwise Lantus would have fallen to a "20 percent market share." 9-JA-1826 (Viehbacher Depo. 197). And Sanofi continued to pay very large rebates—55% of its gross sales in 2018. *Drug Pricing in America: A Prescription for Change, Part II: Hearing Before the Sen. Comm. on Fin.*, at 3:20:10 (Feb. 26, 2019) (testimony of former Sanofi CEO Brandicourt), https://bit.ly/2ugiTV8. Sanofi now faults Mylan for doing the same thing with EpiPen.

Sanofi does not dispute that the industry shifted around the time of Auvi-Q's launch. Rather, it suggests that the EAI class *should have somehow been immune* from this industrywide trend and enjoyed higher prices. But the unrefuted record establishes that payors viewed Auvi-Q's introduction as an opportunity to manage the EAI class and push for more competitive pricing, including soliciting offers for exclusive coverage. *See supra* at 13-14. Mylan's procompetitive response to those incentives cannot support antitrust liability.

4. Sanofi Was Not Foreclosed At All, Let Alone From A Substantial Share Of The Market

Unlawful exclusive dealing generally requires that a competitor be foreclosed from at least 40% of the market. *See McWane*, 783 F.3d at 837; *see also* Jonathan M. Jacobson, *Exclusive Dealing, "Foreclosure," and Consumer Harm*, 70

ANTITRUST L.J. 311, 362 (2002) ("The recent decisions uniformly favor defendants where foreclosure levels are 40 percent or less, and so it is fair to say that foreclosure in excess of that amount is a threshold requirement where foreclosure is the asserted basis of the antitrust violation.").

In the district court, the highest foreclosure that Sanofi even claimed was 31%—that is, supposedly 31% of consumers in the United States had insurance without unrestricted coverage of Auvi-Q. SJ.Op.104 (13-JA-2694), 49-SJA-11101 (Sanofi District Court Brief). That is not enough, as the district court held. 13-JA-2693-98. And even that number is overstated for three reasons.

First, the proper measure of foreclosure, as Areeda and Hovenkamp (¶ 1802g2) point out, is not a static percentage but rather "what percentage of the market is effectively 'unrestricted' during a specific time period." Unrestricted dealers are those without exclusive deals, those whose deals will expire, and those who can terminate their deals easily. *Id.* That describes *every single payor*. And this was borne out in practice—Sanofi regained 80% commercial access overall in 2015, after having a smaller percentage of commercial access in 2014. *See supra* at 28-29.

Second, Sanofi's 31% foreclosure claim assumes that every patient associated with a PBM was "foreclosed" from Auvi-Q if the PBM's main national formulary did not cover Auvi-Q. But payors maintain many individual formularies, and their customers can choose to cover the drugs they wish. *See supra* at 9-10. The single

largest payor, ESI, excluded Auvi-Q from its main national formulary in 2014, but more than 65% of patients who used ESI's formularies had Auvi-Q covered by their insurance. *See supra* at 10. The same is true of MedImpact ([redacted]% of its clients had open plans that treated Auvi-Q equally, and other clients that did not have open plans, like the University of Michigan, added Auvi-Q to T2 of their formularies, SUMF¶106 (34-SJA-7479) (undisputed)). And the same is true of United (where the exclusion Auvi-Q received applied to only [redacted]% of commercial lives, SUMF¶91 (34-SJA-7475) (undisputed)).

So Sanofi's commercial market access cannot be measured by classifying each payor as closed or open based on how its main national formulary treated Auvi-Q. But that is how the documents that Sanofi relies on measured Auvi-Q's coverage. *See, e.g.*, 17-JA-3631 (recording Auvi-Q as "[b]enefit excluded" for all ESI lives instead of disaggregating individual plans).

Third, Sanofi's 31% number includes formularies irrelevant to this case. The district court dismissed Sanofi's claims involving Medicaid formularies, and Medicare formularies were never a part of this case. *See supra* at 6 n.5. But the document Sanofi uses to support its foreclosure number includes "Humana [Medicare] Part D" (5 million lives) and "FFS Medicaid" (9 million lives) as part of its "foreclosure" "calculat[ions]." Br.57 (citing 17-JA-3631).

Sanofi responds with irrelevancies and wild theories. First, it suggests that this Court should follow the *McWane* and *Microsoft* courts, which both observed in dicta that some courts had found illegal foreclosure at less than a 40-50% level. Br.52-53. But that was not the case in either *McWane* or *Microsoft*. In *McWane*, the competing pipe manufacturer was foreclosed from "the two largest distributors, who together controlled approximately 50-60% of distribution," as well as the third-largest distributor. 783 F.3d at 837. In *Microsoft*, the defendant had "exclusive deals with fourteen of the top fifteen access providers in North America." *United States v. Microsoft Corp.*, 253 F.3d 34, 70-71 (D.C. Cir. 2001) (en banc). Sanofi's claimed foreclosure is nowhere close. And, even setting all the above aside, it remains crucial to a rule-of-reason analysis that the *highest* percentage of covered lives from which Sanofi even claims formulary exclusion was only 31%.

Next, Sanofi says that its 31% number understates foreclosure because of "spillover" and that the number was even larger ("more than half the market")[24]

[24] Sanofi's "more than half" claim comes from Professor Scott Morton's deposition. Br.75 (citing 54-SJA-12134). She was hazarding an (incorrect) guess at the percentage of formularies she thought Auvi-Q was foreclosed from. That deposition occurred before her Reply Report, where she stated that there was "no need to devise a new foreclosure metric given that Mylan's ordinary course documents have already done this" and cited the same document Sanofi cites to show the 31% foreclosure number. 51-SJA-11424. At her second deposition (taken after her Reply Report), she said the "*peak share* of what [she] would call foreclosure" was "[redacted]." 24-SJA-5316. Thus, Sanofi's expert herself disavowed the "more than half" claim.

because doctors defaulted to prescribing EpiPen. Br.32-35, 74-75. This is a strange definition of foreclosure. No court has concluded that customers were "foreclosed" from a product they could freely buy and that their insurance would freely cover. And courts must avoid tests that condemn procompetitive behavior because "mistaken condemnations of legitimate business arrangements are especially costly." *NCAA v. Alston*, 141 S. Ct. 2141, 2161 (2021). It would invite condemnation of procompetitive behavior to measure "foreclosure" by the number of people who simply preferred a well-known product. Under that approach, a market leader could be liable for "monopolization" without having lifted a finger.

A final point: the effectiveness of foreclosure as a monopolization strategy depends on denying scale economies to the rival. If the foreclosure does not deny the rival minimum efficient scale, then the rival can stay in the market indefinitely.[25] Sanofi's expert did not "examine[] Auvi-Q for signs of economies of scale." 9-JA-1756. The factual record in fact demonstrates that Mylan's actions did *not* deny its much-larger rival Sanofi economies of scale: Auvi-Q remained on the market until 2015, when safety issues prompted a complete recall.

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[25] *See, e.g.*, *Stop & Shop Supermarket Co. v. Blue Cross & Blue Shield of R.I.*, 373 F.3d 57, 68 (1st Cir. 2004) ("[h]ow much of the market must remain open to support decent competition depends on scale economies" and "high [foreclosure] numbers do not automatically condemn, but only encourage closer scrutiny" based on scale economies and other factors); AREEDA & HOVENKAMP ¶ 768b4 (above-cost single-product discount might be anticompetitive if it "increases the dominant firm's sales so much that it denies rivals economies of scale").

B. Price Was The Clearly Predominant Mechanism Of Exclusion

As shown above, the district court should be affirmed because Mylan's conduct was not anticompetitive based on the established legal framework for evaluating exclusive dealing claims. But the entry of summary judgment against Sanofi can be affirmed for an additional reason.

In *ZF Meritor*, the Third Circuit held that, "*when price is the clearly predominant mechanism of exclusion*, the price-cost test tells us that, so long as the price is above-cost, the procompetitive justifications for, and the benefits of, lowering prices far outweigh any potential anticompetitive effects." 696 F.3d at 275 (emphasis added). That is the case here. There is no evidence in the record that any payor made formulary decisions on any grounds other than price, *see supra* at 45-55, and Sanofi has never asserted that Mylan priced EpiPen below its own cost.

C. Sanofi Proposes Only Unworkable Alternatives To The District Court's Analysis

The Court can scour Sanofi's brief in vain for an alternative to the well-recognized legal test for exclusive dealing that the district court applied. Instead of offering a coherent legal theory, Sanofi makes scattershot arguments about Mylan's supposedly malign intent, or the entrenched share Mylan supposedly had, or other supposedly bad conduct. Sanofi appears to hope to persuade this Court that, regardless of established law or even an alternative theory, those factors in combination suffice to send its case to a jury.

That is not the law. And, even if this Court were to accept Sanofi's premises, Mylan's conduct would pass any test with any modicum of analytical rigor.

1. Sanofi's View Of Intent Evidence Is Contrary To The Law Of This Circuit

Evidence regarding Mylan's intent is immaterial to the issues pending before the court. In *SCFC ILC, Inc. v. Visa USA, Inc.,* this Court proclaimed that "intent to harm a rival, protect and maximize profits, or do all the business if they can is neither actionable nor sanctioned by the antitrust laws." 36 F.3d 958, 969 (10th Cir. 1994). More recently, in *Novell, Inc. v. Microsoft Corp.*, an email from Bill Gates could have been read to "suggest[] an uncharitable intent toward rivals, maybe even a wish to 'hurt' or 'destroy' them." 731 F.3d 1064, 1078 (10th Cir. 2013). But, then-Judge Gorsuch wrote for this Court, "the process of firms . . . competing rather than colluding normally promotes competition and consumer gains—and the intent to undo a competitor in this process should hardly surprise." *Id.* "Were intent to harm a competitor alone the marker of antitrust liability, the law would risk retarding consumer welfare by deterring vigorous competition." *Id.* This Court therefore refused to transform an otherwise-lawful refusal to deal into an unlawful one. *Id.* Under binding precedent, Sanofi's intent evidence should not influence this Court's view of Mylan's conduct. [26]

[26] Other circuits and leading commentors agree. *Qualcomm*, 969 F.3d at 994 n.15

Even if this Court scrutinizes internal Mylan "intent" documents as Sanofi urges (Br.59-60, 80), that evidence conveys nothing useful. The Mylan email asserting "[redacted]," 51-SJA-11489, for example, shows merely that [redacted]. "Firms 'intend' to do all the business they can, to crush their rivals if they can. . . . [U]s[ing] the vigorous, nasty pursuit of sales as evidence of a forbidden 'intent' . . . risk[s] . . . penalizing . . . competition." *A.A. Poultry Farms, Inc. v. Rose Acre Farms, Inc.*, 881 F.2d 1396, 1401-02 (7th Cir. 1989) (Easterbrook, J.). That and other evidence shows only that Mylan responded to competition with the intent to *win*. And, given the way that payors play manufacturers off against each other (to *enhance competition*), winning necessarily would sometimes include Auvi-Q's exclusion from formularies.

By itself, Mylan's intent to beat Sanofi by making exclusive deals establishes nothing. The key question is whether Mylan used *anticompetitive means* to win. Intent evidence does not illuminate that. As Judge Learned Hand famously observed

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(error to "conflate[] the desire to maximize profits with an intent to destroy competition itself"); *Barry Wright*, 724 F.2d at 232 ("'[I]ntent to harm' without more offers too vague a standard in a world where executives may think no further than 'Let's get more business.'"); AREEDA & HOVENKAMP ¶ 1506 ("The document calling for 'hitting,' 'getting,' 'targeting,' or even 'smashing' rivals may merely call for competition. . . . [C]ompetition is the process of trying to prevail over rivals, even to the point of destroying them. An aggressive state of mind is fully consistent with antitrust objectives when the behavior is proper.").

long ago, "[t]he successful competitor, having been urged to compete, must not be turned upon when he wins." *United States v. Aluminum Co. of Am. (ALCOA)*, 148 F.2d 416, 430 (2d Cir. 1945).[27]

2. Sanofi's Theory Of Leveraging Entrenched Demand Is Fatally Flawed And Does Not Condemn Mylan's Contracts Anyway

Sanofi also argues that Mylan leveraged "entrenched" demand to exclude Auvi-Q. Sanofi posits that some patients were unwilling to switch to Auvi-Q, even if EpiPen were excluded from formulary and hundreds of dollars more expensive. Payors knew this, says Sanofi, and thus were unwilling to disadvantage Mylan on formulary, making it impossible for Sanofi to compete when Mylan conditioned rebates on exclusive coverage. Br.62-67.

Confronting an identical claim *against* Sanofi in 2016, the *Eisai* panel was "aware of no court that ha[d] credited this novel theory." 821 F.3d at 406. Likewise today, no court has accepted Sanofi's theory as a basis for liability. And this Court should not be the first. Sanofi's theory is improperly based on customer preference, unsupported by evidence, and tied to no standard.

[27] The district court concluded that Sanofi's intent evidence made no difference because Sanofi was not substantially foreclosed. 13-JA-2692-93. That conclusion was clearly correct; Mylan's intent did not somehow increase the extent of Sanofi's foreclosure.

Improperly based on customer preference: Sanofi bases its claim of entrenched share on ephemeral customer preference. Br.62. But past invocations of this kind of theory involved something far more concrete. In *Eisai*, 821 F.3d at 399, for example, Sanofi's incumbent drug had been approved by the FDA to treat conditions that Eisai's drug could not, and so some patients *could not* be moved. In *In re Remicade Antitrust Litigation*, 345 F. Supp. 3d 566, 579-80 (E.D. Pa. 2018), it was alleged that a patient could be stable on a frequently administered and complex drug, with a doctor unwilling to make her switch; that is unlike this case, where EpiPen is an emergency-use drug, not something that is taken regularly.

The "entrenched" share Sanofi advances here is not so unmovable. Sanofi *could have* used advertising or outreach to change patient and doctor preference. Furthermore, Sanofi made *no attempt* to show that EpiPen users were indifferent as to whether EpiPen cost $5 or $500.

Entrenched share based on preference is fickle and "notoriously difficult to measure." Richard M. Steuer, *Musthavedness*, 81 ANTITRUST L.J. 447, 460-61 (2017); *see also* Herbert Hovenkamp, *The Federal Trade Commission and the Sherman Act*, 62 FLA. L. REV. 871, 892 (2010) ("[T]he question whether any output is contestable is very sensitive to price.").

Without any quantitative test to assess whether pricing practices foreclose an equally efficient competitor,[28] Sanofi's argument invites "mistaken condemnations of legitimate business arrangements," which "are especially costly." *Alston*, 141 S. Ct. at 2161. Nearly every business would fear that it had an immeasurable "entrenched" share based on customer preference. So nearly every business would think twice about offering discounts in exchange for exclusivity, thereby denying consumers the benefits of price cuts. But, again, "[l]ow prices benefit consumers regardless of how those prices are set." *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 223 (1993). Sanofi's approach, if accepted, is *guaranteed* to chill procompetitive behavior.

Unsupported by evidence: The record does not support Sanofi's theory that Mylan's alleged "entrenched share" rendered Sanofi unable to compete. The district court concluded that it need not decide if an entrenched-share theory could ever support a Section 2 claim because Sanofi presented no evidence showing that "'an equally efficient competitor was unable to compete with' Mylan." 13-JA-2701 (quoting *Eisai*, 821 F.3d at 406).

Sanofi's theory, as discussed above, is that payors simply were unable to shift share to Auvi-Q, no matter the relative price of EpiPen vs. Auvi-Q. But unrefuted

[28] Sanofi tries to distinguish *Eisai* by claiming that the record here "indicates that an equally efficient competitor was unable to compete." Br.70. Thus, Sanofi has accepted the "equally efficient competitor" test.

evidence in this case rebutted this: When CVS and ESI removed EpiPen from certain formularies, EpiPen's share all but disappeared. SJ-Op.112 (13-JA-2702). Sanofi responded below with the opinion of Professor Scott Morton. SJ-Op.112-14 (13-JA-2702-04). But, as the district court discerned, she misunderstood the data from those formularies and so "calculated [her] percentage [of entrenched share] using data from plans that . . . *had not excluded EpiPen*." *Id.* (emphasis added).

Now, Sanofi accuses Judge Crabtree of contradicting himself, claiming that he credited Professor Scott Morton's analysis of those formularies as reliable in his *Daubert* decision but then refused to credit it on summary judgment. *See, e.g.*, Br.65. But Sanofi cites no authority holding that a court errs if it holds expert testimony admissible but still finds it incapable of defeating summary judgment.

Indeed, "[e]ven where an expert's evidence is ruled admissible under the *Daubert* standards, a district court remains free to decide that the evidence amounts to no more than a mere scintilla." *Hirsch v. CSX Transp., Inc.*, 656 F.3d 359, 362 (6th Cir. 2011) (citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993)). Accepting Sanofi's argument would be tantamount to holding that any admissible expert opinion is enough to prevent summary judgment *in every case*, even though summary judgment is often entered in antitrust cases with dueling expert testimony. *See, e.g.*, *Eisai*, 821 F.3d at 404-07; *Suture Express, Inc. v. Owens & Minor Distrib.*,

2016 WL 1377342 (D. Kan. Apr. 7, 2016), *aff'd*, 851 F.3d 1029 (10th Cir. 2017), *cert. denied*, 138 S. Ct. 146 (2017).

Besides this supposed contradiction, Sanofi tries to discount Judge Crabtree's well-supported conclusion by suggesting he erred in analyzing several other pieces of evidence. Sanofi is wrong.

- Payor testimony/actions: As the district court pointed out, "[s]everal payors testified that they could have excluded EpiPen in favor of Auvi-Q because they could shift product use from EpiPen to Auvi-Q." 13-JA-2701-02; *see supra* at 33. Equally important, no payor ever testified or even suggested internally that excluding EpiPen was impossible.[29] EpiPen's share vanished when it was excluded from formularies. *See supra* at 33-34. CVS, for example, excluded Mylan from its Advanced Control Formulary and told Mylan that EpiPen's share on that

[29] Sanofi attempts to dismiss this testimony as "self-serving." Br.65. If Mylan were bullying payors into excluding Auvi-Q, however, the payors surely would have had *something* to say about it. Sanofi also hints that Mylan shared its profits with payors through rebates. Its evidence is an allegation in another case in the MDL, an article stating that PBMs like higher prices, and an email from ESI [redacted] Br.65 n.23. The allegation and article are flatly inadmissible hearsay, and, as to the email, it is impossible to understand [redacted] and Sanofi provides no explanation.

formulary was [redacted] and that it would [redacted] —all while demanding deeper rebates. 3-SSA-466-67 (CVS email).

- OptumRx/United: Sanofi says the district court "ignored" United's failed "move against EpiPen in 2008," but cites *the very page where the court addressed this example.* Br.66 (citing 13-JA-2703). The evidence Sanofi offers—an internal Mylan email [redacted] 27-SJA-6097 (emphasis added)—has no bearing on whether EpiPen would retain market share when [redacted].
- Medicaid: The district court also considered Sanofi's evidence that Mylan "retained 40%-70% of Medicaid patients even with restrictions," Br.66, but correctly rejected that evidence as showing any entrenched share. Mylan was excluded in favor of Adrenaclick, not Auvi-Q, on that formulary, and it was Medicaid, not a commercial formulary. SJ-Op.113 (13-JA-2703). Moreover, Adrenaclick had supply problems at the time—meaning pharmacies had to dispense EpiPen to patients even where it was restricted. 20-JA-4496-97; *see also* 13-JA-2703.

Tied to no standard: Sanofi articulates no test that a court could apply to determine whether Mylan's alleged "leveraging" could have excluded "an equally efficient competitor." *Eisai*, 821 F.3d at 406. Sanofi just assumes on appeal that, if it has shown leveraging of entrenched demand, then a jury trial should follow.

Sanofi took a different tack before the district court. There, it provided a theory—Professor Scott Morton's "effective entrant burden" test (EEB)—under which leveraging of share was to be judged to assess antitrust liability. *See supra* at 39. But Judge Crabtree excluded that theory on *Daubert* grounds because it was not accepted in the economic literature, had a high error rate, and was in direct conflict with the undisputed record in this case. *Id.* Sanofi does not appeal that decision.

Instead, Sanofi replaces Professor Scott Morton's EEB calculation with *nothing at all*—nothing measurable, nothing that would allow a law-abiding business to know how aggressively it could compete. No approach could be better designed to chill procompetitive behavior.

Sanofi's theory is adapted from so-called "bundling" cases where a monopolist producer of two or more products can "bundle" those products together to exclude equally efficient rivals who cannot sell all the products in the "bundle." That is a recognized theory in antitrust law, at least in the Third and Ninth Circuits. But extending it beyond cases involving two or more products to single-product

cases is problematic, and the Third Circuit has refused to make such an extension. *ZF Meritor*, 696 F.3d at 274 n.11.

The cases assessing bundles, moreover, do not simply condemn bundling without any numerical inquiry. Instead, the leading cases apply the "discount attribution" test, which is described in some detail in *Cascade Health Solutions v. PeaceHealth*, 515 F.3d 883, 906 (9th Cir. 2008). *See also Collins Inkjet Corp. v. Eastman Kodak Co.*, 781 F.3d 264, 275 (6th Cir. 2015); Report and Recommendations at 99, ANTITRUST MODERNIZATION COMMISSION (Apr. 2007), https://perma.cc/4RZ9-4NFB.[30] Mylan's expert demonstrated below that Mylan passed that test, and Sanofi does not advocate that test on appeal. 41-SJA-9082-93 (Willig Report).

3. Sanofi Cannot Prove Its Case By Combining Insufficient Allegations

Sanofi's final gambit is to claim that other aspects of Mylan's alleged conduct (with no self-evident effect on competition) somehow synergized to foreclose Sanofi. Sanofi tosses every act it can describe pejoratively into its brief and urges

[30] Sanofi itself has advocated use of this test in other litigation. *See* Sanofi Pasteur Inc.'s Motion for Summary Judgment at 6, *Castro v. Sanofi Pasteur Inc.*, No. 2:11-cv-07178-JMV-MAH (D.N.J. Sept. 16, 2016), ECF No. 469-1 ("[P]laintiffs cannot satisfy the 'discount attribution' test. This test, which plaintiffs should be required to meet, mathematically describes when a bundled discount is exclusionary."). And it was part of the plaintiff's (unsuccessful) theory before this Court in *Suture Express*, 851 F.3d at 1036.

this Court to conclude that, together, those acts become illegal monopolization. Sanofi claims that the district court, disagreeing, took "a divide-and-conquer approach that missed the forest for the trees." Br.72; *see also* Br.59-61.

That makes no sense. The traditional way of analyzing antitrust claims is to look at them individually before considering any supposed synergistic effects. *See, e.g., Cal. Comput. Prods., Inc. v. IBM Corp.*, 613 F.2d 727, 746 (9th Cir. 1979) ("The number of . . . issues has required us to consider each instance of IBM's alleged monopolizing conduct separately for purposes of analytical clarity."). And, "where claims of anticompetitive conduct are individually shown in numerous critical respects to be utterly lacking the plaintiff's claims then collectively cannot have any synergistic effect rescuing their validity." *United States v. AMR Corp.*, 140 F. Supp. 2d 1141, 1218 n.28 (D. Kan. 2001), *aff'd*, 335 F.3d 1109 (10th Cir. 2003).

This Court has rejected similar attempts to combine various forms of innocuous conduct and call the combination anticompetitive. In *New Mexico Oncology & Hematology Consultants, Ltd. v. Presbyterian Healthcare Services*, the plaintiff "argue[d] that its claim should not be evaluated under defined categories of anticompetitive conduct, but instead through an *ad hoc* and fact-specific analysis." 994 F.3d 1166, 1173 (10th Cir. 2021). This Court disagreed because the *ad hoc* approach threatened to blur "the line between anticompetitive conduct and aggressive competition." *Id.* By contrast, "courts have been able to adapt the general

inquiry of what is anticompetitive conduct into particular circumstances," which "has allowed the creation of specific rules for common forms of alleged misconduct." *Id.*

In any event, the district court correctly determined that none of Sanofi's smorgasbord of supposedly bad acts was "supported by sufficient summary judgment evidence from which a trier of fact could find or infer that Mylan engaged in anticompetitive conduct." 13-JA-2713.

Deceptive conduct: With regard to Mylan's supposed "deceptive conduct," the district court applied the familiar test first articulated in *National Association of Pharmaceutical Manufacturers, Inc. v. Ayerst Laboratories*, 850 F.2d 904, 916 (2d Cir. 1988), which this court used in *Lenox MacLaren Surgical Corp. v. Medtronic, Inc.*, 762 F.3d 1114, 1127 (10th Cir. 2014). Sanofi's claims of deceptive conduct fell short because the supposed misrepresentations were neither clearly false, nor continued for prolonged periods, nor incapable of neutralization by Sanofi. SJ-Opp.115-20 (13-JA-2705-10).

Sanofi claims the district court should not have subjected its "deceptive conduct" claims to anything so rigorous. Br.72-73. But even Sanofi's authority—*West Penn Allegheny Health System, Inc. v. UPMC*, 627 F.3d 85, 109 n.14 (3d Cir. 2010)—requires a deceptive marketing claim to be based on statements about a rival that are *actually false*. Mylan's supposedly deceptive advertising—depicted in full

color at Br.34—accurately relates EpiPen and Auvi-Q's formulary statuses at certain payors in 2014 and accurately notes that payors make decisions on financial *and clinical* factors. Indeed, payors were able to make a financial decision—that is, to cover the cheaper of Auvi-Q or EpiPen—*only after making the clinical determination* that they were therapeutic alternatives. *See supra* at 13-14. There was nothing false about what Mylan said.[31]

EpiPen4Schools: During the time period relevant to this case, Mylan offered schools four free and freely replaceable pens, and then offered an unlimited additional number of pens at a substantial discount. SJ-Op.120-21 (13-JA-2710-11), SUMF¶136 (34-SJA-7491). There was a second discount for schools that agreed to buy only EpiPen for twelve months. *Id.* Sanofi accuses Mylan of "extracting pledges" from schools to train on EpiPen and not to buy Auvi-Q. Br.55. That is false, and Sanofi cites no evidence that schools were required to make any such pledge.

Sanofi asserts that the program was designed to entrench EpiPen demand. In other words, Sanofi wants this Court to subject Mylan to antitrust liability for building demand for its product by giving it away. Sanofi cites no case where a free giveaway program—especially one that plainly benefited consumers by *helping save*

[31] The other statements Sanofi presents are taken from internal Mylan documents (sometimes laundered through expert reports or depositions of Mylan employees). Br.35, 55. Sanofi presented none of them to the district court and cannot now argue them here. Besides, the statements all are indisputably true—EpiPen did have better formulary coverage than Auvi-Q when these statements were made.

children from anaphylaxis—has been held to constitute an antitrust violation. The best it can muster is a quote from Justice Scalia's dissent in a tying case, which had nothing to do with any giveaway program. Br.56 (citing *Eastman Kodak Co. v. Image Tech. Servs. Inc.*, 504 U.S. 451, 488 (1992) (Scalia, J., dissenting)). This Court should not be the first to condemn such an obviously pro-consumer program.

Alleged Medicaid misclassification: Sanofi's sole piece of evidence of any "misclassification" by Mylan of EpiPen is a statement issued by DOJ in connection with a settlement, but that statement made clear that its claims were "allegations only." *See* Br.37-38 (citing 4-JA-754). And Sanofi's only evidence connecting that supposed misclassification to Mylan's rebating conduct is an email [redacted] Br.37-38 (citing 53-SJA-11902) (emphasis added). So, on Sanofi's own terms, the alleged misclassification [redacted]. *See supra* at 6 n.5.

No court has ever held that an alleged misclassification related to rebating in one market led to antitrust violations in another. Yet Sanofi argues that Mylan somehow harmed competition by allegedly rebating to the government at a rate lower than prescribed by Medicaid regulations. Even if acts with no obvious competitive effect could somehow violate the Sherman Act, the acts alleged here

would fall far short. "Nothing plus nothing times nothing still equals nothing." *Zenith Radio Corp. v. Matsushita Elec. Indus. Co.*, 513 F. Supp. 1100, 1311 (E.D. Pa. 1981).

II. The District Court Correctly Held That There Was No Triable Issue Of Antitrust Injury

As an independent ground for summary judgment, the district court held that Sanofi could not prove it suffered antitrust injury. 13-JA-2713-18. That holding was correct and presents another basis for affirmance. *See Suture Express*, 851 F.3d at 1044-45 (affirming summary judgment because there was "not enough probative evidence" for jury to find that "defendants' conduct "constitute[d] an injury of the kind the antitrust laws are intended to prevent").

Sanofi "must prove antitrust injury, which is to say 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. It must show "that [the] challenged conduct affected the prices, quantity or quality of goods or services, *not just [its] own welfare*." *Cohlmia v. St. John Med. Ctr.*, 693 F.3d 1269, 1281 (10th Cir. 2012) (emphasis added).

This requirement helps courts identify lawsuits that seek to punish rather than promote competition. Such an inquiry becomes especially important when the plaintiff is a competitor of the defendant. *SCFC*, 36 F.3d at 965; *see also* Edward A. Snyder & Thomas E. Kauper, *Misuse of the Antitrust Laws: The Competitor*

Plaintiff, 90 MICH. L. REV. 551 (1991); William J. Baumol & Janusz A. Ordover, *Use of Antitrust to Subvert Competition*, 28 J.L. & ECON. 247, 251-52 (1985). Because Sanofi seeks protection *from* competition, not protection *of* competition, it cannot show antitrust injury.

A. Nothing In The Record Suggests That Mylan's Conduct Raised Prices Or Lowered Output

Raised prices and reduced output are the "hallmarks of anticompetitive behavior." *NCAA v. Bd. of Regents*, 468 U.S. 85, 113 (1984); *see also Christy Sports, LLC v. Deer Valley Resort Co.*, 555 F.3d 1188, 1191 (10th Cir. 2009) (describing "increase[d] prices and reduce[d] output" as "harming consumers"); *SCFC*, 36 F.3d at 972 (no evidence that "price was raised or output decreased"). Sanofi can show neither.

Price: Sanofi must show not just that the price of EAIs rose but that any price increase was "the result of antitrust violations." *Sterling Merch., Inc. v. Nestlé, S.A.*, 656 F.3d 112, 123 (1st Cir. 2011). Sanofi must prove that it was Mylan's rebating—the challenged conduct—that *caused* any increase in EAI prices. The district court correctly concluded that on this record "no reasonable jury could conclude that Mylan's exclusive rebate agreements increased EpiPen prices." 13-JA-2716. Sanofi's overarching claim that Mylan should have offered *lower* rebates—and thereby charged *higher* prices—is disconnected from "injury of the type the antitrust laws were intended to prevent." *Brunswick*, 429 U.S. at 489.

Mylan was the only party to offer competent evidence on the effect its challenged conduct had on price. Professor Willig modeled EpiPen price with and without rebating and determined that, [redacted]. *See* 40-SJA-8995, 41-SJA-9074. Professor Scott Morton, by contrast, modeled only what the price of EpiPen would have been *without competition from Auvi-Q*, which does not address whether the challenged rebating caused a rise in prices. SJ-Op.125-26 (13-JA-2715-16).

On appeal, Sanofi offers only the weak response that this "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." Br.85. That is sheer question-begging. Mylan does not dispute that, as a general matter, net prices rose in 2013-14 before falling in 2015. But there is no evidence that the challenged rebating *caused* the rise. Sanofi cites only Professor Scott Morton's report, and even then Sanofi does not explain how the cited portions of her report (*which do not discuss antitrust injury*) support its position. *Id.* Furthermore, Professor Scott Morton admitted at deposition [redacted]. 24-SJA-5311-12.

"When an expert opinion is not supported by sufficient facts to validate it in the eyes of the law, . . . it cannot support a jury's verdict." *Brooke Grp.*, 509 U.S. at

242; *see also In re Citric Acid Litig.*, 191 F.3d 1090, 1102 (9th Cir. 1999) ("an expert report cannot be used to prove the existence of facts set forth therein"); *SCFC*, 36 F.3d at 968-69. Sanofi claims that these are "dueling expert reports" fit only for a jury, but no reasonable jury could credit Sanofi's unexplained references to its expert's *ipse dixit* over Professor Willig's actual calculations.

In any event, Sanofi ignores its own role in drug pricing, and indeed goes so far as to try and camouflage its role by claiming that Judge Crabtree "condoned Mylan's +500% price escalation . . . because [he] believed there was one quarter in one year (Q1 2015) where net prices dropped briefly." Br.86 (italics omitted). That is a gross mischaracterization for several reasons. As Sanofi well knows, net price, not WAC price, is what matters, so quoting WAC price increases means nothing. Furthermore, Judge Crabtree did not "condone" such a rise but instead noted (correctly) that "EpiPen prices fell when Auvi-Q competed" on price. 13-JA-2715.

Indeed, the undisputed facts demonstrate that Sanofi priced Auvi-Q at a *premium* to EpiPen in 2013 and 2014. *See supra* at 16-18. It is unsurprising, then, that net EpiPen prices did not drop in that period. *Even if* Mylan raised its price, it could still underprice Sanofi during the first two years Sanofi sold Auvi-Q. *Id.*

Once Sanofi began to compete on price in 2015, EpiPen net prices fell. 36-SJA-7967. They fell so much that, at three payors (ESI, CVS, Aetna), [redacted]. 41-SJA-9090-

92. As the district court wrote: "Mylan's rebate offers caused EpiPen prices to *drop* when Sanofi competed against Mylan based on price." 13-JA-2716.[32]

Output: As the district court held, "the undisputed facts show that output [of EAI devices] increased during the relevant time period." 13-JA-2716. Sanofi concedes as much in its brief but tries to get around it in two ways.

First, Sanofi contends that output grew less than Mylan had projected ([redacted] million prescriptions in 2015 vs. [redacted] million allegedly projected). Br.83-84. But the excerpts of the record Sanofi cites—46-SJA-10265, 46-SJA-10267, 37-SJA-8135—say nothing at all about prescriptions, and it is impossible to tell where Sanofi obtained that number. Moreover, Sanofi raised none of this evidence with the district court. Instead, it relied on a Mylan projection that [redacted]. 49-SJA-11115 (Sanofi opposition). Output actually grew by 21%. 61-SJA-13687. The projection *Sanofi* presented to the district court, in other words, shows that output [redacted] than Mylan predicted.

Second, Sanofi relies on *ipse dixit*. That is, Sanofi claims that Mylan's conduct had the "probable effect" of reducing output, Br.84, and further that Professor Scott Morton's unsupported speculation that output would have risen even more created a

[32] Sanofi also suggests that EpiPen prices continued to rise when Auvi-Q was recalled. Br.83. It does not offer any sort of market-wide examination of EpiPen prices to show that EpiPen price rose on average across all payors. *Id.* But, even if there were such a rise, it would be no surprise and could cause *Sanofi* no antitrust injury.

triable issue of fact, Br.86-87. Regardless of what one might theorize to be the *probable* effect of Mylan's conduct (a method of "proof" that requires no evidence), the *actual* effect was that output increased. And Professor Scott Morton admitted at her deposition that she determined the level of output only "directionally." 24-SJA-5304. She performed no calculations to support it but just went with a gut feeling.

That is not enough. Sanofi must point to record evidence to support its views, not merely its expert's say-so. *See, e.g.*, *Brooke Grp.*, 509 U.S. at 242.

B. Mylan Did Not Deprive Consumers Of A Superior Product

Sanofi's claims that consumers suffered antitrust injury because they could not access the supposedly superior Auvi-Q falter at the start. As the district court correctly held, Mylan did not deprive consumers of access to any product, superior or not. 13-JA-2717-18. "[P]atients could always purchase Auvi-Q if a doctor prescribed it for them," with only the price changing, and Auvi-Q was unavailable to patients only when it was recalled. *Id*.[33]

Dodging yet again, Sanofi claims that the real question is whether the "practical effect" of Mylan's actions was to prevent access. Br.87. But the cases Sanofi cites for the "practical effect" language, *Tampa Electric* and *Microsoft*, were not discussing antitrust injury in using that term. Nor would it be at all consistent

[33] Sanofi quotes one patient as saying he could not get Auvi-Q. Br.84. But one patient not understanding that he could pay out-of-pocket for Auvi-Q cannot overcome the uncontroverted fact that Auvi-Q was available.

with the goals of antitrust to condemn the "practical effect" of preventing access *by competing too successfully on price*. If Sanofi was concerned that its product was too expensive for patients to access, the solution was to lower Auvi-Q's price.

Given that consumers always could access Auvi-Q, whether Auvi-Q was a better product than EpiPen is not a relevant antitrust question. But even then, "[n]o reasonable jury could conclude from [the] undisputed facts that Mylan prevented consumers from accessing a higher quality product." SJ-Op.127 (13-JA-2717). Sanofi offered nothing that a reasonable jury could accept to show that Mylan's conduct caused a decline in product quality. *Id.* Payors viewed Auvi-Q and EpiPen as treating the same condition in the same way with the same effectiveness. *See supra* at 13-14. No data in the record show better clinical outcomes with Auvi-Q than with EpiPen. *Id.* at 13.

Moreover, every Auvi-Q had to be recalled in 2015 because it did not reliably deliver the necessary dose of epinephrine. *Id.* at 35. Whatever extra bells and whistles Auvi-Q had, no reasonable jury could conclude that a product that *was so dangerous it had to be recalled from that market entirely* was higher quality than EpiPen. The district court recognized both these points. 13-JA-2717.

Sanofi claims that it was irrelevant that payors viewed the products equally because "PBM policy is no substitute for consumer welfare." Br.87. But payors decided that the products delivered the same drug in the same way and with the same

clinical efficacy. That decision evidenced the lack of any quality differential. And that evidence was undisputed in the record.

Sanofi proclaims (without explanation) that the district court was "wrong" to view the recall as evidence of a lack of superior Auvi-Q quality. Sanofi argues (again without citation or explanation) that only a jury could decide whether the recall indicated that Auvi-Q was not a better product. And Sanofi claims that EpiPen was subject to recalls and that "the manufacturing issues with Auvi-Q were easily surmountable." Br.87-88. But Sanofi cites nothing in the record to show that any unidentified EpiPen recall was comparable to Auvi-Q's complete Class I recall from the market. And the allegation that the problems with Auvi-Q were easily fixed only reaffirms that Sanofi prefers seeking treble damages to doing what the antitrust laws *actually* encourage: fixing the problems, bringing a product that actually works to the marketplace, and competing on price.

Sanofi cites only one piece of "evidence" of supposedly better quality: an internal Mylan document [redacted] Br.84. A flat assertion that one product is better than another is not enough to show antitrust injury. *See NicSand, Inc. v. 3M Co.*, 507 F.3d 442, 456 (6th Cir. 2007) (en banc) (if this were true, "every competitor could proceed to discovery (and avoid showing a true antitrust injury) by asserting an unelaborated claim that it provides better service than its competitors").

Sanofi has not tried to show that Auvi-Q had a better quality-adjusted price than EpiPen or done anything else to create a jury issue beyond reliance on one conclusory internal document. *Cf. FTC v. Qualcomm, Inc.*, 2018 WL 6615050, at *5 (N.D. Cal. Dec. 17, 2018) (finding expert's opinion helpful because it referenced "metrics measuring . . . quality-adjusted prices"). Market competition, not internal speculation, determines whether a product is *actually* superior, and Sanofi's efforts to persuade payors to pay more because it had a better product were a failure.

C. Sanofi's Claim Of "Stymied Innovation" Does Not Suffice

Sanofi's reduced-innovation claim founders for the same reason that its reduced-quality claim does: Auvi-Q was available to consumers the entire time it was on the market, giving consumers the benefits of whatever innovation it offered.

Setting that aside, no court has concluded that lack of innovation, standing alone, constitutes antitrust injury. In the one known case where such a claim was presented, the court rejected it. *VBR Tours, LLC v. Nat'l R.R. Passenger Corp.*, 2015 WL 225328, at *5 (N.D. Ill. Jan. 15, 2015) ("lack of innovation is not a cognizable antitrust injury"). Two of the three cases that Sanofi cites on the point do not even address antitrust injury: *Lorain Journal Co. v. United States*, 342 U.S. 143 (1951), antedated *Brunswick*; and *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297 (3d Cir. 2007), mentioned lack of innovation only as an allegation in the complaint. *Id.* at 318. Sanofi's third case, *United States v. Visa U.S.A., Inc.*, 344 F.3d 229 (2d Cir.

2003), discussed decline in innovation only in conjunction with a decrease in output. *Id.* at 241. Thus, while claiming that this theory of antitrust injury is "well-recognized," Br.84, Sanofi asks the Court to break new ground.

Accepting some open-ended "lack of innovation" as a harm would gut the antitrust injury requirement. Plaintiffs could simply find some small way in which the incumbent product could hypothetically be improved and then claim that the failure to do so "stymied innovation." Br.84. That is what Sanofi attempts to do: it argues that Mylan stymied innovation because it "never had to improve its dated swing-and-jab technology or invest in a smaller EpiPen." Br.85.

Such a vague and standardless inquiry would move antitrust away from clear rules yet again, in defiance of the Supreme Court's recent pronouncements. As Justice Gorsuch's opinion for the Court made clear in the unanimous *Alston* decision, "rules that seek to embody every economic complexity and qualification may well, through the vagaries of administration, prove counter-productive, undercutting the very economic ends they seek to serve. After all, even under the best of circumstances, applying the antitrust laws can be difficult—and mistaken condemnations of legitimate business arrangements are especially costly, because they chill the very procompetitive conduct the antitrust laws are designed to protect." 141 S. Ct. at 2161.

In any event, Mylan's rebates did not cause it to rest on its laurels. Sanofi

implies a connection between the undeveloped smaller EpiPen and Mylan's rebates. Br.10. Sanofi there attempts to fool this Court by citing a document and the deposition of a Pfizer (*not* Mylan) employee to show that Mylan decided not to develop a smaller EpiPen. Sanofi then, immediately following, cites an internal Mylan email (from two years later) [redacted]. There is no suggestion in the latter email—or anywhere else in the record—that Mylan decided to rebate the way it did in lieu of creating a smaller EpiPen.

Moreover, Mylan *was* innovating during the period at issue. Together with partners, it worked on [redacted]. 33-SJA-7417-18. Mylan's decision to innovate in different ways than Sanofi suggests did not cause antitrust injury.

D. Consumers Are Not Injured By The Selection Of An Exclusive Dealer

Finally, the district court made an important point on antitrust injury that Sanofi does not address: "exclusive contracts produce no antitrust injury when a competitor 'had the clear opportunity to compete and did compete, sometimes successfully, for the exclusive . . . contracts.'" 13-JA-2718 (quoting *Race Tires*, 614 F.3d at 84). Other decisions are in accord: "[w]hen one exclusive dealer is replaced by another exclusive dealer, the victim of the competition does not state an antitrust

injury." *NicSand*, 507 F.3d at 456; *see also Indeck Energy Servs., Inc. v. Consumers Energy Co.*, 250 F.3d 972, 977-78 (6th Cir. 2000).

The rationale is straightforward: selection of an exclusive dealer does not injure competition, instead simply moving it from atomistic competition to competition for the contract. And that benefits consumers. *See Paddock Publ'ns, Inc. v. Chicago Tribune Co.*, 103 F.3d 42, 47 (7th Cir. 1996) ("[C]ompetition for the contract makes it possible to have the benefits of exclusivity and rivalry simultaneously.").

Here, "Sanofi had the opportunity to compete for better placement on payors' formularies by offering bigger discounts in exchange for exclusivity for Auvi-Q." SJ-Op.128 (13-JA-2718). Although Sanofi succeeded "in some instances," *id.*, it sought damages for the competitions it lost. Because a competitor-plaintiff cannot show antitrust injury when it was the higher-priced but losing option in a competition for the contract, the district court properly held that "[t]he summary judgment record presents no triable issue of antitrust injury." *Id.*

CONCLUSION

This Court should affirm the grant of summary judgment.

STATEMENT IN SUPPORT OF ORAL ARGUMENT

Mylan believes that oral argument will assist the Court's review of this appeal.

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Respectfully submitted,

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