No. 22-628

In the Supreme Court of the United States

SANOFI-AVENTIS U.S. LLC, PETITIONER

v.

MYLAN INC. AND MYLAN SPECIALTY, LP

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

BRIEF IN OPPOSITION TO CERTIORARI

MICHAEL W. MCCONNELL
Wilson Sonsini Goodrich & Rosati, P.C.
650 Page Mill Road
Palo Alto, CA 94304
(650) 493–9300

CONSTANDINOS HIMONAS
Wilson Sonsini Goodrich & Rosati, P.C.
15 West South Temple
Salt Lake City, UT 84101
(801) 401-8510

STEFFEN N. JOHNSON
Counsel of Record
KEITH KLOVERS
KELSEY J. CURTIS
Wilson Sonsini Goodrich & Rosati, P.C.
1700 K Street, N.W.
Washington, DC 20006
(202) 973–8800
sjohnson@wsgr.com

Counsel for Respondents

QUESTION PRESENTED

Whether the Tenth Circuit correctly affirmed the district court's factbound summary judgment decision that, on this record, there is no genuine dispute that Sanofi was not an equally efficient competitor, was not actually foreclosed from the relevant market, and did not exit the market for any reason attributable to Mylan, but rather on account of an FDA recall related to safety concerns with Sanofi's product.

RULE 29.6 STATEMENT

The parent company of Mylan Inc. and Mylan Specialty, LP is Viatris Inc., a publicly held company.

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INTRODUCTION

In 2013, Sanofi, one of the world's largest pharmaceutical companies, entered the epinephrine auto-injector market. Hoping to compete with Mylan's EpiPen, Sanofi launched a new product called Auvi-Q.

Auvi-Q lasted about three years. In year one, Sanofi intentionally chose not to compete on price—believing Auvi-Q was a superior product that could be differentiated based on quality and sold at a higher price. Sanofi was wrong, and Auvi-Q got little traction. The petition relies heavily on this first year, but without acknowledging the connection between those poor results and Sanofi's deliberate pricing strategy.

In year two, Sanofi changed tactics and started offering rebates and discounts. Sanofi quickly gained access to 80% of the market and won contracts from Mylan, including an exclusive contract with the largest intermediary, Express Scripts Inc. (ESI). Sanofi's petition does not discuss this successful second year. But Sanofi cannot identify any instance when Auvi-Q was excluded or restricted when Sanofi offered better prices. As the court of appeals explained: "The record supports only one conclusion: when Sanofi beat Mylan's prices it succeeded." Pet.App.59a.

In year three, after an "unannounced inspection" of a Sanofi facility (Pet.App.177a) that "follow[ed] reports that Auvi-Q was failing to inject epinephrine" (Pet.App.13a), Sanofi went through an FDA "Class I recall"—a legal process triggered by a "reasonable probability" that using Auvi-Q "w[ould] cause serious adverse health consequences or death." Pet.App.178a. As a result of this disastrous development, Sanofi withdrew from the market, never to return, and later returned the rights to Auvi-Q to its inventors. The

petition does not even mention the FDA recall. It is like *Hamlet* without Fortinbras.

Two years after the recall, Sanofi filed this suit, alleging an exclusive dealing claim and hoping to pin the blame for Auvi-Q's failure on some combination of Mylan's allegedly "entrenched" market share (based on consumer familiarity with its product) and its aggressive—but above-cost—price-cutting. Applying settled antitrust law, both the district court and a unanimous panel of the Tenth Circuit rejected Sanofi's claim on summary judgment, finding that the factual record was bereft of support for the elements of Sanofi's claim. Specifically, Sanofi had to show that it was excluded from a substantial part of the market despite being an equally efficient competitor. But the record showed no such thing.

For starters, it is undisputed that Sanofi had higher costs than Mylan, and thus was less efficient. Pet.App.16a. To boot, Sanofi's own expert admitted that, even at the height of Mylan's success, Sanofi was kept from competing for only "31% of the U.S. [market]"—and then only briefly. Pet.App.54a. Finally, when Sanofi began competing on price, it quickly gained access to 80% of the market. Pet.App.34a. Ultimately, Auvi-Q failed due to an FDA safety recall, not because of anything Mylan did, much less anticompetitively. As the Tenth Circuit pointedly noted, Sanofi relied on "incomplete and cherry-picked" facts, "mischaracterization[s] or misunderstanding[s]," and "serious evidentiary deficienc[ies]." Pet.App.58a.

One example should suffice. In hopes of showing that Mylan's offers "were sufficient to exclude competition regardless of the rival's efficiency or price," Sa-

nofi says that ESI, "the largest dealer in the United States," told it that "*even a 100% discount* would not be enough" to get ESI's business. Pet. i. The petition repeats this anecdote no fewer than *eighteen* times, insisting: "And it was not just talk." Pet. 7. But the following year, when Sanofi cut its prices, ESI shifted business to Sanofi, even granting it exclusive placement on one formulary. It thus turns out that Sanofi's poster child for exclusion was, lo and behold, "just talk."

Sanofi lost this case because it could not support the elements of its exclusive dealing claim with sufficient evidence to convince any reasonable jury. In reaching that factbound conclusion, the Tenth Circuit did not begin to depart from this Court's precedents or any consensus among the lower courts. Rather, it faithfully applied established antitrust law, treating "the consumer welfare standard" as its "guiding principle" and bearing "'the interests of consumers" foremost "in mind.'" Pet.App.46a-47a. Any minor differences among the circuits over the law of exclusive dealing are utterly irrelevant to the outcome of this case. Certiorari should be denied.

STATEMENT

This civil antitrust case involves epinephrine, a drug used for emergency lifesaving treatment from severe allergic reactions. According to Sanofi, Mylan's pricing of its epinephrine auto-injector allowed it to monopolize the market for such products, in violation of Section 2 of the Sherman Act. All four judges to consider that claim below rejected it.

A. The parties and epinephrine auto-injectors

In 2007, Mylan obtained the "exclusive right" to sell an epinephrine auto-injector (or "EAI") called the EpiPen in the United States. Pet.App.12a. As "the first epinephrine auto-injector available on the market" (*ibid.*), it enjoyed commercial success.

Separately, Eric and Evan Edwards developed an alternative epinephrine auto-injector called Auvi-Q. "Auvi-Q differs from the EpiPen in that it is smaller * * * , has a rectangular shape, a needle that retracts (as opposed to one covered before and after injection), and audio instructions." Pet.App.103a. Sanofi acquired the U.S. rights to Auvi-Q, agreeing to pay a royalty of at least 20% based on annual sales and certain "milestone payments." Pet.App.16a, 102a. In January 2013, Sanofi launched Auvi-Q in the United States, where it competed with EpiPen and two other epinephrine auto-injectors. Pet.App.104a.

B. Industry structure

As the Tenth Circuit explained, "'[d]rug pricing is a complex and often confusing issue, shaped by a pharmaceutical distribution and payment system that involves multiple transactions among numerous stakeholders.'" Pet.App.4a-5a (quoting Pharm. Research & Mfrs. of Am., Follow the Dollar 3 (2017)).[1] Although the cost of a prescription drug is typically shared between the patient and her health insurance plan, the process involves many transactions up and down the supply chain. The Tenth Circuit illustrated the nature of these payments:

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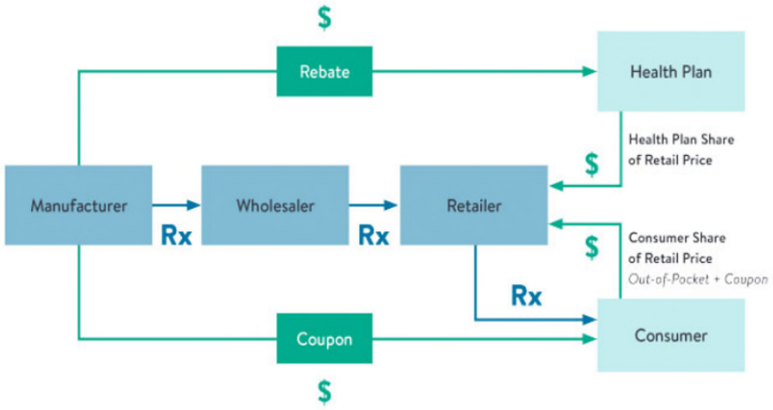
[1] Available at: http://phrma-docs.phrma.org/files/dmfile/Follow-the-Dollar-Report.pdf



Pet.App.6a (citing Charles Roehrig, Altarum, The Impact of Prescription Drug Rebates on Health Plans and Consumers 3 (2018)).

To keep costs down, health plans use a "managed care" system. For prescription drugs, the centerpiece of this system is the "formulary"—a list of covered drugs. Pet.App.6a. As Sanofi's former CEO testified, plans "control the price [of drugs] by controlling access to the formulary; so the tighter the access to any given formulary, the more [plans] have control over price." *Ibid.* (quoting deposition testimony).

To manage their formularies, most health plans hire a Pharmacy Benefit Manager (PBM). PBMs often represent multiple plans, and thus wield "aggregate purchasing power" to "gain greater discounts than the health plans could obtain individually." Pet.App.7a.

Through its formularies, a PBM uses utilization management techniques to "nudge patients toward cost-effective products and negotiate better pricing from drug manufacturers." Pet.App.8a. One such technique is called "tiering," whereby plans separate similar drugs into tiers with different co-payments.

"The lower the tier, the lower the patient's co-payment." *Ibid.* Tiering and other utilization management techniques enable PBMs to extract price concessions from drug makers—to create "price competition among sellers of therapeutically equivalent products" via rebates that "lower prescription drug costs" and help patients obtain "reduced premiums." Pet.App.9a-10a. As Sanofi's own expert told Congress: "The way you get low prices * * * is by the ability to exclude drugs." Pet.App.10a.

To that end, a PBM seeking lower prices "hold[s] an auction" and announces: "Whoever gives me the best price is the one I am going to buy from, and everybody else gets none of my business." *Ibid.* (quoting congressional testimony of Fiona M. Scott Morton, Ph.D., Sanofi's expert in this case)). Sanofi itself regularly uses that very strategy. Pet.App.20a, 34a-35a (citing examples involving Aetna, CVS, and ESI). Indeed, in defending similar litigation, Sanofi has said it is "how the entire branded pharmaceutical industry functions." 10.C.A.App.2037.

"Even if a PBM excludes or disadvantages a particular drug on its national formulary," however, "the health plan may, nevertheless, choose to cover it." Pet.App.7a. Therefore, because health plans often tailor a PBM's default formularies to fit their needs, even "exclusive" coverage on a PBM formulary does not confer exclusivity for any particular health plan or patient. Pet.App.7a-11a.

C. Competition between EpiPen and Auvi-Q

"When it came time to launch [its product], Sanofi decided to market Auvi-Q as a premium alternative to EpiPen." Pet.App.14a. Sanofi thus attempted to compete mainly on quality rather than price, setting

a higher nominal price (the wholesale acquisition cost or "WAC") and offering "pretty small" rebates of 10% or less. Pet.App.16a, 126a. As Sanofi's executives put it internally, "newly launched, differentiated products with a high [cost of good]s"—by which they meant Auvi-Q—"cannot and should not engage in a discounting war" because it would "set off a whole cascade of price discounts" that are "nearly impossible to withdraw." Pet.App.17a. This pricing strategy proved to be a "mistake." Pet.App.57a. PBMs rejected Sanofi's rebate offers for Auvi-Q as "inadequate," "not competitive," and insufficient to "match the Mylan offer." Pet.App.16a.

Sanofi's pricing strategy contrasted with Mylan's, which answered the competition by cutting prices—though always at levels above cost. Pet.App.44a-45a n.7 ("Sanofi does not dispute that it cannot pass the price-cost test"). Before the launch of Auvi-Q, Mylan offered "single digit rebates (roughly 3%-10%)" for EpiPen; but "[a]fter Auvi-Q's introduction, Mylan's rebate offers increased significantly," to 17% in 2014 and 36% in 2015. Pet.App.15a-16a. Consistent with typical managed care models, PBMs "place[d] restrictions on competing products" to obtain the lowest possible prices. Pet.App.16a.

Sanofi faced three significant disadvantages in the epinephrine auto-injector market. First, Sanofi had an uncompetitive cost structure: Auvi-Q's "royalty rate was 20 percent and it had a higher [cost-of-goods-sold] profile than other" products. Pet.App.16a (bracket in original). Second, Sanofi incorrectly assumed that PBMs would allow more than one epinephrine auto-injector within the tiers, but most PBMs concluded that they could cover just one. *Ibid*. Third,

Sanofi "miscalculated how much PBMs would value Auvi-Q's unique attributes." *Ibid.*

In 2014, facing low sales, Sanofi reversed course, deciding for the first time to compete based on price. Auvi-Q quickly won exclusive placement on several formularies, including two of CVS's. Pet.App.32a. Sanofi's gain was Mylan's loss, as EpiPen sales on those CVS formularies "completely disappeared." Pet.App.34a. Sanofi had similar success obtaining placement for Auvi-Q on formularies offered by ESI. Pet.App.20a. By April 2015, Sanofi had gained access to "80% [of the] commercial market" and "increased its investment in the brand." Pet.App.34a.

D. The FDA Class I recall

Sanofi's competitive momentum came to a halt in October 2015, when the FDA investigated a Sanofi facility, leading to a "Class I recall following reports that Auvi-Q was failing to inject epinephrine." Pet.App.13a. A Class I recall involves a "reasonable probability" that using Auvi-Q "w[ould] cause serious adverse health consequences or death." *Ibid.* Sanofi thus withdrew Auvi-Q from the market. Sanofi "never relaunched, electing instead to return Auvi-Q's distribution rights" to its inventors. *Ibid.* Sanofi's petition never mentions the FDA recall or its decision to withdraw Auvi-Q from the market.

E. The district court's decision

In 2017, Sanofi filed suit in the District of New Jersey. Sanofi alleged that Mylan's rebates—which effectively reduce the EpiPen's total price—violated § 2 of the Sherman Act by monopolizing the market for epinephrine auto-injectors. Shortly thereafter, the Judicial Panel on Multidistrict Litigation trans-

ferred Sanofi's case (and others like it) to the District of Kansas.

Sanofi and Mylan later moved for summary judgment. In a factually detailed and well-reasoned 157-page opinion, the district court granted Mylan's motion, finding "no triable issue (1) whether Mylan engaged in anticompetitive conduct violating the Sherman Act, or (2) whether Sanofi sustained an antitrust injury sufficient to support its Sherman Act claims." Pet.App.255a. Having found for Mylan on both antitrust injury and liability, the court declined to reach Mylan's argument that Sanofi's damages theory failed as a matter of law. Pet.App.187a-188a. The court denied Sanofi's summary judgment motion as moot, holding that Sanofi's antitrust claims "fail[] as a matter of law" regardless of whether Mylan possessed monopoly power. Pet.App.256a n.28.

The district court painstakingly evaluated Mylan's challenged conduct: (1) rebate agreements, (2) the purported "leveraging" of "non-contestable demand" to foreclose contestable demand, and (3) commercial speech and its programs providing schools with donated or discounted EpiPens. First, the court held that no reasonable jury could conclude that Mylan's rebate agreements violated the Sherman Act. In so holding, the court declined to apply the price-cost test advocated by Mylan. Pet.App.192a-196a. Rather, while noting that "[e]xclusive dealing arrangements are often entered into for entirely procompetitive reasons, and generally pose little threat to competition," the court conducted a full-fledged rule of reason inquiry. Pet.App.196a (citing cases).

The district court thus assessed the sufficiency of the evidence as to the proportion of foreclosure "'and

the probable immediate and future effects which preemption of that share of the market might have on effective competition'" in light of several quantitative and qualitative factors. Pet.App.198a (quoting *Tampa Electric Co.* v. *Nashville Coal Co.*, 365 U.S. 320, 329 (1961)). Citing Sanofi's view that "exclusive dealing cases generally present fact-intensive inquiries" (Pet.App.199a), the court explained that the courts nonetheless routinely grant summary judgment where the record "presents no genuine factual issue permitting a jury to find that defendant had foreclosed a substantial volume of competition." Pet.App.201a. As an example, the court cited an exclusive dealing case that Sanofi defended and won on summary judgment, *Eisai, Inc.* v. *Sanofi Aventis U.S., LLC*, 821 F.3d 394, 407-408 (3d Cir. 2016).

Applying *Tampa Electric* and Third Circuit cases such as *ZF Meritor, LLC* v. *Eaton Corp.*, 696 F.3d 254 (3d Cir. 2012), the district court identified extensive evidence that Mylan's rebate agreements were short in duration, easy to terminate, and often terminated *by payors*. Pet.App.203a-206a (reviewing several agreements and testimony from several PBM witnesses). The court cited "several examples where payors renegotiated formulary coverage with both Mylan and Sanofi in an effort to secure greater rebates." Pet.App.208a-209a.

The district court also carefully assessed the other *Tampa Electric* factors. As to coercion, the record was "devoid of evidence that would allow a trier of fact to infer coercion." Pet.App.211a. Rather, it showed that "payors could, and often did, walk away from Mylan's exclusive rebate offers" (Pet.App.212a), and that "it's not coercion for a payor to agree to accept a lower price" (Pet.App.216a (citing *Eisai*, 821

F.3d at 399-407)). Indeed, it was often the payors who actively solicited rebate offers, including those offering "price protection" by automatically increasing the rebate to offset any increase in the nominal price. Pet.App.131a-146a, 219a.

Regarding industry practice, the court concluded that "exclusive contracts are 'a normal competitive tool within the [epinephrine auto-injector] industry.'" Pet.App.221a (quoting *Concord Boat Corp.* v. *Brunswick Corp.*, 207 F.3d 1039, 1062 (8th Cir. 2000)). In fact, Sanofi itself had struck exclusive rebate agreements with ESI and CVS and made exclusive rebate offers to OptumRx and MedImpact. Pet.App.220a-221a. The district court specifically noted that such contracts "benefitted consumers" by providing "greater discounts on pharmaceutical products." Pet.App.220a n.22. As the court observed, "consumers gain the most when firms slash costs to the bone and pare price down to cost." Pet.App.222a (citation omitted).

Regarding intent, citing the abundant evidence that Mylan's rebate agreements did not foreclose a substantial share of the market, the court saw no need "to inquire into Mylan's precise motives for the exclusive contracts." Pet.App.223a (cleaned up).

Finally, the court conducted quantitative analysis to examine the "ultimate issue" of "whether Mylan's rebate contracts substantially foreclosed competition. The court observed that "the highest foreclosure percentage calculated by Sanofi's expert was 31%" (Pet.App.225a)—well below the typical minimum threshold of 40%—and that, regardless, Sanofi "had access to 80% of the commercial market within two years" of Auvi-Q's launch (Pet.App.229a).

Taken together, the court concluded that "Sanofi has failed to present a triable issue that Mylan's rebate contracts foreclosed Sanofi from a substantial share of the market." Pet.App.230a.

Second, the district court held that no reasonable jury could find on this record that Mylan leveraged its non-contestable demand for EpiPen to protect its contestable demand from competition. The court first explained that Sanofi's authorities involved "multi-product bundles," and thus did not speak to single-product rebates. Pet.App.232a-234a (discussing *Eisai*, 821 F.3d at 401; *In re Remicade Antitrust Litig.*, 345 F. Supp. 3d 566, 578-580 (E.D. Pa. 2018)). But even if Sanofi's legal theory were sound, the court held, "[the] facts here present no triable issue whether 'an equally efficient competitor was unable to compete with Mylan'" because "the actual data for plans where EpiPen was excluded reveals EpiPen lost significant market share when it was excluded in favor of Auvi-Q." Pet.App.234a-236a. In other words, when Sanofi belatedly decided to compete on price, it could—and frequently did—displace Mylan, including on formularies managed by CVS and ESI.

Third, the court concluded that Sanofi had presented insufficient evidence of other exclusionary conduct amounting to "an overall scheme to restrict competition in the [epinephrine auto-injector] market." Pet.App.237a. Sanofi pointed to two acts: (1) allegedly deceptive speech involving a pharmaceutical study and marketing materials, and (2) the "EpiPen4-Schools" program, under which Mylan provided free or heavily discounted epinephrine auto-injectors to qualifying schools.

As to the allegedly deceptive conduct, the court noted that deceptive acts "can give rise to antitrust liability" if they are "'so widespread and longstanding and practically incapable of refutation that they are capable of injuring both consumers and competitors.'" Pet.App.238a (quoting *Novell, Inc.* v. *Microsoft Corp.*, 731 F.3d 1064, 1079-1080 (10th Cir. 2013) (Gorsuch, J.)). The court found no triable issue involving the allegedly deceptive speech here, which (1) was not clearly false, (2) was short-lived, and (3) was readily neutralized or offset by rivals. Pet.App.238a-245a. Likewise, the court found no triable issue concerning Mylan's schools program, as "nothing in the antitrust laws" prohibits "supplying free EpiPens to schools" and Sanofi could have neutralized Mylan's program by offering its own. Pet.App.245a-247a.

After concluding that each of Sanofi's claims of anticompetitive conduct, standing alone, was "utterly lacking" in "numerous critical respects," the court held that the challenged acts "collectively cannot have any synergistic" anticompetitive effect. Pet.App.248a (citation omitted). The court thus granted summary judgment to Mylan on whether its challenged conduct was anticompetitive.

The district court also granted summary judgment to Mylan on whether Sanofi could establish antitrust injury. After reviewing the extensive record, which is littered with contracts that Sanofi competed for and won, the court held "that no reasonable jury could find that Mylan's conduct produced an antitrust injury," as "Sanofi had the opportunity to compete for better placement on payors' formularies by offering bigger discounts in exchange for exclusivity for Auvi-Q." Pet.App.255a. Indeed, when Sanofi "offered more competitive pricing than Mylan," it succeeded, bene-

fitting consumers. *Ibid.* Thus, "[t]he summary judgment record presents no triable issue of antitrust injury." *Ibid.*

F. The court of appeals' decision

Sanofi appealed, challenging the district court's holdings that (1) there was no "triable issue of exclusionary conduct" (Pet.App.3a), and (2) "no reasonable jury could find that Mylan's conduct produced an antitrust injury" (Pet.App.94a n.29 (quoting Pet.App.254a)). In a well-reasoned 89-page opinion, the Tenth Circuit unanimously affirmed.

The court of appeals ruled de novo based on the absence of any genuine dispute over the presence of exclusionary conduct. Pet.App.61a. Applying the foreclosure standards of *Tampa Electric* and a "full rule of reason analysis" (Pet.App.45a n.7), the court treated "the consumer welfare standard" as its "guiding principle" in analyzing Mylan's conduct, bearing "'the interests of consumers, not competitors, in mind.'" Pet.App.46a-47a (citing *Reiter* v. *Sonotone Corp.*, 442 U.S. 330, 343 (1979), and quoting *Novell*, 731 F.3d at 1072). Because Sanofi did not offer "any evidence of actual or threatened consumer harm," the court stated, it failed to "present a triable issue of monopolization." Pet.App.2a.

Specifically, Sanofi challenged "'price-cutting activities,'" which antitrust law generally protects. Pet.App.52a (quoting *Matsushita Elec. Indus. Co.* v. *Zenith Radio Corp.*, 475 U.S. 574, 594 (1986)). Sanofi did so even though it did not "dispute that it cannot pass the price-cost test," as it could not prove that "(1) the rival's low prices 'are below an appropriate measure of its rival's costs,' and (2 the rival had a 'dangerous probability[] of recouping its investment

in below-cost prices.'" Pet.App.44a-45a n.7. Indeed, Sanofi's expert witness opined that Mylan consistently priced above cost. Pet.App.19a. Sanofi thus needed to present a triable dispute over whether "the anticompetitive effects (if any) of the exclusion [of Sanofi] outweigh any benefits to competition from it," and particularly the "corresponding procompetitive benefit [of] lower prices." Pet.App.51a. Yet Sanofi failed to do so.

In so holding, the court of appeals was careful to "distinguish between restraints with anticompetitive effect that are harmful to the consumer and restraints stimulating competition that are in the consumer's best interest." Pet.App.47a-48a (cleaned up) (quoting *Leegin Creative Leather Prods., Inc.* v. *PSKS, Inc.*, 551 U.S. 877, 886 (2007), and citing *Ohio* v. *Am. Express Co.*, 138 S. Ct. 2274, 2284 (2018), and *Novell*, 731 F.3d at 1072). With that distinction in mind, the court cited extensive undisputed evidence that Mylan's rebate agreements sparked "legitimate competition *for* the formulary" (Pet.App.94a), thus reducing the price that consumers paid. As the court elaborated, "Mylan's exclusive rebate agreements brought about lower prices for epinephrine auto-injectors than if Mylan and Sanofi used preferred or co-preferred rebate agreements." Pet.App.53a.

The court of appeals also analyzed Sanofi's other theories. Like the district court, it found no evidence of foreclosure given Sanofi's extensive use of similar rebates and its success displacing Mylan's EpiPen at PBMs such as CVS and ESI. Pet.App.53a-80a. The court explained that, of the seven principal PBMs, Sanofi was never restricted on three of them; and within just one year, two of the remaining four removed any restrictions (Pet.App.57a)—such that the

31% foreclosure rate in the first year dropped to 20% one year later (Pet.App.58a ("By April 2015, Auvi-Q regained 80% access.")).

The court also rejected Sanofi's theory of entrenched and non-contestable demand, noting that Sanofi failed to invoke the "appropriate legal standard" for assessing it. Pet.App.81a-89a. Indeed, Sanofi failed to provide any briefing "regarding what substantive law ought to apply to Sanofi's claim that Mylan anticompetitively leveraged its entrenched demand," and it "explicitly disavowed" reliance on the one theory it implicitly invoked—a theory of *per se* unlawfulness based on *LePage's Inc.* v. *3M*, 324 F.3d 141, 155 (3d Cir. 2003) (en banc). Pet.App.89a (citing Oral Arg. 7:31). Finally, the court rejected as insufficient Sanofi's theories concerning deceptive speech (Pet.App.90a), Mylan's schools program (Pet.App.90a-92a), and related conduct (Pet.App.92a-93a). Whether "[c]onsidered separately or together," the court concluded, "Sanofi's arguments do not raise a triable issue of exclusionary conduct." Pet.App.94a.

Having found no antitrust violation, the court did not reach the district court's independent holding that Sanofi could not establish antitrust injury. Pet.App.94a n.29.

REASONS FOR DENYING THE PETITION

I. Sanofi's petition for certiorari rests on a host of false factual premises, to the point that its "question presented" is not even presented.

The question supposedly presented is whether "a monopolist's exclusionary conduct" violates § 2 of the Sherman Act if it "would foreclose equally (or potentially equally) efficient rivals from accessing significant channels of distribution." Pet. i. But the Tenth Circuit did not dispute that principle of law. Rather, applying settled antitrust precedent, it affirmed the district court's fact-specific conclusion that the record here contains no evidence that Sanofi was an equally efficient rival (even "potentially" so), that it was foreclosed from significant channels of distribution, or that Mylan forced Sanofi from the market.

As both courts below held, it is undisputed that Sanofi had a higher cost structure (Pet.App.16a) and that, once Sanofi began competing on price, it quickly obtained access to 80% of the market (Pet.App. 30a-34a; Pet.App.229a, 235a-236a). In other words, "the clear answer to Sanofi's problem was offering better prices" (Pet.App.17a), and both courts below were "in full agreement" that "Sanofi 'failed to present a triable issue that Mylan's rebate contracts foreclosed Sanofi from competing" (Pet.App.53a-54a (quoting Pet.App.229a-230a)). What drove Sanofi from the market was not Mylan's pricing but an FDA Class I recall.

As below, therefore, Sanofi relies on "incomplete and cherry-picked" facts, "mischaracterization[s] or misunderstanding[s]," and "serious evidentiary deficienc[ies]." Pet.App.58a. Once that becomes clear, it

turns out that Sanofi's "question presented" is not even presented.

A. The undisputed record shows that Sanofi could compete for business even though it was not an equally efficient rival.

Most fundamentally, the Question Presented (like the putative circuit split) rests on the premise that Sanofi and Mylan were "equally efficient." Pet. i, 2. In one sense this is unsurprising, as Sanofi's own leading authority explains that § 2 is concerned only with "'attempt[s] to exclude rivals on some basis other than efficiency.'" *Aspen Skiing Co.* v. *Aspen Highlands Skiing Corp.*, 472 U.S. 585, 605 (1985).[2] But as the courts below recognized, Sanofi was *not* as efficient as Mylan—it labored under a higher cost structure. Pet.App.16a, 127a.

Both courts below held that undisputed evidence, including Sanofi's internal documents, revealed that Sanofi's "high production costs and royalty rates" put it in "'a bind'": Sanofi had concluded that it "'may already be as aggressive as' it c[ould] be" in discounting, yet "PBMs rejected [its] offers as 'inadequate,' 'not competitive,' and even 'laughable.'" Pet.App.16a; accord Pet.App.127a. Specifically, "Auvi-Q's 'royalty rate was 20 percent and it had a higher [cost-of-goods-sold] profile than other pharmaceutical products.'" Pet.App.16a (alteration in original); accord Pet.App.127a (Mylan's above-cost pricing "put pressure on" Sanofi's bottom line, given its "20 percent"

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[2] Sanofi's heavy reliance on *Aspen Skiing* is telling. As the Court has explained, its holding lies "at or near the outer boundary" of Section 2. *Verizon Commc'ns* v. *Law Offices of Curtis V. Trinko*, 540 U.S. 398, 409 (2004).

royalty and "higher COGS profile") (citing Barry Dep. 31-32)). Put another way, Sanofi was less efficient than Mylan.

Sanofi's cost disadvantage was in fact the reason it initially chose "to market Auvi-Q as a premium alternative to EpiPen." Pet.App.14a; see Pet.App.57a (citing Pet.App.120a-123a (collecting evidence)), 122a. But Sanofi's "refus[al] to seek out exclusivity or deeply discount its 'better mousetrap' * * * turned out to be a mistake," as Sanofi "miscalculated how much PBMs would value Auvi-Q's unique attributes." Pet.App.57a, 17a. "Several PBMs believed" the companies' products were "similar" or "interchangeable." Pet.App.17a.

Faced with undisputed evidence that it had higher costs than Mylan, Sanofi strives to show that it was equally efficient by quoting—some 18 times—one customer's offhand remark that Sanofi could not win its business even with price cuts of "100%" or more. Pet. 4; see also Pet. 22 ("since even 100% discount was not sufficient for Sanofi to access the market through the largest PBM (ESI), Sanofi obviously could not 'capture the business' merely by beating Mylan's prices"); Pet. 6-8, 11, 13, 15-16, 20, 24, 26; accord AAN Br. 13. Warming to its theme, Sanofi assures the Court: "And it was not just talk." Pet. 7.

The problem, as both courts below observed, is the record. Sanofi won business from this customer—ESI, the largest PBM—by offering discounts of well under 100%. Pet.App.30a-31a, 57a-58a, 151a-152a, 212a. By offering both price protection and rebates on Auvi-Q and another drug, Sanofi "reverse[d] its exclusion from ESI's national formulary" and "resecure[d] [its] business." Pet.App.30a, 31a (internal

quotations omitted). In other words, Sanofi's oft-repeated quotation of ESI is "just talk." Pet. 7.

On this record, the Tenth Circuit had no occasion to reject the "equally efficient competitor principle" that Sanofi repeatedly invokes. *E.g.*, Pet. 4. Both courts below simply took stock of the "uncontroverted" proof that Sanofi was less efficient yet managed to win business from Mylan by cutting prices. Pet.App.3a, 59a-60a. Even "accept[ing] Sanofi's non-contestable demand theory," "[the] facts here present no triable issue whether 'an equally efficient competitor was unable to compete with' Mylan." Pet.App.234a. For that reason alone, this case offers no opportunity—much less a good one—to take up the "question presented."

B. The undisputed record shows that Sanofi was not foreclosed from the epinephrine auto-injector market.

But there is more. Sanofi's assertion that it was barred from a substantial share of the epinephrine auto-injector market—that demand "would not move to a new rival in the short term" (Pet. 5)—is equally foreclosed by the undisputed evidence.

As Sanofi concedes (Pet. 25), "an exclusive-dealing arrangement * * * does not violate [the Sherman Act] unless" it is "probable that performance of the contract will foreclose competition in a substantial share of the line of commerce affected." *Tampa Elec.*, 365 U.S. at 327; accord XVIII Philip A. Areeda & Herbert H. Hovenkamp, Antitrust Law ¶ 1802b (5th ed. 2022).[3] Applying *Tampa Electric*, Third Circuit prec-

[3] This analysis proceeds under the rule of reason. Pet.App.44a-45a & n.7 (citing cases); see also *Barry*

edents that Sanofi invokes (including *ZF Meritor*), and other exclusive-dealing cases (see *id.* ¶¶ 1821c-1821d), both courts below carefully analyzed whether Sanofi's evidence created a genuine factual dispute as to market foreclosure. Both courts held that Sanofi's case failed—quantitatively and qualitatively—under a "rule of reason" analysis. Pet.App.50a, 44a-46a & n.7; Pet.App.229a-230a.

As both decisions below recognized, the facts belie any suggestion that Sanofi was kept from "build[ing] up sufficient market share to compete." Pet. 25. And even if the courts below had erred, they applied the proper standard—meaning Sanofi would at most be seeking factbound error correction that would not warrant certiorari. See Rule 10 ("certiorari is rarely granted when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law").

Quantitative foreclosure. As discussed (at 6-7), when Auvi-Q launched, Sanofi "refused to * * * deeply discount its 'better mousetrap,'" thinking it could differentiate its product as "unique." Pet.App.57a, 17a.

Wright Corp. v. *ITT Grinnell Corp.,* 724 F.2d 227, 236 (1st Cir. 1983) (Breyer, J.); *United States* v. *Visa U.S.A., Inc.*, 344 F.3d 229, 237-238 (2d Cir. 2003); *Satellite Television & Associated Res., Inc.* v. *Cont'l Cablevision of Va., Inc.*, 714 F.2d 351, 354 (4th Cir. 1983); *Hornsby Oil Co.* v. *Champion Spark Plug Co.*, 714 F.2d 1384, 1392 & n.6 (5th Cir. 1983); *NicSand, Inc.* v. *3M Co.*, 457 F.3d 534, 544 n.6 (6th Cir. 2006), reh'g en banc granted, opinion vacated (Nov. 22, 2006); *Roland*, 749 F.2d at 393; *Minn. Ass'n of Nurse Anesthetists* v. *Unity Hosp.*, 208 F.3d 655, 660 (8th Cir. 2000); *Aerotec Int'l, Inc.* v. *Honeywell Int'l, Inc.*, 836 F.3d 1171, 1180 n.2 (9th Cir. 2016).

Sanofi believed "offering aggressive rebates" would "'set off a whole cascade of price discounts'"—that "'there are no winners in a price war'" and that, as Sanofi's former CEO testified, "pricing moves are very difficult to reverse." Pet.App.17a-18a. That strategy failed.

After that, however, Sanofi started competing on price—and immediately gained market share. Beyond obtaining placement on all of ESI's formularies —which together amounted to 38% of the market (Pet.App.8a)—Sanofi "reversed exclusivity at * * * Aetna" and "successfully excluded EpiPen" from two CVS formularies. Pet.App.57a-58a. Moreover, other PBMs—such as "Prime, and Cigna[]"—"never restricted or excluded Auvi-Q" in the first place. Pet.App.20a. Of the two remaining formularies, MedImpact stayed with EpiPen only after finding that its cost after discounts was $113 versus $145 for Auvi-Q. Pet.App.59a. Indeed, Sanofi has never identified any instance when Auvi-Q was excluded or restricted when Sanofi offered a better price.

Even "[a]t the height of its allegedly anticompetitive behavior, Mylan only foreclosed Auvi-Q from 31% of the U.S. population" (Pet.App.54a)—well below the minimum threshold of "roughly 40% or 50%" that courts typically require for exclusive dealing claims. Pet.App.54a; see Areeda & Hovenkamp ¶ 1821c (foreclosure of less than 40% is "presumptively harmless to competition"); see also *McWane, Inc.* v. *F.T.C.*, 783 F.3d 814, 837 (11th Cir. 2015) ("Traditionally a foreclosure percentage of at least 40% has been a threshold for liability in exclusive dealing cases."). One year later, due to Sanofi's decision to "offer[] more competitive pricing" (Pet.App.255a), Auvi-Q had displaced Mylan from several formularies and

"regained '80% commercial market' coverage"—*i.e.*, the foreclosure share had dropped to 20%. Pet.App.34a; accord Pet.App.229a (Sanofi "had access to 80% of the commercial market within two years" of entering it); Pet.App.30a-34a; see Pet.App.235a-236a ("the actual data for plans where EpiPen was excluded reveals EpiPen lost significant market share when it was excluded in favor of Auvi-Q").

Aware that 31% foreclosure (at most) is insufficient, Sanofi says the 31% was "amplified" by "spillover effect" to "more than half the market." Pet. 25. But as the court below recognized, Sanofi's spillover theory was not even supported by its own expert, who declined "to endorse any market foreclosure greater than 31%." Pet.App.67a. Without acknowledging the Tenth Circuit's reasons for "refus[ing] to recognize" Sanofi's unprecedented use of "spillover foreclosure" —including its incompatibility with *Tampa Electric* and many factual deficiencies (Pet.App.64a-67a)— Sanofi chastises the court for "[s]ubstituting its own view of economic theory" for Sanofi's expert's. Pet. 14; 25. But since Sanofi's expert never applied Sanofi's spillover theory to her foreclosure analysis, "Sanofi's 'more than half the market' claim lacks any factual support." Pet.App.67a.

Qualitative Foreclosure. Under black-letter antitrust law, "low foreclosure percentages are typically decisive for the defendant." Areeda & Hovenkamp ¶ 1821d. But even if Sanofi could clear that threshold requirement, the undisputed evidence would preclude Sanofi from showing qualitative foreclosure. See also *ibid*. (even "higher percentages are seldom decisive in and of themselves"; they simply call for further analysis under the rule of reason). If, unlike here, a restraint forecloses enough of the market, courts ana-

lyze its "'probable effect' on 'the relevant area of effective competition' and 'the probable immediate and future effects which pre-emption of that share of the market might have on effective competition therein.'" Pet.App.46a (quoting *Tampa Elec.*, 365 U.S. at 329). Under *Tampa Electric*, that entails considering a contract's duration and ease of terminability, evidence of coercion, actual market success, competitors' use of exclusive dealing, and other evidence of the contracts' probable effect. Here, those factors underscore that the petition rests on a false factual premise.

First, it is "undisputed" that Mylan's agreements were short, easy to terminate, and actually *were* terminated—often—by PBMs, which drove the renegotiation process. Pet.App.56a. Most of the contracts "imposed terms of two and a half years or less" and "allow[ed] either party to terminate the agreements without cause on 90-days' written notice or less." Pet.App.56a (citing Pet.App.204a-205a). Exercising their contractual rights, "PBMs invoked these termination provisions and renegotiated rebate agreements annually" or "even more frequently." *Ibid.* Sanofi could "simply wait for the contracts to expire or make alluring offers to initiate termination," making the agreements "of little antitrust concern." Pet.App.55a (collecting cases). And Sanofi successfully did so, obtaining exclusive agreements of its own with CVS and ESI. Pet.App.57a-58a.

Second, "exclusive rebate agreements were a normal competitive tool in the epinephrine auto-injector market," and undisputed evidence "show[ed] that PBMs often instigated exclusivity to stimulate price competition, with Sanofi bidding for and entering into exclusive rebate agreements for Auvi-Q." Pet.App.56a. Thus, "[t]he widespread use of exclu-

sive rebate agreements in the epinephrine auto-injector market"—including by Sanofi—merely "demonstrates the market was functioning properly." Pet.App.56a (citing *Paddock Publications, Inc.* v. *Chicago Trib. Co.*, 103 F.3d 42, 45 (7th Cir. 1996) ("Competition-for-the-contract is a form of competition that [the] antitrust laws protect rather than proscribe."); *Race Tires Am., Inc.* v. *Hoosier Racing Tire Corp.*, 614 F.3d 57, 78-79, 83 (3d Cir. 2010); *NicSand*, 507 F.3d at 453-454 (en banc) (Sutton, J.)). Sanofi has acknowledged that this is "how the entire branded pharmaceutical industry functions." 10-C.A.App.2037. As Sanofi's expert told Congress: "The way you get low prices in the pharmaceutical industry is by the ability to exclude drugs." Pet.App.57a (quoting Hearings, *supra*, at 13 (statement of Dr. Scott Morton)).[4]

Third, as discussed, Sanofi could compete successfully by offering a "'a better deal.'" Pet.App.57a (quoting *Roland Mach. Co.* v. *Dresser Indus., Inc.*, 749 F.2d 380, 394 (7th Cir. 1984)). And it did so—with "resounding success" that enabled it to obtain "80% access to the commercial market" by April 2015, less than two years after its launch. Pet.App.57a-58a. As the court below put it: "The record supports only one conclusion: when Sanofi beat Mylan's prices it succeeded." Pet.App.59a.

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[4] *Amicus* AAN's criticisms of drug pricing practices (Br. 11-12), while unfounded (see Pet.App.70a), apply as fully to Sanofi's rebates as to Mylan's. Likewise, AAN's claim that the Tenth Circuit "focused on the wrong market" (Br. 1) is both incorrect and not presented by Sanofi's petition. AAN's brief thus provides no support for granting review.

Fourth, Mylan did not coerce PBMs into signing any contracts. Pet.App.72a-73a, 210a-219a. Sanofi "fail[ed] to marshal any evidence to support" its "novel theory of coercion." Pet.App.74a, 78a-79a. Rather, "PBMs entered exclusive deals with *both* Mylan and Sanofi whenever they offered the most advantageous terms," and "exclusivity was not *forced upon* PBMs," but rather "*was wielded by* PBMs to push for more competitive pricing." Pet.App.75a (emphasis added) (citing Pet.App.132a-154a), 79a (citing Pet.App.129a-130a). "Unlike [*United States* v. *Dentsply Int'l, Inc.*, 399 F.3d 181 (3d Cir. 2005)], *ZF Meritor*, or *McWane*, no PBM[s] testified that they felt compelled to enter into exclusive agreements with Mylan despite unfavorable terms." Pet.App.74a-75a. Moreover, "several PBMs testified that they could have excluded EpiPen in favor of Auvi-Q because they could shift product use from EpiPen to Auvi-Q." Pet.App.34a. The court below thus "join[ed] the district court in concluding there is no evidence in the record from which to infer coercion." Pet.App.79a.

In sum, "the clear answer to Sanofi's problem was offering better prices." Pet.App.17a. Both courts below were "in full agreement" that "Sanofi 'failed to present a triable issue that Mylan's rebate contracts foreclosed Sanofi' from competing" for "a substantial share of the market." Pet.App.53-54a (quoting Pet.App.230a). And without a factual predicate, there is no legal issue for this Court to resolve.

C. The undisputed record shows that an FDA recall, not Mylan, caused Sanofi's exit from the market.

Finally, there is no evidence that Sanofi was "intentionally excluded" from the epinephrine auto-

injector market *by Mylan*, or that *Mylan* "smother[ed]" it in "infancy." Pet. 25. The petition implies that Sanofi's market share continued to decline until it had no choice but to pull out of the market. In reality, Sanofi steadily gained market share from the moment it cut prices, "increas[ing] its investment in the brand" (Pet.App.34a) and winning accounts with ESI and CVS (Pet.App.57a-58a)—steadily that is, until October 2015, when Sanofi withdrew Auvi-Q from the market pursuant to an "FDA Class I recall." Pet.App.13a.

Remarkably, Sanofi never mentions the undisputed reason its product failed, stating only: "Auvi-Q was taken off the market." Pet. 9. But its "Class I recall" involved "a reasonable probability" that using Auvi-Q "w[ould] cause serious adverse health consequences or death." Pet.App.178a (quoting U.S. Food & Drug Admin., *Recalls Background and Definitions* (July 31, 2014)).[5] The recall came about after the FDA's "unannounced inspection" of a Sanofi facility (Pet.App.177a), "following reports that Auvi-Q was failing to inject epinephrine" (Pet.App.13a). Mylan had nothing to do with this.

* * *

Like its advocacy below, Sanofi's petition rests on "mischaracterization[s]" and "incomplete and cherry-picked" characterizations of the record. Pet.App.58a. Once these "serious evidentiary deficienc[ies]" (*ibid.*) are exposed, it is plain that Sanofi's petition rests on a raft of false premises—that Sanofi was an "equally * * * efficient rival[]," that it was unfairly kept "from

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[5] https://www.fda.gov/safety/industryguidance-recalls/recalls-background-and-definitions.

accessing significant channels of distribution," and that it was Mylan that forced Sanofi out of the market. Pet. i. Certiorari should be denied.

II. Sanofi's alleged circuit split is not presented on these facts and in all events is overstated.

Many of the same mischaracterizations of the record that preclude this Court from resolving the "question presented" also show why Sanofi's alleged circuit split, to the extent that it even exists, is not implicated by the court of appeals' factbound decision. Moreover, the ruling below closely tracks the decisions of other circuits and this Court, and Sanofi's allegedly conflicting cases involved dissimilar markets and discounting arrangements.

A. Sanofi kicks off its case for a circuit split with the tired theme that "Mylan's conduct would exclude equally or more efficient rivals—including ESI telling Sanofi that a 100% discount would not be sufficient to access the market." Pet. 16. According to Sanofi, this evidence "would have been treated as material in other circuits," as "all of them—except the Tenth Circuit—at least attempt to adhere to the equally efficient competitor principle." Pet. 16, 17; accord Pet. 2.

Nothing in the opinion below, however, remotely suggests that—were the facts as portrayed by Sanofi—the court would have "deemed that evidence immaterial." Pet. 17. The court simply ruled based on the *actual* evidence, which "doesn't present a triable issue whether EpiPen's non-contestable demand prevented Auvi-Q from competing as an equally efficient competitor." Pet.App.237a; see *supra* at 18-26. Here, as in Sanofi's own cases, "nothing in the record indicates that an equally efficient competitor was unable to compete with [Mylan]." *Eisai*, 821 F.3d at 406. It is

Sanofi, not the court below, that "refuse[s] to consider directly relevant evidence." Pet. 15.

In a variation on its theme, Sanofi says the ruling below further conflicts with Eighth and Ninth Circuit decisions that apply a price-cost "safe harbor" for exclusive dealing contracts that offer "above-cost discounting" (*Cascade Health Sols.* v. *PeaceHealth*, 515 F.3d 883, 904 (9th Cir. 2008))—and thus do not apply "a full rule-of-reason analysis." Pet. 20 (also discussing *Concord*, 207 F.3d at 1061).

But even assuming, *arguendo*, that the price-cost test would produce different results in some cases, it would not do so here. It is undisputed that Sanofi "had a higher [cost] profile" (Pet.App.16a), and Sanofi adduced no evidence whatsoever that Mylan priced its product below cost (Pet.App.193a-194a)—in fact, Sanofi's expert opined that Mylan priced above cost (Pet.App.19a). That likely explains why "Sanofi d[id] not dispute [below] that it cannot pass the price-cost test," which requires proof that "(1) the rival's low prices 'are below an appropriate measure of its rival's costs,' and (2) the rival had a 'dangerous probability[] of recouping its investment in below-cost prices.'" Pet.App.44a-45a n.7.

Moreover, Sanofi concedes that the price-cost test "derives from the equally efficient competitor principle," seeks "to discern whether a monopolist's conduct could exclude equally efficient rivals," and recognizes that discounts "attributable to the monopolist's 'lower cost structure * * * represent[] competition on the merits'"—all points that further undercut Sanofi's ability to satisfy the price-cost test. Pet. 4, 20 (quoting *Concord Boat*, 207 F.3d at 1061 (in turn quoting *Brooke Grp. Ltd.* v. *Brown & Williamson Tobacco*

Corp., 509 U.S. 209, 223 (1993))). Thus, a ruling from this Court adopting that test would only prolong the inevitable outcome of this litigation—a conclusion that "Sanofi's arguments do not raise a triable issue of exclusionary conduct." Pet.App.94a.

The record also forecloses Sanofi's claim of a conflict with Eleventh Circuit authority, which according to Sanofi has "found a monopolist's exclusionary contracts to be anticompetitive where they made it 'infeasible for distributors to switch' to new entrants." Pet. 3 (quoting *McWane*, 783 F.3d at 834). Setting aside that the Eleventh Circuit requires "a foreclosure percentage of at least 40%" as "a threshold for liability in exclusive dealing cases" (*id.* at 837), it is undisputed that many PBMs here switched to Sanofi once it began competing on price. *Supra* at 22-23.

B. More generally, the court of appeals carefully limited itself to a "fact-specific" ruling (Pet.App.46a, 4a (quoting *Am. Express*, 138 S. Ct. at 2284), and its reasoning accorded with that of other circuits. As Sanofi explains, the Third, Sixth, Eleventh, and D.C. Circuits apply the "'rule of reason,'" "asking whether the 'probable effect' [of the exclusive conduct] is to substantially lessen competition in the relevant market.'" Pet. 3 (alteration in original; citations omitted); see Pet. 15. Likewise, the court below applied the "rule of reason," asking "whether 'performance of the contract will foreclose competition in a substantial share of the line of commerce affected.'" Pet.App.46a (quoting *Tampa Elec.*, 365 U.S. at 327).

The court of appeals was also aligned with other circuits in requiring a showing that Sanofi was equal-

ly efficient (Pet.App.48a),[6] and in holding that § 2 exclusive dealing claims generally require the plaintiff to show "40% or 50%" market foreclosure—not just 31%. Pet.App.54a; see *McWane*, 783 F.3d at 837 ("at least 40%"); Areeda & Hovenkamp ¶ 1821c (under 40% foreclosure is "presumptively harmless"). Moreover, the court's qualitative foreclosure analysis tracked that of the other circuits, which consider the challenged contracts' "duration" and "ease of terminability," "percentage of the market foreclosed by the contracts," evidence of "coercion," actual success on the market, the use of exclusive dealing by competitors, and other probative evidence of the probable effect of the agreements. Compare Pet.App.50a, 55a-58a, with, *e.g.*, *Eisai*, 821 F.3d at 406-407; *Allied Orthopedic Appliances Inc.* v. *Tyco Health Care Grp. LP*, 592 F.3d 991, 996-998 (9th Cir. 2010); *Race Tires*, 614 F.3d at 78-79, 83; *Roland*, 749 F.2d at 394-395; Areeda & Hovenkamp ¶¶ 1821d2, 1821d3.

Far from suggesting a circuit split, much less one requiring this Court's intervention, the court below analyzed numerous decisions from other circuits (and this Court), carefully considering (and in a few cases

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[6] See *Barry Wright,* 724 F.2d at 232; *Eisai*, 821 F.3d at 406; *Int'l Air Indus., Inc.* v. *Am. Excelsior Co.*, 517 F.2d 714, 723 (5th Cir. 1975); *Conwood Co., L.P.* v. *U.S. Tobacco Co.*, 290 F.3d 768, 782 (6th Cir. 2002); *MCI Commc'ns Corp.* v. *Am. Tel. & Tel. Co.*, 708 F.2d 1081, 1113 (7th Cir. 1983); *Morgan* v. *Ponder*, 892 F.2d 1355, 1363 (8th Cir. 1989); *Cascade*, 515 F.3d at 907; *Marrese* v. *Am. Acad. Of Orthopaedic Surgeons*, 706 F.2d 1488, 1497 (7th Cir. 1983); see also Richard A. Posner, *Antitrust Law* 194-195 (Chicago 2d ed. 2001) (exclusionary conduct is "likely in the circumstances to exclude from the defendant's market an equally or more efficient competitor").

distinguishing) Sanofi's authorities.[7] Nowhere did the Tenth Circuit suggest that another circuit had erred, or that it needed to break from settled law governing exclusive dealing cases. And the court certainly did not create a circuit split in issuing a "fact-specific" decision. Pet.App.46a.

C. Finally, the cases that Sanofi cites as evidence of a circuit split involve wholly dissimilar facts. Pet. 2-4, 17-18. For example, most involved either bundled or market-share discounts,[8] neither of which is

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[7] See Pet.App.43a-46a, 53a-54a & n.9, 74a (*ZF Meritor*, 696 F.3d 254); Pet.App.43a, 71a, 73a-74a, 76a (*United States* v. *Dentsply Int'l, Inc.*, 399 F.3d 181 (3d Cir. 2005)). Pet.App.43a, 45a, 74a-75a, 80a (*McWane*, 783 F.3d 814); Pet.App.39a-40a, 49a-51a, 54a, 80a (*United States* v. *Microsoft Corp.*, 253 F.3d 34 (D.C. Cir. 2001) (en banc) (per curiam)); Pet.App.86a (*Cascade*, 515 F.3d 883); Pet.App. 44a-45a n.7, 69a, 72a, 83a (*Concord Boat*, 207 F.3d 1039); Pet.App.44a-45a & n.7, 75a-76a, 83a (*Eisai*, 821 F.3d 394); Pet.App.85a (Sanofi "disclaimed the per se test" of *LePage's*, 324 F.3d at 155 (en banc)); Pet.App.89a (*LePage*'s per se illegality theory "was explicitly disavowed by Sanofi at oral argument. Oral Argument at 7:31").

[8] *Cascade*, 515 F.3d at 900 ("bundled discounting"); *Eisai*, 821 F.3d at 409 ("bundling""); *LePage's*, 324 F.3d at 154 (defendant "bundl[ed] the rebates," "set customer-specific target growth rates in each product line," and "linked" the "size of the rebate * * * to the number of product lines in which targets were met"); *Microsoft*, 253 F.3d at 88 ("bundled price, with no discount for a browserless OS"); *ZF Meritor*, 696 F.3d at 288 ("long-term agreements offering market-share or volume discounts.");; *Concord Boat*, 207 F.3d at 1044 ("volume discount of up to 5% based on the quantity of engines purchased").

at issue here, or distinct markets lacking the unique features of pharmaceutical markets.[9]

III. Sanofi's other attempts to demonstrate the importance of this case are unconvincing.

Beyond asserting a circuit split that, if it exists at all, is not implicated on these facts, Sanofi offers no serious argument that the ruling below warrants certiorari. In fact, most of Sanofi's importance argument (Pet. 21-23) simply repeats its position that "courts cannot agree" on how to apply *Tampa Electric*—that the court below "disregarded the equally efficient competitor standard" and "price-cost test" applied by other circuits. Pet. 21-22. We stand by our answers. See *supra* at 28-33.

Sanofi says certiorari is warranted on account of the "frequency" with which the issue here arises. Pet. 21. But one searches the petition in vain for supporting statistics or analysis.

Quoting a snippet from the decision below, Sanofi declares that review is warranted because the Tenth Circuit held that it "must evaluate Mylan's exclusionary conduct separately." Pet. 10 (quoting Pet.App.42a). But that statement looks quite different together with the very next sentence: "Only then can we evaluate the evidence in totality to see if any 'synergistic effect' saves Sanofi's case." Pet.App.42a

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[9] *LePage's*, 324 F.3d at 145 ("transparent tape market"); *ZF Meritor*, 696 F.3d at 263 ("heavy-duty 'Class 8' truck transmissions"); *McWane*, 783 F.3d at 819 ("ductile iron pipe fittings"); *Microsoft*, 253 F.3d at 47 ("operating system[s]"); *Conwood*, 290 F.3d at 774 ("moist snuff market"); *Cascade*, 515 F.3d at 900-901; *Concord Boat*, 207 F.3d at 1044 ("inboard and stern drive marine engines").

(citations omitted). What's more, the court later stated: "Considered separately or together, Sanofi's arguments do not raise a triable issue of exclusionary conduct." Pet.App.94a; accord Pet.App.248a (district court conclusion).

Sanofi also cites a withdrawn Department of Justice report stating that exclusionary contracts that leverage "uncontestable" share "may in theory produce anticompetitive effects." Pet. 18. But as the balance of the report states, above-cost pricing is generally lawful, and "[i]t would be absurd to require the firm to hold a price umbrella over less efficient entrants. * * * [P]ractices that will exclude only less efficient firms, such as [a competitor] dropping his price nearer to (but not below) his cost, are not actionable." U.S. Dep't of Justice, Competition and Monopoly: Single-Firm Conduct Under Section 2 of the Sherman Act 43 (2008) (quoting R. Posner, Antitrust Law 194-195 (2d ed. 2001)). As it is undisputed that Sanofi had "a higher [cost] profile" than Mylan (Pet.App.16a)—and that Sanofi "cannot pass the price-cost test" (Pet.App.44a-45a n.7)—the withdrawn report cuts against certiorari.

IV. Numerous other independent reasons make this case inappropriate for certiorari.

Sanofi's petition rests on the claim that the lower courts are divided over how the antitrust law treats exclusive-dealing contracts, together with the claim that the court below "disregarded the equally efficient competitor standard" and "price-cost test" applied by other circuits. Pet. 21-22. As we showed in Part I, the Tenth Circuit simply did not hold what the petition says it did. As we showed in Part II, any difference in approach to this question among the circuits

has no conceivable bearing on this case because, on this factual record, Mylan's conduct satisfies every standard. And as we showed in Part III, Sanofi offers no other convincing reason why this case is sufficiently important to warrant review.

In addition, there are at least three independent reasons why this case is an inappropriate vehicle for addressing the law of exclusive dealing.

First, Sanofi would face an alternative ground for affirmance even if the Court were to grant review and reverse. The district court ruled for Mylan "for this second and independent reason: The summary judgment record presents no triable issue of antitrust injury." Pet.App.254a-255a; see Pet.App.249a-255a.

Having found no antitrust violation, the Tenth Circuit chose not to reach antitrust injury. But Sanofi could not surmount that hurdle if it somehow prevailed in this Court on the question it purports to present. Specifically, Sanofi could not show on this record that the "challenged conduct affected the prices, quantity or quality of goods or services, not just [Sanofi's] own welfare." Pet.App.250a.

Rather, the record is "abundantly clear" that consumers *benefitted* from "price competition" sparked by Mylan's rebates. Pet.App.69a. As the district court explained, it is undisputed that Mylan's prices "dropped sharply" when Sanofi began competing on price, such that "no reasonable jury could conclude that Mylan's exclusive rebate agreements increased EpiPen prices." Pet.App.251a-252a. Likewise, "the undisputed facts show[ed] that [Sanofi's] output increased during the relevant time period," "most significantly between 2013 and 2015." Pet.App.253a. "[V]igorous price competition" and expanded output

are precisely what antitrust law "strenuously protect[s]." Pet.App.80a.

Nor did Mylan's conduct reduce consumer choice, as no patient was "prevented from purchasing Auvi-Q" (Pet.App.254a)—at least until Sanofi pulled Auvi-Q from the market due to an FDA Class I recall. The Tenth Circuit likewise found it "abundantly clear in the record" that "PBMs used exclusivity to encourage price competition" "to the ultimate benefit of consumers." Pet.App.69a (citations omitted). That is the very end that the antitrust laws aim to serve.

In sum, regardless of the outcome on the question whether Mylan's conduct violated § 2 of the Sherman Act—which both courts below got right—the only effect of certiorari would be to delay the inevitable ruling for Mylan.

Second, Sanofi's petition raises a host of unfounded factual disagreements with the courts below. It is not worth the Court's time and effort to comb through a summary judgment record on which all four judges below agreed. But if the Court did so, it would find that Sanofi relies on "mischaracterization[s]" and "incomplete and cherry-picked" assertions that are foreclosed by the actual record. Pet.App.58a; see *supra* at 17-28.

Third, the record here would provide an atypical vehicle to take up the law of exclusive dealing. As Sanofi conceded in discussing the "use of exclusive contracts" below, not only is drug pricing in general unique, but "the court shouldn't compare *the* [*epinephrine auto-injector*] *drug market* with other pharmaceutical products" because of its "unique differences." Pet.App.220a (emphasis added). Thus, by

Sanofi's own admission, the facts here would limit the import of any ruling from the Court.

CONCLUSION

For the foregoing reasons, the petition for certiorari should be denied.

Respectfully submitted.

MICHAEL W. MCCONNELL
Wilson Sonsini Goodrich & Rosati, P.C.
650 Page Mill Road
Palo Alto, CA 94304
(650) 493–9300

CONSTANDINOS HIMONAS
Wilson Sonsini Goodrich & Rosati, P.C.
15 West South Temple
Salt Lake City, UT 84101
(801) 401-8510

STEFFEN N. JOHNSON
Counsel of Record
KEITH KLOVERS
KELSEY J. CURTIS
Wilson Sonsini Goodrich & Rosati, P.C.
1700 K Street, N.W.
Washington, DC 20006
(202) 973–8800
sjohnson@wsgr.com

Counsel for Respondents

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