No. 22-

In the Supreme Court of the United States

SANOFI-AVENTIS U.S., LLC, PETITIONER

v.

MYLAN, INC., AND MYLAN SPECIALTY, LP, RESPONDENTS

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

PETITION FOR A WRIT OF CERTIORARI

JOSHUA HALPERN
WEIL, GOTSHAL & MANGES LLP
2001 M Street NW, Suite 600
Washington, D.C. 20036
(202) 682-7000

GREGORY SILBERT
Counsel of Record
YEHUDAH L. BUCHWEITZ
ERIC S. HOCHSTADT
WEIL, GOTSHAL & MANGES LLP
767 Fifth Avenue
New York, N.Y. 10153
(212) 310-8000
gregory.silbert@weil.com

QUESTION PRESENTED

This Court has held that when a firm "attempt[s] to exclude rivals on some basis other than efficiency," that conduct is unlawfully exclusionary. *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 605 (1985) (citation and quotation marks omitted). A number of lower courts have applied this principle to monopolization claims based on exclusive dealing, holding that a monopolist's exclusive contracts are anticompetitive if they "can exclude equally efficient (or potentially equally efficient) rivals." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 281 (3d Cir. 2012).

Respondents' EpiPen held a monopoly in the market for devices to treat a life-threatening allergy condition. When Petitioner launched the first true rival to EpiPen, Respondents used their +90% durable monopoly share to threaten—and indeed punish—market participants for even considering purchasing a competing product from Petitioner. Respondents' penalties were sufficient to exclude competition regardless of the rival's efficiency or price—the largest dealer in the United States informed Petitioner that *even a 100% discount* would not be enough to access consumers. That evidence would have been material under the approach endorsed by Third, Sixth, Eleventh, and D.C. Circuits. Yet, the Tenth Circuit refused to consider it.

The question presented is: When a monopolist's exclusionary conduct would foreclose equally (or potentially equally) efficient rivals from accessing significant channels of distribution, is the monopolist's conduct anticompetitive under § 2 of the Sherman Act?

CORPORATE DISCLOSURE STATEMENT

Per Supreme Court Rule 29.6, Applicant Sanofi-Aventis U.S. LLC certifies that it is a wholly owned subsidiary of Sanofi, and no publicly held company owns 10% or more of its stock.

RELATED PROCEEDINGS

United States District Court for the District of Kansas:

In re EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litigation, No. 2:17-md-02785-DDC-TJJ (Dec. 17, 2020)

United States Court of Appeals for the Tenth Circuit:

Sanofi-Aventis U.S., LLC v. Mylan, Inc. (*In re EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litigation*), No. 21-3005 (July 29, 2022)

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-94a) is published at 44 F.4th 959. The opinion of the district court (Pet. App. 95a-292a) is published at 507 F. Supp. 3d 1289.

JURISDICTION

The judgment of the court of appeals was entered on July 29, 2022. On October 19, 2022, Justice Gorsuch extended the time within which to file a petition for a writ of certiorari to and including Monday, November 28, 2022. The jurisdiction of this Court rests on 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Section 2 of the Sherman Act, 15 U.S.C. § 2, provides:

> Every person who shall monopolize, or attempt to monopolize, or combine or conspire with

> any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

STATEMENT

In the six decades since this Court last considered exclusive dealing,[1] the courts of appeals have developed conflicting tests for monopolization claims. But—until the Tenth Circuit's decision in this case—the courts on different sides of the split have all given effect to a core antitrust principle: the exercise of monopoly power is anticompetitive if it would exclude an equally efficient competitor from the market. Under this principle, evidence showing that an equally efficient competitor could not access the market is directly relevant to a monopolization claim. The court below, by contrast, deemed exactly that kind of evidence immaterial as a matter of law.

In the Third Circuit—where this case was originally filed—a "monopolist willfully ... maintains monopoly power when it competes on some basis other than the merits." *LePage's Inc. v. 3M,* 324 F.3d 141, 147 (3d Cir. 2003) (en banc) (citing *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 605 n. 32 (1985)). Applying this standard, the Third Circuit has found exclusionary contracts to be anticompetitive where they require dealers to exclude new entrants in order to retain

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[1] *See Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320 (1961).

access to a monopolist's "necessary products," *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 277 (3d Cir. 2012), or "to avoid being severely penalized financially;" *LePage's,* 324 F.3d at 159; *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 190 (3d Cir. 2005). Similarly, the Eleventh Circuit found a monopolist's exclusionary contracts to be anticompetitive where they made it "infeasible for distributors to switch" to new entrants. *McWane, Inc. v. FTC*, 783 F.3d 814, 834 (11th Cir. 2015) (quotation marks and alteration omitted). And the D.C. Circuit affirmed a finding of exclusionary conduct where Microsoft's exclusive deals had "a significant effect in preserving its [operating system] monopoly; they help[ed] keep usage of Navigator below the critical level necessary for Navigator or any other rival to pose a real threat to Microsoft's monopoly." *United States v. Microsoft Corp.*, 253 F.3d 34, 71 (D.C. Cir. 2001) (en banc). These decisions recognize that "exclusive dealing arrangements" "harm competition" if they "can exclude equally efficient (or potentially equally efficient) rivals." *ZF Meritor*, 696 F.3d at 281.

This does not mean exclusive dealing by a monopolist is *per se* unlawful. These courts apply the "rule of reason," asking whether the "'probable effect' [of the exclusive conduct] is to substantially lessen competition in the relevant market," *ZF Meritor*, 696 F.3d at 268, and, if so, whether the monopolist's conduct can nonetheless be justified by "valid business reasons," *LePage's*, 324 F.3d at 163; *e.g.*, *Conwood Co. v. U.S. Tobacco Co.*, 290 F.3d 768, 783 (6th Cir. 2002).

In some exclusive dealing cases, other circuits have instead applied a "price-cost" safe harbor—a rule of *per se* legality. *See, e.g.*, *Cascade Health Sols. v. PeaceHealth*, 515 F.3d 883, 900 (9th Cir. 2008) ("part[ing] ways with the Third Circuit by adopting a cost-based standard"). Drawing from this Court's predatory pricing (as opposed to exclusive dealing) precedents, they have held that a monopolist's conduct is lawful as long as the monopolist's prices "are above some measure of incremental cost." *Id.* at 901 (citing *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 223 (1993)). Although it differs from the rule-of-reason analysis by interposing a new threshold defense, the price-cost safe harbor also derives from the equally efficient competitor principle. It is premised on the idea that exclusion achieved through above-cost discounts can be attributable to the monopolist's "'lower cost structure ... and so represents competition on the merits.'" *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1061 (8th Cir. 2000) (quoting *Brooke Grp.*, 509 U.S. at 223).

In this case, there was robust evidence that respondents (collectively, Mylan) intentionally maintained their monopoly by structuring exclusionary contracts so that an equally efficient competitor could not access the market. As one buyer told petitioner Sanofi, even *a 100% discount*—giving its products away for free—would not be enough to access consumers, because of the penalty Mylan would inflict for allowing competition. But the court of appeals never even considered this or other evidence showing that Mylan wielded monopoly power to exclude competition and maintain its monopoly. Instead, the court deemed this evidence immaterial as a matter of law and then granted summary judgment to Mylan.

1. For decades, EpiPen held an entrenched monopoly in the market for epinephrine auto-injectors, devices used to treat a life-threatening allergy condition called anaphylaxis. As Mylan, the seller of EpiPen, put it: "we are the market for anaphylactic shock with over 98%

market share." 6 CA10 Joint Appendix ("JA") 1142. EpiPen was the only device patients knew, the only one that a network of grandparents, babysitters, and school nurses were trained to use in life-threatening emergencies. According to Mylan's sworn testimony in a different case, "substitution" away from EpiPen "presents a distinct concern for patient safety." 4 JA 809.

The evidence in this case showed that a substantial portion of Mylan's monopoly market share—as much as 70%—was non-contestable, meaning that consumer demand is "sticky" and would not move to a new rival in the short term. A new entrant could compete only for the contestable portion of the market, as patients and their networks of caretakers gradually became acclimated to a different emergency-use device.

The evidence also showed that Mylan used its non-contestable share and monopoly power to maintain its monopoly and prevent competition from EpiPen's first and only true rival, Sanofi's Auvi-Q. Launched in 2013, Auvi-Q had the same active ingredient as EpiPen (epinephrine) but a new and more advanced means of delivery.

Aware that Auvi-Q "will be a significant threat to our EpiPen business," App. 104a, Mylan resolved to "block further competition," 51 CA10 Sealed Joint Appendix ("SJA") 11498, and "restructure [its existing] contracts for exclusivity," App. 15a. To prepare for Auvi-Q's launch, Mylan—which then had over 99% market share—exercised its monopoly pricing power to raise EpiPen prices three times, by 30%, in a single year. Then it offered pharmacy benefit managers (PBMs), who negotiate drug prices and coverage for insurers, a steep discount off those increased prices—but only if they agreed to exclude Auvi-Q from insurance coverage. As one Mylan executive explained, "We will only pay rebates if a client is willing to exclude Auvi-Q." App. 215a.

Mylan's non-contestable share and monopoly power ensured that its discount offers (conditioned on exclusion) would be much more valuable to PBMs than Sanofi's or any potential rival's, regardless of efficiency. A PBM that refused to exclude Auvi-Q would have to pay the undiscounted price for the share of EpiPens that was non-contestable. And with Mylan's monopoly pricing power, it could set the undiscounted price at a level that would offset any potential discount offered by a competitor. The court below illustrated this effect using the example of a monopolist with non-contestable share of 70%—within the range that Mylan itself claimed was non-contestable during this period, and the range of non-contestable share found by Sanofi's expert (and deemed admissible by the district court). As the court explained, if monopolist Firm A offered distributors a 10% rebate conditioned on excluding Firm B, then "Firm B would need to offer a 33.3% rebate on each widget to make the distributor indifferent between (a) buying exclusively Firm A's widgets or (b) buying seven widgets from Firm A, and three from Firm B." App. 84a n.21.

And, of course, if the monopolist offered rebates higher than 10% conditioned on exclusion—as Mylan did—the rival would have to discount its products even further. A monopolist with high non-contestable share can compel a rival to discount its products over 100%—*pay the buyer* to take the product—just to access the contestable portion of the market. A monopolist with non-contestable share can therefore break the competitive process to maintain its monopoly. It can prevent equally or more efficient competitors from competing by setting the delta between its undiscounted and discounted prices large enough so that the rival could never close the gap. And it can exclude competition in this way while continuing to earn monopoly profits and raise prices for consumers.

That is exactly what Mylan did. Market analysts correctly predicted that Sanofi would need to provide rebates multiples higher than Mylan to even merit consideration. 51 SJA 11368. After hiking up prices 30% to anticipate Auvi-Q's launch, Mylan began offering much bigger discounts than it had in the past, but conditioning them on exclusion (even though no device in this class had ever been excluded from insurance coverage).[2]

There was a mountain of evidence—unmentioned by the court of appeals—that Mylan wielded monopoly power to exclude competition on grounds other than efficiency. For example, the largest PBM, Express Scripts Inc. (ESI), told Sanofi that a 100% discount would not be enough to access the market. And it was not just talk. ESI excluded Auvi-Q even though Sanofi offered to discount more than Auvi-Q's entire book of business with ESI—$18 million in savings on a different Sanofi product—just to allow Auvi-Q to reach consumers. Sanofi later had to double that amount to $36 million, an effective Auvi-Q discount of well over 100%, just to claw back the access required to even attempt to compete against EpiPen.

Another PBM reported being held "hostage" by Mylan's exclusionary tactics. And yet another large PBM, MedImpact, excluded Auvi-Q only after Mylan explicitly threatened to punish it using non-contestable

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[2] As Auvi-Q was preparing to launch, PBMs widely reported that their "main objective [was] to provide easy and open access" to all epinephrine auto-injectors. 16 JA 3535. But Mylan knew PBMs would be "heavily impacted if they work[ed] against us," and that the threat of "lost rebate $'s" could be leveraged to exclude Auvi-Q. App. 125a.

share. Sanofi had offered a better per-unit price, and MedImpact first told Mylan—but not Sanofi—that it would prefer Auvi-Q and exclude EpiPen. Mylan shot back that even if EpiPen were blocked, EpiPen would still "maintain[] 40% - 70% market share," App. 236a. And Mylan threatened to "terminate its current contract," and require MedImpact's members to buy EpiPen at a higher list price. 36 SJA 8101. MedImpact and Mylan then quickly agreed on a revised Mylan offer to exclude Auvi-Q instead. When Sanofi heard this "surprising news," 5 JA 902, it went to MedImpact *that very same day* and asked for a chance to increase the offer, 29 SJA 6429. But MedImpact refused even to consider any terms Sanofi might propose. MedImpact later told Sanofi that it would need to double Mylan's rebate to "even open the conversation" about restoring access. App. 155a.

Sanofi's *internal, contemporaneous* analysis confirmed that no Auvi-Q price could be low enough to offset Mylan's access penalty: "Epi-Pen's high market share coupled with high discount creates *an obstacle that cannot be overcome via discounting*." Appellant's Br. 39, ECF No. 010110529173 (emphasis added). In particular, Sanofi's analysis showed that, because of EpiPen's dominant market position, Sanofi would have to discount Auvi-Q by more than 100% to offset the "increase in EpiPen's cost to [the] plan" if the plan gave access to Auvi-Q. *Id.* In other words, a competitor (even a more efficient one) could not access the market by offering a better product at a better price than EpiPen.

Mylan's plan to "block further competition" worked exactly as Mylan intended. 51 SJA 11498. Its exclusionary contracts with PBMs blocked Auvi-Q from approximately 31% of the market. Mylan then amplified this foreclosure using what it called the "spillover effect."

Mylan's research confirmed that doctors would not regularly prescribe Auvi-Q unless it was covered by more insurers. So Mylan devised a marketing plan to "put Sanofi out of business," App. 149a, in which Mylan sales representatives warned doctors not to prescribe Auvi-Q because one-third of their patients would be unable to get it. Mylan also knew the exclusions would cause some doctors to "*erroneously* presume [EpiPen] is safer or more effective than [Auvi-Q]," 4 JA 816, and Mylan's marketing materials actively promoted this misunderstanding, falsely suggesting Auvi-Q had been excluded for "clinical" reasons, App. 150a.

Even as it excluded its only competitor, Mylan continued to increase prices for the EpiPen. Indeed, even Mylan's *net* price—after the substantial rebates it paid to exclude Auvi-Q—rose from $111 in early 2013, the year Auvi-Q launched, to $150 in late 2015, when Auvi-Q was taken off the market. Mylan's profits per pen in 2013-2015 (when Auvi-Q was on the market) far exceeded 2012 (pre-Auvi-Q) levels. App. 119a. That Mylan's net price *increased* when there was competition shows the competitive process was broken.

2.a Sanofi filed this Sherman Act § 2 monopolization case against Mylan in the District of New Jersey in 2017. The Judicial Panel on Multidistrict Litigation transferred the case to the District of Kansas. Following the close of coordinated discovery with the other cases in Kansas, Sanofi requested a remand to the District of New Jersey, but the District Court for the District of Kansas declined.

In December 2020, the district court issued two decisions relevant to this petition. One decision rejected Mylan's *Daubert* challenge to the opinion of Sanofi's expert economist concerning Mylan's non-contestable (or entrenched) share. The court deemed this evidence suitable for a jury because the expert "provided a reliable basis for considering each piece of evidence to reach her conclusion that Mylan had an entrenched share of 50-70% of the [epinephrine auto-injector] market." *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, No. 17-md-2785-DDC-TJJ, at 77 (D. Kan. Dec. 17, 2020), ECF No. 2253-1. Mylan did not appeal this *Daubert* ruling.

The second decision granted summary judgment to Mylan. The district court concluded "that Mylan's exclusive 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 [epinephrine auto-injector] market." App. 230a. Sanofi appealed the order granting summary judgment.

2.b. The Tenth Circuit affirmed. Despite this Court's admonition that anticompetitive conduct is "not to be judged by dismembering it and viewing its separate parts, but only by looking at it as a whole," *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962), the Tenth Circuit took the opposite approach: "We reject this argument. For the sake of accuracy, precision, and analytical clarity, we must evaluate Mylan's exclusionary conduct separately." App. 42a (citation omitted). The court therefore did not consider the significance of Mylan's non-contestable share until page 77 of its decision.

When it finally reached the issue, the court held that Mylan's use of non-contestable share was immaterial as a matter of law. The court therefore never even mentioned (in its 89-page opinion) the evidence that Mylan used non-contestable share and monopoly pricing power to structure exclusionary contracts so that equally efficient competitors could not compete. The court never mentioned, for example, that ESI told Sanofi a 100% discount would not be enough to access the market; that Mylan told MedImpact EpiPen would retain 40%–70% share if MedImpact tried to exclude it; that Sanofi's contemporaneous internal analysis showed it would need discounts above 100% to offset Mylan's penalty for giving access to Auvi-Q; or other similar evidence.

Instead of examining the *facts* in the summary judgment record, the court searched for a *theory*. Sanofi had provided it with one that would have prevailed in other circuits: "Because giving Auvi-Q away for free would not have been enough to access consumers at the largest payor, this was clearly a market where an equally efficient competitor was unable to compete." Reply Br. 7, ECF No. 010110594702 (quotation omitted). But the Tenth Circuit believed some additional "legal standard" was needed to "evaluate [whether] Mylan's leveraging of entrenched share ... is a material issue of fact." App. 85a. It rejected what it described as the "legal theory Sanofi seemed implicitly to rely upon," which it called "*LePage's* per se illegality" standard. App. 89a. But *LePage's* did not apply a per se liability rule. It was a rule-of-reason (not per se) case, just like this one.[3]

Having rejected Third Circuit precedent—under which Mylan's non-contestable share plainly is mate-

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[3] The lower court stated that "Sanofi wisely disclaim[ed] the per se test" at oral argument, which the court then construed to be a "disavow[al]" of *LePage's*. App. 85a, 89a. But since *LePage's* actually applied a rule-of-reason standard, Sanofi's acknowledgement at oral argument that this is a rule-of-reason case did not implicitly disavow *LePage's* or any of the other precedents Sanofi relied on.

rial—the court faulted Sanofi for "not provid[ing]" a different theory. App. 84a-85a. It identified what it said were three alternatives, but none of the supposed alternatives was actually a theory of liability. Two of them were *safe harbors*—per se rules of *non*-liability that operate as threshold defenses. Those are the price-cost test and the discount-attribution test.

The price-cost test—which this Court has applied to predatory pricing, but never exclusive dealing—states that a defendant's pricing behavior cannot give rise to antitrust liability unless "the prices complained of are below an appropriate measure of [the defendant's] costs." *Brooke Grp.*, 509 U.S. at 222; *see also Eisai, Inc. v. Sanofi-Aventis U.S., LLC*, 821 F.3d 394, 409 (3d Cir. 2016) (under "the price-cost test ... above-cost pricing ... is *per se* legal"). The discount-attribution test is an application of "*Brooke Group*'s safe harbor for above-cost discounting" to bundled product discounts, which are not present in this single-product case. *Cascade*, 515 F.3d at 904.[4]

The point of the price-cost test (and its discount-attribution application) is to provide a safe harbor for low prices *unless* "discounts have the potential to exclude a *hypothetical* equally efficient" competitor. *Cascade*, 515 F.3d at 906. But a monopolist with high non-contestable share undoubtedly *can* exclude equally or more efficient competitors. If it conditions discounts on exclusion, it can set the delta between its undiscounted and discounted

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[4] A "bundled discount" is when a buyer must purchase specified amounts of Product A to receive a discount on a different Product B. The "'discount attribution' standard" holds that there is no liability for such discounts unless, after allocating the "the full amount of the discounts ... to the competitive product," the "resulting price of the competitive product ... is below the defendant's incremental cost." *Cascade*, 515 F.3d at 906.

prices so that a rival would have to discount over 100% to access the contestable portion of the market. And because the monopolist's smaller discounts go further (they apply to non-contestable share too), the monopolist can exclude equally efficient rivals while keeping its discounted price above its own marginal cost.

The other alternative "theory" the court of appeals considered also is not a theory of liability. "Effective Entrant Burden" (EEB) is a tool proposed by Sanofi's expert to explain the burden a monopolist's non-contestable share places on new market entrants. Unlike the expert's conclusion that Mylan had non-contestable share of 50%-70%—which the district court found to be "reliable" in its *Daubert* ruling—EEB did not survive a *Daubert* challenge. That means Sanofi's expert could not use EEB at trial. But it does not mean direct evidence that Mylan actually used non-contestable share and monopoly pricing power to exclude competition is immaterial to whether Mylan intentionally maintained its monopoly.

Because the court did not consider Mylan's leveraging of non-contestable share to be material, the remainder of its analysis ignored Mylan's non-contestable share. The court found Sanofi was not substantially foreclosed from competing "because Mylan's exclusive rebate agreements were short and easily terminable." App. 55a. Other circuits hold that exclusive contracts are *not* terminable when, "'in spite of the legal ease with which the relationship can be terminated, the distributors have a strong economic incentive to continue buying defendant's product.'" *McWane*, 783 F.3d at 834 (quoting *Dentsply*, 399 F.3d at 194) (cleaned up). That was certainly true here, but the evidence—like ESI saying 100% discount wouldn't be enough—involved Mylan's non-contestable share, so the court disregarded it. Similarly, the court held Sanofi was not foreclosed because of "the absence of any coercion," even though Mylan actually did coerce payors by leveraging EpiPen's non-contestable share (like its threat to MedImpact to charge full price for the 40%-70% of the market it said it would retain if MedImpact tried to exclude EpiPen instead of Auvi-Q). App. 57a. And the court found that "exclusive rebate agreements were a normal competitive tool," without acknowledging that Mylan's monopoly and non-contestable share made its exclusionary demands anything but "normal" or that no device in this class had ever been excluded before Auvi-Q. App. 60a.

The court applied its theory-instead-of-facts approach to disregard other culpable conduct too. Mylan knew (as confirmed by its market research) that many doctors would not prescribe Auvi-Q unless it substantially increased its insurance coverage. Mylan explained this in a presentation it called "Understanding the 'spill over' effect." App. 148a-149a. But according to the Tenth Circuit, the spillover effect didn't exist. Substituting its own view of economic theory for the actual behavior of market actors, the court (incorrectly) stated that "[s]pillover foreclosure is predicated on a breakdown of rational behavior," which it called "a foundational principle of modern economics," and it therefore "refuse[d] to recognize" spillover. App. 64a-66a.[5] *But see Dentsply*, 399 F.3d at 189 ("The Supreme Court on more than one occasion has emphasized that economic realities rather than a formalistic approach must govern review of antitrust activity.").

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[5] It is perfectly rational for doctors to prescribe the dominant firm's product that is covered by insurance, rather than the new entrant's product that might not be covered.

REASONS FOR GRANTING THE PETITION

Except for the Tenth Circuit below, lower courts broadly agree that the exercise of monopoly power is anticompetitive if it would exclude an equally efficient competitor from the market. The lower courts diverge only on the question of how to best implement that standard at summary judgment. The Third, Sixth, and Eleventh Circuits apply a traditional rule-of-reason analysis, reviewing the full factual record for evidence that a monopolist has excluded rivals "on some basis other than the merits." In the Eighth and Ninth Circuits, by contrast, the plaintiff must first surmount a cost-based filter and prove that the monopolist priced below its marginal costs, before the Court will review the full record for anticompetitive conduct. The Tenth Circuit jettisoned both approaches and blazed a third path, in which it declined to apply the price-cost filter, yet still refused to consider directly relevant evidence. In the Third, Sixth, and the Eleventh Circuit, the direct evidence that Mylan's conduct was designed to exclude equally or more efficient rivals—for example, ESI's statement that even a 100% discount would not be sufficient for competitors to access the market—would plainly be material to whether Mylan unlawfully maintained its monopoly and impermissibly foreclosed the market. But the Tenth Circuit would not even consider it.

The question presented carries considerable importance to consumers and the business community alike. But because this Court has not addressed exclusive dealing for over sixty years, lower courts have been left with the awkward task of retrofitting those precedents to address modern commercial realities. That exercise has left the circuits divided and confused, and left the market without guidance on whether and when a monopolist's exclusive dealing violates the antitrust laws. This Court's intervention is necessary.

The court of appeals' decision is also wrong. The summary judgment evidence showed that Mylan penalized dealers so severely for carrying Sanofi's product that Sanofi had to discount over 100% just to access consumers through the largest dealer in the market. The Tenth Circuit deemed that evidence *immaterial,* despite the fact that it bears directly on whether an equally efficient competitor could access the market. That was contrary to this Court's settled approach, which is to "resolve antitrust claims on a case-by-case basis, focusing on the 'particular facts disclosed by the record.'" *Eastman Kodak Co. v. Image Tech. Servs. Inc.*, 504 U.S. 451, 467 (1992) (citation omitted). The Court should grant certiorari, reverse the Tenth Circuit's judgment, and inject some much-needed clarity into the law of exclusive dealing.

I. The Circuit Courts Are in Conflict as to When Exclusive Dealing by a Monopolist Raises a Triable Question at Summary Judgment

Mylan explicitly conditioned discounts on excluding rivals, and its discount structures were "heavily weighted" toward exclusion. 55 SJA 12405. There was direct evidence 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. This and other similar evidence is obviously material to whether Mylan intentionally maintained its monopoly and harmed the competitive process.

And it would have been treated as material in other circuits. While the courts of appeals have adopted different tests for exclusive dealing claims involving discounting, all of them—except the Tenth Circuit—at least attempt to adhere to the equally efficient competitor principle. In a case similar to this one, the Third Circuit sustained liability where a monopolist "used its position as a supplier of necessary products to persuade [buyers] to enter into [exclusive] agreements." *ZF Meritor*, 696 F.3d at 277. Like in this case, "losing the [monopolist] as a supplier was not an option," and if dealers purchased from a new entrant "there would still have been a significant demand from [consumers] for [the monopolist's] products." *Id.* at 278. Upholding liability for monopolization, the Third Circuit explained that the monopolist's "exclusive dealing arrangements can exclude equally efficient (or potentially equally efficient) rivals, and thereby harm competition, irrespective of below-cost pricing." *Id.* at 281.

Similarly, in *LePage's*—which the Tenth Circuit misunderstood to be a "per se illegality" case—the en banc Third Circuit said of bundled discounts that "even an equally efficient rival may find it impossible to compensate for lost discounts on products that it does not produce." 324 F.3d at 155 (quoting Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 749, at 83-84 (Supp. 2002)). And in another Third Circuit case, where a plaintiff accused Sanofi of leveraging "incontestable demand" for a medication, the court rejected the claim because of a failure of proof: "[N]othing in the record indicates that an equally efficient competitor was unable to compete with Sanofi." *Eisai*, 821 F.3d at 406. Here, by contrast, there is abundant evidence that equally efficient competitors could not compete with Mylan's EpiPen, yet the Tenth Circuit deemed that evidence immaterial as a matter of law.

Other circuits faced with exclusive dealing claims likewise hold—contrary to the Tenth Circuit—that the exercise of monopoly power to exclude rivals without regard to efficiency is anticompetitive. Following guidance from this Court, the Sixth Circuit has explained in a case involving exclusive dealing and other misconduct that "'[i]f a firm has been attempting to exclude rivals on some basis other than efficiency, it is fair to characterize its behavior as predatory or exclusionary." *Conwood*, 290 F.3d at 783 (quoting *Aspen Skiing.*, 472 U.S. at 605). Similarly, the Eleventh Circuit found exclusive dealing to be anticompetitive where the monopolist "made it infeasible for distributors to drop the monopolist [] and switch to [a rival]." *McWane*, 783 F.3d at 838.

The U.S. Department of Justice too has explained that exclusionary conduct like Mylan's is anticompetitive:

> [C]ommentators and panelists generally agree that even where a single-product loyalty discount is above cost when measured against all units, such a discount may in theory produce anticompetitive effects, especially *if customers must a carry a certain percentage of the leading firm's products* and the discount is structured to induce purchasers to *buy all or nearly all needs beyond that "uncontestable" percentage from the leading firm.*

U.S. Dep't of Just., Competition and Monopoly: Single-Firm Conduct Under Section 2 of the Sherman Act 107

(2008) (emphasis added), available at https://www.justice.gov/sites/default/files/atr/legacy/2009/05/11/236681.pdf.[6]

Exclusionary contracts that leverage non-contestable share are anticompetitive because it is not the *low* (discounted) price that does the dirty work. It is the difference between that price and the *high* (undiscounted) price—set using the monopolist's pricing power—that coerces the exclusion of rivals. Even the most efficient new market entrant cannot compete against the penalty (undiscounted) price the monopolist can inflict on dealers for giving a competitor market access. As the Justice Department put it, when buyers "must purchase some substantial quantity from the monopolist," they "effectively are coerced by the *structure* of the discount schedule (as opposed to the level of the price) to buy all or substantially all of the supplies they need from the monopolist. Where such a result occurs, the Department believes that the volume discount structure would unlawfully foreclose competing suppliers ... and thus may be challenged." Competitive Impact Statement at 18, *United States v. Microsoft Corp.*, 56 F.3d 1448 (D.C. Cir. 1995) (No. 94-1564) (emphasis added), *available at* http://www.usdoj.gov/ atr/cases/f0000/0045.pdf.

In some circuits, defendants may assert a price-cost (or, in certain cases, discount-attribution) safe harbor to exclusive dealing claims involving discounting. These

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[6] The Justice Department subsequently withdrew this report because it was not sufficiently "aggressive[]" in its approach to monopolist who "use their dominance in the marketplace to stifle competition." *See* Press Release, U.S. Dep't of Just., Justice Department Withdraws Report on Antitrust Monopoly Law (May 11, 2009), available at https://www.justice.gov/opa/pr/justice-department-withdraws-report-antitrust-monopoly-law.

courts permit monopolists to point to above-cost pricing as a threshold defense, without a full rule-of-reason analysis. The price-cost defense is not available here because Mylan relied on non-contestable share (rather than low prices) to exclude competition. *See ZF Meritor*, 696 F.3d at 277 ("[B]ecause price itself was not the clearly predominant mechanism of exclusion, the price-cost test cases are inapposite, and the rule of reason is the proper framework ...."). But even when it does apply, the price-cost (or discount-attribution) test attempts to discern whether a monopolist's conduct could exclude equally efficient rivals. When low prices are the mechanism of exclusion, "a firm's ability to offer above cost discounts is attributable to 'the lower cost structure of the alleged predator'"—in other words, attributable to efficiency—"'and so represents competition on the merits.'" *Concord Boat*, 207 F.3d at 1061 (quoting *Brooke Grp.*, 509 U.S. at 223). The discount-attribution safe harbor applies this principle to bundled discounts, "mak[ing] the defendant's bundled discounts legal unless the discounts have the potential to exclude a *hypothetical* equally efficient producer." *Cascade*, 515 F.3d at 906.

When monopolists, like Mylan, can force new entrants to discount over 100% to access consumers, there is no question the monopolists can exclude equally efficient rivals. Regardless of efficiency, a competitor must price below zero—pay the buyer—in order to compete against the monopolist. The summary judgment record shows that this is precisely what happened in this case. But the Tenth Circuit deemed this evidence immaterial as a matter of law. That holding conflicts with the law of other circuits, the standards advanced by the Justice Department, and the decisions of this Court. *See Aspen Skiing*, 472 U.S. at 604 (monopolist's conduct is anticompetitive when it "attempt[s] to exclude rivals on some basis other than efficiency") (quotation omitted).

II. The Question Presented Is Important and Merits This Court's Review

Exclusive dealing is a commonly used "improper means of maintaining a monopoly," *Dentsply*, 399 F.3d at 187. Not all exclusive dealing is anticompetitive, but it is of particular concern when practiced by a monopolist because "a dominant firm can impose exclusive deals on downstream dealers to strengthen or prolong its market position," *McWane*, 783 F.3d at 827 (quoting IIIB Philip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 760b7, at 54 (3d ed. 2008) (cleaned up)). Despite the frequency and importance of this conduct, no one—neither businesses nor courts—can say with any confidence when exclusive dealing will be actionable. As a result, monopolistic conduct goes unchecked, competition and innovation are stifled, and consumers ultimately pay the price.

This Court "most recently considered an antitrust challenge to an exclusive contract in *Tampa Electric*," more than sixty years ago. *Microsoft Corp.*, 253 F.3d at 68. The Tenth Circuit found *Tampa Electric* to be "not particularly illuminating." App. 46a. In the absence of exclusive-dealing precedents from this Court, the lower courts have attempted to adapt principles from other areas of antitrust law that present different considerations. The result is that courts cannot agree (and parties cannot know) what test the courts will apply or even what they are testing for.

This case illustrates the confusion. The court of appeals disregarded the equally efficient competitor standard Sanofi had asserted, and faulted Sanofi for not proposing a cost-based standard like the price-cost or discount-attribution test. The Eighth and Ninth Circuits have applied cost-based standards in exclusive-dealing cases involving (multi-product) discounting, and the dissenters in *LePage's* (including then-Judge Alito) would have done so as well. *See Cascade*, 515 F.3d at 900 ("part[ing] ways with the Third Circuit by adopting a cost-based standard"); *Concord Boat*, 207 F.3d at 1061 (same); *LePage's*, 324 F.3d at 181 (Greenberg, J., dissenting) (same); *see also ZF Meritor*, 696 F.3d at 351 (Greenberg, J., dissenting) ("I believe the Supreme Court's precedent compels ... applying ... the *Brooke Group* price-cost test and granting a presumption of lawfulness to ... above-cost prices."). The Tenth Circuit believed "the price-cost test has some benefits," which it apparently did not find in the equally efficient competitor principle. App. 88a n.26.

The irony is that the whole point of the price-cost test is to apply the equally efficient competitor principle when a monopolist uses *low* prices to exclude rivals. *See, e.g.*, *ZF Meritor*, 696 F.3d at 333 (Greenberg, J., dissenting) ("This point is precisely where the *Brooke Group* price-cost test comes into play.... [W]here the contract ... provides discounted but above-cost prices ... any equally efficient competitor ... had an ongoing opportunity to offer competitive discounts to capture the ... business."). But 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. And Mylan did not use *low* prices to exclude Auvi-Q. It used *high* prices—the monopoly rent it would charge on the "40% - 70% market share" it told MedImpact it would maintain even if EpiPen were blocked. App. 236a. That is how Mylan could raise EpiPen's net price from $111 to $150 while simultaneously excluding a new rival. And, apart from being inapplicable, the price-cost test was not even in the right ballpark: it is a "*safe harbor* for above-cost discounting" to be deployed (if at all) as a threshold *defense*—not, as the Tenth Circuit believed, as a theory of materiality. *Cascade*, 515 F.3d at 904 (emphasis added).

This Court has "repeatedly emphasized the importance of clear rules in antitrust law." *Pac. Bell Tel. Co. v. linkLine Commc'ns*, 555 U.S. 438, 452 (2009). And this Court has explained that "[s]ummary judgments"—like the one granted here—"have a place in the antitrust field" because "[s]ome of the law in this area is so well developed that ... the rule at times can be divined without a trial." *White Motor Co. v. United States*, 372 U.S. 253, 259 (1963).

No one could seriously describe the law of exclusive dealing as "clear" or "well developed" after the 60+ year hiatus since this Court last addressed it. The lower courts do not know what test to apply or why. Some monopolists believe (with support in the pages of the Federal Reports) that they will be immune from any antitrust liability as long as they price above their own incremental cost. Other businesses believe (again with caselaw support) that no such immunity exists in exclusive dealing cases like this one. Without clear rules, firms cannot conform their conduct to the law; parties variously over- and under-enforce the Sherman Act; and the innovation from competition never fully materializes.

III. The Decision Below Is Incorrect

When a new market entrant cannot give away a better mousetrap for free because of the penalties the monopolist will inflict, that market is not competitive. Yet the Tenth Circuit concluded this fact was not even *material* to whether Mylan intentionally maintained its monopoly. So the court never mentioned that ESI told Sanofi a 100% discount on Auvi-Q would not be sufficient to access consumers and compete side-by-side with EpiPen. Just like the court never mentioned Mylan's threat to MedImpact—after MedImpact said it would accept Sanofi's better-priced offer—that Mylan would maintain "40 – 70% market share" even if MedImpact excluded it, and would cancel its contract so the plan would have to buy those millions of EpiPens at monopoly-increased prices. Like the court never mentioned Sanofi's internal, contemporaneous analysis concluding that "Epi-Pen's high market share coupled with high discount creates an obstacle that cannot be overcome via discounting." Appellant's Br. 39, ECF No. 010110529173 (emphasis added). Instead, the court vanquished this and other purportedly immaterial evidence from the record and then determined that "the clear answer to Sanofi's problem was offering better prices." App. 17a.

That was contrary to this Court's settled approach, which is to "resolve antitrust claims on a case-by-case basis, focusing on the '*particular facts disclosed by the record.*'" *Eastman Kodak*, 504 U.S. at 456 (citation omitted, emphasis added). Accepting Sanofi's evidence as true for summary judgment, Mylan's conduct was plainly anticompetitive. It leveraged its monopoly pricing power and non-contestable network of users to exclude its only potential rival so it could maintain its EpiPen monopoly. And there is no doubt Mylan's exclusionary tactics would keep equally efficient competitors from accessing consumers. No producer is so efficient that it can discount its products over 100% and still turn a profit.

The Tenth Circuit's approach permits monopolists like Mylan to break the competitive mechanism and deprive consumers of the protections of the antitrust laws. In *Tampa Electric*, this Court held a plaintiff must show that the "probable effect" of an exclusion is to "substantially lessen competition in a line of commerce." 365 U.S. at 326, 329. In Sherman Act § 2 cases like this one (involving unilateral action by a monopolist), courts find substantial foreclosure "even though the contracts foreclose less than the roughly 40% or 50% share usually required in order to establish a § 1 violation" (involving concerted activity). *Microsoft*, 253 F.3d at 70. Mylan's exclusive contracts locked Sanofi out of 31% of the market, and Mylan amplified that foreclosure to more than half the market with what it called "the spillover effect."

Beyond that, Mylan—which had over 99% of the market when Auvi-Q launched—intentionally excluded its *only* potential rival before the rival could build up sufficient market share to compete. As Mylan put it: "[I]f we d[o] not begin our 'war game' scenarios *now* and begin to restructure contracts [for exclusivity] *now* we may be too late to do it after Auvi-Q gets momentum." App. 15a.

In other circuits, a monopolist cannot maintain its monopoly by smothering a new entrant in its infancy: "When a monopolist's actions are designed to prevent one or more new or potential competitors from gaining a foothold in the market by exclusionary, *i.e.* predatory, conduct, its success in that goal is not only injurious to the potential competitor but also to competition in general." *LePage's*, 324 F.3d at 159; *see also McWane*, 783 F.3d at 836 ("[C]ompetitors and competition are linked ...: 'in a concentrated market with very high barriers to entry, competition will not exist without competitors.'") (quoting *Spirit Airlines, Inc. v. Nw. Airlines, Inc.*, 431 F.3d

917, 951 (6th Cir. 2005)); *id.* at 839 (finding harm to competition where monopolist's exclusionary contracts "stunted the growth of ... [its] only rival ... and prevented it from emerging as an effective competitor"). This case involves a highly concentrated market with high entry barriers, but the Tenth Circuit held that "[t]he monopolist's successful elimination of a rival alone is an insufficient condition to prove harm to competition." App. 50a.

The Tenth Circuit also held that "Mylan's exclusive rebate agreements were short and easily terminable," even though Sanofi could not restore access unless it discounted over 100% (paid the buyer). App. 55a. The Third and Eleventh Circuits, in contrast, correctly hold that, even if contractual terms allow for termination, an exclusive agreement is not easily terminable when "'the distributors have a strong economic incentive to continue buying defendant's product.'" *McWane*, 783 F.3d at 834 (quoting *Dentsply*, 399 F.3d at 194).

The Tenth Circuit ruled against Sanofi, but consumers were the real losers. Mylan prevented their insurance plans from covering a newer, better product to address a life-threatening health condition. And Mylan continued to raise EpiPen's prices for consumers, even as it excluded EpiPen's only potential rival and maintained its towering monopoly.

CONCLUSION

For the foregoing reasons, the Court should grant the petition.

Respectfully submitted.

JOSHUA HALPERN
WEIL, GOTSHAL & MANGES LLP
2001 M Street NW, Suite 600
Washington, D.C. 20036
(202) 682-7000

GREGORY SILBERT
Counsel of Record
YEHUDAH L. BUCHWEITZ
ERIC S. HOCHSTADT
WEIL, GOTSHAL & MANGES LLP
767 Fifth Avenue
New York, N.Y. 10153
(212) 310-8000
gregory.silbert@weil.com

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