No. 22-628

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

REPLY BRIEF FOR PETITIONER

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

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Other Authorities

INTRODUCTION

When a new entrant competing against a monopolist cannot give away its superior product for free, then something has gone badly wrong in the marketplace. That is what happened here.

The evidence at summary judgment showed that Mylan's exclusive EpiPen contracts penalized the largest PBM so heavily that even a 100% discount on Auvi-Q was not enough to access the market. In the Third Circuit and elsewhere, that evidence would have been *material* to the question of anticompetitive conduct because it shows that Mylan's exclusive contracts could foreclose even an equally-efficient competitor (EEC) from the market.

But without clear guidance from this Court, the Tenth Circuit refused to consider Sanofi's best evidence, deeming it immaterial as a matter of law. Mylan defends that decision by claiming the Tenth Circuit implicitly embraced the EEC test when it faulted Sanofi for having a higher cost structure than Mylan. But the EEC test asks whether *a hypothetical equally efficient competitor* could surmount the monopolist's exclusions to access the market, not whether the nascent competitor was in fact more efficient. Whatever errant "test" the Tenth Circuit applied, it wasn't the EEC standard adopted by the Third Circuit and others.

Alternatively, Mylan makes an extended harmless-error-style argument, insisting that the evidence ignored by the lower court was "just talk" and outweighed by other evidence in the summary judgment record. BIO 20-28. That is wrong and irrelevant. Sanofi is seeking this Court's review of the *legal*

standard under which the evidence should have been assessed, not the weight assigned to any particular piece of evidence. Mylan's myriad factual arguments pose no obstacle to this Court's review.

The decision below is wrong, but there is one point on which Sanofi and the Tenth Circuit agree: in the words of the authoring judge, "*this is an important case*," Oral Arg. 2:35-2:45,[1] one that will have dramatic consequences for our national economy. Businesses across the country face decisions every day about whether, and on what terms, to enter exclusive contracts. And while their conduct is regularly challenged, exclusive-dealing cases rarely percolate up to the courts of appeals, let alone this Court. That is why it has been more than a half-century since this Court last considered exclusive dealing, and why the court below characterized this Court's precedents as "not particularly illuminating" on the question presented. Pet. App. 46a. This Court should grant the petition and clarify that exclusive dealing by a monopolist is anticompetitive if it would exclude an equally efficient competitor from the market.

I. The Tenth Circuit Split from the Third Circuit and Others in Failing to Apply the Equally Efficient Competitor Test

The Tenth Circuit believed that Mylan's decision to leverage its noncontestable share was not "material" to the legal issue of anticompetitive conduct. As a result, the decision below never mentions that ESI, the largest PBM in the country, told Sanofi a 100% discount

---

[1] Available at https://www.ca10.uscourts.gov/sites/ca10/files/oralarguments/21-3005.mp3.

would not be enough to access the market; that Mylan successfully threatened another major PBM, MedImpact, that EpiPen was sticky and would retain 40%–70% share even if MedImpact tried to exclude it; and that Sanofi's contemporaneous internal analysis showed it would need discounts above 100% to offset Mylan's penalty for giving access to Auvi-Q. In the Third Circuit, where this case was originally filed, all of this evidence would have been material to whether "an equally efficient competitor was unable to compete" with Mylan's exclusive offer. *Eisai, Inc.* v. *Sanofi Aventis U.S., LLC*, 821 F.3d 394, 406 (3d Cir. 2016). But the Tenth Circuit declined to apply the EEC principle and disregarded this key evidence as a result.

Mylan offers two explanations for the decision below, but neither mitigates the case for certiorari.

First, Mylan attempts to shoehorn the decision below into alignment with EEC principles. BIO 17. Although the Tenth Circuit's 89-page opinion never once mentions (let alone endorses) the EEC test, Mylan claims to discern that test in the court's observation that "Sanofi was *not* as efficient as Mylan." BIO 18 (emphasis in original). According to Mylan, the EEC test "rests on the premise that Sanofi and Mylan were 'equally efficient,'" and Sanofi's claims failed because the new entrant with a technologically advanced product had a higher cost structure than the monopolist with 99% market share.

But Mylan fundamentally misunderstands the EEC test, and its effort to salvage the Tenth Circuit's opinion only further underscores the split created by the decision below. Under the EEC test, "[t]he relevant question is not . . . whether a particular plaintiff

was equally efficient, *but whether the challenged bundling practices would have excluded an equally efficient rival*." *Cascade Health Sols. v. PeaceHealth*, 515 F.3d 883, 906 (9th Cir. 2008) (emphasis added) (quoting 3 Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 749a at 322-23 (Supp. 2006)). The inquiry necessarily focuses on a *hypothetical* competitor, rather than the actual plaintiff, because (1) competitors do not know their rivals' confidential cost structures in advance of litigation, and (2) cost structures change over time and new entrants almost always have higher costs than established firms upon launch. *See id.*

According to Mylan, the Tenth Circuit applied an "actual competitor" version of the test, and permitted Mylan to escape liability for conduct that would have excluded any equally efficient rival, merely because Sanofi (a new entrant) was not *yet* as efficient as Mylan (an entrenched monopolist). Had the Tenth Circuit faithfully applied the EEC test used by other circuits, instead of its actual-competitor deviation, Sanofi's costs would not have provided a basis for dismissal. The Tenth Circuit split with the other circuits "in requiring a showing that Sanofi was equally efficient." BIO 30-31 (citing Pet. App. 48a).

Second, Mylan claims the split isn't dispositive because the evidence ignored by the Tenth Circuit would not have changed the outcome of summary judgment proceedings. In Mylan's words, it was all "just talk." *See* BIO 3, 19, 20.

That is wrong and beside the point. Sanofi's petition does not ask this Court to weigh pieces of evidence, but instead to clarify the proper standard for

exclusive dealing so that the Tenth Circuit can review all of the material evidence in the proper light. In any event, it wasn't just talk: ESI reversed its exclusion on Auvi-Q and allowed Sanofi to regain some market access, *only* because Sanofi agreed to discount Auvi-Q well above 100% with $36 million dollars in additional rebates from an entirely separate and unrelated product line. Pet. App. 79a. As the terms of Sanofi's reentry make clear, Mylan's exclusionary strategy made it impossible for competitors to access the market regardless of efficiency, unless they were willing to pay the buyer (discount over 100%) to take the product. Rather than grapple with that evidence, the Tenth Circuit simply ignored it—because, by Mylan's telling, Auvi-Q costs more to make than EpiPen.

The decision below thus squarely presents the question whether exclusive dealing claims against monopolists are governed by the EEC test applied in other circuits or instead by the nonsensical "competitor's actual costs" approach advocated by Mylan in its brief in opposition.

II. This Case Presents an Ideal Vehicle to Address the Standard for Monopolization Through Exclusive Dealing

Unable to meaningfully dispute the split, Mylan purports to identify a host of subsidiary findings by the lower courts that supposedly stand in the way of the question presented. BIO 20-28. But the standard for exclusive dealing is both independent of, and *antecedent to*, all of those purported obstacles. The lower courts' conclusions with respect to foreclosure, the voluntary recall, and antitrust injury were all infected by

their application of an incorrect legal standard for anticompetitive conduct. If this Court reverses on the question presented, and the Tenth Circuit is forced to grapple for the first time with Sanofi's evidence, all the subsidiary dominoes will fall on remand.

Quantitative foreclosure. Mylan argues Sanofi's exclusive dealing claim fails because it was foreclosed from less than "roughly 40%" of the market, pre-spillover, which Mylan claims is "the minimum threshold . . . that courts typically require for exclusive dealing claims." BIO 22. But that 40% threshold applies only in Section 1 cases involving non-monopolists. In Section 2 cases like this one involving monopolists, the lower courts agree that the "monopolist's use of exclusive contracts . . . may give rise to a § 2 violation even though the contracts foreclose less than the roughly 40% or 50% share usually required in order to establish a § 1 violation." *United States v. Microsoft Corp.*, 253 F.3d 34, 70 (D.D.C. 2001); *LePage's Inc. v. 3M*, 324 F.3d 141, 159 (3d Cir. 2003) (en banc) (same); *McWane, Inc. v. FTC*, 783 F.3d 814, 837 (11th Cir. 2015) (same). So once again, Mylan's attempts to rescue the decision below only highlight why it would lose in other circuits. That is a reason to grant cert, not deny it.

Mylan also claims Sanofi wasn't foreclosed from the market because it managed to "regain[] '80% commercial market' coverage" after reversing the exclusion at ESI. BIO 23 (quoting Pet. App. 34a). But, as already explained, Sanofi restored that access only by discounting beyond 100% of cost and paying $36 million in rebates on a different product. Pet. App. 79a.

These untenable conditions on market access exemplify, rather than undermine, Sanofi's foreclosure. This is the whole point of the EEC test: no company should be forced to give away its product just to have the privilege of competing against a monopolist. Sanofi was not "obliged to pursue any imaginable alternative, regardless of cost or efficiency, before it c[ould] complain that [Mylan] has restrained competition." *Buffalo Broad. Co. v. Am. Soc'y of Composers, Authors & Publishers*, 744 F.2d 917, 925 (2d Cir. 1984) (citation omitted). The Tenth Circuit reached a different conclusion only because it failed to consider the evidence through the "special lens" applicable to a monopolist like Mylan in determining whether its conduct would exclude an equally efficient competitor. *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 488 (1992) (Scalia, J., dissenting).

Qualitative foreclosure. Mylan also presents the issues of coercion, contract duration, and Sanofi's exclusive offers as additional obstacles to the question presented. But the Tenth Circuit's errant judgments on those issues flowed from its predicate failure to consider Sanofi's evidence. Had the Tenth Circuit applied the right test and considered all of the relevant evidence, it would have recognized that Mylan leveraged its entrenched "40%-70%" market share against any formulary that chose to favor Auvi-Q over EpiPen. Pet. App. 236a. It also would have understood that the duration and termination provisions in Mylan's contracts were a complete sideshow because Mylan's entrenched share made it practically "infeasible for distributors to . . . switch" away from EpiPen regardless. *McWane*, 783 F.3d at 834; *United States v. Dentsply*

Int'l, Inc., 399 F.3d 181, 189 (3d Cir. 2005) (same). And if the Tenth Circuit had applied the EEC test, it would have understood that Sanofi made exclusive offers to *restore access*, after Mylan had already successfully leveraged its entrenched share to foreclose competition. *See Standard Oil Co. v. United States*, 337 U.S. 293, 307 (1949) (distinguishing between the monopolist's exclusive dealing and the new entrant's efforts "to establish a foothold against the counterattacks of [the] entrenched" firm). Once this Court reverses on the operative standard for anticompetitive conduct, a fact-finder reviewing the full evidence would easily discern genuine issues for trial.

Voluntary recall. Mylan blames the product recall for Sanofi's long-run exit. But drug-device recalls are "commonplace," 22 CA10 Joint Appendix ("JA") 4836-37, and "EpiPen has undergone similar recalls but it hasn't affected its marketability," Daubert Op. 66. The reason Sanofi didn't bring the product back to market is that Mylan's exclusionary contracting strategy made it impossible to compete. Appellant's CA10 Br. 45-46. The Tenth Circuit would have recognized this, had it reviewed the full factual record under the correct EEC standard.

Antitrust injury. The Tenth Circuit never reached the question of antitrust injury, but Sanofi clearly suffered one. It is blackletter antitrust law that "competitors suffer antitrust injury when they are forced from the market by exclusionary conduct." *Viamedia Inc. v. Comcast Corp.*, 951 F.3d 429, 482 (7th Cir. 2020), *cert. denied* 141 S. Ct. 2877 (2021). As the Tenth Circuit has previously explained, "foreclosure of even a single significant competitor can lead to higher prices and

reduced output." *Lenox MacLaren Surgical Corp. v. Medtronic Inc.*, 762 F.3d 1114, 1119 & n.3, 1129 (10th Cir. 2014). And that is precisely what happened here. Once Mylan eliminated its first and only true rival, it was able to raise the EpiPen's price to such unprecedented levels that even Congress felt compelled to intercede.[2] Not only that, but Mylan's success in driving Sanofi from the market also left patients without lifesaving devices during the protracted EpiPen shortages of 2018 and 2019. Daubert Op. 93.[3] When Mylan pressed its "foot on [Auvi-Q's] throat," 4 JA 738, the anaphylaxis community paid the price, AAN Amicus Br. 16-20.

This case thus squarely presents the question whether exclusive dealing by a monopolist should be judged under the EEC standard.

III. The Question Presented Is of Fundamental Importance to the National Economy and to Consumers Nationwide

This is an important case with substantial implications for the national economy. That is why eight amicus briefs were filed in Tenth Circuit, and why many more will be filed if this Court takes up the question presented. Businesses of every kind face decisions every day about whether, and under what terms, to

---

[2] *See* Toni Clarke, *U.S. Lawmakers Blast Mylan CEO over 'Sickening' EpiPen Price Hikes*, REUTERS (Sept. 21, 2016), https://www.reuters.com/article/us-mylan-nl-epipen-congress/u-s-lawmakers-blast-mylan-ceo-over-sickening-epipen-price-hikes-idUSKCN11R2OG.

[3] *See* Meg Tirrell & Leanne Miller, *EpiPen Shortage Has Parents Struggling During Back-to-School Season*, CNBC (Aug. 17, 2018), https://www.cnbc.com/2018/08/17/epipen-shortage-has-parents-struggling-during-back-to-school-season.html.

enter exclusive dealing arrangements. While the EEC principle provides them a predictable and administrable standard, the Tenth Circuit's ad hoc "actual competitor" approach does the opposite, leaving firms to guess about their rivals' costs and new entrants without any protections until they've achieved economies of scale. As the authoring judge recognized at the outset of oral argument, "this is an important case." Oral Arg. 2:35-2:45.

Mylan offers no meaningful response to the importance of the issue on which the circuits are now divided. It claims the judgment below is "fact-specific," relevant only to pharmaceutical market for epinephrine auto-injectors, and inapplicable to cases involving "bundled or market-share discounts." BIO 30-33, 36-37. But Mylan's own contentions in the court of appeals prove otherwise. Mylan told the Tenth Circuit that "exclusive contracts are *common*," and that the exclusive rebates in this case are "economically indistinguishable" from market-share discounts and other rebate structures. Appellees' Br. 44, 49 n.19. While every exclusive dealing case is highly fact-specific, the problem here is that the Tenth Circuit applied the wrong *legal theory* to the facts, and that errant decision will have significant consequences for businesses and consumers economy-wide. AAN Amicus Br. 3-4, 14-20.

As the leading anaphylaxis patient group explains, "[t]he Tenth Circuit's decision undermines the welfare of the millions of Americans who suffer from anaphylaxis and depend on EAI devices in life-threatening situations." AAN Amicus Br. 4. Under the Tenth Circuit's logic, firms with Mylan's dominant share could attempt

to block any lifesaving drugs with impunity, on the *theory* that patients can always access those drugs by paying the full list price "out of pocket." Pet. App. 48a. But that dangerous holding blinkers *reality* for the millions of Americans without access to insurance or other assistance to pay for those drugs. AAN Amicus Br. 14-15, 19; *see also Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 528 (1983) ("Coercive activity that prevents its victims from making free choices between market alternatives is inherently destructive of competitive conditions . . . .").

The standard for exclusive dealing is thus vitally important, but it frequently evades this Court's review. That is because the overwhelming majority of non-frivolous antitrust cases end in settlement and not judgment on the merits.[4] And those cases that do end in judgment are almost always decided "on the ground that the plaintiff failed to show a substantial *anticompetitive effect*," and not based on the predicate issue presented in the petition regarding the standard for *exclusionary conduct*. *NCAA v. Alston*, 141 S. Ct. 2141, 2161 (2021) (emphasis added). That is why it has been more than seven years since a petition has even raised the standard for exclusive dealing under the antitrust laws. *See, e.g.*, Petition for Writ of Certiorari, *McWane, Inc. v. FTC*, 577 U.S. 1216 (2016) (No. 15-706). This case thus presents an important opportunity to revisit this issue and to fill the voids left by this Court's prior precedents, which the Tenth Circuit

---

[4] Robin D. Adelstein & Eliot Turner, *US: Settling Class Actions*, Global Competition Review (Feb. 2, 2021), https://globalcompetitionreview.com/guide/the-settlements-guide/first-edition/article/us-settling-class-actions.

rightly deemed "not particularly illuminating." Pet. App. 46a. Without guidance from this Court, the decision below will spawn even more confusion, businesses will be left guessing, and consumers will be left holding the bag.

* * *

Mylan wielded its dominant user network to break the epinephrine auto-injector market, foreclose its lone real competitor, and raise EpiPen's prices to unprecedented levels. That Sanofi could not give away its better mousetrap for free was clear evidence of this breakdown. But the Tenth Circuit failed to see the signs. It gave Mylan a free pass to monopolize, and it badly botched exclusive dealing law in the process. The decision below is unmoored from economic reasoning, it is at odds with common sense, and it would provide a blueprint for monopolists to break the competitive mechanism in future cases. This Court should grant the petition and inject some much-needed clarity into this area of the law.

CONCLUSION

For the foregoing reasons and those stated in the petition for a writ of certiorari, the petition should be granted.

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

MARCH 2023