

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*

**BRIEF FOR AMICUS CURIAE ALLERGY &
ASTHMA NETWORK IN SUPPORT OF
PETITIONER**

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INTEREST OF AMICUS CURIAE¹

The Allergy & Asthma Network is a leading non-profit patient-centered network uniting individuals, families, healthcare professionals, industry leaders and government decision-makers to improve health and quality of life for the millions of people affected by asthma, allergies, and related conditions. It has served as a leading advocate for patients for over 35 years, and seeks to ensure that federal and state laws, policies, regulations, and resources support its goal to achieve optimal health outcomes for people living with these chronic conditions.

SUMMARY OF ARGUMENT

A company that uses its market power to foreclose rivals from accessing significant channels of distribution engages in anticompetitive practice under the Sherman Act because it harms consumer welfare. The Tenth Circuit reached a contrary result here because it focused on the wrong market, leading it to ignore the effects of Mylan’s conduct on the consumers whose lives depend on epinephrine auto-injector (EAI) devices.

¹ No counsel for a party authored this brief in whole or in part, and no person other than amicus and its counsel made any monetary contribution intended to fund the preparation or submission of this brief. Counsel for both parties were timely notified of amicus’s intent to file this brief.

While recognizing that Mylan engaged in exclusionary conduct to protect the market position enjoyed by the EpiPen, the Tenth Circuit concluded that, as a matter of law, Mylan had not engaged in anticompetitive practices. The court did so by focusing on purported competition among drug manufacturers to be listed in drug formularies, the lists of drugs covered by particular health plans. Such formularies are generally created by pharmacy benefit managers (PBMs), which are purchasing cooperatives through which health plans collectively negotiate with drug manufacturers to establish pricing and rebates for medications. Here, Mylan combined its dominant and non-contestable market share, repeated price hikes for the EpiPen, and increased rebates to the PBMs to prevent a competitor from being listed on formularies. In doing so, it cut off its competitor's access to the primary channels of distribution for medical devices.

This Court has long recognized that the “fundamental goal” of antitrust law is to protect consumer welfare. *Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of Univ. of Oklahoma*, 468 U.S. 85, 107 (1984) (internal quotation marks omitted). The Tenth Circuit erroneously concluded that competition—even competition based on exclusionary conduct—among drug manufacturers in issuing rebates to PBMs provided a substitute for competition for consumers because benefits granted to PBMs would be passed on to those consumers. While perhaps defensible in theory, the Tenth Circuit’s belief falters in reality.

Academics and policymakers recognize that drug-makers’ competition to be included in formularies does

not align with the interests of consumers and patients. Thus, contrary to the Tenth Circuit’s assumption, competition for third-party payors does not necessarily advance the Sherman Act’s fundamental goal of promoting consumer welfare.

The pricing and competition for formularies described in the Tenth Circuit’s opinion affect consumers much differently than the third-party payors on which the court focused. Third-party payors benefit if both prices and rebates increase—they can pass on higher prices to patients and their caregivers while collecting the rebate payments for themselves. But patients are worse off when they have to foot the increased bill for their EAI devices. Moreover, rebates to third-party payors restrict patient choice when they are given in exchange for exclusive coverage, as was the case here. These rebates leave patients with fewer choices in the near-term and less innovation in the long-term. No price cuts offset these detriments for patients.

For a court to truly weigh consumer welfare, its analysis of competition in the EAI device market cannot focus solely, or even primarily, on rebates offered to woo third-party payors. It must focus more broadly on consumers’ costs and choices when purchasing EAI devices. The harms of a contrary approach are well illustrated here. Even as a new, alternative option entered the EAI device market, prices continued to rise despite no corresponding increase in production costs. And while distributors received rebates, this helped few consumers. Instead of lower prices and more choice as competition increased, millions of patients

paid higher prices while losing the opportunity to choose which EAI device to purchase.

The 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. Moreover, by propounding an analysis based on an inappropriately limited view of the scope of competition under section 2 of the Sherman Act, the Tenth Circuit's decision has the potential to do still further harm in future cases. This Court should grant the petition for certiorari and reverse the Tenth Circuit's judgment.

REASONS FOR GRANTING CERTIORARI

A. Mylan dominates the market for EAIs on which millions of Americans depend for life-saving treatment.

1. Millions of Americans suffer from anaphylaxis, a life-threatening allergic reaction, caused by food, insect, latex, environmental, or pharmaceutical allergens. Pet. App. 11a. If not treated immediately, anaphylaxis can be fatal. *Id.* EAIs are drug-device products that carry a dose of epinephrine in an auto-injector designed for fast, reliable use to treat anaphylaxis. *Id.*

EAI devices are designed for easy administration because, to be effective, they must be available quickly in an emergency. Physicians therefore recommend patients carry two EAI devices at all times in case of a

severe allergic reaction.² Moreover, EAI devices must be simple enough that any patient, parent, caregiver, or teacher can use them under the stress of anaphylaxis. Most EAI devices include labels instructing the patient, caregiver, or even an untrained bystander how to administer an injection.³

Each EAI device requires its own procedure for use. The unique procedure involved for their use means that EAI devices are generally not considered to be interchangeable at the pharmacy. Until 2018, pharmacists in most states could not substitute another EAI device for the device a patient was prescribed.⁴ Beginning in 2018, pharmacists had access to an approved, generic EpiPen and could substitute a generic EpiPen for a branded EpiPen.⁵ But a pharmacist cannot

² See *Paul A. Greenberger, MD; Dana V. Wallace, MD; Phillip L. Lieberman, MD; and Sean M. Gregory, PhD*, “Contemporary issues in anaphylaxis and the evolution of epinephrine autoinjectors,” 119 *Annals of Allergy and Asthma Immunology* 333, 335 (2017).

³ Jay Portnoy, M.D., Rolin L. Wade, M.S., Catherine Kessler, PhD, “Patient Carrying Time, Confidence, and Training with Epinephrine Autoinjectors: The RACE Survey” 7 *The Journal of Allergy and Clinical Immunology: In Practice*, Issue 7, at 2253 (Sept.–Oct. 2019) (“RACE Survey”).

⁴ Andrew Abe, PharmD, “Path to Approval First Truly Generic EpiPen,” *Pharmacy Times*, Oct. 8, 2018 (available at <https://www.pharmacytimes.com/view/path-to-approval-first-truly-generic-EpiPen>).

⁵ *Id.*

substitute a different type of EAI device such as Auvi-Q for a prescription for a branded EpiPen.⁶

Patients and caregivers are the ultimate purchasers of EAI devices. They, along with their physicians, determine which EAI device to purchase. Because the stakes are high, patients want a convenient and reliable EAI device that they can conveniently carry and that they and others can properly administer. Patients' failure to carry EAI devices is a documented problem. Pet. App. 12a.⁷ When choosing among EAI devices, physicians, patients, and caregivers consider features like reliability, size, ease of use, and price.

2. The EpiPen was introduced in the 1980s as the first EAI device. It was long the market leader and the only available EAI device. Pet. App. 12a. Between 2007 and 2012, EpiPen accounted for a least 90% of EAI prescriptions in the United States. Pet. App. 12a. As the Tenth Circuit noted, “[o]ther than a few fringe competitors, EpiPen was the epinephrine auto-injector market.” *Id.*

The EpiPen has changed little since it was first introduced approximately 40 years ago, and, for most of that time, patients enjoyed relatively stable prices. But in 2007, Mylan acquired the rights to the EpiPen and began sharply increasing prices. Between 2008 and 2016, Mylan raised the EpiPen’s Wholesale

⁶ *Id.*

⁷ See also Portnoy, et al., RACE Survey, 7 The Journal of Allergy and Clinical Immunology: In Practice, Issue 7, at 2255–58.

Acquisition Cost price six-fold from \$98.57 per unit in 2008 to \$608.61 in 2016. Pet. App. 118a.

In 2013, Sanofi launched a new EAI device called Auvi-Q. Unlike previous EpiPen competitors, Auvi-Q featured a different, rectangular shape, approximately the size of a credit card and the thickness of a smartphone. Pet. App. 13a. It also featured audio instructions on how to properly administer the injection. *Id.* Unlike EpiPen, Auvi-Q did not require a “swing and jab motion.” *Id.* Auvi-Q was, thus, offered as a more convenient way to carry and administer epinephrine than an EpiPen. Market research by Mylan and others found that Auvi-Q would be heavily favored by patients. Pet. App. 12a–14a. And while Mylan considered redesigning the EpiPen to match Auvi-Q’s advantages, it abandoned those plans as too expensive and time consuming. Pet. App. 14a.

B. Competition in the PBM market does not necessarily translate into benefits for drug consumers.

The Tenth Circuit erroneously focused its analysis on only part of the EAI device market, looking to the effects of Mylan’s conduct on drug providers rather than the patients who purchase and use the devices. The court discussed at length the structure of how pharmaceutical products like EAI devices are priced and sold, but did so with its eye trained almost entirely on the mechanisms used by third-party payors (primarily PBMs and health insurers) to manage classes of pharmaceuticals and obtain lower prices from pharmaceutical manufacturers. Pet. App. 3a–11a. The

court described this market as “a different, more powerful form” of competition than competition directly for patients. Pet. App. 94a. In doing so, the court assumed that competition among these third-party payors would necessarily and inevitably translate into benefits for the patients who rely on these life-saving medications. This was a mistake.

1. Contrary to the Tenth Circuit’s assumption, savings and rebates for third-party payors do not necessarily benefit patients. Rather than get passed on to patients, benefits get absorbed in a complex web of payments between patients, manufacturers, pharmacies, insurers, and PBMs that the court barely acknowledged even exists.⁸

Rebate payments to PBMs—the nearly exclusive focus of the Tenth Circuit—are just one aspect of a much larger picture. Pharmaceutical products themselves flow from manufacturers to retail pharmacies and then to patients.⁹ Payments, on the other hand, flow in every direction:

- from patients to pharmacies for the purchase of drugs;

⁸ Joanna Shepherd, *Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs*, 38 Yale L. & Pol'y Rev. 360, 369 Figure 2 (2020) (“Conflicts of Interest”).

⁹ *Id.* at 368.

- from patients to health plans in the form of insurance premiums;
- from pharmacies to manufacturers for the wholesale acquisition of drugs;
- from PBMs to pharmacies for the remaining cost of drugs other than the patient's portion;
- from health plans to PBMs as reimbursement for filled prescriptions;
- from manufacturers to PBMs as rebates and administrative fees; and
- from PBMs to health plans as a share of rebates received by the PBM.

Thus, a single purchase of an EAI device may include a half-dozen or more different payment flows. And each of those payments is subject to negotiation by the parties involved or the purchasing and prescribing decisions of patients and physicians.¹⁰

The Tenth Circuit's analysis focused almost exclusively on only one payment path: rebates from manufacturers to PBMs and insurers. It did not look to patient choice or costs, other than acknowledging that patients can pay the full list price of an EAI device out of pocket if they prefer a product that their insurance excludes. Pet. App. 9a, 48a, 54a. Because the Tenth Circuit did not fully consider the complexities of the marketplace, it wrongly concluded that competition to

¹⁰ *Id.* at 373.

be included in PBMs' formularies through rebates necessarily advances patients' interests.

2. Third-party payors' utilization management models may lead to increased list prices and overall costs to patients. Looking to only one aspect of the web of payments and negotiations affecting the prices and availability of pharmaceutical products, the Tenth Circuit described PBMs' negotiation for manufacturers' rebates. Pet. App. 9a–11a. Because PBMs are the largest payors—and negotiators—for pharmaceuticals they can, in theory, negotiate low prices by using their volume buying power to obtain rebates that individual patients could not obtain on their own.¹¹ But, as is often the case, what works in theory falls flat in reality.

Real-world evidence shows that the PBMs' middleman role often fails to benefit patients. Payors' negotiated rebates are opaque, even to the insurers who contract with them. PBMs often do not disclose their rebate levels with health insurers.¹² And in some instances, PBMs do not pass along any portion of the rebate to insurers.¹³ PBMs also sometimes

¹¹ Robin Feldman, "Perverse Incentives: Why Everyone Prefers High Drug Prices-Except for Those Who Pay the Bills," 57 Harvard J. on Legis. 303, 323, 325 (2020) ("Perverse Incentives").

¹² Mark Meador, *Squeezing the Middleman: Ending Underhanded Dealing in the Pharmacy Benefit Management Industry Through Regulation*, 20 Annals Health L. 77, 82 (2011) ("Squeezing the Middleman").

¹³ Shepherd, *Conflicts of Interest*, 38 Yale L. & Pol'y Rev. at 376.

recharacterize portions of rebates as administrative or other fees to avoid sharing with insurers.¹⁴

Moreover, while rebates are a large source of revenues for PBMs (approximately \$23 billion in 2016, Pet. App. 5a), they create a perverse incentive for manufacturers to increase their list prices.¹⁵ Rather than create formularies based on which drugs are least expensive overall, PBMs have an incentive to prefer drugs that pay higher rebates, even if the net cost for patients is higher.¹⁶ Drug A, listed at a high price, combined with a high rebate, provides more revenue for a PBM than Drug B with a low list price and low rebate. This is so even if the overall net cost after rebates of Drug B is substantially lower than for Drug A.

Consider this illustration. Suppose Drug A costs \$100 and the PBM negotiated a 20% rebate, while Drug B costs \$50 and the PBM negotiated a 10% rebate. The net price (paid by patients and their insurers) of Drug A is \$80, and of Drug B is \$45. The PBM receives rebate checks of \$20 from each sale of Drug A, but only \$5 from each sale of Drug B. In each instance, the remainder of the cost of the drug ultimately is passed through to patients (through co-pays or co-insurance). The PBM, therefore, has an incentive to choose the higher-priced, higher-rebate drug even

¹⁴ *Id.*

¹⁵ Meador, “Squeezing the Middleman”, 20 *Annals Health L.* at 82 (2011).

¹⁶ Shepherd, Conflicts of Interest, 38 *Yale L. & Pol'y Rev.* at 376.

though it means that patients—directly or through their insurance premiums—have to pay more for needed medical services.¹⁷

For similar reasons, PBMs' rebate structures push up list prices. PBMs receive higher revenues if manufacturers offer the same rebate but increase the drug's list price. Thus, manufacturers can raise both list prices and rebate offers to "compete" for formulary placement, without reducing their profits or the prices patients pay.¹⁸ In such a scenario, the manufacturer maintains its profit margin and the PBM receives a higher share of rebate, but those increased prices have to be paid by someone. That someone is typically the consumer, either through increased out-of-pocket payments, or increased insurance premiums.¹⁹

¹⁷ See also Craig Garthwaite and Fiona Scott Morton, "Perverse Market Incentives Encourage High Prescription Drug Prices," *Pro Market*, the publication of the Stigler Center at the University of Chicago Booth School of Business, Nov. 1, 2017 (available at <https://promarket.org/2017/11/01/perverse-market-incentives-encourage-high-prescription-drug-prices/>) ("Suppose the manufacturer raises its list price by \$10 and its rebate by \$9. The result is a \$1 higher net price so the manufacturer is better off. If a lack of competition allows a PBM to return \$8 to the payer instead of the full \$9, the PBM is better off by \$1 also. The PBM has little reason to bargain with manufacturers to keep prices from increasing in the first place; indeed their incentive is to encourage higher prices and higher rebates. Meanwhile, the payer's drug costs increase by \$2.").

¹⁸ Shepherd, Conflicts of Interest, 38 Yale L. & Pol'y Rev. 360, 378 (2020)

¹⁹ Feldman, Perverse Incentives, 57 Harvard J. on Legis. at 342.

The disconnect between what benefits third-party payors and what promotes consumer welfare is even more pronounced in a monopolistic market like that for EAI devices. The record indicates that EpiPen held an entrenched, non-contestable market share of up to 70%. Pet. App. 81a, 236a. With that entrenched share, Mylan could use its monopoly pricing power to punish PBMs that did not exclude Auvi-Q (or any other new entrant into the EAI device market). This ability to punish explains why one PBM informed Sanofi that even a 100% discount on Auvi-Q would not be enough to access the market. Excluding new entrants into the EAI device market in order to avoid the penalty that a monopolist like Mylan can impose may be good business for PBMs, but it is bad for the consumers who rely on (and pay for) those devices.

Drugmakers and the Secretary of Health and Human Services agree that rebates drive up prices for consumers.²⁰ A manufacturer that lowers the list price, thus reducing rebates to PBMs, may find itself excluded in favor of a higher-priced drug offering higher rebates.²¹ Recognizing this, policymakers have sought to shift the focus of competition between drugmakers from rebates to PBMs to direct discounts to patients. In January 2019, for example, the Department of Health and Human Services proposed

²⁰ Shepherd, Conflicts of Interest, 38 Yale L. & Pol'y Rev. 360, 379 (2020)

²¹ *Id.*

regulations to curtail rebates to third-party payors.²² It noted that rebates reward and encourage increased list prices, and that rebates are not reflected in patients' out-of-pocket costs.²³

3. Because the Tenth Circuit focused nearly exclusively on the PBM marketplace, it missed the obvious fact that patients lose when drug prices increase. Uninsured patients and even many patients with health insurance must pay the full list price of drugs out of pocket. And all insured patients absorb the increasing costs of drugs through higher premiums.

Uninsured patients—nearly 10% of Americans—must pay the list price when they fill their prescription.²⁴ They do not gain any benefit from the rebate competition from drug manufacturers for formulary placement. Rather, they feel the full brunt of the impact of EAI device price increases—including continued price increases after the launch of Auvi-Q and competition between EpiPen and Auvi-Q for formulary placement. Pet. App. 18a–34a.

Many insured patients must meet deductibles before insurance begins to pay for prescriptions. Thus, a

²² “Fact Sheet: Trump Administration Proposes to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients,” Department of Health and Human Services (available at <https://www.hhs.gov/sites/default/files/20190131-fact-sheet.pdf>).

²³ *Id.*

²⁴ Shepherd, Conflicts of Interest, 38 Yale L. & Pol'y Rev. 360, 362 (2020)

significant portion of insured individuals whose drug prices are negotiated by PBMs and subject to rebates from those PBMs pay the full list price of their drugs at the pharmacy. PBMs still get rebates when insureds pay full list price, but the rebate does not get returned to the patient or applied to the patient's out-of-pocket cost.²⁵ And while rebates collected by PBMs and (sometimes) shared with insurers *should* serve to lower patients' premiums, those indirect savings are spread across all insured members, rather than benefitting the purchasers of the rebated drugs who paid the inflated cost for medical devices.

Even for patients whose insurance covers their EAI device, savings negotiated between manufacturers and PBMs are generally not shared with patients at the pharmacy. Patients with co-insurance or who have not yet met their deductibles are typically charged the list price, even if the PBM negotiated a rebate with the manufacturer. A patient's cost-sharing amount may even exceed what the patient would pay without insurance. But "language in PBM contracts may discourage or prohibit pharmacists from informing insured patients about the lower cash price, at the risk of the pharmacy being excluded from the PBM's network."²⁶ Thus, patients are harmed both by increased out-of-pocket costs (unmitigated by rebates paid only

²⁵ PhRMA, Follow the Dollar: Understanding How the Pharmaceutical Distribution and Payment System Shapes the Prices of Brand Medicines, at 12 (Nov. 2017), <https://onphr.ma/2MTiXWT>.

²⁶ *Id.* at 6.

to third-party payors) and by higher premiums to cover years of drug price increases.

An EAI device (or multiple devices depending on a patient's needs) must be purchased annually to replace expired units. Thus, patients must pay for new EAI devices year after year at inflated prices without getting the benefit of the rebates discussed in the Tenth Circuit's decision.

The effect of increasing drug prices is that many patients forgo necessary filling or refilling of their EAI prescriptions to avoid costs. "A significant body of evidence establishes that, as out-of-pocket costs for drugs increase, patients are less likely to adhere to their medication routines."²⁷ Patients at risk of life-threatening anaphylaxis may thus decide to risk a severe allergic reaction without an EAI device rather than pay hundreds or thousands of dollars. This outcome—the antithesis of promoting consumer welfare—is made more likely by the Tenth Circuit's decision blessing Mylan's anticompetitive conduct.

C. Mylan's exclusionary conduct harmed consumer welfare.

The Tenth Circuit's focus solely on competition in the PBM market caused it to overlook the demonstrated harms that Mylan's exclusionary conduct has already caused. That conduct has resulted in higher

²⁷ Shepherd, Conflicts of Interest, 38 Yale L. & Pol'y Rev. 360, 380 (2020)

prices, reduced consumer choice, and a stifling of innovation in the EAI device market.

1. The most concerning aspect of the Tenth Circuit’s focus on competition in the PBM market as a substitute for competition for consumers is that it fails to take into account that Mylan’s conduct led to significantly higher EpiPen prices. Between 2009 and 2016, Mylan raised the list price of EpiPen by over 500%, despite Auvi-Q’s entrance in the marketplace. Pet. App. 18a–20a. Mylan failed to lower its price even after years of double-digit price increases. Pet. App. 18a–19a. In fact, Mylan continued to raise prices each year that Auvi-Q was on the market. *Id.* If the Tenth Circuit were correct that competition for inclusion on PBM formularies is a “more powerful form” of competition than competition directly for patients, Pet. App. 94a, then this result should be impossible.

Mylan was able to raise its prices precisely because of the PBM distribution model described above. That model incentivizes drug makers to increase rebates in order to insulate themselves from competition. Thus, as Mylan continued to increase the price of the EpiPen, it also increased rebates to PBMs. Pet. App. 16a. The EpiPen’s large rebates made it attractive to PBMs even as the increasing list prices caused direct pocket-book harm to consumers. The Tenth Circuit ignored that fact because it incorrectly assumed that competition to be listed in drug formularies necessarily benefitted consumers.

2. Because the Tenth Circuit’s analysis hinged on its misunderstanding of the purported benefits of

negotiated rebates, such as lower premiums or copays, Pet. App. 53a, it actively ignored the most obvious outcome of Mylan’s exclusionary conduct: lack of product choice.

Patients choose EAI devices in part based on familiarity with the device and confidence that they and others will have the device available and ready to use quickly in an emergency. Many patients have strong preferences for their EAI device—whether for the familiarity of the EpiPen, or the convenient size and shape of Auvi-Q. But with a closed formulary, a patient with a strong preference for an excluded EAI device may not be financially able to pay out of pocket for their preferred device, and instead be forced to buy a disfavored device.

Moreover, the reality is that patients largely lack any ability to shop between PBMs or health plans based on the plans’ formularies. Most patients are at the mercy of the health plans negotiated and offered by their employers. Others may be forced to choose the lowest cost plan available to them, without evaluating whether their preferred drugs are available on the plan’s formulary. Even after a patient is locked into a health plan and cannot switch to a new plan that covers their preferred device, payors and PBMs may change the formulary mid-year. Courts have recognized that contracting parties’ voluntary arrangements may cause antitrust injuries to downstream participants who are affected by those arrangements. *See Complete Entm’t. Res. LLC. v. Live Nation Entm’t, Inc.*, 2017 WL 6512223, at *3 & n.5 (C.D. Cal. Oct. 16, 2017) (“[E]xclusive contracts—while voluntary on

both sides—may harm competition because the structure of those contracts undermines the incentive of the venues to keep fees down ... one cannot simply assume that the venues' voluntary economic choices will prevent anticompetitive harm to non-contracting third-parties.”).

Yet the Tenth Circuit concluded that there was no antitrust injury as a result of Mylan’s conduct because if a patient had been prescribed Auvi-Q (or another excluded device), the patient could always obtain it by paying the full list price out of pocket. Pet. App. 48a. But being forced to pay a significantly higher price for a preferred product due to a third-party’s exclusion of coverage for that product is plainly an antitrust injury. *See Blue Shield of Va. v. McCready*, 457 U.S. 465, 480–81 (1982) (“As a consumer of psychotherapy services entitled to financial benefits under the Blue Shield plan, we think it clear that McCready was within that area of the economy ... endangered by [that] breakdown of competitive conditions resulting from Blue Shield’s selective refusal to reimburse.”) (citations and quotation marks omitted).

3. Separate and apart from the higher prices and reduced options patients face in the present day, Mylan’s anticompetitive conduct will continue to have negative effects on consumer welfare well into the future, because a corollary result of Mylan’s exclusionary conduct was to stymie product improvement and innovation.

When a competing drug or device is successfully blocked from formularies nationwide, there is no

incentive to invest further in innovation or improvements in the dominant product—in this case, the EpiPen. Before the launch of Auvi-Q, Mylan’s executives feared that its innovative and convenient design would cause consumers to favor the new product. Pet. App. 13a–14a. Research showed that many physicians favored Auvi-Q’s design, and Mylan even considered redesigning the EpiPen. *Id.* Yet after successfully blocking Auvi-Q from nationwide formularies, Mylan made no improvements to the EpiPen’s form and function. Having defeated its competition, Mylan stopped innovating as well.

Stunting innovation is a well-recognized form of harm to competition. *Lorain Journal Co. v. United States*, 342 U.S. 143, 154 (1951) (monopolist-newspaper liable when it refused to do business with advertisers that worked with an upstart radio competitor); *see also Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 318 (3d Cir. 2007); *United States v. Visa U.S.A., Inc.*, 344 F.3d 229, 241 (2d Cir. 2003). But the Tenth Circuit did not consider this harm in its decision.

In practice, Mylan’s exclusionary conduct harmed the welfare of consumers who need affordable access and choice in filling their prescriptions for life-saving medical devices. The Tenth Circuit’s determination that, as a matter of law, Mylan’s conduct was not anticompetitive calls out for this Court’s review.

CONCLUSION

This Court should grant the petition for certiorari and reverse the judgment.

Respectfully submitted,

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