No. 21-3005

IN THE UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

IN RE EPIPEN (EPINEPHRINE INJECTION, USP)
MARKETING, SALES PRACTICES
AND ANTITRUST LITIGATION

SANOFI-AVENTIS U.S., LLC,
Plaintiff, Counterclaim-Defendant, and Appellant,

v.

MYLAN, INC.,
Defendant and Appellee,

and

MYLAN SPECIALTY, LP,
Defendant-Counterclaimant and Appellee.

On Appeal from the United States District Court
for the District of Kansas, No. 2:17-MD-02785-DDC-TJJ
Hon. Daniel D. Crabtree, U.S.D.J.

BRIEF FOR THE AMERICAN ANTITRUST INSTITUTE AS AMICUS CURIAE IN SUPPORT OF PLAINTIFF, COUNTERCLAIM-DEFENDANT, AND APPELLANT AND REVERSAL

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Appellate Rule 26.1(a), the American Antitrust Institute states that it is a nonprofit, non-stock corporation. It has no parent corporations, and no publicly traded corporations have an ownership interest in it.

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INTEREST OF AMICUS CURIAE[1]

The American Antitrust Institute ("AAI") is an independent nonprofit organization devoted to promoting competition that protects consumers, businesses, and society. It serves the public through research, education, and advocacy on the benefits of competition and the use of antitrust enforcement as a vital component of national and international competition policy. AAI enjoys the input of an Advisory Board that consists of over 130 prominent antitrust lawyers, law professors, economists, and business leaders. See http://www.antitrustinstitute.org.[2] AAI submits this brief because competition and consumers will be severely injured if the rule of reason is misapplied and monopoly power is discounted in evaluating the exclusionary behavior of monopolists.

INTRODUCTION AND SUMMARY OF ARGUMENT

In this case, Sanofi alleges that Mylan anticompetitively foreclosed Sanofi's Auvi-Q product from the epinephrine auto injector market ("EAI market") and thereby illegally monopolized it. On the facts at the summary judgment stage, Mylan's EpiPen product had a monopoly in the EAI market with a market share

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[1] All parties consent to the filing of this amicus brief. No counsel for a party has authored this brief in whole or in part, and no party, party's counsel, or any other person—other than amicus curiae or its counsel—has contributed money that was intended to fund preparing or submitting this brief.

[2] Individual views of members of AAI's Board of Directors or Advisory Board may differ from AAI's positions.

exceeding 99%, immediately prior to the Auvi-Q entering the market in 2013. Both Mylan and Sanofi recognized that the Auvi-Q was innovative and that it had distinguishable qualitative features that would lead many doctors and patients to prefer it over the EpiPen. Both also recognized that the Auvi-Q would be a significant threat to Mylan's EpiPen business, so much so that Mylan had unsuccessfully tried to acquire the product in 2008. Mylan and Sanofi both expected the Auvi-Q to gain 30 percent or more of the market within three years. *See* Sanofi Br. at 6–10.

Instead of responding to this market share threat by competing on quality and price, which would have manifested in lower net EpiPen prices and lower profits, Mylan realized that its unusually large utilization rate among current allergy sufferers—its monopoly—could itself be wielded to prevent doctors and patients from making the anticipated switch to the Auvi-Q. It knew that the realities of the marketplace would prevent pharmacy benefit managers (PBMs) from simply pivoting to the Auvi-Q immediately and, indeed, many might never switch. So in response to the Auvi-Q's entry—the EpiPen's first significant competitor in years—Mylan counterintuitively raised the net price for the EpiPen. More surprising in the face of competition, Mylan's profits increased.

At the core of Mylan's strategy, Mylan used its entrenched EpiPen base to prevent significant competition for the remaining part of the EAI market. It increased list prices dramatically and then offered rebates to the PBMs expressly conditioned on a promise to downgrade or altogether exclude the Auvi-Q on their formularies (meaning patients who would have preferred the Auvi-Q would lack meaningful access to it). No matter how large the counter-rebate Sanofi offered, no matter how much better the Auvi-Q was than the EpiPen, no matter how much doctors and patients preferred it, Sanofi could not compete. The PBMs would lose more by foregoing the EpiPen rebate and paying the now astronomical EpiPen list price on claims by Mylan's entrenched base than they could earn in a market carrying both the EpiPen and the Auvi-Q—a market open to competition.

Mylan succeeded in leveraging its entrenched base to prevent significant competition for the remaining, unentrenched part of the EAI market. The product that both parties expected to reach more than 30% market share—a prediction that proved demonstrably correct in the Canadian market—was a commercial failure in the United States. It never obtained more than a 12% share in the EAI market, and Sanofi often managed those limited sales only by unprofitably cross-subsidizing them.

Mylan eliminated its only competitor simply by virtue of having a monopoly, and its rebate strategy could work only because of its monopoly. This is the

essence of illegal monopolization under Section 2 of the Sherman Act, and it is nothing new. Both courts and economists have long accepted that a monopolist can employ rebates (sometimes called a "rebate 'trap'" or "rebate wall," *see* Fed. Trade Comm'n, Report on Rebate Walls 2 (2021)), to suppress competition. The question before the district court was whether Section 2 of the Sherman Act forbids a monopolist from crushing its competitor by the weight of its size instead of competing in the market. The answer should have been a resounding yes.

But the district court granted summary judgment in favor of Mylan, holding that no reasonable juror could find that the elimination of the Auvi-Q caused monopoly prices to persist, degraded the quality and variety of available EAI-device options for doctors and patients to choose from, or blocked beneficial innovation in the EAI market. The district court apparently believed that Mylan's "competition" to pay PBMs for a monopoly position warranted protection over and above Sanofi's competition to provide the best anaphylaxis treatment to consumers of EAI devices. The district court was incorrect. The antitrust laws protect competition to promote consumer welfare, not monopoly to promote PBM welfare. A monopolist that wishes to maintain its dominant position is free to earn it by competing to better serve consumers, but it is not permitted to purchase protection from rivalry.

The district court committed two key errors in reaching the wrong result. First, the district court failed to draw the necessary inference that both Mylan and the PBMs earned more from exclusion payments than they would have earned from competition, at consumers' expense. Under the rule of reason as applied to exclusionary conduct by a monopolist, a plaintiff establishes a prima facie case by proving harm to competition and consumers, after which the burden shifts to the defendant to establish an offsetting efficiency justification. The district court's failure to draw the necessary inference of a misalignment between PBM and consumer interests caused it to overlook both that Sanofi successfully established its prima facie case on the summary judgment facts and that Mylan failed to introduce any record evidence suggesting its exclusion payments generated an efficiency.

Second, the district court failed to account for the economic implications of monopoly power throughout its analysis of whether a reasonable juror could conclude that Mylan's exclusion payments to PBMs caused anticompetitive effects. A monopoly market structure is a salient economic fact that bears on the second element of a monopolization claim (anticompetitive conduct), not solely on the first element (monopoly power). Because it was not attuned to the particular structure and circumstances of the EAI market, which is a two-firm market with high entry barriers, the district court failed to recognize that anticompetitive effects are essentially guaranteed if Mylan has excluded its only meaningful rival on some basis

other than efficiency. For the same reason, the district court also failed to recognize that the level of foreclosure necessary to achieve an anticompetitive effect in the EAI market was significantly lower than what would be necessary in a more competitive market. The district court apparently deferred to an innate skepticism of competitor antitrust claims, but that skepticism should have carried no weight on the summary judgment facts of this case.

ARGUMENT

I. THE DISTRICT COURT MISAPPLIED THE RULE OF REASON

A. Sanofi Established Harm to Competition and Consumers on the Summary Judgment Facts

The U.S. Supreme Court has set forth binding standards for applying the rule of reason in cases alleging exclusionary conduct by a monopolist, which the district court failed to properly apply here. In *Aspen Skiing Co. v Aspen Highlands Skiing Corp.*, the Court articulated a three-part inquiry to determine whether conduct is exclusionary. The fact-finder must look at the impact of the alleged conduct on (1) competition, (2) consumers, and (3) the monopolist. 472 U.S. 585, 605 (1985) ("[It] is relevant to consider [the conduct's] impact on consumers," "whether it has impaired competition," and whether the monopolist "has been 'attempting to exclude rivals on some basis other than efficiency.'" (citation omitted)).

In *Kodak*, the Supreme Court made clear that the *Aspen Skiing* inquiry involved a shifting of burdens. *See Eastman Kodak Co. v Image Tech Servs. Inc.*, 504 U.S. 451, 483 (1992). In reversing the district court's grant of summary judgment, the Court relied on evidence of harm to competition and consumers, suggesting that Kodak "took exclusionary action to maintain its monopoly." *Id*. Therefore, to avoid liability, Kodak was required to identify a valid business justification—*i.e*., some legitimate efficiency basis—for its conduct. *Id*. Because factual questions remained as to the validity of Kodak's explanation, the Court concluded that summary judgment was inappropriate. *Id*. at 486

The D.C. Circuit's opinion in *Microsoft* operationalized the Supreme Court's *Aspen Skiing-Kodak* framework by adopting a rule-of-reason burden-shifting approach for most monopolization claims. *See United States v. Microsoft Corp.*, 253 F.3d 34, 59 (2001) (noting that the Supreme Court's *Standard Oil* decision identifies the rule of reason as the proper inquiry under both Sections 1 and 2 of the Sherman Act). Under the *Microsoft* test, a plaintiff must prove the first two prongs of the *Aspen Skiing* Court's inquiry in its prima facie case—harm to competition and consumers. *Id.* at 58. To avoid summary judgment, a plaintiff must put forth sufficient facts showing that the challenged conduct "affected the prices, quantity or quality of goods or services" available in the market and interfered with "'a healthy and unimpaired competitive process.'" *JetAway Aviation, LLC v. Bd. of*

Cnty. Comm'rs, 754 F.3d 824, 847 (10th Cir. 2014) (Holmes, J., concurring) (internal citation omitted). This initial inquiry produces a filtering effect, preventing needless litigation, because plaintiffs that can make only weak assertions regarding monopoly power and anticompetitive effects will be "weeded out." Andrew I. Gavil, *Exclusionary Distribution Strategies by Dominant Firms: Striking a Better Balance*, 72 Antitrust L.J. 3, 62, 77 (2004).

If the plaintiff establishes its prima facie case, however, the burden then shifts to the defendant. The defendant must provide a procompetitive justification for its conduct. *Microsoft*, 253 F.3d at 163–64. Burden shifting is appropriate because a monopolist is in the best position to discover its own reasons for adopting a particular marketing strategy. *See* Gavil, *supra*, at 73, 77. If the defendant cannot show some legitimate business justification rooted in improved efficiency, courts can feel confident that the strategy was adopted for an exclusionary purpose and may properly condemn the defendant's actions.

In this case, the district court erred in failing to recognize that Sanofi has met its initial burden. The summary judgment facts require an inference that Mylan possesses monopoly power in the EAI market, which Mylan does not meaningfully dispute. SJ Op. at 87–88, n.19; *see* Mylan Opp. to Sanofi SJ Mtn. at 61 (acknowledging that "Mylan has not moved for summary judgment on [monopoly power]").

Sanofi also has shown that disputed material facts exist as to whether Mylan's exclusion payments reasonably contributed to maintaining its EpiPen monopoly. Specifically, Sanofi introduced evidence demonstrating that Mylan acted with the intent to exclude competition to maintain its dominant market position rather than to engage in competition on the merits, and that Mylan succeeded in driving the Auvi-Q out of the market. SJ Op. at 102, 82, 46; Sanofi Br. at 44–46. Harm to consumers also is present, in the form of increased net prices for EAI devices to treat anaphylaxis, SJ Op. at 19–20; Sanofi Br. at 82, and the denial of meaningful patient access to a differentiated product that, on the summary judgment facts, is innovative and preferred by doctors and patients for its unique attributes. SJ Op. at 124–128; Sanofi Br. at 83–85. Sanofi therefore cleared the high hurdle of proving a prima facie monopolization case, which is enough to create a genuine issue of fact for a jury: whether the conduct was unreasonably anticompetitive taking into account all of the evidence.

B. Mylan Has Proffered No Efficiency Justifications

Given the evidence of both harm to consumers and Sanofi's exit from the market, which eliminated 100% of the competitive pressure on Mylan to lower prices or improve the features of the EpiPen, the absence of *any* efficiency justifications in the record should have crystallized the denial of Mylan's summary judgment motion. Einer Elhauge, *Defining Better Monopolization Standards*, 56

Stanford L. Rev. 253, 323 (2003) ("Where the conduct in fact does not increase the monopolist's efficiency at all, then the issue is easy."); Phillip Areeda & Herbert Hovenkamp, Antitrust Law ¶ 651e2 (4th and 5th eds. 2013-2020) ("The easiest case is conduct by a monopolist that clearly injures rivals and has no business justification"; "About the best that can be said for such an action is it might fail and result in no harm at all, but it is not likely to produce a social benefit."); Gavil, *supra*, at 77 ("the real challenge" are the cases that involve "significant inefficiencies *and* significant efficiencies").

Usually, exclusive dealing strategies are implemented using market share rebates, or loyalty or bundled discounts, or some other kind of metering device that has the potential to be procompetitive by improving the efficiency of the firm securing exclusivity rights. *See* Jonathan M. Jacobson, *Exclusive Dealing, "Foreclosure," and Consumer Harm*, 70 Antitrust L.J. 311, 357–60 (2002) (cataloguing nine pro-competitive justifications for exclusive dealing arrangements). When they also harm rivals, such arrangements sometimes can present difficult analytical challenges for courts.

But the summary judgment facts show that there is no evidence or even a contention in the record that Mylan's payments served to reduce Mylan's costs or

improve its profitability, *other than* by eliminating competition.[3] Mylan does not dispute this, nor could it. *See* SJ Op. at 82, 94 ("Mylan never argues that its rebate contracts aren't exclusionary contracts."). Having obtained the monopoly share of the market in 2007, Mylan would have long since achieved efficient operating scale in 2013, when the Auvi-Q entered the market. Sanofi Br. at 6. Other than in "natural monopoly" industries subject to rate regulation, a monopolist that uses exclusionary contracts to secure market share *over and above* the monopoly market share cannot generate additional efficiency, because a monopolist by definition is already extracting the maximum amount of profit it can extract from the market (and inflicting deadweight loss on consumers). *See* Elhauge, *supra*, at 326, 307 n.163 (noting that this is true where any firm has 50% of a market and uses exclusionary contracts to secure additional share on top of the 50%; otherwise the industry should be subject to utility rate regulation).

[3] The district court did observe that "exclusive dealing" is categorically capable of having efficiency justifications, SJ Op. at 82, but it did not find a genuine dispute as to any material facts in the record suggesting that *Mylan's* alleged scheme improved Mylan's efficiency. Such a material fact would be necessary to create a genuine dispute because efficiencies from exclusive dealing cannot be presumed *sub rosa*. Andrew I. Gavil & Steven C. Salop, *Probability, Presumptions and Evidentiary Burdens in Antitrust Analysis: Revitalizing the Rule of Reason for Exclusionary Conduct*, 168 U. Penn. L. Rev. 2107, 2137–38 (2020); *see Microsoft*, 253 F.3d at 64 (monopolist must "substantiate" its claimed justification and proffer "evidence in support").

Given the absence, on the summary judgment facts, of even any pretext that Mylan's rebate payments improved its operating efficiency, and the economic illogic of any such argument, Mylan's rebate payments conditioned on denying market share to the Auvi-Q are "naked exclusion." *See* Areeda & Hovenkamp, *supra* ¶ 768a5 (defining "naked exclusion" as payments for the purchase of "nothing but the exclusionary right."). The payments are explicitly conditioned on disadvantaging or excluding Auvi-Q from formularies and securing market share *above* the monopoly level of market share, not on any kind of volume assurance or distributor-investments necessary to allow Mylan to efficiently calibrate its production capacity or maintain the economies of scale it had already realized. *See* Jacobson, *supra*, at 357–60. In both form and substance, then, the payments are simply bribes used to purchase protection from competition.

The district court was taken in by Mylan's evidence that some PBMs not only acceded to this system of exclusion payments, but actively solicited such payments in attempting to play Mylan and Sanofi off of one another and chose Sanofi over Mylan when Sanofi offered the higher exclusion payment. SJ Op. at 93–100. But competition to offer the most attractive bribe for a monopoly position is not the *market* competition that antitrust law protects and that benefits consumers. For the district court to presume that, not a natural monopoly, but a *bargained-for* monopoly is preferable to market competition is "nothing less than a frontal assault on

the basic policy of the Sherman Act." *Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 695 (1978).

Our free-enterprise system requires a conclusive presumption that monopolies inflict deadweight loss on consumers, diminishing their welfare, while market competition "yield[s] the best allocation of our economic resources, the lowest prices, the highest quality and the greatest material progress." *N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 4 (1958). This view of competition as preferable to monopoly in promoting consumer welfare is based on "faith in the value of competition," meaning it is not open to second-guessing. *Standard Oil Co. v. FTC*, 340 U.S. 231, 248 (1951); *see Nat'l Soc'y of Prof'l Eng'rs*, 435 U.S. at 695 ("Even assuming occasional exceptions to the presumed consequences of competition, the statutory policy precludes inquiry into the question whether competition is good or bad.").

The point is not that the district court was necessarily wrong in believing that higher EpiPen rebates, coupled with elimination of the Auvi-Q, is the superior market outcome relative to lower EpiPen rebates, coupled with access to both products. The point is that antitrust law does not allow federal judges to make this decision. *See Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408 (2004) ("antitrust courts" should not "act as central planners, identifying the proper price, quantity, and other terms of dealing—a role for which they

are ill-suited"). Nor does it permit Mylan or the PBMs to do so. *N.C. State Bd. of Dental Exam'rs v. FTC*, 574 U.S. 494, 505 (2015) ("[A]ctive market participants cannot be allowed to regulate their own markets free from antitrust accountability."). Antitrust law requires that the free market must decide the optimal mix of price, quality and variety of products in the marketplace, through the mechanism of the consuming public's revealed preferences. *See* Robert Bork, The Antitrust Paradox 90 (1977) ("Consumer welfare, as the term is used in antitrust, has no sumptuary or ethical component, but permits consumers to define by their expression of wants in the marketplace what things *they* regard as wealth.") (emphasis added).

The district court thought that PBMs' role in encouraging a system of exclusion payments casts the payments in an innocent light, but the district court got this backwards. If anything, the fact that PBMs preferred exclusivity payments to head-to-head competition requires the inference that PBMs earned profits on exclusivity payments that exceeded what they would have earned from competition. Otherwise, rational PBMs would have insisted that the EpiPen and Auvi-Q products compete on the price and quality *of anaphylaxis treatment* to market-test the profits they were earning from the manufacturers' rebate payments. That competition would have also provided added assurance that Mylan and Sanofi were providing the best bargains to health plans and patients that the manufacturers' (otherwise hidden) cost structures will allow. *See* Elhauge, *supra*, at 324 ("[T]here

is ordinarily a plain, less restrictive alternative to using exclusionary conditions to guarantee the monopolist a share above 50%. Namely, the firm can use vigorous above-cost price competition and internal expansion through sales without conditions that discriminate against rivals.").

The logical inference that PBMs earned supracompetitive profits, at consumers' expense, from Mylan's exclusion payments (or Sanofi's "competing" exclusion payments) is bolstered by the opacity and rampant pricing mischief in PBM markets that have been well chronicled by leading experts in the pharmaceutical industry. *See* Robin Feldman, *The Devil in the Tiers*, 8 J. Law & Biosci. 1 (2021). The problem is that health plans compensate PBMs based on the size of the discount they can obtain from drug manufacturers, and "the system goes off the rails" because such "spread pricing" creates "[p]erverse incentives and strategic behaviors [that] have derailed the process." *Id*. at 13.

As Professor Feldman explains:

> To increase the spread and profitability for the PBMs, drug companies can raise the list prices of their drugs and then offer steeper rebates. As a result, PBMs can report a greater spread, thereby increasing their pay, even if net price remains the same or increases. This creates upward pressure on drug prices, as drug companies offer—and PBMs demand—greater and greater spreads.

Id. at 13–15 (noting that "the PBM industry is highly concentrated, with three PBMs controlling 85% of the market"); *see also* Fed. Trade Comm'n, Report on Rebate Walls 2–3 (2021). The district court failed to recognize that this strategy is

easily executed when the drug company has a monopoly on a life-saving treatment, like Mylan does, because there is no competitive check on the size of the high rebates and *higher* drug-price increases it can offer to, and impose upon, PBMs and health plans, respectively. *See* Sanofi Br. at 18, 54 (rebates only "partly offset" the 25-30% list-price increases each year Auvi-Q was on the market).[4]

The district court simply assumed that higher drug manufacturer rebates to PBMs were indicative of healthy competition. It failed to consider the possibility that the tradeoff between high PBM rebates and monopoly EpiPen pricing favors PBMs and Mylan at the expense of consumers. Yet, the empirical evidence in the pharmaceutical industry suggests this is *typically* the case. Feldman, *supra*, at 6 ("Worse yet, as this study demonstrates, drug prices are rising at a faster pace than rebates, with the result that the rebates only begin to offset the substantial increases."); *id*. at 21, Fig. 1 (Chart showing that average dosage-unit price of

[4] The district court stated that "undisputed facts suggest that the exclusive offers promoted competition in the EAI market" because the exclusive offers allowed payors to obtain "higher discounts for their customers." SJ. Op. at 100. This statement makes no sense, because Sanofi's evidence is that Mylan's list-price increases exceeded the amount of its rebates, meaning drug prices net of rebates increased as a result of Mylan's strategy, as the district court recognized elsewhere it its opinion. SJ Op. at 19. The payors' customers therefore experienced price hikes, not discounts. The district court's citation to *Menasha Corp*. is inapposite, because the consumers in that case were found to have benefitted from the exclusive arrangement *in addition to* the retailers.

branded drugs net of rebates increased every year from 2010-2017, despite increased size of rebates and growing spreads between pre- and post-rebate price).[5] Economists have done the math showing that drug monopolies can readily earn more by maintaining a monopoly and sharing some of the excess profits with a partner than by submitting to market competition. *See, e.g.*, Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *Activating Actavis*, 28 Antitrust 16, App'x (2013) (specifying the economic model under which brand and generic firms mutually profit when they split the brand's monopoly profit horizontally to delay generic entry, thereby prolonging the monopoly and maintaining high prices for consumers).

The district court lost sight of "'the central concern of our antitrust jurisprudence,'" which is "'[t]he risk that private regulation of market entry, prices, or output may be designed to confer monopoly profits on members of an industry at the expense of the consuming public.'" *N.C. State Bd. of Dental Exam'rs*, 574 U.S. at 505–06 (2015) (internal citation and alteration omitted). The Sherman Act is a "'consumer-welfare prescription,'" not a PBM welfare prescription. *Reiter v. Sonotone Corp.*, 442 U.S. 330, 343 (1979) (internal citation omitted). None of the

[5] Moreover, as Sanofi points out, PBMs could not switch to Auvi-Q even if they wanted to because of Mylan's entrenched share. Monopoly utilization rates coupled with foregone rebates on monopoly list prices would have been too much to overcome. *See* Sanofi Br. at 18–19.

summary judgment facts suggest consumers benefitted from Mylan's PBM payments; all of them suggest that Mylan and PBMs benefitted while consumers were harmed. Coupled with the elimination from the EAI market of the one and only competitive check on EpiPen pricing and quality, and the absence of any record evidence of any business justification other than eliminating competition, this should have been an easy case under a proper application of the rule of reason on the summary judgment facts.

II. MONOPOLY POWER IS RELEVANT TO THE ANTICOMPETITIVE CONDUCT ELEMENT OF A MONOPOLY-MAINTENANCE OFFENSE

The district court also erred by ignoring the rule that "[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue." *Trinko*, 540 U.S. at 411. "Always" means that a court's finding of a monopoly market structure in the course of evaluating the first element of a monopolization claim (monopoly power) cannot be set aside in the course of evaluating the second element of a monopolization claim (anticompetitive conduct). *See Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962) (Plaintiffs should be given "the full benefit of their proof without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each.").

Monopoly power has important implications for the likelihood of anticompetitive effects. Although the district court, in its brief monopoly power analysis,

did recognize that a monopoly market structure generally favors a finding of foreclosure, SJ Op. at 87–88, it effectively quarantined this finding from the remainder of its opinion. Consequently, it was not attuned to the particular structure and circumstances of the EAI market, which is a two-firm market with high entry barriers.[6] Mylan has a unique level of power as the monopolist in this market, and anticompetitive effects are essentially guaranteed if Mylan has excluded its only rival on some basis other than efficiency. The district court also failed to account for the unique characteristics of Mylan's monopoly power in evaluating the level of foreclosure needed to cause competitive harm in the EAI market, which is uniquely low.

A. The Risks of Anticompetitive Effects from Mylan's Exclusive Dealing in the EAI Market Could Not Be Higher

"[T]he purpose of the inquiries into market definition and market power is to determine whether an arrangement has the potential for genuine adverse effects on competition." *FTC v. Indiana Fed'n of Dentists*, 476 U.S. 447, 460 (1986). The federal antitrust agencies have explained why a monopoly market structure implicates this potential: "If a firm has retained its market share even after its price has increased relative to those of its rivals, that firm already faces limited competitive

[6] Significant entry barriers included FDA approval, intellectual property, marketing costs, "spillover," and more. Sanofi Br. at 6.

constraints, making it less likely that its remaining rivals will replace the competition lost if one of that firm's important rivals is eliminated." U.S. Dep't of Just. & Fed. Trade Comm'n, Horizontal Merger Guidelines § 5.3 (2010).

The district court here was not attuned to *Mylan's* monopoly power in the EAI market. The district court correctly recited the rule that, "'[b]ehavior that otherwise might comply with antitrust law may be impermissibly exclusionary when practiced by a monopolist.'" SJ Op. at 82–83 (quoting *United States v. Dentsply Int'l*, Inc., 399 F.3d 181, 187 (3d Cir. 2005)); *see also Kodak*, 504 U.S. at 488 (Scalia, J., dissenting) (a monopolist's activities must be "examined through a special lens," and "[b]ehavior that might otherwise not be of concern to the antitrust laws—or that might even be viewed as procompetitive—can take on exclusionary connotations when practiced by a monopolist."); *LePage's Inc. v. 3M*, 324 F.3d 141, 151–52, (3d Cir. 2003) (en banc) ("[A] monopolist is not free to take certain actions that a company in a competitive (or even oligopolistic) market may take, because there is no market constraint on a monopolist's behavior.").

It also correctly recited the rule that "'[e]xclusive dealing arrangements," specifically, "are of special concern when imposed by a monopolist.'" SJ Op. at 82–83 (quoting *ZF Meritor, LLC v. Eaton Corp*., 696 F.3d 254, 271 (3d Cir. 2012)). Indeed, the federal courts are in agreement that exclusive dealing by a mo-

nopolist is viewed with greater suspicion than exclusive dealing by a non-monopolist. *See, e.g.*, *McWane, Inc. v. FTC*, 783 F.3d 814, 836–37 (11th Cir. 2015); *Microsoft*, 253 F.3d at 70; *Dentsply*, 399 F.3d at 197; *U.S. Healthcare, Inc. v. Healthsource, Inc.*, 986 F.2d 589, 597-98 (1st Cir. 1993) (Boudin, J.).

But the district court never considered the "special concern" posed by a monopolist's exclusive dealing in a two-firm market with high entry barriers. In a market where a protected monopoly has only one other capable rival, the likelihood that "remaining rivals will replace the competition lost" if that rival is eliminated falls to zero. Consequently, as this Court has recognized, the elimination of a monopolist's only rival is a very strong predictor of anticompetitive effects. *JetAway*, 754 F.3d at 845 (Holmes, J., concurring) ("[N]otably, prior to the commencement of the allegedly anticompetitive conduct, consumers … had a meaningful choice between two competitors, and we found this fact to be significant in evaluating whether the defendants' conduct produced an antitrust injury."); *Full Draw Prods. v. Easton Sports, Inc*., 182 F.3d 745, 754 (10th Cir. 1999) ("Because defendants' alleged boycott reduced a competitive market of two producers to a market of one monopolist, Full Draw quite clearly alleged substantial injury to competition from defendants' group boycott."); *see also Viamedia, Inc. v. Comcast Corp*., 951 F.3d 429, 452 (7th Cir. 2020) (understanding that "the immediate effect

of Comcast's conduct was to force out its only competitor in that market to gain monopoly power … helps in assessing Comcast's alleged conduct").

The district court's statement that "'[e]xclusive dealing agreements are often entered into for entirely procompetitive reasons, and generally pose little threat to competition,'" SJ Op. (quoting *ZF Meritor*, 696 F.3d at 270), could not have been further divorced from the economic realities of the particular structure and circumstances of the EAI market. The threat to competition from eliminating a monopolist's only capable rival in a market protected by entry barriers is enormous.

B. Substantial Foreclosure in a Monopolized Market Depends on the Monopolist's Ability to Constrain or Eliminate Rivals

The district court also failed to appreciate the extent to which Mylan's monopoly power bears directly on whether foreclosure is sufficiently substantial to cause anticompetitive effects. *See* Thomas Krattenmacher & Steven Salop, *Anticompetitive Exclusion: Raising Rivals' Costs to Achieve Power Over Price*, 96 Yale L.J. 215, 263 (1986) (The likelihood that exclusion will increase prices in the market "depends on the ability and willingness of consumers to switch to other unexcluded firms (including entrants) and on the incentives of the purchasers of exclusionary rights and other unexcluded firms to continue to compete."). Monopoly power can significantly lower the level of foreclosure that is sufficient to constrain or eliminate rivals, for reasons that require careful attention.

As a rule, if new entrants are foreclosed from any share of a market, then their investments in research and innovation will have a comparatively smaller payoff and will be recouped more slowly than they otherwise would be. Whether the percentage share of the market that is foreclosed is sufficiently "substantial" to cause competitive harm necessarily is a fact question and rarely will be the same in two different markets. Depending on the particular characteristics of the market, the sufficient share can sometimes be quite small. *See LePage's*, 324 F.3d at 158–60, 180.

Professor Feldman provides an example of how a dominant firm can take advantage of a market's unique characteristics to deter new entry by strategically foreclosing a small share of the market, thereby maintain its monopoly, and warding off socially desirable investments that threaten it, at minimal cost to itself:

> Imagine if Budweiser approached bar owners in a state offering $1 off each bottle of Bud sold, if the owners agree not to put any craft beers on the menu. If the bar owners normally sell two million bottles of Bud in a year, that offer is worth $2 million. Now imagine a small craft-beer company trying to break into the market—an entrant that might start off by selling 10,000 bottles at $3 each. Even if the new entrant discounted the price down to a single penny per bottle in comparison to the normal $3 price, the bar owners would save only about $30,000. The new entrant could never match Budweiser's $2 million offer.

Feldman, *supra*, at 15. The district court failed to consider whether payments to strategically foreclose even a relatively small percentage of the market would be sufficient for Mylan to successfully maintain its monopoly and harm competition

and consumers in the EAI market, which is the appropriate benchmark. *See, e.g., Dentsply*, 399 F.3d at 191 (test is whether conduct keeps sales "below the critical level necessary for any rival to pose a real threat").

Relatedly, the district court also misunderstood the relevance of the duration and terminability of the rebate contracts. The district court reasoned that, because the short duration and easy terminability of exclusionary contracts proved exculpatory in other cases involving completely unrelated markets, they should be exculpatory here, too. SJ Op. at 90. However, as discussed above, Sanofi alleges, and has demonstrated through direct evidence, that Mylan had the power to deprive Sanofi of the necessary scale for the Auvi-Q to be *viable*, not merely to deprive Sanofi of the ability to compete effectively once the Auvi-Q launched and entered the market.

All that matters for purposes of competition and consumer welfare is that the short duration and easy terminability of the rebate contracts were not short *enough* or easily terminable *enough* to prevent Mylan from driving the Auvi-Q out of the market. *See* Areeda & Hovenkamp, *supra* ¶ 1802c (distinguishing between "long-run exclusionary effects" when exclusive dealing is used to "slow the rival's expansion" versus "short-run exclusionary effects" when exclusive dealing is used "as an entry deterrence device."). Moreover, any nominal contractual freedom to switch from the EpiPen to the Auvi-Q should have been beside the point; PBMs

lacked the *financial* freedom to switch because of Mylan's monopoly utilization rate coupled with its unprecedented increase in list prices, as discussed above. The duration and terminability could have been even shorter and easier and there would be no economically logical reason to suspect it would make a difference.

To be sure, it is possible that longer and harder-to-terminate contracts would have been even worse for competition, because they would have locked-in PBMs and locked-out new entrants that much more forcefully. But the district court overlooked that the short duration and easy terminability of the contract provisions also benefitted Mylan by giving it flexibility to restore the preexisting monopoly status quo that much faster and more easily upon Sanofi's exit. And Mylan still got to send a clear message to other potential entrants that any attempts at innovative entry will be greeted with overwhelming monopoly power and astronomical spreads between high rebates and higher list prices. If this Court does not reverse, that message will have the same economic impact as a very-long-term and very-hard-to-terminate exclusive.

The district court seemed to cast a jaundiced eye over the evidence of foreclosure out of a genuine concern about the risk that antitrust law can fall prey to misuse by business plaintiffs. SJ Op. at 122. This concern has become well-worn in antitrust law. When a rival is injured because a more efficient competitor has deprived it of market share—that is, injured by *competition itself*—the risk is that

the rival may have an economic incentive to try to bring even a meritless antitrust case against the efficient competitor. The axiom that antitrust law protects "competition, not competitors," which the district court cited repeatedly, Slip op. at 101, 122, 123, recognizes that allowing the rival to proceed with its case in these circumstances would be inimical to the consumer-welfare goal of the antitrust laws. By forcing a more-efficient competitor to defend lawful practices in an antitrust court, the rival raises the competitor's costs and, ironically, accomplishes the opposite of antitrust law's goal: it makes the competitor *less* efficient, forcing the competitor to raise its prices, reduce its output, or reduce the quality of its products *to the detriment of consumers*.

Here, however, the district court failed to recognize that, when a market is monopolized, protecting competition and consumers sometimes *requires* protecting competitors. *McWane*, 783 F.3d at 836 ("'[I]n a concentrated market with very high barriers to entry, competition will not exist without competitors.'") (quoting *Spirit Airlines, Inc. v. Northwest Airlines, Inc.*, 431 F.3d 917, 951 (6th Cir. 2005)). The key point of the famous language the district court cited is that the antitrust laws were passed "'*for* the protection of competition, not competitors.'" Slip Op. at 123 (quoting *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc*., 429 U.S. 477, 488 (1977)) (emphasis added). It means the laws seek to enjoin only conduct that harms consumers through injury to the competitive process. It does not mean the

laws hesitate to protect competitors as a *means* of protecting competition and consumer welfare. Gavil, *supra*, at 81, n.262 (explaining that the "oft-repeated and misused" language is an "empty slogan" in a context where "[t]here can be no competition without competitors.").

Antitrust law recognizes exclusion offenses precisely because protecting competitors is sometimes necessary to prevent harm to competition and consumers, even if it is not *why* we do it.[7] *See, e.g., Dentsply*, 399 F.3d at 191 (explaining how exclusionary conduct that slows growth of competitors also harms competition and consumers); *LePage's*, 324 F.3d at 159 (Successful exclusionary conduct by a monopolist against rivals is "not only injurious to the potential competitor but also to competition in general."). There is no cause for skepticism of an antitrust claim predicated on exclusionary conduct by a monopolist in a two-firm market with high entry barriers. On the contrary, if a monopolist destroys its only rival on some basis other than efficiency in these circumstances, harm to competition and consumers is all but assured.

[7] It is for the same reason that antitrust law gives antitrust standing to competitors to recover lost profits—a right that aptly illustrates what the Supreme Court does *not* mean when it says antitrust law "protects competition, not competitors."

CONCLUSION

For the foregoing reasons, the decision below should be reversed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH RULE 32(a)(7)

Pursuant to Fed. R. App. P. 32(g)(1) and Circuit Rule 32(A), this amicus brief is proportionately spaced, has a typeface of 14 points, and contains 6,475 words, excluding the portions exempted by Fed. R. App. P. 32(f).

s/ Randy M. Stutz

June 4, 2021

CERTIFICATE OF SERVICE

I hereby certify that on this 4th day of June, 2021, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Tenth Circuit using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

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