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United States Court of Appeals
Tenth Circuit

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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 - Appellant,

v.

MYLAN, INC.,

Defendant - Appellee,

and

MYLAN SPECIALTY, LP,

Defendant Counterclaimant - Appellee.

OPEN MARKETS INSTITUTE; AMERICAN ANTITRUST INSTITUTE; ALLERGY & ASTHMA NETWORK; THE COMMITTEE TO SUPPORT THE ANTITRUST LAWS; PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION; INTERNATIONAL CENTER FOR LAW & ECONOMICS AND SCHOLARS OF

No. 21-3005

LAW AND ECONOMICS; THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA; J. GREGORY SIDAK,

Amici Curiae.

Appeal from the United States District Court
for the District of Kansas
(D.C. No. 2:17-MD-02785-DDC-TJJ)
(507 F. Supp. 3d 1289)

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J. Gregory Sidak, Golden Oak, Florida; Jeffrey A. Lamken, Lucas M. Walker, Lauren M. Weinstein and Kenneth E. Notter III of MoloLamken LLP, Washington, D.C., for Amicus Curiae J. Gregory Sidak.

Before **MORITZ**, **BALDOCK**, and **EID**, Circuit Judges.

BALDOCK, Circuit Judge.

"Competition is a tough weed, not a delicate flower." —George Stigler

Despite the extraordinary length of this opinion, this appeal presents a simple question. Can a plaintiff present a triable issue of monopolization without offering any evidence of actual or threatened consumer harm? We conclude such a plaintiff cannot.

I.

Plaintiff Sanofi-Aventis U.S., LLC ("Sanofi") sued Defendants Mylan, Inc. and Mylan Specialty, LP (collectively "Mylan") under Section 2 of the Sherman Antitrust Act. 15 U.S.C. § 2. Sanofi, one of the world's largest pharmaceutical companies, alleges Mylan, the distributor of EpiPen, monopolized the epinephrine auto-injector market effectively and illegally foreclosing Auvi-Q—Sanofi's innovative epinephrine auto-injector—from the market. The parties cross-moved for summary judgment. The

district court, holding no triable issue of exclusionary conduct, granted Mylan's motion for summary judgment. Exercising jurisdiction under 28 U.S.C. § 1291, we affirm.[1]

A.

The following facts are either uncontroverted, or, where genuinely controverted, are viewed in the light most favorable to Sanofi, the party opposing the grant of summary judgment to Mylan.[2] *Scott v. Harris*, 550 U.S. 372, 378–80 (2007). We are mindful, however, that when "opposing parties tell two different stories, one of which is blatantly contradicted by the record, so that no reasonable jury could believe it, a court should not adopt that version of the facts for purposes of ruling on a motion for summary judgment." *Id.* at 380. Sanofi's allegations of monopolization center around industry-specific practices in the prescription drug market. We must, therefore, begin with an indispensable, albeit technical, overview of the prescription drug market.

"Before a patient can go to the pharmacy (or mailbox) to pick up their prescription, the medicine must make its way from the pharmaceutical manufacturer to

[1] The Judicial Panel on Multidistrict Litigation transferred this case from the District of New Jersey to the District of Kansas for coordinated or consolidated pretrial proceedings. We have jurisdiction to hear Sanofi's appeal because the right to appeal ripened when the district court granted summary judgment on Sanofi's sole claim, "not upon eventual completion of multidistrict proceedings in all of the consolidated cases." *Gelboim v. Bank of Am. Corp.*, 574 U.S. 405, 408 (2015).

[2] In outlining the facts, we borrow language without indication from the district court's excellent Memorandum and Order. *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litig.*, 507 F. Supp. 3d 1289 (D. Kan. 2020). Record and source quotations are cleaned up without indication. We see no need to redact statements sealed on appeal which were published unredacted by the district court.

the pharmacy." Pharm. Research & Mfrs. of Am., Follow the Dollar 3 (2017) [hereinafter *Follow the Dollar*], http://phrma-docs.phrma.org/files/dmfile/Follow-the-Dollar-Report.pdf. The distribution chain starts with the manufacturer who sells to a wholesaler for the wholesale acquisition cost ("list price"). Wholesalers then sell to the pharmacy, who dispense the product to the patient with a doctor's prescription.

While prescription drug distribution is conventional, the payments are not. "Drug pricing is a complex and often confusing issue, shaped by a pharmaceutical distribution and payment system that involves multiple transactions among numerous stakeholders." *Id.* at 1. The cost of prescription drugs is shared between the patient and a patient's health plan, so the amount a patient pays depends on the existence and extent of the patient's insurance. An uninsured patient pays the price set by the pharmacy. An insured patient pays—depending on the insurance policy's terms—a co-payment (a fixed dollar amount), a co-insurance payment (a percentage of the drug's price), or the full price. If the insured is paying a co-payment or co-insurance, the health plan covers the balance.

At this point, the drug has been purchased, but the amount paid to the pharmacy does not typically represent the drug's actual price. Health plans can effectively reduce the price of a drug by negotiating rebates with drug manufacturers. Charles Roehrig, Altarum, The Impact of Prescription Drug Rebates on Health Plans and Consumers 7 (2018), https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf. A rebate is a partial refund on the purchase price of an item. Even though the health plan must circle back post-purchase to collect the rebate, we

can say the rebate is, in effect, a price discount. The cost savings from rebates are substantial. One report found "health plans received manufacturer rebates of $23 billion [in 2016], which is 12% of point-of-purchase spending." *Id.* These rebate agreements are at the heart of the present dispute.

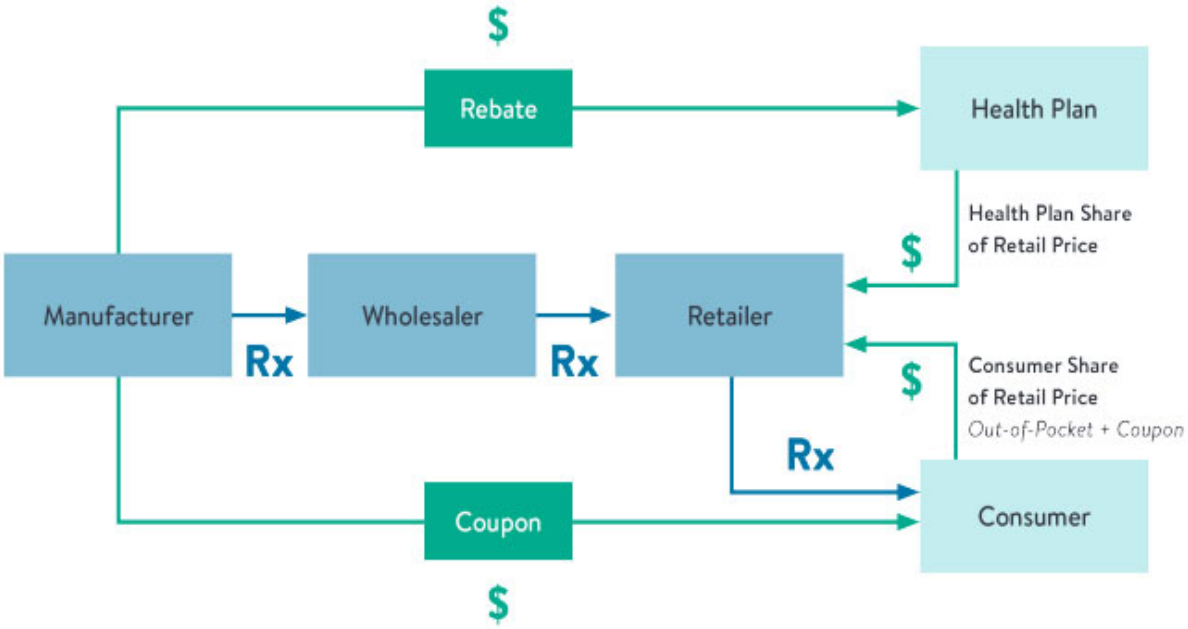

Figure 1. Visual representation of the flow of prescription drugs (Rx) and payments ($). Id. *at 3.*

To understand why drug manufacturers offer rebates, we must explain the role of health plans. The managed care health plan is the most common form of commercial health insurance in the United States. "Managed care" means the health plan controls patients' access to benefits to reduce costs. By controlling patients' access to benefits, a managed care health plan adjusts coverages and premiums to meet patient demands. Managed care health plans control patients' access to things like providers, medical procedures, and, relevant to this appeal, prescription drugs. By purchasing managed

care health plans, the patient relinquishes some treatment-choice autonomy for lower premiums.

Health plans control patients' access to prescription drugs by utilizing formularies. A formulary is a list of drugs covered by the health plan and is usually structured as "open" or "closed." An "open" formulary generally covers many, or sometimes all, drugs, whether they are listed on the formulary or not. A "closed" formulary only covers drugs listed on the formulary. Health plans are not required to cover all available prescription drugs. Some formularies cover a wide range of drugs to treat the same condition, while others are more restrictive. Choice comes at a cost. At his deposition, Sanofi's former CEO testified that health plans "can control the price [of a pharmaceutical product] by controlling access to the formulary; so the tighter the access to any given formulary, the more you have control over price." When a formulary covers more drugs, it increases the health plan's costs which, in turn, raises the patient's premiums.

Some health plans develop and manage their own formularies, but most retain Pharmacy Benefit Managers ("PBMs") to do so on their behalf. PBMs are effectively purchasing cooperatives. Instead of hundreds or thousands of health plans individually negotiating formulary access and rebates, the PBM acts in their collective interest, wielding the health plans' aggregate purchasing power to gain greater discounts than the health plans could obtain individually. After negotiating rebates with drug manufacturers, PBMs develop national formularies that health plans can adopt or customize in response to a particular plan's needs. Even if a PBM excludes or

disadvantages a particular drug on its national formulary, the health plan may, nevertheless, choose to cover it.

The PBM industry is "highly consolidated," with three PBMs processing about 70% of all prescription drug claims. *Follow the Dollar*, *supra*, at 7. The number of patients enrolled in a particular health insurance plan is often referred to as the number of "covered lives." Sanofi's expert economist, Fiona M. Scott Morton, Ph.D., estimates that, as of January 2015, the seven largest PBMs managed prescription drug benefits for 86% of covered commercial lives.[3] The PBMs are: Express Scripts ("ESI") (38%), CVS Caremark ("CVS") (20%), OptumRx (10%), Prime Therapeutics ("Prime") (7%), MedImpact (6%), Cigna (4%), and Aetna (1%).

To reduce health plan costs, PBMs control access to the formularies using what are called utilization management ("UM") techniques. By utilizing UM techniques, PBMs can nudge patients towards cost-effective products and negotiate better pricing from drug manufacturers. A PBM may only employ UM techniques after its pharmacy and therapeutics committee—a group of medical experts evaluating prescription drugs' efficacy, safety, and availability—determines two or more products are therapeutically equivalent (that is they have the same clinical effect and safety profile). A drug class that is subject to UM techniques is called a "managed class." Four commonly used

[3] The district court and parties call these seven entities "payors." For clarity, we refer to these seven entities as PBMs even though some of them are health insurers.

UM techniques are relevant to this appeal: (1) formulary tiering, (2) step edits, (3) prior authorizations, and (4) formulary exclusion.

Formulary Tiering. Formularies often use at least three tiers corresponding to different co-payments. The lower the tier, the lower the patient's co-payment. Generics are usually placed on the lowest tier (Tier 1), while branded drugs occupy the higher tiers (Tier 2 and Tier 3). When a PBM wants to cover multiple branded drugs, the PBM might place its preferred products on the lower tier (Tier 2), and less preferred products on the higher tier (Tier 3).

Step Edits. With a step edit, the PBM requires the patient to try a cheaper drug first and treatment failure before covering a more expensive drug.

Prior Authorizations. A PBM can require, before it will cover a specific drug, a formal request from the patient's physician asserting the patient meets certain criteria developed by the PBM.

Formulary Exclusion. Finally, PBMs may exclude drugs from the formulary. When a PBM excludes a drug from coverage, the patient can seek a medical necessity exemption or pay out of pocket for the product.

By using UM techniques, PBMs create some degree of price competition among sellers of therapeutically equivalent products. Drug manufacturers offer rebates and price protection for better formulary placement and to disadvantage rival products. Rebates are partial refunds that are calculated as some percentage of the list price. Price protection is an agreement to refund some, if not all, of the drug's increased price above some specified level. Implementing UM techniques for therapeutically

equivalent drugs is how PBMs lower prescription drug costs. Sanofi's expert recognized as much, testifying before Congress:

> The way you get low prices in the pharmaceutical industry is by the ability to exclude drugs. What do I mean by that? You identify a few therapeutic substitutes and you essentially hold an auction. I am happy to buy any one of these drugs. Whoever gives me the best price is the one I am going to buy from, and everybody else gets none of my business.
>
> When you can do that, you force price competition.

Prescription Drug Pricing and Negotiation: Overview and Economic Perspectives for the Medicare Prescription Drug Benefit: Hearing Before the S. Comm. on Fin., 110th Cong. 13 (2007) [hereinafter *Hearings*] (statement of Fiona M. Scott Morton, Ph.D., Professor of Economics, Yale School of Management). Patients are, in turn, enriched in the form of reduced premiums and reduced cost-sharing. Br. of Amicus Curiae Pharm. Care Mgmt. Ass'n (PCMA) in Supp. of Appellees 22; Roehrig, *supra*, at 7.

PBMs commonly solicit multiple rebate offers from manufacturers, including different rebate offers for different levels of formulary placement. For convenience, these bids are usually submitted in the form of "bid grids." A bid grid is a table with several cells, each of which represents a different level of formulary control and rebate percentage. Drug manufacturers offer higher rebates conditioned on the drug's exclusive or preferred (lower tier) status on the formulary. The manufacturer might also offer a higher rebate if the PBM agrees to subject competing products to additional restrictions like a step edit or prior authorization. *See generally supra* p. 9.

After a PBM and manufacturer agree on price concessions, the PBM enters an agreement with the manufacturer which typically includes the entire bid grid. The

rebate agreement does not require the PBM or health plan to make specific formulary decisions. Instead, only if and when a coverage option is selected by a PBM's client (the health plan) is the manufacturer obligated to provide the agreed-upon level of price concessions. This preserves flexibility for a PBM's client to, for example, receive the rebate for covering a drug that is otherwise excluded on the PBM's national formulary. PBMs may sign rebate agreements with multiple manufacturers for drugs in the same therapeutic class. Sanofi alleges, through the use of these rebate agreements, Mylan illegally monopolized the market for epinephrine auto-injectors.

B.

Millions of Americans suffer from anaphylaxis, a life-threatening allergic reaction caused by exposure to allergens such as foods, insect stings, pets, latex, or medications. The reaction occurs within seconds or minutes of exposure. Anaphylaxis causes a person's blood pressure to drop and restricts their airways, blocking breathing. If anaphylaxis is not treated immediately, it can be fatal. Epinephrine is the first-line treatment for anaphylaxis. An epinephrine auto-injector is a medical device used to inject a fixed dose of epinephrine through a spring-activated needle. Physicians prescribe epinephrine auto-injectors to patients at risk for anaphylaxis. Patients who suffer from anaphylaxis should always carry an epinephrine auto-injector, but failing to do so is a documented problem.

In 2007, defendant Mylan obtained the exclusive right to market, distribute, and sell EpiPen and EpiPen Jr. Auto-Injectors (collectively "EpiPen") in the United States. Introduced in the 1980s, EpiPen was the first epinephrine auto-injector available on

the market. Shaped like a pen, a patient administers EpiPen by removing a cap and swinging it against the thigh, causing the needle to protract and inject epinephrine. The patient then removes the device and a plastic shield covers the needle. After acquiring the rights to distribute EpiPen, Mylan invested substantially in marketing the product. Between 2007 and 2012, EpiPen accounted for at least 90% of epinephrine auto-injector prescriptions in the United States. Other than a few fringe competitors, EpiPen was the epinephrine auto-injector market.

Figure 2. Visual comparison of Auvi-Q (left) and EpiPen (right).

That all changed in 2013 when plaintiff Sanofi launched a new epinephrine auto-injector called Auvi-Q. Twin brothers Eric and Evan Edwards invented Auvi-Q after becoming frustrated with EpiPen's design. The brothers suffered from anaphylaxis and knew from experience that EpiPen's size and shape made it inconvenient to carry. Auvi-Q treats anaphylaxis with the same active ingredient (epinephrine) and same delivery mechanism (auto-injector) as EpiPen. Auvi-Q differs from EpiPen in that it is smaller (the thickness of a smart phone and size of a credit card), has a rectangular

shape, has a needle that retracts (as opposed to one covered before and after injection), and plays audio instructions. To administer Auvi-Q, the patient removes its cover and follows the audio instructions. When the patient presses the device against a patient's leg, the needle fires to inject epinephrine and retracts automatically. Unlike EpiPen, Auvi-Q does not require a swing-and-jab motion. No clinical studies show Auvi-Q is safer or more effective treating anaphylaxis, but market research suggested Auvi-Q would, nevertheless, be heavily favored among patients. Sanofi marketed Auvi-Q until October 28, 2015, when it initiated an FDA Class I recall following reports that Auvi-Q was failing to inject epinephrine. An FDA Class I recall is appropriate when a reasonable probability exists that the use of a product will cause serious adverse health consequences or death. Sanofi never relaunched Auvi-Q, electing instead to return Auvi-Q's distribution rights. Auvi-Q is currently sold by the inventors' company, operating under the name kaleo, Inc.

From the outset, Mylan knew Auvi-Q was a potentially disruptive product. Auvi-Q offered patients a solution to one of EpiPen's most significant problems: its size and shape. This would make Auvi-Q a particularly attractive option for certain patient populations who do not carry bags or purses. Mylan recognized that "physician research evaluating Auvi-Q and EpiPen perception/messaging had indicated strong interest in the new device." Mylan understood the research to show that "many physicians believed more patients would be willing to carry an Auvi-Q auto-injector," and some had "expressed strong interest and intent to prescribe Auvi-Q for a percentage of new and repeat patients." In 2012, Mylan's then-President

acknowledged that Auvi-Q "is a real competitor with some potential/perceived advantages." Concerned about Auvi-Q's arrival, Mylan even researched the possibility of redesigning EpiPen, but abandoned the plans because it would take too much time and money.

When it came time to launch, Sanofi decided to market Auvi-Q as a premium alternative to EpiPen. Sanofi's strategy was to seek a mix of Tier 2 and Tier 3 access for Auvi-Q—but "not Tier 2 at all cost." In his deposition, Auvi-Q's then-"brand lead" testified that Sanofi was "not planning for a lot of tier two access" and was "perfectly fine with tier two or tier three." *See In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litig.*, 507 F. Supp. 3d 1289, 1309 (D. Kan. 2020) (collecting further evidence). At the time, this marketing strategy may have made sense. Before 2012, no formulary excluded a non-EpiPen epinephrine auto-injector. But around the time of Auvi-Q's launch, patients and health plans became increasingly cost conscious. Where previously patients wanted choice, they were now accepting tighter formularies for lower premiums. PBMs adapted by increasingly using UM techniques to lower drug prices and decrease health plan costs. Sanofi observed that PBMs, "with the assistance of their health plan and PBM partners, are increasingly influencing physician prescribing decisions and patient use" by "erecting administrative hurdles (e.g., Step-Edits and prior authorizations)" and "co-pays." Several PBMs—including CVS, ESI, and UnitedHealthcare—began adding more drugs to their exclusion lists. Sanofi also observed an increasing use of exclusion-type formularies and a demonstrated ability to dramatically impact market share with

formulary exclusions. PBMs also increasingly asked for price protection—not just in the epinephrine auto-injector market, but across all product markets.

Meanwhile, Mylan was also preparing a strategy for Auvi-Q's launch. In December 2011, Mylan's Director of National Accounts suggested implementing a "proactive" strategy where Mylan "should begin to identify opportunities to restructure our contracts for exclusivity language." He recognized that if Mylan did not "begin its 'war game' scenarios now and begin to restructure contracts now it may be too late to do it after Auvi-Q gets momentum." Mylan developed a strategy for responding to Auvi-Q's launch that included strengthening EpiPen's formulary positions by adding, for example, "exclusivity language in 2012 contract renewals," causing "PBMs to be heavily impacted if they work against Mylan," or encouraging PBMs "to require prior authorization" for Auvi-Q. *See id.* at 1309–10 (collecting instances of Mylan encouraging a strategy to exclude or disadvantage Auvi-Q). Before Auvi-Q's launch, Mylan was offering single digit rebates (roughly 3%–10%) conditioned on equivalent access to the formulary as other epinephrine auto-injectors. After Auvi-Q's introduction, Mylan's rebate offers increased significantly: EpiPen's average rebate grew from 17% in 2014 to 36% in 2015. Mylan was also no longer satisfied with co-equal access; Mylan demanded exclusive or preferred formulary placement. And Mylan's higher rebates now required some PBMs to place restrictions on competing products (like step edits or prior authorizations).

Sanofi's initial marketing strategy was unsuccessful. At launch, Sanofi adopted contracting guidelines for Auvi-Q that authorized "pretty small" rebates, in the range

of 3%–10% for Tier 2 with no price protection and no rebate strategy for Tier 3 coverage. PBMs rejected these offers as "inadequate," "not competitive," and even "laughable," telling Sanofi these rebates "couldn't match the Mylan offer." Sanofi learned that Mylan was making offers conditioned on exclusivity that PBMs "couldn't refuse." Shortly after Auvi-Q's launch, Sanofi began questioning whether its offers were "being aggressive enough," but Sanofi recognized it was "in a bit of a bind and may already be as aggressive as" it can be given its high production costs and royalty rates. Auvi-Q's "royalty rate was 20 percent and it had a higher [cost-of-goods-sold] profile than other pharmaceutical products." Sanofi believed its initial strategy "made sense based on its understanding of the market environment" but it "couldn't have foreseen the unprecedented rebates that were given competitively by Mylan which forced Sanofi then into an aggressive rebating strategy to be able to negotiate access." So, "what made sense at launch made less sense after the competitive response to exclude Auvi-Q from the marketplace, and what it required for Sanofi to claw back appropriate patient access made it challenging from a [profit-and-loss] perspective."

Sanofi also miscalculated how much PBMs would value Auvi-Q's unique attributes. Several PBMs believed Auvi-Q delivered a treatment that was similar to or interchangeable with EpiPen. Departing from their previous practice of not excluding epinephrine auto-injectors, some PBMs decided to cover just one epinephrine auto-injector product. *Id.* at 1311 (collecting evidence). Auvi-Q's introduction was seen by many PBMs as an opportunity to manage the epinephrine auto-injector class and push for more competitive pricing. *Id.* at 1311–12 (collecting evidence). Indeed,

several PBMs told both Mylan and Sanofi that they intended to cover only one epinephrine auto-injector product and encouraged them to compete on price. *Id.* at 1312 (collecting evidence).

Even though the clear answer to Sanofi's problem was offering better prices, Sanofi was concerned that offering aggressive rebates during its first year of launch would "set off a whole cascade of price discounts" which would be "nearly impossible to withdraw." Sanofi believed, according to an internal presentation, that "newly launched, differentiated products with a high [cost of good]s cannot and should not engage in a discounting war," and "there are no winners in a price war." While being deposed, Sanofi's former CEO testified that, by September 2013, the company was not yet ready to authorize discounting to match Mylan's offers. He explained why:

> The first objective is really to establish the value proposition of a product with your customer, and pricing moves are very difficult to reverse in the future.
>
> It's a typical corporate approach where we'd say, you know, well, we know what a price decrease is going to cost us. Are you sure that you have done everything on all of the other levers of marketing really to explain that value proposition and—and avoid that.
>
> So it's a judgment call as to when you do that, but six months after launch would be potentially waving the white flag a little bit too early on the ability of the marketing and the sales team to explain that value proposition.

In the months leading up to Auvi-Q's launch, Mylan implemented various price increases for EpiPen. In 2012—the year before Sanofi's launch—Mylan raised EpiPen's price three times. And during the period of Sanofi's distribution of Auvi-Q

(2013 through 2015), EpiPen's net price, on average, increased.[4] According to Dr. Scott Morton, "Mylan's average net price to PBMs was $111 per device when Auvi-Q first entered the market," which increased steadily through the end of 2014, decreased sharply at the beginning of 2015 (when Sanofi competed on price, *see infra* Section I.C *2015 Formulary Coverage*), and increased again to about $150 per device by the time Sanofi exited the market. Mylan's costs, during the same period, increased between 4.3% to 6.5% annually.

Figure 3. EpiPen and Auvi-Q price per pen over time.

[4] Net price here means average list price per pen net any rebates, administrative fees, and price protection.

In 2016, Mylan submitted a "U.S. EpiPen Profitability Analysis" to Congress as a supplement to its congressional testimony. The analysis shows that EpiPen's sales increased from 4.5 million pens and $200 million in gross sales in 2009 to 8.3 million pens and $912 million in gross sales in 2015. Mylan's analysis also shows that its gross profit margin increased from 56% per pen in 2010 to 72% per pen in 2015. Using the data from Mylan's U.S. EpiPen Profitability Analysis, Sanofi's expert concluded that "profits per pen throughout 2013–2015 were far above what Mylan earned in 2012." And she found "from 2013 to 2015, while Auvi-Q was in the market, Mylan earned $219 million, $313 million, and $312 million respectively, or $30, $40, and $38 on a per-pen basis" and "across these three years, annual profits increased by 80% relative to 2012, or 67% on a per-pen basis."

C.

Most of Sanofi's specific allegations of monopolization center around Mylan's rebate agreements and EpiPen's formulary coverage from 2013 to 2015. Every year or two, PBMs solicit bids from drug manufacturers for formulary coverage. As described in more detail below, four PBMs—ESI, Aetna, OptumRx/UnitedHealthcare, and MedImpact—excluded or restricted Auvi-Q from coverage in 2014. But in 2015, two of the four—ESI and Aetna—removed those restrictions. Three PBMs—CVS, Prime, and Cigna—never restricted or excluded Auvi-Q, covering it on Tier 2 or Tier 3 without restriction. The following section describes the formulary coverage Mylan and Sanofi negotiated for their respective products from 2013 to 2015.

2013 Formulary Coverage

In 2013, the year of Auvi-Q's launch, many PBMs—including ESI, CVS, Prime, Aetna, and Cigna—covered Auvi-Q on Tier 3 pending formal review by their pharmacy and therapeutics committees. OptumRx/UnitedHealthcare did not cover Auvi-Q at launch because it had a policy of "not covering new products to market with the same active ingredients as other covered products" until its pharmacy and therapeutics committee reviewed the product.

2014 Formulary Coverage

The following section describes the coverages Mylan and Sanofi negotiated for their respective products on the seven largest PBMs' formularies in 2014.

PBM #1: Express Scripts ("ESI"). When Sanofi launched Auvi-Q, it initially planned to offer ESI rebates in the 5% range. But in early 2013, ESI advised Sanofi to offer higher rebates if it wanted to compete with Mylan's offer. Sanofi's revised final rebate offer was 30% for exclusive Tier 2 coverage, 20% for co-preferred Tier 2 coverage, and 10% for Tier 3 access. Sanofi did not offer any price protection. *See generally supra* p. 9. Mylan, on the other hand, offered a range of rebates, including a 23% rebate with price protection for plans who chose to make EpiPen the exclusive epinephrine auto-injector. Sanofi's expert placed the overall value of Mylan's discounts (rebate plus price protection of 10%) at "approximately 30%." ESI announced EpiPen was the exclusive epinephrine auto-injector on ESI's 2014 National Preferred and High Performance Formularies. But this only affected about "35% of ESI commercial lives." In other words, Auvi-Q remained covered for roughly "2 out

of 3 ESI commercial patients." ESI's corporate designee testified that it exclusively covered EpiPen because it resulted in a "lower net cost for our plans." EpiPen's list price was lower, and Mylan offered price protection.

PBM #2: CVS Caremark ("CVS"). In late 2012, CVS asked Mylan and Sanofi to complete the CVS "bid document" to submit bids that would become effective July 1, 2013. The bid request explained: "Incremental Rebates for Additional Controls (exclusion opportunities) may be used for custom clients in 2013/14, as well as future template exclusions effective January 1, 2014." Both Mylan and Sanofi offered CVS a variety of rebates, and CVS memorialized the bids in agreements effective July 1, 2013. Mylan offered a 7% rebate for Tier 2 co-preferred coverage, a 9% rebate for 1-of-1 Tier 2 coverage on managed plans, and a 14% rebate for 1-of-1 Tier 2 coverage on closed plans. Sanofi offered a 10% rebate for 1-of-1 or 1-of-2 coverage on any tier. On its national formulary, CVS covered both products from July 1, 2013 to July 1, 2014, placing EpiPen on Tier 2 and Auvi-Q on Tier 3.

PBM #3: OptumRx/UnitedHealthcare. In February 2013, OptumRx asked Mylan to offer a 30% rebate for EpiPen in exchange for OptumRx making it the exclusive branded epinephrine auto-injector product on UnitedHealthcare's formulary for the remainder of 2013 and for 2014. Initially, Mylan did not make that offer. But in April 2013, Mylan offered a 17% rebate conditioned on EpiPen being the exclusive branded epinephrine auto-injector on UnitedHealthcare's formulary. OptumRx rejected the bid stating, "if Mylan did not offer a better rebate for EpiPen, the product would be placed into a benefit exclusion." Mylan understood that UnitedHealthcare

would decide at its July formulary meeting "whether Auvi-Q or EpiPen will be the future sole epinephrine auto-injector covered under its benefits" and that, "if Auvi-Q is selected, EpiPen will become excluded." OptumRx told Mylan to submit a revised offer "by June 14th to meet deadline of July" formulary meeting. Mylan knew that OptumRx disadvantaged EpiPen in the late 2000s after Twinject—another epinephrine auto-injector device—made a higher rebate offer.

In Sanofi's negotiations with OptumRx, Sanofi offered rebates ranging from 2% to 7% for co-preferred status with EpiPen, but Sanofi did not offer price protection or any rebate for unrestricted placement on the non-preferred formulary brand tier (Tier 3). After OptumRx rejected Sanofi's earlier offers, it set a deadline of June 28, 2013 for Sanofi to submit a revised proposal.

Mylan submitted a revised bid to OptumRx on June 13, 2013. It presented UnitedHealthcare with seven different rebate options conditioned on various formulary placements, ranging from 2% for co-preferred positioning to 22% for exclusive formulary positioning. Mylan's offer also included 8% price protection and made all proposed rebates effective July 1, 2013. Sanofi submitted its revised bid on June 28, 2013. Sanofi's rebate offer was based on progressive effective dates. Sanofi offered a 7% rebate for coverage on any tier, effective August 1, 2013 through December 31, 2013. Then, beginning January 1, 2014 through December 31, 2015, Sanofi offered a 22% rebate plus 9% resetting price protection in exchange for exclusive epinephrine auto-injector formulary positions. *See generally In re EpiPen*, 507 F. Supp. 3d at 1315

(explaining resetting price protection, which resets each year, is less valuable than cumulative price protection).

OptumRx and UnitedHealthcare rejected Sanofi's June 28 offer. OptumRx's corporate designee testified: "The Mylan offer was better for two reasons." First, Mylan's double-digit rebates started earlier. Second, Mylan's price protection was more valuable because it was based on an earlier list price and did not reset each year. OptumRx told Sanofi that its offer "is not close to what is needed." On July 12, 2013, Sanofi submitted another revised offer to OptumRx. The revised offer was not as price competitive as Mylan's offer, so OptumRx rejected it. OptumRx and UnitedHealthcare memorialized Mylan's offers in a rebate agreement effective July 1, 2013. OptumRx and UnitedHealthcare did not enter an agreement with Sanofi for Auvi-Q rebates. UnitedHealthcare excluded Auvi-Q from its formularies for about 60% of its commercial lives for the second half of 2013 through the first half of 2015. And OptumRx restricted Auvi-Q with a step edit or prior authorization on its 2014 standard national formularies for external health plan clients. *See generally supra* p. 9.

PBM #4: Prime Therapeutics ("Prime"). When Auvi-Q launched, Mylan offered Prime two rebate options memorialized in a rebate agreement effective April 1, 2013 through December 31, 2015: 8% for Tier 2 co-preferred coverage, and 12% for placement as the exclusive branded product on Tier 2. In early 2014, Prime renegotiated its EpiPen rebate agreement with Mylan. Prime had been "pushing Mylan very hard for price protection." So, Mylan offered Prime the same 8% rebate for Tier 2 co-preferred coverage and the same 12% rebate for Tier 2 exclusive coverage described

above, but Mylan also offered a 17% rebate plus price protection if EpiPen was the exclusive epinephrine auto-injector device on Tier 2 with "all other auto-injectors listed tier 3 or higher with step therapy restriction." Mylan "encouraged" Prime to disadvantage Auvi-Q with a step edit, but Prime refused. Instead, Prime asked Mylan to increase its rebate for exclusive Tier 2 placement. Mylan responded by increasing its offer for exclusive Tier 2 coverage from 12% to 14%. The 8%, 14%, and 17% rebate options were memorialized in an amendment to Prime's EpiPen rebate agreement, effective April 1, 2014 through December 31, 2015.

In early 2013, Prime asked Sanofi to submit rebate proposals for Auvi-Q, and repeatedly told Sanofi that certain Prime clients would consider placing a new product on Tier 2 only if a rebate proposal contained price protection. Sanofi's account executive told Prime that his internal request for price protection was "denied nationally due to the reduction of price for Auvi-Q, prior to launch, to be equal with EpiPen." Sanofi eventually offered Prime a 17% rebate plus price protection for Tier 2 equal access. Sanofi memorialized its offers to Prime in an agreement effective April 1, 2014 through December 31, 2015. Sanofi did not offer rebates for exclusive Tier 2 coverage. Prime continued to list EpiPen as the exclusive epinephrine auto-injector device on Tier 2 of its national formulary in 2014 with Auvi-Q on Tier 3 without restrictions. But, during that time, Prime's clients continued to make independent determinations for their formularies—for example, from 2013 to 2015, Horizon Blue Cross Blue Shield of New Jersey covered both Auvi-Q and EpiPen on Tier 2.

PBM #5: MedImpact. With Auvi-Q's launch, MedImpact used the entry of a new epinephrine auto-injector as a "negotiation technique." MedImpact intended to "create a perception" with both Mylan and Sanofi that "there is a very good possibility that the other product would be a formidable challenger to their product on our formularies" to induce them "to offer as large a rebate as possible." Before Auvi-Q's launch, Mylan was paying MedImpact a 5% rebate for Tier 2 formulary coverage. In early 2013, Mylan offered MedImpact a 10% rebate if EpiPen was the only branded epinephrine auto-injector on Tier 2. MedImpact responded by asking Mylan to submit a better offer, and specifically asked for a rebate offer conditioned on MedImpact placing a step edit on Auvi-Q.

MedImpact also solicited a "1 of 1 offer" from Sanofi. MedImpact told Sanofi that it "wishes to have only one product in the category" and that "all other products" would be "Not Covered or [Tier 3 Prior Authorization]/Step Edit" on MedImpact's controlled and closed plans. Sanofi responded by offering MedImpact several rebate options, including 4% for exclusive preferred coverage on the closed formulary. MedImpact rejected Sanofi's offer as "not competitive" and invited Sanofi to submit a revised offer. Both Mylan and Sanofi submitted revised bids in March 2013. The bids included a slew of rebates. Among other bids, Sanofi offered MedImpact a 15% rebate for 1-of-1 coverage on a closed formulary. Mylan offered MedImpact a 13% rebate for EpiPen's exclusive formulary position on Tier 2 and placement of all other epinephrine auto-injectors on the highest copay tier with a step edit. In late April 2013, MedImpact informed Mylan that it was going to "go with Auvi-Q." Mylan responded

with a final offer that included: a 5% rebate for unrestricted placement on Tier 2; a 10% rebate for exclusive preferred brand placement; a 20% rebate for exclusive preferred brand placement, with all other branded epinephrine auto-injector products "placed on the highest copay tier" and subject to step edit; and a 22% rebate to be the exclusive product in the lowest preferred branded tier, with all other epinephrine auto-injector products (branded or generic) "placed on the highest copay tier" and subject to step edit.

Ultimately, MedImpact made EpiPen the preferred epinephrine auto-injector with Auvi-Q "in a Non-Formulary position with a step edit." MedImpact concluded that EpiPen had "a better price, net of rebate"—with EpiPen costing $113/device compared to Auvi-Q's $145/device—and its "decision to stick with EpiPen" was also based upon "the potential for disruption, and observation of market adoption rates." Sanofi asked if it could submit another offer. MedImpact initially declined, but in the fall of 2013, Sanofi renegotiated with MedImpact to provide higher rebates, ranging from 5% to 20%, for MedImpact's custom clients. Even though Auvi-Q was step edited on MedImpact's three standard commercial formularies, custom clients remained eligible for Sanofi's rebates if they covered Auvi-Q. For example, one MedImpact client—the University of Michigan—covered Auvi-Q on Tier 2. Also, on open plans (15% of MedImpact's clients) Auvi-Q shared equal preferred positioning with EpiPen.

PBM #6: Aetna. In May 2013, Aetna recognized a "revenue opportunity by placing a prior authorization or step edit on Auvi-Q," but doing so could "risk"

"member and provider dissatisfaction." Later that month, Mylan offered Aetna a 15% rebate plus price protection conditioned on Tier 2 formulary placement for EpiPen and Tier 3 formulary placement for Auvi-Q with a step edit on Aetna's national formulary. Mylan and Aetna memorialized Mylan's rebate offers in an amendment to Mylan's rebate agreement with Aetna, effective January 1, 2014 through December 31, 2015.

Aetna also negotiated with Sanofi, but Aetna only agreed to Sanofi's offer for a 25% rebate for exclusive Tier 2 coverage on Aetna's Qualified Health Plans in 2014. In August 2013, Aetna announced that it would place a step edit on Auvi-Q on its national formulary in 2014. In March 2014, Aetna offered to remove the restriction on Auvi-Q beginning June 1, 2014, in exchange for Sanofi offering a 30% to 40% rebate for unrestricted Tier 3 access. Sanofi's corporate representative explained that Sanofi was "not willing to" offer Aetna's proposed rebates, so Auvi-Q's step edit stayed in place for the rest of 2014.

PBM #7: Cigna. Before Auvi-Q's launch, Cigna asked Mylan to provide a rebate offer for "exclusive epinephrine positioning." Mylan responded with a 10% rebate offer conditioned on EpiPen being the sole preferred brand. Cigna responded by asking whether there was any "further opportunity (above 10%) for any lines of business where we are able to implement NDC blocks and/or Step therapy on competing products?" In June 2013, Mylan offered Cigna a 13% rebate for placement as the sole preferred epinephrine auto-injector with all other epinephrine auto-injectors "branded or generic placed on the highest copay tier of such Plan (i.e. Tier 3 or higher) and subject to a step therapy edit." Cigna did not accept Mylan's offer for sole

preferred placement. Instead, Cigna signed a contract with Mylan for a 7% rebate for EpiPen, conditioned only on co-preferred coverage.

At the same time, Sanofi offered Cigna a 12% rebate for placement as a co-preferred epinephrine auto-injector through December 2013, and a 15% rebate for placement as a co-preferred epinephrine auto-injector from January 2014 through December 2015. Cigna did not accept the proposal, and Auvi-Q remained on the formulary as non-preferred without a rebate agreement. Sanofi then offered Cigna a 35% rebate for co-preferred formulary placement or a 20% rebate for Tier 3 access. Cigna again declined the offer, and Auvi-Q remained on Tier 3 with no rebate agreement through 2014. In 2015, though, Sanofi and Cigna entered a Rebate Agreement that included a 20% rebate for Auvi-Q as a non-preferred brand.

Other PBMs and Health Plans. Like the PBMs described above, other PBMs made formulary decisions for Auvi-Q and EpiPen in 2014.[5] In negotiations with these other PBMs, Mylan asked some of them to exclude Auvi-Q. In the end, some PBMs covered: (a) both Auvi-Q and EpiPen on the preferred brand tier; (b) EpiPen on the preferred tier and Auvi-Q on the non-preferred tier; (c) EpiPen on the preferred tier

[5] Sanofi details Mylan's rebate negotiations and agreements with Humana but we do not see how they are relevant. Mylan successfully blocked Auvi-Q on Humana's Medicare formularies by doubling the rebate offer from 5% to 10% in 2013, and then increasing it to 14% in 2014. But Humana *never excluded* Auvi-Q on its *commercial* formularies. No one explicitly defines the relevant market in this case, but it appears to be, based on the arguments presented, the commercial U.S. market for epinephrine auto-injectors. Humana's exclusion of Auvi-Q on its Medicare formularies is, therefore, wholly irrelevant.

and placed a restriction on Auvi-Q; and (d) Auvi-Q on the preferred tier and EpiPen on the non-preferred tier. Some PBMs chose to cover only one device and selected EpiPen, but at least one PBM restricted EpiPen in favor of Auvi-Q.

2015 Formulary Coverage

After discovering PBMs were more interested in Mylan's exclusive rebate offers than paying a premium for Auvi-Q, Sanofi "changed its contracting strategy" and "made deeper offers" to PBMs to gain formulary access. Sanofi's former CEO, Chris Viehbacher, testified at his deposition that, after seeing the "very aggressive approach on pricing to try to exclude Auvi-Q," "it became clear to Sanofi that there was no choice but to try to gain an access to the marketplace by significantly discounting." Thus, in early 2014 Viehbacher proposed "making an offer that kicks Mylan off a formulary. If Mylan knows we can be aggressive it may help." Sanofi's change in "contracting strategy" had an "impact on its profitability" but it helped Sanofi to "resecure the ESI business starting in 2015" and secured a "tier two parity agreement for 2015" with Aetna. "So those deeper offers started to pull Sanofi's access back."

Express Scripts (ESI). First, Sanofi was able to reverse its exclusion from ESI's national formulary. Sanofi made a "portfolio contract" offer for Auvi-Q that provided an additional 2% rebate on Lantus if Auvi-Q was removed from the exclusion list. Lantus is Sanofi's market-leading insulin drug which in 2013–2014 had "somewhere around $4 billion in sales"—a "formidable" volume unmatched by any Mylan product. Additionally, Sanofi offered ESI price protection. Initially, ESI decided to "reverse exclusion and exclude EpiPen and prefer Auvi-Q." But after more analysis, ESI

concluded that it could "decrease the cost per [prescription] significantly" for both EpiPen and Auvi-Q "without excluding." So, ESI decided to cover both products on its national formularies but exclude EpiPen in favor of Auvi-Q on its High Performance Formulary. ESI's corporate designee testified that ESI "did our job there" and "lowered the overall net cost for its plans, and in many cases, for members, depending on what their specific benefit design would have been."

Aetna. Next, Sanofi offered Aetna a 65% rebate, with price protection, conditioned on Aetna listing Auvi-Q as the exclusive epinephrine auto-injector on its formulary for 2015. In response, Aetna developed a 2015 formulary design that would (1) make Auvi-Q the exclusive preferred product on its value formularies, and (2) make Auvi-Q and EpiPen co-preferred on its premier formularies. Aetna then used Sanofi's offer as leverage to threaten Mylan with EpiPen's exclusion. By doing so, Aetna was able to induce a 45% rebate plus 10% price protection from Mylan for EpiPen to be co-preferred on Tier 2. Sanofi ultimately agreed to pay Aetna a 30% rebate plus 12% price protection for Auvi-Q to be co-preferred on Tier 2 (*i.e.*, a lower rebate than Mylan for the same access). Effective January 1, 2015, Aetna made EpiPen and Auvi-Q co-preferred on its value and premier formularies.

CVS. Sanofi also improved its coverage at CVS by offering rebates of 40% for unrestricted coverage, 50% for exclusive preferred coverage, and 65% for exclusive formulary coverage with EpiPen excluded, plus 10% price protection. Sanofi and CVS memorialized these offers in a rebate agreement effective July 1, 2014 through December 31, 2015. With this offer, Sanofi secured co-preferred Tier 2 formulary

coverage for Auvi-Q on CVS's Preferred Drug List, and Auvi-Q became the sole preferred drug (with EpiPen excluded) on CVS's Value Based Formulary beginning July 1, 2014, and CVS's Advanced Control Formulary beginning October 1, 2014. CVS used Sanofi's offer to pressure Mylan to increase its rebates to avoid EpiPen's exclusion on the Preferred Drug List. Mylan agreed to a 34% rebate for 1-of-1 status on closed plans as well as an additional 5% incremental base rebate "on all Plan types," if Auvi-Q is excluded. Even though Mylan tried to reverse EpiPen's exclusion from CVS's Value and Advanced Control formularies, CVS continued to exclude EpiPen until early November 2015—after Auvi-Q was recalled from the market.

Other PBMs. Finally, in 2015, Sanofi successfully maintained its previous formulary coverage at many PBMs including Prime and Cigna. But Sanofi's success was not unlimited; it was unable to secure coverage with all PBMs in 2015. For example, UnitedHealthcare sought to renegotiate with Sanofi, expressly requesting an offer for exclusive formulary coverage and telling Sanofi its target rebate was 60% plus 6% cumulative price protection with a base date of December 1, 2014. Sanofi declined to make an exclusive offer, offering instead a lower rebate—35% rebate plus 8% price protection with a list price base date of January 1, 2015—for coverage on any tier. In contrast, Mylan offered a higher rebate (37% plus 8% price protection) for exclusive coverage and, as a result, maintained its position as the exclusive epinephrine auto-injector on the formulary. And in March 2014, Sanofi asked MedImpact what rebate it should offer to secure removal of the step edit on Auvi-Q. In response, MedImpact told Sanofi that it "would need to offer a discount in the upper 30s to low

40s with Price Protection to even open the conversation." MedImpact recognized "it would be very difficult for Sanofi to neutralize the savings advantage from Mylan's exclusive rebate offer given the current share" of Auvi-Q. After internal discussion, Sanofi declined to offer MedImpact such a discount.

Sanofi's increased price competition also impacted Mylan. PBMs approached Mylan with requests for deeper discounts using Sanofi's competition in the epinephrine auto-injector market as leverage. For example, after Sanofi increased its rebate offer to Prime in late 2014, Prime told Mylan months later that "Sanofi is aggressively selling in the market," "that we are starting to see some share shift in certain areas," and that "there has been some discussions around a possible move to an equal status due to this shift and the possible upcoming generic entry." Prime reminded Mylan that it was seeking "overall enhancements on terms and on price protection." Prime asked that Mylan "take the items discussed into consideration and please provide your most competitive offer to Prime." In response, Mylan offered better price protection.

In April 2015, after seeing Auvi-Q had regained "80% commercial market" coverage, Sanofi's newly-appointed CEO, Dr. Olivier Brandicourt, asked for an "upside proposal for Auvi-Q, to drive profitable growth," and "increased its investment in the brand." Sanofi began seeing Auvi-Q's market share increase in 2015.

D.

Despite Auvi-Q's frequent exclusion, several PBMs testified that they could have excluded EpiPen in favor of Auvi-Q because they could shift product use from EpiPen to Auvi-Q. *In re EpiPen*, 507 F. Supp. 3d at 1324 (collecting evidence). This

testimony is confirmed by the record. On at least two occasions, patients shifted to Auvi-Q after EpiPen was excluded. First, CVS excluded EpiPen from its Advanced Control Formulary in 2014 and told Mylan in 2015 that its market share on that formulary was "all but gone." CVS used its Advanced Control Formulary as a "trial balloon of sorts" and determined it would not be "a big deal excluding EpiPen" because there had "been no noise or complaints." Mylan confirmed that EpiPen utilization on plans that adopted the CVS Value Formulary, including plans of large corporations like Comcast and Home Depot, "completely disappeared in Q4 2014." CVS projected that if it excluded EpiPen in favor of Auvi-Q on its national formulary, EpiPen's share would drop from 66% to 7%, with Auvi-Q's share increasing from 10% to 75%. Second, when ESI excluded EpiPen from its High Performance Formulary, EpiPen's share for plans that adopted the exclusion list "dropped from an average of 94% in the end of 2014, to about 12% by June 2015." When Sanofi crafted its 2015 ESI bid, it also assumed this shift in market share would occur. Sanofi predicted that excluding EpiPen in favor of Auvi-Q would achieve 89% market share for Auvi-Q on plans adopting the exclusion list.

Broader industry practice also supports the PBMs' testimony that they could have excluded EpiPen in favor of Auvi-Q. PBMs are, as one of Sanofi's consultants observed, "able to transition market share from the product that has been excluded to the new product" and are "willing to remove market leaders in certain circumstances." ESI, for example, excluded many popular products with high market shares, including

GlaxoSmithKline's leading asthma medication Advair and Gilead's leading hepatitis C treatment Sovaldi.

As part of its marketing efforts, Sanofi employed pharmaceutical sales calls. Between April 2013 and July 2013, the percentage of targeted physicians writing Auvi-Q prescriptions increased from 10.3% to 22.6%. The percentage also increased for targeted allergists (39.2% to 61.6%) and targeted pediatricians (4.3% to 15.2%). Sanofi reported that "more than three in four allergists" and "one in four pediatricians" who were called on by Sanofi's sales force "converted" to prescribe Auvi-Q. In 2014, when Sanofi's overall share of epinephrine auto-injector prescriptions declined, Sanofi concluded that "prescribers who have been detailed show a smaller drop in Auvi-Q share compared to those not called on." Sanofi's study of 24 months of data—from August 2013 to July 2015—concluded that Sanofi's "sales force generated 15% of all" Auvi-Q prescriptions.[6]

II.

In 2017, Sanofi sued Mylan under Section 2 of the Sherman Act alleging monopolization. 15 U.S.C. §§ 2, 15. Sanofi originally filed the action in the District of New Jersey, but the Judicial Panel on Multidistrict Litigation transferred the case to the District of Kansas for coordinated discovery with a related consumer class action.

[6] Some evidence relied upon by the district court in granting summary judgment is absent from the record on appeal. Because the parties did not object to the use of that evidence, we perfect the record by taking judicial notice of the missing facts. *See St. Louis Baptist Temple, Inc. v. FDIC*, 605 F.2d 1169, 1172 (10th Cir. 1979).

After discovery, the parties cross-moved for summary judgment on the two elements of Sanofi's claim: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966). Sanofi moved on the first element, Mylan on the second. In a learned order, the district court granted Mylan's motion and denied Sanofi's motion as moot. *In re EpiPen*, 507 F. Supp. 3d at 1382. The district court held Sanofi could not survive summary judgment because, based on the undisputed summary judgment facts, no reasonable jury could conclude Mylan engaged in exclusionary conduct—the second element of monopolization. *Id.* at 1363. Sanofi appeals.

III.

We review a district court's grant of summary judgment on a monopolization claim de novo. *Lenox MacLaren Surgical Corp. v. Medtronic, Inc.*, 762 F.3d 1114, 1118 (10th Cir. 2014). Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). We view the facts and draw reasonable inferences in the light most favorable to the nonmoving party—which in this case is Sanofi. *Scott*, 550 U.S. at 378. A factual dispute is "genuine" if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). An issue of fact is "material" if it "might affect the outcome of the suit under the governing law." *Id.*

"Summary judgment procedure is properly regarded not as a disfavored procedural shortcut, but rather as an integral part of the Federal Rules as a whole, which are designed to secure the just, speedy and inexpensive determination of every action." *Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986) (quotation omitted). "Summary judgment is of particular importance in the area of antitrust law, because it helps to avoid wasteful trials and prevent lengthy litigation that may have a chilling effect on pro-competitive market forces." *MLB Props., Inc. v. Salvino, Inc.*, 542 F.3d 290, 309 (2d Cir. 2008) (cleaned up); *see also Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 73 (3d Cir. 2010).

Because the Judicial Panel on Multidistrict Litigation transferred this case from the Third Circuit, we must initially decide an issue of first impression for our Circuit: whose substantive law applies? Our sister circuits unanimously agree that "when one district court transfers a case to another, the norm is that the transferee court applies its own Circuit's cases on the meaning of federal law." *AER Advisors, Inc. v. Fid. Brokerage Servs., LLC*, 921 F.3d 282, 288 & n.5 (1st Cir. 2019) (collecting cases from the Second, Fourth, Fifth, Eighth, Ninth, Eleventh, and D.C. Circuits). We see no reason to depart from the consensus view. Our caselaw, therefore, has "stare decisis effect," and the Third Circuit's caselaw "merits close consideration." *In re Korean Air Lines Disaster of Sept. 1, 1983*, 829 F.2d 1171, 1176 (D.C. Cir. 1987) (R. Ginsburg, J.).

IV.

Section 2 of the Sherman Act makes it illegal to "monopolize" any part of the trade or commerce among the several states. 15 U.S.C. § 2. The offense of monopolization "has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Grinnell*, 384 U.S. at 570–71. The second element is often called the "exclusionary conduct" element. To survive summary judgment, the plaintiff must present a triable issue of both (1) monopoly power and (2) exclusionary conduct. *See* 3 Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 618, at 67 (4th ed. 2015).

The issue of monopoly power—the power to "raise prices substantially above a competitive level without losing so much business that the gambit becomes unprofitable"—is not in play here. *Novell, Inc. v. Microsoft Corp.*, 731 F.3d 1064, 1070 (10th Cir. 2013) (Gorsuch, J.); *see, e.g.*, *United States v. Microsoft Corp.*, 253 F.3d 34, 51 (D.C. Cir. 2001) (en banc) (per curiam); William M. Landes & Richard A. Posner, *Market Power in Antitrust Cases*, 94 Harv. L. Rev. 937 (1981). The district court held there was no triable issue of exclusionary conduct, meaning, for purposes of summary judgment, it was unnecessary to reach the issue of monopoly power. Thus, the sole issue on appeal is whether the district court properly granted summary judgment on the exclusionary conduct element.

A.

"A firm violates § 2 only when it acquires or maintains, or attempts to acquire or maintain, a monopoly by engaging in exclusionary conduct." *Microsoft*, 253 F.3d at 58. Writing for the Supreme Court, Justice Scalia observed:

> The mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system. The opportunity to charge monopoly prices—at least for a short period—is what attracts "business acumen" in the first place; it induces risk taking that produces innovation and economic growth. To safeguard the incentive to innovate, the possession of monopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive *conduct*.

Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 407 (2004). *See generally* Robert L. Heilbroner, The Worldly Philosophers 293–97 (7th ed., rev. 1999) (discussing Joseph Schumpeter's views on entrepreneurship and innovation underlying Justice Scalia's observations); Paul A. Samuelson & William D. Nordhaus, Economics 540–42 (12th ed. 1985) (explaining Schumpeter's hypothesis that imperfect competition is the "wellspring of innovation and technological change").

"Whether any particular act of a monopolist is exclusionary, rather than merely a form of vigorous competition, can be difficult to discern." *Microsoft*, 253 F.3d at 58; *see also, e.g.*, Frank H. Easterbrook, *The Limits of Antitrust*, 63 Tex. L. Rev. 1, 26 (1984) ("Low prices and large plants may be competitive and beneficial, or they may be exclusionary and harmful."). Competitive and exclusionary conduct look alike and "the means of illicit exclusion, like the means of legitimate competition, are myriad." *Microsoft*, 253 F.3d at 58; *see also, e.g.*, *Novell*, 731 F.3d at 1072. "The challenge for

an antitrust court lies in . . . distinguishing between exclusionary acts, which reduce social welfare, and competitive acts, which increase it." *Microsoft*, 253 F.3d at 58; *Novell*, 731 F.3d at 1072. The courts, with time and a gathering body of experience, have been able to "adapt this general inquiry to particular circumstances, developing considerably more specific rules for common forms of alleged misconduct"—like tying, predatory pricing, or exclusive dealing. *Novell*, 731 F.3d at 1072.

Real-world monopolists may engage in allegedly exclusionary conduct which does not fit within a single paradigm, instead exhibiting characteristics of several common forms of alleged misconduct. In these situations, the courts disaggregate the exclusionary conduct into its component parts before applying the relevant law. The Supreme Court, for example, separated a price-squeeze claim into a duty-to-deal and predatory-pricing claim. *Pac. Bell Tel. Co. v. linkLine Commc'ns, Inc.*, 555 U.S. 438, 449–52, 457 (2009). Holding the plaintiff could not state a duty-to-deal or predatory-pricing claim, the Supreme Court "decline[d] the invitation to recognize" a "new form of antitrust liability," stating "[t]wo wrong claims do not make one that is right." *Id.* at 457. In granting summary judgment to Mylan on Sanofi's monopolization claim, the district court disaggregated Mylan's allegedly exclusionary conduct into several common forms of alleged misconduct and, after applying the relevant law, concluded that—considered separately or together—the facts presented no triable issue of exclusionary conduct. *See In re EpiPen*, 507 F. Supp. 3d at 1363.

The district court's methodology was flawed, so says Sanofi, because it took "a balkanized view of the evidence that badly missed the forest for the trees." Appellant's

Opening Br. 3. After all, "Sanofi should have received 'the full benefit of all its proof without tightly compartmentalizing the various factual components.'" Appellant's Opening Br. 72 (cleaned up) (quoting *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962)). We reject this argument. *See Ne. Tel. Co. v. AT&T Co.*, 651 F.2d 76, 95 n.28 (2d Cir. 1981); *Cal. Comput. Prods., Inc. v. IBM Corp.*, 613 F.2d 727, 746 (9th Cir. 1979). For the sake of accuracy, precision, and analytical clarity, we must evaluate Mylan's allegedly exclusionary conduct separately. *See N.M. Oncology & Hematology Consultants, Ltd. v. Presbyterian Healthcare Servs.*, 994 F.3d 1166, 1173–74 (10th Cir. 2021). Only then can we evaluate the evidence in totality to see if any "synergistic effect" saves Sanofi's case. *Ne. Tel. Co.*, 651 F.2d at 95 n.28; *Cal. Comput. Prods.*, 613 F.2d at 746; *cf. linkLine*, 555 U.S. at 457.

Mylan's allegedly exclusionary conduct can be split up into three categories: (1) Mylan's use of exclusive rebate agreements; (2) the leveraging of EpiPen's entrenched demand to deny Sanofi a meaningful opportunity to compete for the non-entrenched demand; and (3) other conduct working in concert to lock Sanofi out of the market, including Mylan's EpiPen4Schools program and the misclassification of EpiPen as a generic drug for Medicaid purposes. We take each in turn and conclude that, considered separately or together, the district court properly held the summary judgment facts present no triable issue of exclusionary conduct.

B.

Sanofi alleges Mylan's rebate agreements were anticompetitive exclusive dealing contracts. "An exclusive dealing arrangement is an agreement in which a buyer

agrees to purchase certain goods or services only from a particular seller for a certain period of time." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 270 (3d Cir. 2012). "The primary antitrust concern with exclusive dealing arrangements is that they may be used by a monopolist to strengthen its position, which may ultimately harm competition." *Id.* (citing *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005)); *see also Perington Wholesale, Inc. v. Burger King Corp.*, 631 F.2d 1369, 1374 (10th Cir. 1979); *McWane, Inc. v. FTC*, 783 F.3d 814, 832 (11th Cir. 2015). "The best example of a possible threat to competition exists where a market is already heavily concentrated and long-term exclusive dealing contracts . . . foreclose so large a percentage of the available . . . outlets that entry into the concentrated market is unreasonably constricted." *E. Food Servs., Inc. v. Pontifical Catholic Univ. Servs. Ass'n*, 357 F.3d 1, 8 (1st Cir. 2004); 11 Areeda & Hovenkamp, *supra*, ¶ 1802, at 72.

"Despite some initial confusion, today exclusive dealing contracts are not disfavored by the antitrust laws." *E. Food Servs.*, 357 F.3d at 8. Courts repeatedly explain that exclusive dealing agreements are often entered into for entirely procompetitive reasons and pose very little threat to competition even when utilized by a monopolist. *See, e.g.*, *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 333 (1961); *Jefferson Par. Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 45 (1984) (O'Connor, J., concurring in the judgment); *ZF Meritor*, 696 F.3d at 270; 11 Areeda & Hovenkamp, *supra*, ¶ 1810, at 161 ("Exclusive-dealing arrangements can produce beneficial results greatly exceeding their potential for harm." (cleaned up)). For example, exclusive deals might ensure a buyer with a predictable source of inputs from an otherwise

volatile supply market, *United States v. Am. Can Co.*, 230 F. 859, 883 (D. Md. 1916); enable buyers to group repeat purchases into a single contract to reduce the cost of using the market, 11 Areeda & Hovenkamp, *supra*, ¶ 1811c; or prevent distributors from free riding on a manufacturer's promotional investments, Howard P. Marvel, *Exclusive Dealing*, 25 J.L. & Econ. 1, 7 (1982). *See also* Robert H. Bork, The Antitrust Paradox 303 (1978); Richard A. Posner, Antitrust Law 230 (2d ed. 2001). Thus, exclusive dealing contracts are "frequently upheld when challenged on antitrust grounds." *Race Tires Am.*, 614 F.3d at 76 (citing *E. Food Servs.*, 357 F.3d at 8; *Barr Labs., Inc. v. Abbott Labs.*, 978 F.2d 98, 111 (3d Cir. 1992)). In fact, some courts and commentators suggest exclusive dealing contracts should be treated as "presumptively lawful in all but a few carefully defined circumstances." 11 Areeda & Hovenkamp, *supra*, ¶ 1810, at 161; *see E. Food Servs.*, 357 F.3d at 8; Bork, *supra*, at 303.

1.

To analyze the legality of exclusive dealing contracts, we apply the rule of reason.[7] *Jefferson Par.*, 466 U.S. at 44–45 (O'Connor, J., concurring in the judgment)

[7] There is some law in the Third Circuit suggesting "in the context of exclusive dealing, the price-cost test may be utilized as a specific application of the 'rule of reason' when the plaintiff alleges that price is the vehicle of exclusion." *ZF Meritor*, 696 F.3d at 273 (citing *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1060–63 (8th Cir. 2000)); *id.* at 320–24, 344 (Greenberg, J., dissenting); *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 408–09 (3d Cir. 2016). The Supreme Court developed the price-cost test to analyze predatory-pricing claims. *See Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 222–27 (1993). A predatory-pricing plaintiff must prove: (1) the rival's low prices "are below an appropriate measure of its rival's costs," and (2) the rival had a "dangerous

(citing *Tampa Elec.*, 365 U.S. at 333–35); *Perington Wholesale*, 631 F.2d at 1374; *ZF Meritor*, 696 F.3d at 271. *See generally McWane*, 783 F.3d at 835 (providing background on how *Tampa Electric* is now read to permit a full rule of reason approach to exclusive dealing cases).

"The rule of reason requires courts to conduct a fact-specific assessment of 'market power and market structure to assess the challenged restraint's actual effect' on competition." *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2284 (2018) (cleaned up) (quoting *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 768 (1984)). Whether an exclusive dealing arrangement is an "unreasonable restraint on competition," *Cont'l T. V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 49 (1977), depends on whether "performance of the contract will foreclose competition in a substantial share of the line of commerce affected." *Tampa Elec.*, 365 U.S. at 327; *see also ZF Meritor*, 696 F.3d at 271. This analysis requires us to consider not only the percentage of the market

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probability[] of recouping its investment in below-cost prices." *Id.* Sanofi does not dispute that it cannot pass the price-cost test.

Mylan urges us to affirm on this basis, but its briefing is too cursory for us to do so. *See* Br. of Appellees 66. Even within the *ZF Meritor* panel there was substantial disagreement about when the price-cost test is the appropriate rule of reason analysis for exclusive dealing contracts. Mylan's two paragraphs of briefing are insufficient for us to determine whether the Third Circuit's approach is correct and how it should apply in this case. We leave for another day whether, in the Tenth Circuit, the price-cost test is the appropriate rule of reason analysis where "a firm uses a single-product loyalty discount or rebate to compete with similar products." *Eisai*, 821 F.3d at 409. We, therefore, choose to apply the full rule of reason analysis to Mylan's exclusive rebate agreements. This approach is consistent with Third Circuit precedent—which merits close consideration in this case—because *ZF Meritor* clearly states the price-cost test "may be utilized as a specific application of the 'rule of reason.'" 696 F.3d at 273.

foreclosed by the contested contract, but also "the probable effect of the contract on the relevant area of effective competition" and "the probable immediate and future effects which pre-emption of that share of the market might have on effective competition therein." *Tampa Elec.*, 365 U.S. at 329.

Standing alone, these standards are not particularly illuminating. After all, every completed contract could be said to "foreclose competition" for the subject matter of that contract. *Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227, 236 (1st Cir. 1983) (Breyer, J.); Bork, *supra*, at 137. And the term "substantially foreclose competition" is not a self-contained, or clearly-defined yardstick.

To delineate between permissive and prohibited exclusionary contracts, we need some guiding principle—some standard that allows us to quickly and easily resolve whether exclusive contracts harm competition. In our Circuit, this is the consumer welfare standard. *Novell, Inc. v. Microsoft Corp.*, 731 F.3d 1064 (10th Cir. 2013) (Gorsuch, J.). "Congress designed the Sherman Act as a 'consumer welfare prescription.'" *Reiter v. Sonotone Corp.*, 442 U.S. 330, 343 (1979) (quoting Bork, *supra*, at 66); *see* 7 Areeda & Hovenkamp, *supra*, ¶ 1503a, at 401–04. In earlier days, antitrust was built upon the assumption that protection of rivalry was the best means of promoting competition. The promotion of atomistic competition at all costs, however, led to puzzling outcomes: "If a monopolist so much as expanded its facilities to meet anticipated demand, or failed to keep its prices high enough to permit less efficient rivals to stay afloat, it could find itself held liable under section 2." *Novell*, 731 F.3d at 1072.

The emphasis of antitrust policy has wisely shifted from "protection of competition as a process of rivalry to the protection of competition as a means of promoting economic efficiency." *Olympia Equip. Leasing Co. v. W. Union Tel. Co.*, 797 F.2d 370, 375 (7th Cir. 1986) (Posner, J.); *see also Novell*, 731 F.3d at 1072. The lawful monopolist, after all, must be "free to compete like everyone else; otherwise the antitrust laws would be holding an umbrella over inefficient competitors." *Olympia Equip.*, 797 F.2d at 375; *see also* Posner, *supra*, at 196. Under the consumer welfare standard, we still seek to "protect[] the process of competition," but we do it "with the interests of consumers, not competitors, in mind." *Novell*, 731 F.3d at 1072. As the Supreme Court explains, the goal is to "distinguish[] between restraints with anticompetitive effect that are harmful to the consumer and restraints stimulating competition that are in the consumer's best interest." *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 886 (2007); *accord Am. Express*, 138 S. Ct. at 2284. Consequentially, with the adoption of the consumer welfare standard, antitrust became indifferent to the preservation of inefficient competitors. "[A] consumer has no interest in the preservation of a fixed number of competitors greater than the number required to assure his being able to buy at the competitive price." *Marrese v. Am. Acad. of Orthopaedic Surgeons*, 706 F.2d 1488, 1497 (7th Cir. 1983) (Posner, J.).

Some amici curiae urge us to either supplant or supplement our consumer welfare standard with a consumer choice framework. Because of the industry at issue,

we must necessarily reject this invitation.[8] In urging us to reverse the district court, these amici argue the district court erred by failing to consider the patients' deprivation of choice arising from Mylan's exclusive rebate agreements. At the outset, it is hard to say patients were ever deprived of choice. Even when a patient's health plan excluded Auvi-Q, the patient could seek a medical necessity exemption or otherwise pay out of pocket for the device. But even if the inability to choose between multiple *covered* products was considered a deprivation of choice, it would subvert the health insurance industry to adopt a consumer choice framework.

"Antitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue," *Trinko*, 540 U.S. at 411, and when a patient purchases health insurance, the patient necessarily relinquishes some treatment-choice autonomy in exchange for lower premiums. Adopting a consumer choice framework would frustrate, for example, the patient who sought out a health plan with a tighter formulary and lower premiums, because the health plan would be obligated to cover both EpiPen and Auvi-Q when covering EpiPen alone would be cheaper. The proper balance between health plan premiums and formulary coverage is better struck through the workings of the private market than the judiciary. Thus, our only concern in this case is whether Mylan's exclusive rebate agreements hurt or threaten to hurt consumers

[8] Introducing a consumer choice framework, even as a supplement to the consumer welfare standard, may inappropriately re-entangle the courts in what Judge Bork called the "antitrust paradox." *See* Bork, *supra*, at 79–89.

through reduced output or increased prices. *See* 11 Areeda & Hovenkamp, *supra*, ¶ 1802b, at 75.

2.

In the exclusive dealing context, we can broadly state that an exclusive dealing contract is anticompetitive under the consumer welfare standard if it harms consumers by excluding rivals. *See Roland Mach. Co. v. Dresser Indus., Inc.*, 749 F.2d 380, 394 (7th Cir. 1984) (Posner, J.); *Microsoft*, 253 F.3d at 58; 3 Areeda & Hovenkamp, *supra*, ¶ 651b1, at 103. In a case like this where buyers instigated exclusivity to obtain lower prices, the rival plaintiff must prove two things to show the exclusive dealing agreements are anticompetitive. First, the rival plaintiff must show that the agreements are likely to foreclose it from doing business in the relevant market. *See Tampa Elec.*, 365 U.S. at 334; *Roland Mach.*, 749 F.2d at 394 ("If there is no exclusion of a significant competitor, the agreement cannot possibly harm competition."); *E. Food Servs.*, 357 F.3d at 8–9; 11 Areeda & Hovenkamp, *supra*, ¶ 1802b, at 75 ("A 'foreclosure' injury to a private firm occurs when that firm is denied access to a market that would presumably be open absent the challenged restraint."). To determine whether the challenged exclusive agreements are likely to foreclose a competitor from the market, courts generally look at (among other things) the duration, ease of terminability, and percentage of the market foreclosed by the contracts. *See, e.g.*, *E. Food Servs.*, 357 F.3d at 8; 11 Areeda & Hovenkamp, *supra*, ¶ 1802g2, at 101–02.

Second, the rival plaintiff must show that, once foreclosed, the defendant could reduce output or increase prices and those consumer harms would outweigh any

consumer benefit received from the period of lower prices. *See Roland Mach.*, 749 F.2d at 394; *Microsoft*, 253 F.3d at 59; *Novell*, 731 F.3d at 1075; *Barry Wright*, 724 F.2d at 237–38; 11 Areeda & Hovenkamp, *supra*, ¶ 1802, at 72; *cf., e.g.*, *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 222–27 (1993). The monopolist's successful elimination of a rival alone is an insufficient condition to prove harm to competition. *See Prods. Liab. Ins. Agency, Inc. v. Crum & Forster Ins. Cos.*, 682 F.2d 660, 663 (1982) (Posner, J.) ("Now there is a sense in which eliminating even a single competitor reduces competition. But it is not the sense that is relevant in deciding whether the antitrust laws have been violated."); *Univ. Life Ins. Co. of Am. v. Unimarc Ltd.*, 699 F.2d 846, 853 (7th Cir. 1983) (Posner, J.) ("That 'there's a special providence in the fall of a sparrow,' William Shakespeare, Hamlet act 5, sc. 2, lines 233–34, is not the contemporary philosophy of antitrust." (cleaned up)); Br. of Amicus Curiae J. Gregory Sidak in Supp. of Appellees 20–23. It does not automatically follow that a monopolist can freely engage in the requisite anticompetitive conduct—reducing output or increasing prices—once it forecloses its competitor from the market using exclusive deals. If the monopolist pushes prices above the competitive level, the foreclosed competitor might develop alternative channels of distribution, *see Omega Envtl., Inc. v. Gilbarco, Inc.*, 127 F.3d 1157, 1163 (9th Cir. 1997), or might reenter the market and compete for the challenged contracts, *see* John Bates Clark, The Control of Trusts 26–27 (1st ed. 1901), effectively pushing prices back down to the competitive level. Thus, to present a triable issue of monopolization where the exclusive deals were entered into for a corresponding procompetitive benefit—here, lower prices—the

plaintiff must "prove that the . . . effect of the exclusion will be to raise prices above (and therefore reduce output below) the competitive level, or otherwise injure competition; [plaintiff] must show in other words that the anticompetitive effects (if any) of the exclusion outweigh any benefits to competition from it." *Roland Mach.*, 749 F.2d at 394; *see, e.g.*, *Microsoft*, 253 F.3d at 59; *Race Tires Am.*, 614 F.3d at 75; *Dentsply*, 399 F.3d at 196–97; Easterbrook, *supra*, at 26–28.

We recognize our test seems onerous, but the Supreme Court consistently reminds us that "mistaken inferences" in a case driven by "price-cutting activities" can be "especially costly, because they chill the very conduct the antitrust laws are designed to protect": slashing prices. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986); *accord Brooke Grp.*, 509 U.S. at 223; *Weyerhaeuser Co. v. Ross-Simmons Hardwood Lumber Co.*, 549 U.S. 312, 319 (2007); *see Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 340 (1990). "[A]ntitrust rules are court-administered rules" which "must be designed with the knowledge that firms ultimately act, not in precise conformity with the literal language of complex rules, but in reaction to what they see as the likely outcome of court proceedings." *Town of Concord v. Bos. Edison Co.*, 915 F.2d 17, 22 (1st Cir. 1990) (Breyer, C.J.). No one can seriously dispute that exclusive rebate agreements stimulate price competition in the prescription drug market. Sanofi's own expert witness, Dr. Scott Morton, recognized as much, testifying before Congress that "[t]he way you get low prices in the pharmaceutical industry is by the ability to exclude drugs." *Hearings*, *supra*, at 13. Price cutting in concentrated industries seems "sufficiently difficult to stimulate that

we hesitate before embracing a rule that could"—through the unintentional prohibition of the monopolist's legitimate use of exclusive rebate agreements—"stabilize 'tacit cartels' and further encourage interdependent pricing behavior." *Barry Wright*, 724 F.2d at 235. Our rule, therefore, adequately protects the legitimate use of exclusive rebate agreements in the prescription drug market.

3.

Because Mylan's exclusive rebate agreements brought about lower prices for epinephrine auto-injectors than if Mylan and Sanofi used preferred or co-preferred rebate agreements, *see supra* Section I.C, Sanofi must prove that (1) Mylan's exclusive rebate agreements were likely to foreclose Auvi-Q from the epinephrine auto-injector market, and (2) after Auvi-Q's foreclosure, Mylan could reduce output or increase prices above the competitive level, and the reduced output or increased prices would produce anticompetitive effects outweighing the procompetitive benefits from the period of lower prices. Sanofi fails to present a triable issue that Mylan's rebate agreements were likely to foreclose it from doing business in the epinephrine auto-injector market. We, therefore, affirm the district court's judgment on that element alone.

The district court, applying *ZF Meritor*'s seven-factor test,[9] concluded Sanofi "failed to present a triable issue that Mylan's rebate contracts foreclosed Sanofi" from

[9] We think the district court's use of the *ZF Meritor* seven-factor test was appropriate given our case-specific deference to the Third Circuit. Although our analysis today does not directly reference *ZF Meritor*'s factors, it follows the same general principles. These principles are:

competing in the epinephrine auto-injector market. *In re EpiPen*, 507 F. Supp. 3d at 1355. We are in full agreement. At the height of its allegedly anticompetitive behavior, Mylan only foreclosed Auvi-Q from 31% of the U.S. population. *See id.* at 1353 (collecting evidence that Auvi-Q was not covered or step edited for 31% of the population). That means Auvi-Q was still covered and available for nearly 70% of the U.S. population. And remember, patients whose health plans excluded or restricted Auvi-Q could still pay out of pocket for the device if they so desired.

But percentage of market foreclosure is only half the inquiry. While we recognize that a "monopolist's use of exclusive contracts, in certain circumstances, 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,"

> There is no set formula for evaluating the legality of an exclusive dealing agreement, but modern antitrust law generally requires a showing of (1) significant market power by the defendant, (2) substantial foreclosure, (3) contracts of sufficient duration to prevent meaningful competition by rivals, and (4) an analysis of likely or actual anticompetitive effects considered in light of any procompetitive effects. Courts will also consider (5) whether there is evidence that the dominant firm engaged in coercive behavior, and (6) the ability of customers to terminate the agreements. (7) The use of exclusive dealing by competitors of the defendant is also sometimes considered.

ZF Meritor, 696 F.3d at 271–72 (cleaned up).

Microsoft, 253 F.3d at 70, this is not one of those cases.[10] Mylan's exclusive rebate agreements did not impair Sanofi's opportunity to compete for several reasons.

First, Mylan's exclusive rebate agreements were short and easily terminable. It is axiomatic that short, easily terminable exclusive agreements are of little antitrust concern; a competitor can simply wait for the contracts to expire or make alluring offers to initiate termination. *See, e.g.*, *Omega Envtl.*, 127 F.3d at 1163–64 ("The short duration and easy terminability of these agreements negate substantially their potential to foreclose competition." (cleaned up)); *Methodist Health Servs. Corp. v. OSF Healthcare Sys.*, 859 F.3d 408, 410 (7th Cir. 2017) (Posner, J.) ("Most of the contracts expire every year or two, giving other competitors, such as plaintiff, a shot at obtaining the next contract by outbidding defendant." (cleaned up)); *U.S. Healthcare, Inc. v. Healthsource, Inc.*, 986 F.2d 589, 596 (1st Cir. 1993) (holding termination on 30 days' notice is normally a *de minimis* constraint); *Balaklaw v. Lovell*, 14 F.3d 793, 799 (2d Cir. 1994) (holding "opportunities for competition remain" where the contract's term was three years but it "may be cancelled without cause upon six-months' notice"); *see also, e.g.*, *Roland Mach.*, 749 F.2d at 395; *Paddock Publ'ns, Inc. v. Chi. Tribune Co.*, 103 F.3d 42, 47 (7th Cir. 1996) (Easterbrook, J.); *Barry Wright*, 724 F.2d at 237; 11

[10] Section 1 of the Sherman Act makes "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States" illegal. 15 U.S.C. § 1. Exclusive dealing can be challenged under both § 1 and § 2. *See, e.g.*, *ZF Meritor*, 696 F.3d at 267 (challenging defendant's exclusive deals under both § 1 and § 2). For background on how the exclusive dealing analysis sometimes differs under § 1 and § 2, see 1 Antitrust Section, ABA, Antitrust Law Developments § 2C-2-b (9th ed. 2022).

Areeda & Hovenkamp, *supra*, ¶ 1802g2, at 101 ("Even an exclusive-dealing contract covering a dominant share of a relevant market need have no adverse consequences if the contract is let out for frequent rebidding."); Marvel, *supra*, at 6. The undisputed summary judgment facts show that most of the contracts imposed terms of two and a half years or less and included termination provisions allowing either party to terminate the agreements without cause on 90-days' written notice or less. *In re EpiPen*, 507 F. Supp. 3d at 1344 (collecting evidence). Furthermore, the summary judgment record establishes that PBMs invoked these termination provisions and renegotiated rebate agreements annually and, sometimes, even more frequently. *Id.* at 1344–45 (collecting evidence). Mylan's exclusive rebate agreements made the epinephrine auto-injector market hard to enter midyear but did not "stifle competition over the longer run." *Paddock Publ'ns*, 103 F.3d at 45.

Second, exclusive rebate agreements were a normal competitive tool in the epinephrine auto-injector market to stimulate price competition. The undisputed summary judgment facts show that PBMs often instigated exclusivity to stimulate price competition, with Sanofi bidding for and entering into exclusive rebate agreements for Auvi-Q. *See In re EpiPen*, 507 F. Supp. 3d at 1307–08, 1311–12 (collecting evidence). The widespread use of exclusive rebate agreements in the epinephrine auto-injector market—and the pharmaceutical drug market more broadly—does not suggest Mylan acted anticompetitively. Rather, this demonstrates the market was functioning properly. *See Paddock Publ'ns*, 103 F.3d at 45 ("Competition-for-the-contract is a form of competition that antitrust laws protect rather than proscribe."); *Race Tires Am.*,

614 F.3d at 83 ("It is well established that competition among businesses to serve as an exclusive supplier should actually be *encouraged*."); *NicSand, Inc. v. 3M Co.*, 507 F.3d 442, 453–54 (6th Cir. 2007) (en banc) (Sutton, J.); Benjamin Klein & Kevin M. Murphy, *Exclusive Dealing Intensifies Competition for Distribution*, 75 Antitrust L.J. 433, 437, 450 (2008). After all, Sanofi's *own expert* testified before Congress that "*[t]he way you get low prices* in the pharmaceutical industry *is by the ability to exclude drugs*." *Hearings*, *supra*, at 13 (statement of Dr. Scott Morton) (emphasis added).

Third, in the absence of any coercion, *see infra* Section IV.B.4.c, we are left with the firm and singular conclusion that Sanofi "need only offer a better product or a better deal" to reverse, and possibly wield, exclusivity. *Omega Envtl.*, 127 F.3d at 1164; *see, e.g.*, *NicSand*, 507 F.3d at 447; *Paddock Publ'ns*, 103 F.3d at 45. When Sanofi entered the epinephrine auto-injector market, it prepared to take its place as the market's premium product: Sanofi priced Auvi-Q at a premium and refused to seek out exclusivity or deeply discount its "better mousetrap." *In re EpiPen*, 507 F. Supp. 3d at 1307–09 (collecting evidence). This turned out to be a mistake; PBMs rejected Sanofi's initial offers as "inadequate," "not competitive," and even "laughable." *Id.* at 1310. Sanofi's initial strategy failed to accommodate PBMs' increasing reliance on UM techniques to push down drug prices. *Id.* at 1307–08. But after being excluded or restricted on four of the seven largest PBMs' formularies in 2014, Sanofi changed its contracting strategy and made deeper offers to reverse exclusivity. *Id.* at 1321. The shift in strategy was a resounding success. In 2015, Sanofi not only maintained its formulary coverage from 2014, but also reversed exclusivity at ESI and Aetna.

Moreover, Sanofi successfully excluded EpiPen on ESI's High Performance formulary and CVS's Value Based and Advanced Control formularies.[11] By April 2015, Auvi-Q regained 80% access to the commercial market and Sanofi was investigating long-term marketing strategies. *Id.* at 1323–24. The captain of a sinking ship, we note, rarely continues to chart his course.

Sanofi challenges our de novo conclusion that it only had to offer a better price to reverse or wield exclusivity, but its arguments suffer from a serious evidentiary deficiency. According to Sanofi, PBMs excluded Auvi-Q even when Sanofi offered better per-unit prices than Mylan. But Sanofi's incomplete and cherry-picked bids do not support the story it tells. Throughout Sanofi's briefing is a mischaracterization or misunderstanding of pricing. Price, in this case, depends not only on list price, but the rebates, price protection, and effective dates of rebates. Sanofi alleges ESI excluded Auvi-Q in 2014 even after it offered better prices than Mylan. While we agree with Sanofi that it offered *higher rebates* (30% for exclusivity versus Mylan's 23%), the

[11] Sanofi tries to downplay the significance of its clear success by suggesting PBMs "might experiment at the margins, excluding EpiPen from their smallest and most highly managed formularies," but "none would dare block EpiPen from a major formulary." Appellant's Opening Br. 39–40. But the summary judgment record undercuts Sanofi's assertion. For example, in 2015, ESI initially decided to reverse exclusion and exclude EpiPen in favor of Auvi-Q on its national formulary. *In re EpiPen*, 507 F. Supp. 3d at 1321. ESI only reversed course after further analysis uncovered it could decrease the cost per prescription for both EpiPen and Auvi-Q without excluding EpiPen. *Id.* And CVS used its exclusion of EpiPen on its Advanced Control Formulary as "a trial balloon of sorts." *Id.* at 1324. After hearing "no noise or complaints" arising from EpiPen's exclusion, CVS projected that it could exclude EpiPen in favor of Auvi-Q on its national formulary. *Id.*

record belies Sanofi's claim that it offered *better prices*. ESI concluded Mylan's offer was better because it included price protection—something Sanofi did not offer—and resulted in cheaper per-unit costs because EpiPen's list price was lower.

Sanofi makes the same deficient argument about OptumRx/UnitedHealthcare and MedImpact. In 2014, Sanofi offered OptumRx/UnitedHealthcare a 27% rebate with 9% price protection for exclusive epinephrine auto-injector coverage, while Mylan only offered a 22% rebate with 8% price protection. It may appear that Sanofi was rejected despite offering better prices, but this conclusion is misleading for two reasons. First, Sanofi's 27% offer was weeks too late. Second, Mylan's offer started earlier (July 1, 2013 versus January 1, 2014) and Mylan's price protection was based on an earlier list price. OptumRx/UnitedHealthcare excluded Auvi-Q because Mylan's rebate offer was timely and superior. MedImpact also excluded Auvi-Q in 2014 because Mylan offered better rebates. After discounts, MedImpact would pay $113 per EpiPen versus $145 per Auvi-Q.

The record supports only one conclusion: when Sanofi beat Mylan's prices it succeeded. For instance, Sanofi reversed Auvi-Q's exclusion on ESI's national formulary and successfully excluded EpiPen on ESI's High Performance formulary; Sanofi secured exclusive formulary positioning for Auvi-Q on Aetna's value formularies and co-preferred positioning on Aetna's premier formularies; and Sanofi obtained Auvi-Q's co-preferred formulary placement on CVS's Preferred Drug List and exclusive formulary positioning on CVS's Value Based Formulary and Advanced Control Formulary. *Id.* at 1321–22. PBMs were not afraid of excluding popular, high-

market share products if another product offered better exclusive pricing. *See id.* at 1324 (discussing ESI's exclusion of the market-leading drugs Advair and Sovaldi). "[PBMs] testified that they could have excluded EpiPen in favor of Auvi-Q because they could shift product use from EpiPen to Auvi-Q." *Id.* at 1324. Sanofi fails to bring forth a triable issue of exclusionary conduct because exclusive rebate agreements were a normal competitive tool in the epinephrine auto-injector market, Mylan's exclusive rebate agreements were short and easily terminable, and Mylan did not coerce any PBMs.

Sanofi tries to save its plainly deficient case by arguing: "Mylan's clear plan confirms Sanofi's substantial foreclosure." Appellant's Opening Br. 59. We recognize that some caselaw suggests intent evidence is relevant in antitrust analysis. But in these cases, intent is only relevant to whether the challenged conduct is fairly characterized as "exclusionary." *E.g.*, *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 602 (1985). When the challenged conduct is so wholly devoid of any inference of exclusionary effect, intent cannot save the plaintiff's case. Nor should it. *See* 7 Areeda & Hovenkamp, *supra*, ¶ 1506, at 438–39. Intent evidence is too easily misleading. The miscreant's declarations are also "legitimately used by business people in the heat of competition." *Morgan v. Ponder*, 892 F.2d 1355, 1359 (8th Cir. 1989); *A.A. Poultry Farms, Inc. v. Rose Acre Farms, Inc.*, 881 F.2d 1396, 1401–02 (7th Cir. 1989) (Easterbrook, J.); *Barry Wright*, 724 F.2d at 232; *see also* Herbert Hovenkamp, *The Monopolization Offense*, 61 Ohio St. L.J. 1035, 1039 (2000) ("[A]ny competitively energetic firm 'intends' to prevail over its actual or potential rivals.").

So it is with Sanofi's intent evidence; phrases like it is important to "hammer Sanofi at launch" or Mylan's need to "pre-empt Auvi-Q" are statements representative of normal business competition. *See* 7 Areeda & Hovenkamp, *supra*, ¶ 1506, at 441. "Were intent to harm a competitor alone the marker of antitrust liability, the law would risk retarding consumer welfare by deterring vigorous competition—and wind up punishing only the guileless who haven't figured out not to write such things down." *Novell*, 731 F.3d at 1078. Intent does not save Sanofi's case.

4.

Sanofi makes several objections to our de novo conclusion that no triable issue of exclusionary conduct exists in this case. First, Sanofi alleges Mylan foreclosed it from more than half the market because of spillover foreclosure. Second, Sanofi argues we should not weigh its use of exclusive contracts against it. Third, Sanofi contends Mylan's offers were coercive. Finally, Sanofi maintains its desperate attempts to regain epinephrine auto-injector market access by granting incremental rebates on a different drug (Lantus) exemplifies foreclosure. None of these arguments undermine our conclusion.

a.

Sanofi begins by challenging our de novo conclusion that, at most, Auvi-Q was foreclosed from 31% of the market. According to Sanofi, EpiPen's "spillover foreclosure" blocked Auvi-Q from more than half the market. Spillover foreclosure is the idea that doctors act on imperfect information and fail to prescribe Auvi-Q even when it is better for the patient and covered by the patient's insurance. Basically,

doctors want to prescribe covered drugs to their patients, but patients are covered by many different health plans and each health plan covers different products, so doctors—instead of researching each patient's coverage before prescribing a product—tend to default to the product that they know is most widely covered in the region. The aggregate effect of this behavior is, "if one or more large plans in a region has excluded Auvi-Q, the prescribers tend to prescribe EpiPen to patients in the region, even if the health plans for those patients provide equal or even preferred access to Auvi-Q or other [epinephrine auto-injector] devices." *In re EpiPen*, 507 F. Supp. 3d at 1320. We reject Sanofi's spillover foreclosure theory for both factual and legal reasons.

Spillover foreclosure is predicated on a breakdown of rational behavior. Rational choice theory, a foundational principle of modern economics, presumes a decisionmaker "maximize[s] their utility from a stable set of preferences and accumulate[s] an optimal amount of information and other inputs in a variety of markets." Gary S. Becker, The Economic Approach to Human Behavior 14 (1976). In a perfect world, we would expect doctors to assemble an optimal amount of information about every drug that could treat the patient's condition before deciding what drug to prescribe. This information would include the upsides and downsides of each product, and the costs of each product—including whether any is covered by the patient's insurance. In our perfect world, we would expect the doctor to prescribe the drug that produces the highest utility (a function of the expected benefits and risks of the drug) per patient dollar (a function of formulary coverage). For example, if the ideal Auvi-Q patient (someone who needs a pocketable epinephrine auto-injector)

walked into the doctor's office, we would expect the doctor (after assembling optimal information) to prescribe Auvi-Q if the co-payment or out-of-pocket cost to the patient was the same or substantially similar as EpiPen. After all, the doctor knows this patient will receive a higher utility per dollar from Auvi-Q than EpiPen. In economic terms, we would call this doctor "rational." With the rational doctor, the highest foreclosure percentage Sanofi could claim is 31%—the percentage of the U.S. population for which Auvi-Q was either not covered or restricted. *In re EpiPen*, 507 F. Supp. 3d at 1353.

According to Sanofi, this is not what happens in the real world. Doctors cannot possibly retain an encyclopedic knowledge of prescription drug coverages for thousands of health plans, *see* Christine Jolls, Cass R. Sunstein & Richard Thaler, *A Behavioral Approach to Law and Economics*, 50 Stan. L. Rev. 1471, 1477 (1998), and doctors' busy schedules may prevent them from investigating every patient's individual drug coverage before prescribing a product, *see* Staffan Burenstam Linder, The Harried Leisure Class 60–76 (1970). So doctors default to the drug they know is most widely covered by health plans. This, of course, is a stark departure from the rational doctor. This imperfect doctor could be said to exhibit "irrational" behavior.[12] Due to the doctor's irrationality, we can expect prescriptions to be written for the inferior, widely-covered drug even when the patient's insurance covers a superior, less-widely covered drug. This irrational behavior is what Sanofi calls "spillover

[12] The term "rational" and "irrational" are economic terms. Doctors that act "irrationally" may nevertheless act, in the eyes of society, appropriately or reasonably. *See, e.g.*, Richard A. Posner, Economic Analysis of Law § 1.1 (9th ed. 2014).

foreclosure." Combining spillover foreclosure and contractual foreclosure, Sanofi estimates Mylan foreclosed Auvi-Q from over half the market.

We refuse to recognize Sanofi's theory of spillover foreclosure for three reasons. First, Sanofi's theory of spillover foreclosure depends on crediting market participants' irrationality as a means of measuring market foreclosure. This squarely contradicts the Supreme Court's guidance in *Tampa Electric* where foreclosure was measured only by contractual foreclosure—that is, the percentage of the market covered by the contested contracts. *See* 365 U.S. at 330–33. We are unaware of, and Sanofi fails to cite, any case where market foreclosure was measured, not by contractual foreclosure, but by the irrational behavior of market participants.

Second, any spillover foreclosure is subject to neutralization by vigorous competition. The clear problem with Sanofi's theory is spillover foreclosure is not actual foreclosure—it does not prevent customers from accessing Auvi-Q. Spillover foreclosure is a nebulous byproduct of irrational doctors. If a patient knew their insurance covered both EpiPen and Auvi-Q, the patient could simply ask the doctor to prescribe Auvi-Q. This leads us into another question raised by Sanofi's briefing: should we consider spillover foreclosure because Mylan ran an advertising campaign to amplify spillover foreclosure? No. Quite simply, any harm from Mylan's advertising campaign or spillover foreclosure was "readily susceptible to neutralization or other offset by rivals." *Lenox*, 762 F.3d at 1127 (citing *Am. Prof'l Testing Serv., Inc. v. Harcourt Brace Jovanovich Legal & Prof'l Publ'ns, Inc.*, 108 F.3d 1147, 1152 (9th Cir. 1997)). Mylan's advertising campaign intended to push the narrative EpiPen

was the "preferred brand" for epinephrine auto-injectors for "95 million patients" because "Auvi-Q will be a difficult product for patients to obtain."[13] Sanofi could easily neutralize the effects from these advertisements and otherwise reduce or eliminate spillover foreclosure by advertising to physicians or patients. The record confirms this. Sanofi directly advertised to doctors and the message recall surveys indicated positive results. One survey, for example, concluded that 28% of health care providers "recalled messaging that Auvi-Q was *preferred* over EpiPen." *In re EpiPen*, 507 F. Supp. 3d at 1330 (emphasis added); *see also id.* at 1328–30 (collecting evidence). So long as Auvi-Q is front of mind for patients or prescribers, any spillover foreclosure will be minimal.

Finally, any recognition of spillover foreclosure intolerably raises the risk of false condemnation under the antitrust laws and disincentivizes procompetitive behavior. "[M]ost every rule proves over- or under-inclusive in some way. We often accept a degree of over- and under-inclusion as the price that must be paid for the benefits associated with a clear rule of law." *Novell*, 731 F.3d at 1073. Our rule, prohibiting the use of spillover foreclosure to bolster market foreclosure, is under-inclusive in the sense it might err "by permitting a deleterious practice," rather than err by "condemning a beneficial practice." Easterbrook, *supra*, at 2. But our rule is correct

[13] The district court reviewed this evidence under the deceptive speech doctrine. *In re EpiPen*, 507 F. Supp. 3d at 1360–61. That analysis is clearly correct. Our present analysis is only meant to address Sanofi's use of the advertisements to argue for recognition of spillover foreclosure.

because limiting the risk of false condemnation is a central tenet of modern antitrust jurisprudence. *See, e.g.*, *Am. Express*, 138 S. Ct. at 2287 (quoting *Brooke Grp.*, 509 U.S. at 226); *Matsushita*, 475 U.S. at 594; *Leegin*, 551 U.S. at 895; Easterbrook, *supra*, at 15–17. "Rules that seek to embody every economic complexity and qualification may well, through the vagaries of administration, prove counter-productive, undercutting the very economic ends they seek to serve." *Barry Wright*, 724 F.2d at 234. Any alternative rule, we note, might discourage the use of exclusive agreements by a dominant firm in a market where competition-for-the contract is a legitimate competitive tool to bring about low prices for the consumers. *See Paddock Publ'ns*, 103 F.3d at 45. "[W]e must be concerned lest a rule or precedent that authorizes a search for a particular type of undesirable pricing behavior end up by discouraging legitimate price competition." *Barry Wright*, 724 F.2d at 234.

We also agree with the district court and reject Sanofi's spillover foreclosure for factual reasons. To begin with, Sanofi fails to adequately quantify spillover foreclosure into any foreclosure percentage. *See In re EpiPen*, 507 F. Supp. 3d at 1354. Sanofi simply says, when combined with contractual foreclosure, spillover foreclosed Auvi-Q from "more than half the market." Appellant's Opening Br. 57. But Sanofi's "more than half the market" claim lacks any factual support. Sanofi's claim comes from Dr. Scott Morton's deposition where she was hazarding a guess at the percentage of formularies she thought Auvi-Q was foreclosed from. Later, Dr. Scott Morton seemingly disavowed the "more than half the market claim" by reiterating that there was "no need to devise a new foreclosure metric given that Mylan's ordinary course

documents have already done this" and citing documents showing the highest foreclosure was 31%. Br. of Appellees 64 n.24. Importantly, Dr. Scott Morton's theory of spillover foreclosure is different than Sanofi's theory. Sanofi uses spillover foreclosure to supplement any contractual foreclosure, while Dr. Scott Morton uses spillover foreclosure to bolster her claims about entrenched share. *In re EpiPen*, 507 F. Supp. 3d at 1354–55 ("With her opinion, Dr. Scott Morton simply asserts that spillover effects increased Mylan's entrenched market share—but not that any market *foreclosure* occurred."). *See generally infra* Section IV.C (discussing entrenched share). Because these are different concepts and Dr. Scott Morton does not appear to endorse any market foreclosure greater than 31%, Sanofi fails to marshal sufficient evidence supporting a "genuine" issue of foreclosure higher than 31%. *Anderson*, 477 U.S. at 248; *In re EpiPen*, 507 F. Supp. 3d at 1354.

b.

Sanofi contends we should not weigh its use of exclusive rebate offers against it when deciding whether Mylan engaged in any exclusionary conduct. According to Sanofi, the fact that it capitulated to offering exclusive rebates after Mylan's scheme shifted the PBMs' focus from equal access to exclusive coverage for epinephrine auto-injectors "cut[s] decisively in favor of liability." Appellant's Opening Br. 72. We agree with Sanofi that the fact it had itself signed an exclusive agreement would not preclude it from suing on the antitrust violation, *Perington Wholesale*, 631 F.2d at 1375, but we completely disagree with Sanofi's understanding of the relevance of its use of exclusive dealing contracts in our analysis.

The use of exclusive contracts by a defendant's rivals is relevant for two reasons. First, such use illuminates the "particular structure and circumstance of the industry at issue," *Trinko*, 540 U.S. at 411, and reveals whether competition was effectively waged for the contract. *See NicSand*, 507 F.3d at 454 ("If [*PBMs*] have made exclusivity a barrier to entry, one cannot bring an antitrust claim against a [*manufacturer*] for acquiescing to that requirement."); *Paddock Publ'ns*, 103 F.3d at 45; *Race Tires Am.*, 614 F.3d at 78–79. There are industries where competition-for-the-contract is the dominant form of competition between rivals—and one that must, therefore, be protected. *Paddock Publ'ns*, 103 F.3d at 45 ("Every year or two, General Motors, Ford, and Chrysler invite tire manufacturers to bid for exclusive rights to have their tires used in the manufacturers' cars."); *Menasha Corp. v. News Am. Mktg. In-Store, Inc.*, 354 F.3d 661, 663 (7th Cir. 2004) (Easterbrook, J.); *Race Tires Am.*, 614 F.3d at 76; *see NicSand*, 507 F.3d at 447–48 (examining an industry where competition *for the shelf*, as opposed to *on the shelf*, was the dominant form of competition). The epinephrine auto-injector industry is—at least for some PBMs—one such industry. Sanofi's use of exclusive rebate agreements confirms what is otherwise abundantly clear in the record: PBMs used exclusivity to encourage price competition. *See, e.g.*, *Paddock Publ'ns*, 103 F.3d at 45 (observing competition-for-the-contract can drive down the price of a product "to the ultimate benefit of consumers"); *Hearings*, *supra*, at 13; Klein & Murphy, *supra*, at 450. So, Mylan's use of exclusive rebate agreements in an industry where competition-for-the-contract is a legitimate form of competition

does not raise an inference of exclusionary conduct. *See Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1062 (8th Cir. 2000).

Second, and somewhat related, the competitors' use of exclusive contracts might suggest that customers are instigating exclusivity—a circumstance that sometimes eases any anticompetitive concern arising from a monopolist's use of exclusive dealing contracts.[14] We call this phenomenon customer-instigated exclusive dealing. Richard M. Steuer, *Customer-Instigated Exclusive Dealing*, 68 Antitrust L.J. 239 (2000). Customer-instigated exclusive dealing occurs when a customer announces to "would-be suppliers that it will commit to buy from only one of them and that if they hope to be selected they had better offer their products on the most attractive terms—lower prices, assured supply, guaranteed pricing, or other special treatment." *Id.* at 239; *see NicSand*, 507 F.3d at 447–48.

When the party instigating exclusive dealing is the end user, we are not particularly concerned about the anticompetitive effects of the arrangement.[15] Steuer, *supra*, at 250. End users are typically the consumers of the goods, but an end user is any buyer who cannot directly pass along the increased cost of a good to a downstream market participant. Health plans (through PBMs) are end users because they must

[14] This does not mean that exclusive dealing arrangements instigated by the monopolist cannot be procompetitive or that exclusive dealing arrangements instigated by the customer cannot be anticompetitive.

[15] We have no occasion to decide whether this logic applies equally to customer-instigated exclusive dealing by non-end users (like distributors).

ultimately pay the balance for any covered drug. End users are "less likely to be motivated by a desire to weaken interbrand competition by diminishing the strength of alternate suppliers and their brands." *Id.* Because end users must eventually reenter the market once the exclusive deal expires, they have every incentive to ensure alternative suppliers remain in the market. The last thing an end user wants "is to reduce the number of competing suppliers available in the future." *Id.* Buyers are unlikely to "shoot themselves in the feet" by signing exclusive contracts that entrench the seller "as a monopolist that then can apply the squeeze." *Menasha*, 354 F.3d at 663; *see also* Bork, *supra*, at 304–05; Posner, *supra*, at 230.

These observations partially underlie the reasoning of *Barry Wright*, 724 F.2d at 237–38. In *Barry Wright*, the defendant—a producer of mechanical snubbers—agreed to provide Grinnell—a major snubber user—with nearly all its requirements at a low price. One of the defendant's competitors sued alleging exclusionary practices in violation of Sherman Act § 2. In deciding the requirements contract was not exclusionary, then-Judge Breyer noted that—even though there was foreclosure of 50% of the relevant market—the likely anticompetitive effects of the contract were overstated. *Id.* at 237. Judge Breyer wrote:

> Grinnell is not a small firm that defendant could likely bully into accepting a contract that might foreclose new competition. To the contrary, it was Grinnell, not defendant, that sought the extensions for 1978 and 1979. Moreover, Grinnell had every interest in promoting new competition. Grinnell could have obtained snubbers without placing such large orders had it given up the "special" extra 5 to 10 percent price discount, a matter of a few hundred thousand dollars per year. Had Grinnell believed that the long-term nature of the contracts significantly interfered with new entry, or

> inhibited the development of a new source of supply, it is difficult to understand why it would have sought the agreements.

Id. at 237–38 (cleaned up). In other words, because Grinnell was an end user, it was highly unlikely the requirements contract was anticompetitive. Grinnell would not be enticed by present exclusivity discounts if the discounts expose it to exploitation by a dominant supplier in the future.

The epinephrine auto-injector market exemplifies an industry fueled by customer-instigated exclusive dealing. Even though PBMs did not historically manage the epinephrine auto-injector class, the introduction of Auvi-Q was seen by many PBMs as an opportunity to instigate price competition through exclusive rebate agreements. *In re EpiPen*, 507 F. Supp. 3d at 1308, 1311–12 (collecting evidence); *see, e.g.*, *id.* at 1316 (explaining MedImpact explicitly solicited "1 of 1 offers" from Sanofi and told Sanofi that it wished to cover only one epinephrine auto-injector product). Contrary to Sanofi's assertion, PBMs—not Mylan—instigated the use of exclusive deals to drive down prices, and Sanofi's refusal to press for exclusivity until 2014 does not suggest Mylan acted anticompetitively. Rather, it suggests Sanofi acted imprudently. Thus, the district court correctly concluded that exclusive contracts are a normal competitive tool within the epinephrine auto-injector industry and weighed that in favor of granting summary judgment. *Id.* at 1352 (citing *Concord Boat*, 207 F.3d at 1062).

c.

Sanofi also attacks our de novo conclusion that Mylan's exclusive rebate agreements were not exclusionary by arguing Mylan coerced PBMs into exclusivity.

Coercion—although unnecessary to establish a successful exclusive dealing case—will often be present in successful exclusive dealing cases because the presence of coercion in such cases casts doubt on the assumption that the exclusive deals are naturally procompetitive. *See Race Tires Am.*, 614 F.3d at 77. Exclusive deals tend to create efficiencies far more often than they inflict consumer harm, *see, e.g.*, *E. Food Servs.*, 357 F.3d at 8; *Barry Wright*, 724 F.2d at 237; Bork, *supra*, at 304–05; Posner, *supra*, at 230, because a buyer will generally only agree to exclusivity if the seller offers something to the buyer that is worth more than the cost of giving up alternative sources of supply. *See* Bork, *supra*, at 304–05 ("[E]fficiencies are the reality, and the fear of foreclosure is chimerical."). We can therefore generally presume exclusive deals are procompetitive. But this assumption is thrown out the window when record evidence suggests coercion by the monopolist. *Dentsply* is a good example.

In *Dentsply*, the United States brought an antitrust suit against Dentsply—the dominant artificial tooth manufacturer—for implementing a clause in its distribution contracts which prohibited distributors from adding further tooth lines to their product offerings. 399 F.3d at 184–85. The United States presented testimony that distributors were dissatisfied with the exclusive-dealing clause, but "none of them have given up the popular Dentsply teeth to take on a competitive line." *Id.* at 185. The distributor's testimony suggested Dentsply was willfully maintaining its monopoly power by imposing an "all-or-nothing" choice on distributors. Partly because of this testimony, the Third Circuit reversed the district court's judgment in favor of Dentsply and ordered the district court to grant the Government's injunctive relief.

The presence of coercion also explains the Third Circuit's decision in *ZF Meritor*, 696 F.3d 254, and the Eleventh Circuit's decision in *McWane*, 783 F.3d 814. In *ZF Meritor*, the Third Circuit affirmed the jury's verdict holding the monopolist's use of exclusive dealing agreements posed a threat to competition where buyer testimony suggested the terms of the exclusive agreements were unfavorable, but they agreed to such terms because they would otherwise be unable to satisfy consumer demand. 696 F.3d at 285. And in *McWane*, the Eleventh Circuit affirmed the Federal Trade Commission's ruling that a monopolist's exclusive dealing agreements were anticompetitive where they were unilaterally imposed by fiat upon distributors with no corresponding benefit. 783 F.3d at 834.

Sanofi fails to marshal sufficient evidence suggesting that Mylan engaged in any coercion. Sanofi, instead of presenting evidence like *Dentsply*, *ZF Meritor*, or *McWane*, develops its own novel theory of "coercion in the relevant sense." Appellant's Opening Br. 68–71. According to Sanofi, PBMs who refused Mylan's exclusive rebate agreements "would face the penalty of EpiPen's ever-rising list price multiplied by Mylan's dominant share, without the safeguard of price protection, and barely offset by a small EpiPen access rebate." Appellant's Opening Br. 68. But if that was the "practical reality" of the market, why is there no PBM testimony to that effect? We cannot infer coercion from abstract theories.[16] Unlike *Dentsply*, *ZF*

[16] Sanofi cites some stray documents where PBMs, for example, "reported being held 'hostage' by Mylan's exclusionary offers." Appellant's Opening Br. 69. But these isolated, informal, out-of-court remarks in a record of 13,680 pages are insufficient for a jury to find Mylan coerced PBMs. "The mere existence of a scintilla

Meritor, or *McWane*, no PBM testified that they felt compelled to enter into exclusive agreements with Mylan despite unfavorable terms. Instead, the clear evidence presented by the record discloses PBMs entered exclusive deals with *both* Mylan and Sanofi whenever they offered the most advantageous terms. *See, e.g.*, *In re EpiPen*, 507 F. Supp. 3d at 1313 (Mylan-ESI 2014 exclusive deal); *id.* at 1314–15 (Mylan-OptumRx/UnitedHealthcare 2014 exclusive deal); *id.* at 1317 (Mylan-MedImpact 2014 exclusive deal); *id.* at 1318 (Mylan-Aetna 2014 exclusive deal); *id.* at 1321–22 (Sanofi-ESI 2015 exclusive deal); *id.* at 1322 (Sanofi-CVS 2015 exclusive deal).

We are not alone in our conclusion. In *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, the plaintiff brought a similar, if not identical, claim against Sanofi (yes, the same Sanofi)—the marketer of Lovenox—for allegedly monopolizing the anticoagulant drug market. 821 F.3d 394 (3d Cir. 2016); *see infra* Section IV.C (analyzing Sanofi's theory of anticompetitive leveraging of entrenched share). Sanofi created a loyalty-discount program which provided hospitals with larger discounts as their volume of Lovenox purchases increased—not dissimilar to Mylan's exclusive rebate offers. The plaintiff argued Sanofi's loyalty-discount program foreclosed it from competing because the "threat of not obtaining a higher discount (ranging up to 30% off) 'handcuffed hospitals'"—who had to buy at least some Lovenox due to its "unique cardiology indication"—to Sanofi's loyalty-discount program. *Eisai*, 821 F.3d at 401, 407. The

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of evidence in support of the plaintiff's position" will not preclude summary judgment. *Anderson*, 477 U.S. at 252.

Third Circuit rejected the plaintiff's theory of coercion. Hospitals who failed to purchase greater quantities of Lovenox did not "risk penalties or supply shortages," but only the loss of a larger discount. *Id.* at 406. "[T]he threat of a lost discount is a far cry from the anticompetitive conduct at issue in *ZF Meritor* or *Dentsply*." *Id.* at 407. Applying that same logic here, Sanofi fails to demonstrate coercion because the loss of an additional discount was the only consequence PBMs faced for rejecting Mylan's exclusive rebate agreements.

Since the parties argued this case, the Fifth Circuit released *Pulse Network, L.L.C. v. Visa, Inc.*, 30 F.4th 480 (5th Cir. 2022). According to Sanofi, *Pulse* confirms that there is a triable issue Mylan deployed coercive pricing to monopolize the epinephrine auto-injector market. To explain why we disagree, we must provide a detailed background of the *Pulse* decision. Pulse sued Visa for allegedly monopolizing or attempting to monopolize the debit network market—which facilitates financial transactions between merchants and customers using debit cards. *See id.* at 484–86; *cf. Am. Express*, 138 S. Ct. at 2280 (overviewing the analogous credit network market). In 2010, Congress passed a law which (1) required debit card issuers to enable at least two unaffiliated debit networks on all cards and (2) bestowed upon merchants total autonomy to choose which debit network to route transactions over. *Pulse*, 30 F.4th at 486. Because merchants must pay a per-transaction fee to utilize a debit network, merchants generally route transactions over the network with the lowest fees per-transaction. Putting this together, if a customer uses a Visa-branded debit card, the

merchant can route the transaction over Visa's network or another unaffiliated but activated debit network—like Pulse's network.

Visa allegedly monopolized the debit network market by implementing a new two-charge policy. Instead of charging merchants only a per-transaction fee, Visa began charging merchants a fixed monthly fee to use its ubiquitous debit network. Simultaneously, Visa substantially reduced its per-transaction fee. According to Pulse, Visa used its "market dominance to foist on merchants a high fixed fee they wouldn't ordinarily accept," and used the "revenues from that unavoidable upfront fee to artificially lower is per-transaction fees," effectively foreclosing rivals. *Id.* at 491. The narrow issue before the Fifth Circuit was whether Visa's two-charge policy inflicted an antitrust injury upon Pulse. *See generally Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977) ("Plaintiffs must prove antitrust injury, which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful."). The Fifth Circuit held Pulse satisfied the antitrust injury requirement because Visa's two-charge policy foreclosed rivals and forced merchants to pay a higher total cost (fixed plus per-transaction fees) than before. *Pulse*, 30 F.4th at 491.

Sanofi's efforts to bolster its case by relying on *Pulse* are unconvincing. To begin with, our dispositive analysis is concerned with the merits of Sanofi's claim. *Pulse*, on the other hand, is an antitrust standing case where the court assumed an antitrust violation. *See id.* To the extent we can glean anything about the merits of Pulse's claim from the Fifth Circuit's antitrust standing analysis, it provides limited

utility in this case. Visa's allegedly anticompetitive scheme relied upon a two-charge structure absent from the epinephrine auto-injector market. Mylan did not impose on PBMs an unavoidable upfront fee to subsidize lower per-unit prices on the backend. Sanofi's complaints about Mylan's exclusive rebate offers are equivalent to Pulse "complaining only that Visa had slashed its per-transaction prices," which is a complaint about increased, not decreased, competition. *Id.*

Sanofi has another theory of coercion but fails to substantiate it with any evidence. Sanofi alleges exclusivity was partially triggered by Mylan's price escalation. Appellant's Opening Br. 70. According to Sanofi, PBMs aggressively manage a therapeutic class where there is high list price escalation. Mylan supposedly took advantage of this by raising EpiPen's list price to trigger tighter formulary controls and then bid for exclusivity. By doing so, according to Sanofi, Mylan was able to coerce PBMs, who would have otherwise preferred co-equal access, into exclusive rebate agreements.[17] But this theory is doomed because Sanofi fails to

[17] We have reasons to be skeptical of the viability of this strategy as a method of coercion. Raising a drug's list price can expose the manufacturer to congressional scrutiny and serious legal repercussions. *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-idUSKCN11R2OG. For example, Martin Shkreli was recently banned for life from the pharmaceutical drug industry because of his role in hiking the price of the drug Daraprim. Dan Mangan, *Pharma Bro Martin Shkreli Banned for Life from Drug Industry in Monopoly Case, Ordered to Pay $64.6 Million*, CNBC (Jan. 14, 2022), https://www.cnbc.com/2022/01/14/pharma-bro-martin-shkreli-banned-for-life-from-drug-industry-ordered-to-pay-64point6-million.html. And if Mylan increased EpiPen's price to trigger tighter formulary controls, PBMs could punish Mylan by

marshal any evidence to support it. Contrary to Sanofi's assertions, exclusivity was not forced upon PBMs; exclusivity was wielded by PBMs to push for more competitive pricing. *See, e.g.*, *In re EpiPen*, 507 F. Supp. 3d at 1311–12. We hold the district court properly considered the absence of coercion as a factor in the exclusive dealing analysis and we join the district court in concluding there is no evidence in the record from which to infer coercion.

d.

Sanofi also challenges our de novo conclusion that because Sanofi reversed exclusivity and regained 80% market access it was not substantially foreclosed. According to Sanofi, just because it "was 'able to enter and grow despite' Mylan's scheme does not end the analysis." Appellant's Opening Br. 76 (quoting *McWane*, 783 F.3d at 840). We should, according to Sanofi, infer substantial foreclosure because Sanofi was only able to overcome exclusion by paying a $36 million access tax on Lantus. Lantus is Sanofi's market-leading insulin drug, which in 2013–2014 had somewhere around $4 billion in sales in the United States—a formidable volume unmatched by any Mylan product.

We assume Sanofi's proposition is correct that a monopolist can be liable under § 2 even when its rival was "able to enter and grow." *McWane*, 783 F.3d at 840. But we cannot infer substantial foreclosure simply because Sanofi had to offer lower prices

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eating higher prices for a competitor or they could retaliate against Mylan in other therapeutic classes.

through a portfolio bid to compete with Mylan. In substance, Sanofi's offer to provide a 2% incremental Lantus rebate for the reversal of Auvi-Q's exclusion is just an indirect price cut on Auvi-Q. And we cannot and should not infer any exclusionary conduct on the part of Mylan simply because Sanofi had to slash its prices to compete with Mylan. Under our consumer welfare standard, this argument is a clear non-starter. The Lantus payments may prove "harm to one or more *competitors*," but they do nothing to satisfy Sanofi's burden to prove "harm to the competitive *process* and thereby harm [to] consumers." *Microsoft*, 253 F.3d at 58; *see also, e.g.*, *Brooke Grp.*, 509 U.S. at 224.

The only acceptable inference to draw in this case is the Lantus payments exemplified vigorous price competition—something we strenuously protect. *See, e.g.*, *Matsushita*, 475 U.S. at 594 ("But cutting prices in order to increase business often is the very essence of competition. Thus, mistaken inferences in cases such as this one are especially costly, because they chill the very conduct the antitrust laws are designed to protect."); *Atl. Richfield*, 495 U.S. at 340 ("Low prices benefit consumers regardless of how those prices are set, and so long as they are above predatory levels, they do not threaten competition."); *Brooke Grp.*, 509 U.S. at 222–27. We agree with the district court that "Sanofi's increased rebate offers for Lantus certainly didn't harm competition. Just the opposite, they promoted it." *In re EpiPen*, 507 F. Supp. 3d at 1351 n.22.

C.

Sanofi's next argument is Mylan leveraged its entrenched share to monopolize the epinephrine auto-injector market. Entrenched share (a.k.a. non-contestable demand) is "the portion of the market that—even in the face of entry of an alternative—will not switch away from the incumbent's product, at least in the shorter term." *Id.* at 1355–56 (quoting Dr. Scott Morton's expert report). Non-entrenched share (a.k.a. contestable demand) is, by reason of deduction, that portion of the market that will switch away from an incumbent's product in the short term. According to Dr. Scott Morton, EpiPen, as the incumbent epinephrine auto-injector, had a "committed customer base that would not easily switch away from the EpiPen." She explains, "even when faced with competition from an innovative product, and even were there not significant barriers to entry, Mylan would still be able to keep a significant portion of the market, at least in the shorter term."[18] Sanofi suggests EpiPen's entrenched demand may have been as high as 50–70% of the market.

[18] EpiPen's entrenched share arises either because (a) consumers preferred EpiPen to Auvi-Q, or (b) consumers exhibited something called status quo bias—that is, even though they might have preferred Auvi-Q in the abstract, they viewed any switch from a familiar-but-inferior product to an unfamiliar-but-superior product as an unacceptable loss. *See* William Samuelson & Richard Zeckhauser, *Status Quo Bias in Decision Making*, 1 J. Risk & Uncertainty 7 (1988); *see also* Daniel Kahneman, Jack L. Knetsch & Richard H. Thaler, *Anomalies: The Endowment Effect, Loss Aversion, and Status Quo Bias*, 5 J. Econ. Persp. 193, 197–99 (1991) ("[I]ndividuals have a strong tendency to remain at the status quo, because the disadvantages of leaving it loom larger than advantages."). *See generally* Daniel Kahneman & Amos Tversky, *Prospect Theory: An Analysis of Decision Under Risk*, 47 Econometrica 263 (1979). This latter explanation is a specific theory of behavioral economics. We neither reject nor endorse the application of behavioral economics to antitrust analysis.

To quickly summarize its argument, Sanofi contends that a monopolist—with an entrenched share—commits monopolization when it offers loyalty discounts to compete for the market's non-entrenched share.[19] Loyalty discounts (a.k.a. all-unit or cliff discounts) "are a particular form of non-linear pricing in which the unit price of a good declines when the buyer's purchases meet a buyer-specific minimum threshold requirement." Bruce H. Kobayashi, *The Economics of Loyalty Discounts and Antitrust Law in the United States*, 1 Competition Pol'y Int'l 115, 116 (2005). Loyalty discounts are extremely common and take on a variety of forms: an airline's frequent flyer program and a deli's buy-ten-sandwiches-get-one-free punch card are but two common examples. Mylan's rebates are properly characterized as a specific type of loyalty discount called a volume-based loyalty discount, which grants the buyer a discount on all units if the buyer reaches a certain purchase threshold—*e.g.*, an offer for 25% off if you buy three or more items. Mylan, of course, never conditioned EpiPen's rebates on a specific quantity of EpiPens sold. But by conditioning EpiPen's rebates on certain formulary positioning, Mylan in effect conditioned the rebates on the rough volume of sales associated with the given formulary placement.

Litigants and scholars have only recently begun to raise antitrust concerns about volume-based loyalty discounts. *See, e.g.*, *Concord Boat*, 207 F.3d 1039; *Eisai*, 821

[19] Although Sanofi focuses on Mylan's exclusive rebate offers, its theory cannot be limited to this situation. Following Sanofi's logic, its theory would apply any time an entrenched monopolist offers loyalty discounts conditioned on sales exceeding the entrenched portion of the market.

F.3d 394; Kobayashi, *supra*, at 118. Sanofi alleges the entrenched monopolist's use of loyalty discounts—conditioned on sales exceeding entrenched demand—is anticompetitive because the loyalty discounts effectively foreclose competition for the non-entrenched demand. *See, e.g.*, Appellant's Opening Br. 61 ("So, as a matter of basic 'math,' a price concession by Sanofi would not go nearly as far as the same concession by Mylan."). To reach a jury on this issue, Sanofi must show that Mylan's alleged leveraging of entrenched demand raises a factual issue that is "material."[20] Fed. R. Civ. P. 56(a); *Anderson*, 477 U.S. at 247–48.

We look to the substantive law to decide whether an issue of fact is material for purposes of summary judgment. *Id.* at 248. "Only disputes over facts that might affect the outcome of the suit under the governing law will preclude the entry of summary judgment." *Id.* Sanofi describes a phenomenon where an entrenched firm might be able to offer hard-to-match discounts to the non-entrenched share by offering loyalty discounts conditioned on sales exceeding the entrenched demand.[21] But Sanofi does

[20] We can affirm the grant of summary judgment "on any ground supported by the record, so long as the appellant has had a fair opportunity to address that ground." *Lincoln v. BNSF Ry. Co.*, 900 F.3d 1166, 1180 (10th Cir. 2018) (quoting *Alpine Bank v. Hubbell*, 555 F.3d 1097, 1108 (10th Cir. 2009)). At oral argument, Sanofi was asked to clarify what substantive legal standard ought to apply to Mylan's alleged leveraging of entrenched share. Because Sanofi failed to do so, we can affirm the grant of summary judgment on the basis of "materiality." *See* Fed. R. Civ. P. 56(a).

[21] We need not determine whether Sanofi's theory actually persists in practice. For the purposes of this case, it is sufficient to examine Sanofi's theory in the abstract. To generalize Sanofi's theory, assume a distributor needs to buy 10 widgets. Two manufacturers, Firm A and Firm B, sell slightly differentiated widgets at the same price. For 70% of the distributor's customers, they require Firm A's widgets (entrenched demand). The other 30% of customers are indifferent between Firm A's

not provide us any legal standard by which to evaluate Mylan's alleged leveraging of entrenched share, making it impossible for us to determine whether there is a material issue of fact. *See id.* We could overlook this oversight if Sanofi's theory inherently lends itself to only one legal standard—but it does not. At least four legal standards exist by which to evaluate Mylan's alleged leveraging of entrenched demand. First, the entrenched monopolist's use of loyalty rebates could be a per se violation of § 2

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or Firm B's widgets (non-entrenched demand). If Firm A offered the distributor a 10% rebate conditioned on the distributor buying all ten units from it, Firm B would need to offer a 33.3% rebate on each widget to make the distributor indifferent between (a) buying exclusively Firm A's widgets or (b) buying seven widgets from Firm A, and three from Firm B.

The entrenched monopolist's use of loyalty discounts *might* make it harder for a rival to compete for the non-entrenched portion of the market, but we cannot immediately discern any reduction in consumer welfare from this situation because the loyalty discounts lower aggregate prices. *See, e.g.*, Klein & Murphy, *supra*, at 450 (explaining that ex ante competition for exclusive or preferred formulary placement "will substantially lower the pharmaceutical manufacturers' prices"); *Hearings*, *supra*, at 13 ("The way you get low prices in the pharmaceutical industry is by the ability to exclude drugs." (statement of Dr. Scott Morton)); Bork, *supra*, at 137 ("All business activity excludes. . . . Antitrust, therefore, must be able to distinguish [proper and beneficial] efficiency exclusion from improper exclusion."). "By adopting exclusivity, a [PBM] can be thought of as acting as the bargaining agent for all its loyal consumers, so they are made better off as a group. If, alternatively, the [PBM covered] both brands and left it up to ex post competition between manufacturers to determine prices, consumers would have indulged their individual brand preferences and driven up prices for everyone." Klein & Murphy, *supra*, at 452. Sanofi's briefing fails to answer the *material* question—whether Mylan's use of loyalty rebates hurt or threatened to hurt consumers—and instead answers an *immaterial* one—whether Mylan's use of loyalty rebates hurt or threatened to hurt a competitor. *Brunswick*, 429 U.S. at 488 ("The antitrust laws, however, were enacted for 'the protection of competition not competitors.'" (quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962))); *see, e.g.*, *Novell*, 731 F.3d at 1072; *Crum & Forster*, 682 F.2d at 663–64; Bork, *supra*, at 61.

because it may foreclose the non-entrenched portion "of the market to a potential competitor." *LePage's Inc. v. 3M*, 324 F.3d 141, 155 (3d Cir. 2003) (en banc). At oral argument, Sanofi wisely disclaimed the per se test.[22] Second, the entrenched monopolist's use of loyalty rebates may be anticompetitive when, after applying the full amount of the loyalty rebates to the non-entrenched portion of the market, the resulting price is below the monopolist's cost. *Cascade Health Sols. v. PeaceHealth*, 515 F.3d 883, 906 (9th Cir. 2008). This is the discount-attribution test.[23] Third,

[22] The entrenched monopolist's use of loyalty discounts may be procompetitive or competitively neutral, Kobayashi, *supra*, at 117, 121–22, which necessarily means a per se rule is inappropriate. *E.g.*, *Leegin*, 551 U.S. at 886–87. We should not, after all, deter the entrenched monopolist's use of loyalty discounts if it would lead to lower consumer prices and higher welfare. *See FTC v. Church & Dwight Co., Inc.*, 665 F.3d 1312, 1316–17 (D.C. Cir. 2011) (D. Ginsburg, J.) (collecting criticism of the *LePage's* decision because it condemns behavior which does not obviously reduce, and may even promote, consumer welfare); *cf.* Timothy J. Muris & Vernon L. Smith, *Antitrust and Bundled Discounts: An Experimental Analysis*, 75 Antitrust L.J. 399, 403 (2008) (discussing experiments in the analogous context of bundling which showed that "even when competitors are excluded, such exclusion does not reduce long-run average consumer or total surplus").

[23] We worry about the administrability of this test. To determine prospectively whether its loyalty rebates would offend the discount-attribution test, the entrenched firm must calculate the entrenched share before applying the aggregate discounts to the non-entrenched share. But entrenched share based upon consumer preference is impossible to calculate with any objective precision. On a cold and complete record, Dr. Scott Morton (former Deputy Assistant Attorney General for Economic Analysis) can only guess that EpiPen's entrenched share was somewhere between 50%–70%. This is too imprecise. Without an administrable test of liability, the entrenched monopolist would never risk offering loyalty rebates even if it would bring about increased consumer welfare. *See Bos. Edison Co.*, 915 F.2d at 22. We are uncomfortable with such a result because, as then-Judge Breyer observed, "we must be concerned lest a rule or precedent that authorizes a search for a particular type of undesirable pricing behavior end up by discouraging legitimate price competition." *Barry Wright*, 724 F.2d at 234; *see also, e.g.*, Easterbrook, *supra*, at 2 ("If the court errs by condemning a beneficial practice, the benefits may be lost for good. Any other

applying Dr. Scott Morton's Effective Entrant Burden ("EEB") test,[24] the entrenched monopolist's use of loyalty discounts would be anticompetitive when the extent of entrenched share and the magnitude of discounts makes it too hard for a rival to compete for the non-entrenched share.[25] *See* Fiona M. Scott Morton & Zachary Abrahamson, *A Unifying Analytical Framework for Loyalty Rebates*, 81 Antitrust L.J. 777 (2017) (introducing Dr. Scott Morton's EEB test). Fourth, the entrenched monopolist's use of loyalty rebates is lawful "as long as the prices being charged are

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firm that uses the condemned practice faces sanctions in the name of stare decisis, no matter the benefits.").

[24] For some background, Dr. Scott Morton quantified EEB as:

$$\text{EEB} = \frac{(\text{exclusionary rebate \%}) \times (\text{share with exclusion})}{(\text{contestable share})}$$

The basic theory is when EEB is high, the defendant's loyalty rebate scheme is anticompetitive. EEB is higher when the loyalty rebate is high (*i.e.*, Mylan is offering lower prices) and when non-entrenched demand is low (*i.e.*, when customers prefer EpiPen). Thus, Dr. Scott Morton's test is an inadequate proxy for consumer welfare because EEB will generally punish a firm for offering better prices or having the preferred product.

We are unsure whether we can consider the EEB test as a potential legal standard since the district court excluded Dr. Scott Morton's EEB test in a contemporaneously-filed *Daubert* opinion—a disposition Sanofi does not challenge on appeal. This is a thorny question which we are not going to entangle ourselves in. Assuming we could adopt the EEB test as a legal standard, it does not change our analysis. Sanofi never proposed a substantive legal standard *on appeal*, preventing us from determining whether Mylan's alleged leveraging of entrenched demand presents a "material" question of fact.

[25] The EEB test suffers the same administrability problems as the discount-attribution test—it relies upon the extent of entrenched share which is difficult to objectively derive. *See supra* note 23.

not predatory"—that is price is not below cost. *linkLine*, 555 U.S. at 455; *see, e.g.*, *Brooke Grp.*, 509 U.S. at 222–23. One group of amici curiae—which includes Nobel laureate Vernon L. Smith and several serious legal and economic scholars—persuasively argues that this fourth legal standard, often called the price-cost test, should apply to Sanofi's theory. Br. of Amici Curiae Int'l Ctr. for Law & Econ. & Scholars of Law & Econ. in Support of Appellees and Affirmance 4–15; *see, e.g.*, *Brooke Grp.*, 509 U.S. at 223 ("[T]he exclusionary effect of prices above a relevant measure of cost . . . is beyond the practical ability of a judicial tribunal to control without courting intolerable risks of chilling legitimate price-cutting."); *Matsushita*, 475 U.S. at 594; *Atl. Richfield*, 495 U.S. at 340.[26]

[26] The downside to the price-cost test is that it may not, when compared to another standard, catch as many anticompetitive uses of loyalty discounts by an entrenched monopolist. But the price-cost test has some benefits. First, the price-cost test limits the risk of false condemnation for welfare-enhancing price competition and does not discourage "legitimate price competition." *Barry Wright*, 724 F.2d at 234; *Bos. Edison Co.*, 915 F.2d at 22 ("[Antitrust rules] must be designed with the knowledge that firms ultimately act, not in precise conformity with the literal language of complex rules, but in a reaction to what they see as the likely outcome of court proceedings."); *see, e.g.*, *Brooke Grp.*, 509 U.S. at 223; Klein & Murphy, *supra*, at 444–48; Easterbrook, *supra*, at 15–17; *cf.* Muris & Smith, *supra*, at 403. Second, the price-cost test is objectively (and prospectively) administrable—unlike any test dependent on the extent of entrenched consumer preference. *See* Richard M. Steuer, *Musthavedness*, 81 Antitrust L.J. 447, 460–61 (2017); *supra* notes 23, 25. Third, because the price-cost test is easier to administer, it results in reduced costs of administration. *See, e.g.*, Easterbrook, *supra*, at 12–13, 16 ("Litigation costs are the product of vague rules combined with high stakes, and nowhere is that combination more deadly than in antitrust litigation."). Fourth, the price-cost test, because it is unlikely to disincentivize the use of loyalty rebates by an entrenched firm, will not inadvertently encourage collusion in the market. *See Trinko*, 540 U.S. at 408; *Barry Wright*, 724 F.2d at 235 ("Price cutting in concentrated industries seems sufficiently difficult to stimulate that we hesitate before embracing a rule that could, in practice,

Sanofi does not explicitly mention *any* of these legal standards in its briefing, and the one legal theory Sanofi seemed to implicitly rely upon—*LePage's* per se illegality—was explicitly disavowed by Sanofi at oral argument. Oral Argument at 7:31. Without any briefing by the parties regarding what substantive law ought to apply to Sanofi's claim that Mylan anticompetitively leveraged its entrenched demand, we refrain from deciding this issue independently. And in the absence of an appropriate legal standard, we cannot decide whether this issue is material. *See Anderson*, 477 U.S. at 248. After all, for at least one of these legal standards (the price-cost test), the existence and leveraging of entrenched share is wholly immaterial to the issue of liability. We decline Sanofi's invitation to send this "issue of fact" to the jury without the opportunity to first adjudge whether the existence and leveraging of entrenched share is material. Summary judgment is, therefore, inescapable. *See* Fed. R. Civ. P. 56(a).

D.

Sanofi's final argument is Mylan's other conduct worked in synergy to lock Sanofi out of the market, including Mylan's deceptive marketing, the EpiPen4Schools program, and the misclassification of EpiPen as a generic drug for Medicaid purposes. We already disposed of Sanofi's deceptive marketing argument while discussing spillover foreclosure. To recap, we rejected Sanofi's argument that "Mylan developed

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stabilize 'tacit cartels' and further encourage interdependent pricing behavior."); *Novell*, 731 F.3d at 1073.

a deceptive marketing program to augment the spillover effects of its contracts," Appellant's Opening Br. 55, because that marketing was "readily susceptible to neutralization." *Lenox*, 762 F.3d at 1127. But we have not discussed Sanofi's arguments pertaining to the EpiPen4Schools program or the misclassification of EpiPen as a generic drug for Medicaid purposes. We take each in turn.

Through the EpiPen4Schools program, Mylan donated over one million free EpiPens to schools. The program offered schools four free EpiPens and unlimited additional EpiPens at a substantial discount. There was an additional discount offered if a school agreed to refrain from buying rival epinephrine auto-injectors for twelve months. According to Sanofi, "Mylan fortified its entrenched network by extracting pledges from schools to train on EpiPen and not to buy Auvi-Q." Appellant's Opening Br. 55. We take this argument to be analogous to the deceptive marketing claim: Mylan was able to enhance foreclosure by donating EpiPens to schools.[27]

[27] In discussing Mylan's EpiPen4Schools program, Sanofi might be trying to make an additional argument by using the vogue antitrust buzzword: "network effects." *E.g.*, Appellant's Opening Br. 56. "In markets characterized by network effects, one product or standard tends towards dominance, because 'the utility that a user derives from consumption of the good increases with the number of other agents consuming the good.'" *Microsoft*, 253 F.3d at 49 (quoting Michael L. Katz & Carl Shapiro, *Network Externalities, Competition, and Compatibility*, 75 Am. Econ. Rev. 424, 424 (1985)). *But see id.* ("In technologically dynamic markets, however, such entrenchment may be temporary, because innovation may alter the field altogether." (citing Joseph A. Schumpeter, Capitalism, Socialism and Democracy 81–90 (Harper Perennial 1976) (1942))). Sanofi argues the difference in administration of EpiPen and Auvi-Q created network effects in the epinephrine auto-injector industry. Patients receive additional utility from carrying the device that a greater proportion of the population carries because there is an increased chance that a bystander would properly administer the patient's device in an emergency. *See, e.g.*, Appellant's Opening Br.

We agree with the district court that "[n]o reasonable factfinder could infer from these undisputed facts that Mylan engaged in anticompetitive activity by offering free EpiPens to schools." *In re EpiPen*, 507 F. Supp. 3d at 1362. First, the EpiPen4Schools program did not prohibit schools from buying Auvi-Q. A school could accept Mylan's four free EpiPens, buy additional discounted EpiPens, and still buy Auvi-Q. The only penalty schools faced for purchasing other epinephrine auto-injectors was losing access to deeper EpiPen discounts. *Id.* Second, any disadvantage Sanofi faced because of this program could have been neutralized by implementing its own charitable program. *Cf. Lenox*, 762 F.3d at 1127. Sanofi never implemented a similar program to provide free Auvi-Q devices to schools and there is no evidence suggesting Sanofi was unable to do so. If Sanofi implemented such a program, any extraordinary demand built from Mylan's EpiPen4Schools program would have been neutralized. We refuse to subject

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20 ("And with 30 years of market dominance, EpiPen had cultivated a 'network' of teachers, neighbors, and school nurses trained exclusively to swing and jab.").

The problem is "there is no consensus among commentators on the question of whether, and to what extent, current monopolization doctrine should be amended to account for" network effects. *Microsoft*, 253 F.3d at 50; *see, e.g.*, Michael L. Katz & Carl Shapiro, *Systems Competition and Network Effects*, 8 J. Econ. Persp. 93, 113 (1994) ("[W]e are far from having a general theory of when government intervention is preferable to the unregulated market outcome."). We cannot reach any argument pertaining to network effects because Sanofi's offhand use of the term does not satisfy its obligation to provide us with its "contentions and reasons for them." Fed. R. App. P. 28(a)(8)(A); *Exum v. U.S. Olympic Comm.*, 389 F.3d 1130, 1133 n.4 (10th Cir. 2004) ("Scattered statements in the appellant's brief are not enough to preserve an issue for appeal."). With such substantial disagreement about the proper role of network effects in antitrust analysis, Sanofi's obligation was to brief us on the proper role of network effects in our analysis. Sanofi's failure to do so constitutes waiver of that argument.

Mylan to antitrust liability for building demand through a free giveaway program of a life-saving device like EpiPen without any evidence of a decrease in consumer welfare.

Sanofi also alleges Mylan fortified its exclusionary conduct by misclassifying EpiPen as a generic drug for Medicaid purposes.[28] An appellant's opening brief must identify "appellant's contentions and the reasons for them, with citations to the authorities and parts of the record on which the appellant relies." Fed. R. App. P. 28(a)(8)(A). "Consistent with this requirement, we routinely have declined to consider arguments that are not raised, *or are inadequately presented*, in an appellant's opening brief." *Bronson v. Swensen*, 500 F.3d 1099, 1104 (10th Cir. 2007) (emphasis added). Sanofi's briefing fails to adequately explain the relevance of any alleged Medicaid misclassification on Mylan's ability to monopolize the private market or clearly describe where the district court erred. Thus, we cannot say Sanofi has *adequately presented* its argument. Moreover, Sanofi does not cite any legal authority to support its argument. For these reasons, we hold Sanofi's Medicaid misclassification argument is too perfunctorily raised to consider. It is, therefore, waived. *See, e.g.*, *United States v. Walker*, 918 F.3d 1134, 1151 (10th Cir. 2019) (quoting *United States v. Wooten*, 377 F.3d 1134, 1145 (10th Cir. 2004)).

[28] We note that something feels suspect about permitting a private plaintiff to bring a monopolization claim when the alleged misconduct derives from the defendant defrauding the government.

V.

When antitrust and the health insurance industry meet, a *nearly* impenetrable fog descends upon what might otherwise be a manageable case. What occurred in this case is no different than the competition which occurs at thousands of retail stores across the country—ranging from supermarket behemoths to family-owned mercantiles. These stores bring about lower prices for their customers by engaging in the exact same practices Sanofi complains of—and, astoundingly, the stores often discover and utilize these practices without exploiting any special economic expertise. For example, a mercantile might enter discussions with several bakeries to decide whose bread will occupy its shelves. During these negotiations, the mercantile can solicit lower wholesale prices by promising a bakery preferred positioning at the front of the aisle where sales are higher. And every so often, when a bakery offers low enough wholesale prices, the mercantile might exclusively stock that bakery's bread. Despite being unable to choose between multiple brands of bread, the mercantile's customers are unlikely to complain. They are, after all, compensated in the form of lower retail prices. By deciding to stock only one bakery's bread, the mercantile does not eliminate competition in the bread market—instead competition takes on a different, more powerful form, but one that is harder to intuitively understand.

The same thing happened in the epinephrine auto-injector market: instead of competing *on* the formulary, Mylan and Sanofi competed *for* the formulary. Mylan's legitimate competition *for* the formulary must not now expose it to liability. "The successful competitor, having been urged to compete, must not be turned upon when

he wins." *United States v. Aluminum Co. of Am.*, 148 F.2d 416, 430 (2d Cir. 1945) (L. Hand, J.). Without any evidence of harm *to* competition—as opposed to harm *from* competition—Sanofi cannot present this case to a jury. Considered separately or together, Sanofi's arguments do not raise a triable issue of exclusionary conduct. For the reasons stated herein, we **AFFIRM** the district court's judgment.[29]

[29] Sanofi also appeals the district court's alternative and independently sufficient basis for summary judgment that "no reasonable jury could find that Mylan's conduct produced an antitrust injury." *In re EpiPen*, 507 F. Supp. 3d at 1366. Given our previous analysis, we need not decide the issue of antitrust injury. "When a court concludes that no [antitrust] violation has occurred, it has no occasion to consider [antitrust injury]." *Levine v. Cent. Fla. Med. Affiliates, Inc.*, 72 F.3d 1538, 1545 (11th Cir. 1996) (quoting 2A Areeda & Hovenkamp, *supra*, ¶ 335f, at 101); *accord Doctor's Hosp. of Jefferson, Inc. v. Se. Med. All., Inc.*, 123 F.3d 301, 306 (5th Cir. 1997); *Hairston v. Pac. 10 Conference*, 101 F.3d 1315, 1318 (9th Cir. 1996).