IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

REGENERON PHARMACEUTICALS, INC.	)	C. A. No.: 22-00697-RGA-JLH
	)	
Plaintiff,	)	**JURY TRIAL DEMANDED**
	)	
v.	)	**PUBLIC VERSION**
	)	
AMGEN INC.,	)	
	)	
Defendant.	)	

OPENING BRIEF OF DEFENDANT AMGEN INC.
IN SUPPORT OF ITS MOTION TO DISMISS

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NATURE AND STAGE OF THE PROCEEDING

Defendant Amgen Inc. ("Amgen") moves under Federal Rule of Civil Procedure 12(b)(6) to dismiss the Complaint filed by Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron").

INTRODUCTION AND SUMMARY OF ARGUMENT

Regeneron, a very large drug company, complains that its competitor Amgen sets its prices too low. Regeneron sells Praluent®, which treats high LDL ("bad") cholesterol, and Amgen sells a competing medicine, Repatha®. Powerful insurance companies and other drug buyers use competition between Regeneron and Amgen to obtain significant price concessions on these drugs. Amgen, Regeneron alleges, has lowered the prices of Repatha® and its other medicines in order to convince insurance companies and health plans to cover Repatha®, and to do so exclusively. Regeneron complains in this action about that competition, insisting it cannot compete for contracts on these terms and at these low prices. But antitrust law does not condemn—indeed, it embraces—competition and low prices. For that reason, Regeneron's claims face a very high bar, and its allegations do not come close to meeting the standards required to state a claim.

Amgen and several other biotechnology companies have developed PCSK9 inhibitors, a novel class of medicines that treat high LDL cholesterol. These medications, taken intravenously, can be used by patients when, for example, more conventional high-cholesterol medicines, such as statins, have not been effective. PCSK9 inhibitors cost more than statins and other oral medications, however, and health insurers are wary about covering them.

Since 2015, there have been two PCSK9 inhibitors available to U.S. patients, Repatha® and Praluent®. (A third, Leqvio®, was approved at the end of 2021). As a result, health insurers and other buyers, such as pharmacy benefit managers ("PBMs"), have been able to pit Regeneron and Amgen against one another to drive down dramatically the prices they pay for these drugs. That is not surprising, because these insurers and PBMs are massive companies with an enormous

amount of market clout. Large PBMs like CVS/Caremark have annual sales in the hundreds of billions of dollars—more than ten times larger than Amgen. Both Amgen and Regeneron have granted significant price concessions in order to persuade these buyers to cover their medicines and make them available to patients—particularly since Repatha® and Praluent® are similar enough that many health plans believe that they need not cover both of them.

Invoking the antitrust laws, Regeneron now asks the Court to interfere with this competition. But even ignoring the many errors and false assumptions in Regeneron's complaint, the Supreme Court has cautioned courts to be skeptical of litigants seeking to impose antitrust liability for low prices. "To avoid chilling aggressive price competition, [courts] have carefully limited the circumstances under which plaintiffs can state a Sherman Act claim by alleging that prices are too low."[1] Applying the Court's guidance, just last week the Tenth Circuit dismissed another antitrust case challenging rebate agreements, explaining that "[t]he proper balance between health plan premiums and formulary coverage is better struck through the workings of the private market than the judiciary."[2] And a company like Regeneron, with $16 billion in annual sales, neither needs nor is legally entitled to any special protection from competition.

Regeneron has failed to allege facts plausibly suggesting that Amgen's price reductions violate the antitrust laws. Regeneron claims that Amgen provides rebates on two of its other medicines—Otezla® and Enbrel®—in three agreements with large drug buyers—Express Scripts Part D, Express Scripts Commercial, and Optum Commercial—in return for their agreement to cover Repatha® exclusively, i.e., excluding Praluent®. Even if that were true (and it is not), under well-established case law, to have the potential to be exclusionary, contracts must block access to

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[1] *Pacific Bell Tel. Co. v. linkLine Commc'ns, Inc.*, 555 U.S. 438, 451 (2009).

[2] *In re: EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, --- F.4th ---, 2022 WL 3009140, at *19 (10th Cir. July 29, 2022).

at least 40%–50% of sales in the market, and lock in customers for significant periods of time. That is not the case here. Regeneron does not allege that Amgen's contract with Express Scripts Part D expressly provides for exclusivity, and its claim of "de facto" exclusivity is not plausible. Moreover, Regeneron's allegations of exclusivity for Amgen's contract with Optum Commercial are belied by the contract itself (which the Court may consider on this motion). That leaves only Amgen's agreement with Express Scripts Commercial, which Regeneron alleges covers *only 15% of the alleged market*. That is far too low to support a claim of competitive foreclosure.

Nor does Regeneron plausibly allege that any of these contracts "lock-in" customers for a significant period of time. The contracts themselves show just the opposite—each allows PBMs and insurers to stop covering Repatha® and start covering Praluent® *at any time* and *for any reason*. That also precludes a finding that the contracts are exclusionary.

Regeneron fares no better with its allegations of "below cost" pricing. Customers benefit from low prices, even if allegedly below cost. For that reason, courts do not allow antitrust claims based on below-cost pricing unless the plaintiff alleges that the prices will knock out the competition and allow the defendant to raise prices later to recoup its losses on these sales. But there are no plausible allegations here that Regeneron, a massive drug company, is likely to remove Praluent® from the market or that, if it did, other competitors would not step in.

Similarly, Regeneron has not adequately alleged, as it must to state an antitrust claim for exclusionary conduct, that Amgen has somehow *coerced* PBMs and insurers to treat Repatha® favorably by threatening to withhold discounts on a "must have" drug with "monopoly power." Regeneron spends pages and pages explaining how Amgen's Otezla® purportedly has "monopoly power" and that Amgen supposedly withholds rebates on Otezla® from Optum and Express Script unless they select Repatha® as their exclusive PCSK9 inhibitor. But, as the contracts confirm,

Amgen does not condition *any* discounts for Otezla® on these customers covering Repatha®.

Nor do Regeneron's allegations that Amgen grants rebates on Enbrel® for PBMs and insurers that choose to cover Repatha® plausibly suggest "coercive" or exclusionary conduct because PBMs and health plans have numerous alternatives to Enbrel®. PBMs and health plans that are dissatisfied with the pricing on Enbrel® can simply choose to cover other treatments for rhetumatoid arthritis instead, including, most prominently, Humira®, the best selling drug in the world. Enbrel® is not a "must have"—indeed, Optum has designated Humira®, not Enbrel®, the "preferred" rheumatoid arthitis drug on its drug formulary. Because Regeneron has failed to plead facts plausibly suggesting that Enbrel® has market power, it has failed to plead that granting rebates on Enbrel® in exchange for favorable coverage for Repatha® could be coercive or exclusionary.

Regeneron can, of course, choose to make a better offer to PBMs and insurers than Amgen. Indeed, the Complaint notably omits any plausible allegations about why Regeneron could not offer more favorable terms on its own massive blockbuster drugs—like Dupixent®, a pharmacy benefit drug (like Praluent® and Repatha®) that costs over $50,000 per year and earned Regeneron over $4 billion[3] in the U.S. in 2021—in return for favorable treatment for Praluent®. If Regeneron makes a better offer, PBMs and insurers are completely free to switch coverage from Repatha® to Praluent®, as they have numerous times in the past several years. But what Regeneron apparently wants is a competitive shield from this Court—something the antitrust laws do not provide.

STATEMENT OF FACTS

I. Competition Among PCSK9 Inhibitors

Patients often participate in a prescription drug plan—either through commercial insurance or Medicare Part D—that pays some or all of the costs of their prescription medications. *See*

[3] Form 10-K, https://investor.regeneron.com/static-files/c9a14dfa-086f-4c2f-8a1b-ed5d018edacc.

Compl. ¶¶ 46–48. As a result, the costs of prescription drugs in the U.S. are largely borne by these third-party payors ("TPPs"). *Id.* TPPs, in turn, often contract with PBMs to manage their prescription plans. *Id.* The "three most dominant" PBMs in the United States are Express Scripts, Inc. ("ESI"), CVS/Caremark ("CVS"), and UnitedHealthcare/OptumRx ("Optum"). *Id.* ¶ 53.

Manufacturers of branded prescription medicines compete not only by convincing physicians and patients on the merits of their products, but also by offering competitive prices to these large buyers. *Id.* ¶ 51. One way that TPPs and PBMs work to obtain better drug prices is by maintaining "formularies," which list medicines that a particular TPP covers and under what terms. *Id.* ¶ 49. TPPs (or their PBMs) then negotiate with manufacturers for rebates off the medicines' list prices in return for favorable formulary coverage. *Id.* ¶ 51. When TPPs and PBMs can credibly claim that a drug has close substitutes, they can demand and receive even larger rebates from manufacturers in order to include their medicines on formularies. *See id.* ¶¶ 52, 62.

Praluent® and Repatha® are direct competitors. Regeneron alleges that PBMs and TPPs have extracted "unprecedented" rebates by "pit[ting]" the two drugs "against each other" in "head-to-head competition" for exclusive formulary placement. *Id.* ¶¶ 51–53 n.51, 62. Of course they have. Repatha® and Praluent® have competed vigorously from the start. Initially, ESI chose to cover both drugs. ESI then determined it could obtain higher rebates if it chose to include only one PCSK9 inhibitor on its formularies and, from July 2018 to July 2019, covered only Praluent®. *Id.* ¶¶ 55, 76. ESI switched to Repatha® in July 2019. *Id.* Similarly, for the past four years, CVS and Optum have regularly switched between covering both drugs, and covering only one. Currently, CVS chooses to cover only Praluent® and Optum chooses to cover only Repatha®.

Repatha® and Praluent® were the only PCSK9 inhibitors approved by the FDA until December 2021, when "the FDA approved a new PCSK9 inhibitor manufactured by Novartis

Pharmaceuticals Corporation . . . called Leqvio®." *Id.* ¶ 42. Regeneron's most recent Form 10-K filed with the SEC identifies Leqvio® as a "Competitor Product" to Praluent®.[4]

II. Regeneron's Flawed Allegations Regarding Otezla® and Enbrel® Rebates

A. Regeneron Alleges That Amgen Has Conditioned Customers' Rebates on Otezla® and Enbrel® on Customers Covering Repatha® and Not Praluent®

The Complaint focuses on rebates that it alleges Amgen provided in its agreement with ESI relating to commercial health plans ("ESI Commercial") and with Optum relating to commercial plans ("Optum Commercial"). Regeneron claims "Amgen has conditioned significant rebates for Enbrel® and Otezla®," over which it says Amgen has "monopoly" or "market" power, respectively, on these PBMs granting "exclusivity or practical exclusivity" for Repatha® on their formularies. *Id.* ¶¶ 18, 96, 113, 119. Regeneron alleges these "highly valuable" rebates have foreclosed Praluent® from accessing these PBMs' businesses, which allegedly cover 15.27% and 7.05%, respectively, of PCSK9 inhibitor prescriptions, because the customers "cannot avoid purchasing," and thus "cannot afford" to "los[e] rebates" on, Otezla® and Enbrel®. *Id.* ¶¶ 3, 18–19, 71, 96.

While Regeneron does not allege that Amgen's agreement with ESI relating to Medicare Part D ("ESI Part D") expressly conditions rebates on Repatha® exclusivity, it alleges "de facto" exclusivity because, it claims, "Amgen's conduct directed at ESI Commercial drove ESI's Part D formulary," allegedly covering 7.7% of the market, "to exclude Praluent® as well." *Id.* ¶¶ 81, 96.

Regeneron also alleges that "other, relatively smaller Third-Party Payors . . . such as Humana, Cigna, and Prime" cover only Repatha®, although it does not allege why. *See id.* ¶ 96.

B. Amgen's Contracts With Optum Commercial and ESI Commercial Show That They Are Not Exclusionary, and That Key Allegations Made by Regeneron Are Incorrect

The Court may evaluate Regeneron's allegations in light of the actual agreements

[4] Form 10-K, https://investor.regeneron.com/static-files/c9a14dfa-086f-4c2f-8a1b-ed5d018edacc

referenced in the Complaint. *See infra* at 8–9 (Standard of Review).

1. The Contracts Do Not Provide Bundled Rebates On Otezla®

Regeneron's allegation that Amgen offers a rebate on Otezla® for Repatha® coverage is simply wrong. Amgen's contracts show that Otezla® rebates are independent of Repatha®, and that Amgen does not condition Otezla® rebates on ESI Commercial or Optum Commercial favorably covering Repatha® (or not covering Praluent®).[5]

2. The Contract Terms Relating To Enbrel® Rebates Stand In Stark Contrast To Regeneron's Allegations

Regeneron alleges that Amgen offers rebates on Enbrel® to Optum Commercial and ESI Commercial that apply only if those customers cover Repatha® exclusively. But Amgen's actual agreements with those PBMs show that Regeneron's allegations are deeply flawed.

Amgen's contract with Optum Commercial provides for rebates on Enbrel® that are not dependent on Repatha® coverage, [redacted][6] [redacted][7] [redacted]

[5] *See, e.g.*, Declaration of Eric J. Stock ("Stock Decl."), Ex. A, at Ex. A § 5A.viii (pp. 38–39), § 5B.viii (pp. 72–74), § 5C.viii (p. 88) (Optum Commercial) (listing conditions for Otezla® rebates, none of which requires Repatha® coverage); *id.*, Ex. B, at Attach. A-1 (ESI Commercial) (listing "footnotes" describing conditions for Otezla® rebates; no footnote applicable to Otezla® requires Repatha® coverage). [redacted] *See id.* at Attach. A-2 § 3(ii). But that does not matter for Regeneron's claim here, which is based on the (incorrect) notion that a customer's failure to cover *Repatha®* will result in lost Otezla® rebates.

[6] *See, e.g.*, *id.*, Ex. A, at Ex. A § 5A.iv (pp. 15–19) (generally); *id.*, Ex. A, at Ex. A § 5A.iv.e (p. 19) ([redacted]).

[7] *See, e.g.*, *id.*, Ex. A, at Ex. A § 5A.iv.e (p. 19) [redacted]. Leqvio®, the other PCSK9 inhibitor, is administered by healthcare providers and thus is a medical benefit, not a drug benefit that appears

[redacted][8]

Importantly, neither of the two Amgen agreements—with Optum Commercial and ESI Commercial—contractually *requires* the customer to cover Repatha® or to cover it exclusively. The contracts instead provide that *if* these customers choose to cover Repatha® under certain proposed terms, they will earn the different levels of rebates specified.[9] Under the agreements, Optum Commercial and ESI Commercial can remove Repatha® from their formularies at any time and for any reason, simply by switching coverage to Praluent® and foregoing the extra rebates, and presumably that is exactly what they would do if Regeneron offered more competitive terms.

STANDARD OF REVIEW

Under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Where allegations fail plausibly to state such a claim, "this basic deficiency should . . . be exposed at the point of minimum expenditure of time and money by the parties and the court." *Twombly*, 550 U.S. at 558 (quotation marks omitted). Doing so is particularly important in antitrust cases that lack a plausible basis to "avoid the potentially enormous expense of discovery" in such cases. *Id.* at 559.

"While normally resolution of a motion to dismiss is limited to review of the allegations in

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on drug formularies. [redacted]

[8] *See, e.g.*, Ex. B, Attach. A-1 (listing "footnotes" describing conditions for Enbrel® rebates that do not depend on Repatha® coverage); *id.*, Ex. B, Attach. A-2 § 3(ii).

[9] *See, e.g.*, *id.*, Ex. A, Ex. A § 5A.iv.e; *id.*, Ex. B, Attach. A-2 § 3 (for both contracts, specifying different rebate levels Amgen will give the customer if it covers Amgen's drugs under specified terms, without requiring the customer to achieve any particular coverage or rebate level).

the complaint, 'a court may consider an undisputedly authentic document that a defendant attaches as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document.'" *City of Pittsburgh v. W. Penn Power Co.*, 993 F. Supp. 332, 336 n.10 (W.D. Pa.) (quoting *Pension Benefits Guar. Corp. v. White Consol. Indus.*, 998 F.2d 1192, 1196 (3d Cir. 1993)). Courts routinely consider written agreements where, as here, antitrust claims are based on them. *See, e.g.*, *Warren Gen. Hosp. v. Amgen Inc.*, 2010 WL 2326254, at *4 (D.N.J. June 7, 2010) ("[T]he Complaint's characterization of [plaintiff] as a direct purchaser is squarely contradicted by the purchase contracts on which the Complaint relies."), *aff'd*, 643 F.3d 77 (3d Cir. 2011); *Pro Search Plus, LLC v. VFM Leonardo, Inc.*, 2013 WL 3936394, at *2 n.2 (C.D. Cal. July 30, 2014) (considering allegedly exclusionary contracts "[b]ecause [the] Complaint relies upon the contracts").

The Court may therefore consider Amgen's *actual agreements* with ESI Commercial and Optum Commercial, because they comprise a fundamental part of Regeneron's antitrust claims. *See, e.g.*, Compl. ¶ 186 ("Amgen has entered into agreements with at least ESI Commercial, ESI Part D, and UHC/Optum Commercial, whereby Amgen has conditioned and tied the availability of rebates for Otezla® and Enbrel® upon exclusive or *de facto* exclusive formulary coverage for the purchase Repatha®."). Moreover, "[w]hen there is a disparity between a complaint's allegations and the written instruments on which the allegations or claims are based, the written instrument controls." *Warren Gen. Hosp.*, 2010 WL 2326254, at *3 (citing *ALA, Inc. v. CCAir, Inc.*, 29 F.3d 855, 859 n.8 (3d Cir. 1994)). Thus, while Regeneron's allegations fail on their own, the Court can also disregard Regeneron's inaccurate claims regarding contracts it can see for itself.

ARGUMENT

I. Regeneron Has Not Plausibly Alleged Any Anticompetitive Conduct

Regeneron's federal and state antitrust claims all require Amgen to have "engaged in anticompetitive conduct." *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 402 (3d Cir.

2016); *see Cnty. of Tuolumne v. Sonora Comm. Hosp.*, 236 F.3d 1148, 1160 (9th Cir. 2001); *Menkes v. St. Lawrence Pilots Ass'n*, 269 Fed. Appx. 54, 55 n.3 (2d Cir. 2008). Where, as here, the challenged conduct is exclusionary contracting, the "rule of reason" (discussed below) governs the analysis. *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 271 (3d Cir. 2012). Where "price is [allegedly] the clearly predominant mechanism of exclusion," then "predatory pricing principles, including the price cost-test . . . control." *Id.* at 273–274. Under these standards, Regeneron has failed to allege that either Amgen's contract terms or its low prices are actionable.

A. Regeneron's Allegations That Amgen's Contracts Are Unlawful Fail Under The Rule Of Reason

"Exclusive dealing agreements are often entered into for entirely procompetitive reasons, and generally pose little threat to competition." *ZF Meritor*, 696 F.3d at 270. It is only in the "rare case" that "exclusive dealing would pose a threat to competition." *Id.* at 285. Indeed, even exclusive rebate agreements have been recognized as procompetitive: "No one can seriously dispute that exclusive rebate agreements stimulate price competition in the prescription drug market." *In re: EpiPen*, 2022 WL 3009140, at *20. Thus, accepting on this motion Regeneron's assertion (Counts 1–2) that "pricing . . . is not the clearly predominant means by which [Amgen] forecloses competition," Compl. ¶¶ 148, 157, "the rule of reason is the proper framework . . . to evaluate [those] claims," *ZF Meritor*, 696 F.3d at 277. Under the rule of reason:

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

Id. at 271–72 (citations omitted, emphases added).

Regeneron has failed to allege that Amgen's agreements with ESI Commercial, ESI Part D, and Optum Commercial are anticompetitive under these standards. Regeneron (1) fails to allege Amgen's agreements with ESI Part D and Optum Commercial are exclusive or *de facto* exclusive; (2) alleges only 15.27% foreclosure—far short of the 40% to 50% courts generally require for "substantial foreclosure"; (3) does not plausibly allege the contracts are of sufficient duration to be exclusionary; (4) fails to allege coercion; and (5) itself employs exclusive dealing.

1. Regeneron Has Not Plausibly Alleged That Amgen's Agreements With ESI Part D Or Optum Commercial Are Exclusive

"A threshold requirement for any exclusive dealing claim is necessarily the presence of exclusive dealing." *ZF Meritor*, 696 F.3d at 282. This requires either an "express exclusivity requirement" or "*de facto* exclusivity," i.e., where although dealing exclusively in the defendant's products is not expressly required, doing so is nonetheless "as effective as mandatory." *Id.* Regeneron has failed to plausibly allege either for ESI Part D or Optum Commercial.

First, Regeneron does not allege that Amgen's ESI Part D contract provides any bundled rebate in exchange for covering Repatha® (and, in fact, it does not). Regeneron's sole allegation with respect to ESI Part D is instead speculation on "information and belief" that "Amgen's conduct directed at *ESI Commercial* drove ESI's Part D formulary . . . to exclude Praluent®" as well because "formulary access decisions" for "commercial and Part D plans" are "generally made on a consistent or uniform basis in the interest of administrative convenience." Compl. ¶ 81 (emphasis added). Putting aside Regeneron's failure to assert facts in support of this conclusory assertion, even if ESI Part D did include Repatha® just for "administrative convenience," that would not make Amgen's contract with ESI Part D *de facto* exclusive. Regeneron's allegations provide no facts whatsoever that plausibly explain why ESI Part D could not, at any time, simply forego this supposed "administrative convenience." Moreover, drug manufacturers and PBMs

typically negotiate their Medicare and commercial rebates separately in order to satisfy transparency in drug price reporting requirements—indeed, that is one reason why there are *separate agreements*. One prominent example of a PBM's commercial and Part D formularies treating Repatha® differently is UnitedHealthcare, which covers only Repatha® on its commercial formulary, but covers both Repatha® and Praluent® for Part D.[10] Regeneron's claims of "*de facto*" exclusivity based on supposed "administrative convenience" are thus implausible.

Second, Regeneron does not plausibly allege that Amgen's agreement with Optum Commercial conditions any rebate on Repatha® exclusivity, or that the agreement prohibits Optum Commercial's formulary from covering Praluent®. *See* Compl. ¶¶ 82–85. Regeneron's Complaint is mere speculation, pled "on information and belief." *Id.* ¶ 84. Moreover, Regeneron's speculation is incorrect—[redacted][11] [redacted] Thus, it is not exclusive.

Regeneron's fallback theory appears to be that "even 'equal' formulary position [is] *de facto* exclusive." Compl. ¶ 17. Treating Repatha® and Praluent® equally, however, is not exclusivity—it is just the opposite. Regeneron's two additional arguments do not show otherwise.

First, Regeneron contends that Praluent® was penalized in the marketplace because it was under "the threat of an injunction" while "Amgen's patent-litigation . . . was still pending before the Federal Circuit." *Id.* But under the *Noerr-Pennington* doctrine, any purported effects from Amgen's patent lawsuit cannot support an antitrust claim because the lawsuit is protected by the

[10] *See* Stock Decl., Ex. G at 9; *id.*, Ex. H at 7. For each formulary cited in this memorandum of law, the Declaration of Eric J. Stock includes a URL to the publicly available version online.

[11] *See, e.g.*, Stock Decl., Ex. A, at Ex. A § 5A.iv.e (p. 19).

First Amendment. *See In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 147–49 (3d Cir. 2017). Regeneron does not contend that the lawsuit was in any way a sham. *Id.*

Second, Regeneron complains that even if the contract allows Optum Commercial to treat Repatha® and Praluent® equally, Amgen's "massive sales force" can "influence physicians to prescribe Repatha® over Praluent®." Compl. ¶ 17. That is a complaint about Amgen being competitive and supporting its product; it is not a legally cognizable grievance. Regeneron's choice not to deploy a significant sales force for Praluent® raises questions about its ability to prove causation in this case, but it cannot turn a non-exclusive agreement into an exclusive one.[12]

2. Regeneron Makes No Plausible Claim That Amgen's Agreements With ESI And Optum Foreclose It From A Substantial Portion Of The Market

In pleading exclusive dealing, "'[t]he share of the market foreclosed is important because, for the contract to have an adverse effect upon competition, the opportunities for others to enter into or remain in that market must be significantly limited.'" *ZF Meritor*, 696 F.3d at 286 (quoting *United States v. Microsoft Corp.*, 253 F.3d 34, 70 (D.C. Cir. 2001)) (alteration and ellipses omitted). Consequently, anticompetitive exclusive dealing requires not simply foreclosure, but "*substantial* foreclosure." *Id.* at 271 (emphasis added); *see also Eisai*, 821 F.3d at 403 ("Although the test is not total foreclosure, the challenged practices must bar a substantial number of rivals or severely restrict the market's ambit." (alteration and quotations omitted)).

While "[t]here is no fixed percentage at which foreclosure becomes substantial," *Eisai*, 821 F.3d at 403 (quotations omitted), "foreclosure of 40% to 50% is usually required," *ZF Meritor*,

[12] Nor is there antitrust significance to Regeneron's unsupported claims that Amgen's salespeople "disseminate[d] misleading facts regarding the safety and availability of Praluent®," Compl. ¶ 66. Absent coercion to heed the allegedly false admonitions, allegations of "deception, reprehensible as it is, can be of no consequence so far as the Sherman Act is concerned." *Santana Prods., Inc. v. Bobrick Washroom Equip., Inc.*, 401 F.3d 123, 132 (3d Cir. 2005).

696 F.3d at 286 (citing *LePage's Inc. v. 3M*, 324 F.3d 141, 159 (3d Cir. 2003)). The Third Circuit has accordingly rejected exclusive dealing challenges to agreements foreclosing just 15% of the market, *see Barr Labs, Inc. v. Abbott Labs.*, 978 F.2d 98, 111 (3d Cir. 1992), while upholding challenges to agreements foreclosing 85% of the market, *see ZF Meritor*, 696 F.3d at 287.

Regeneron cannot overcome this hurdle. According to Regeneron, the alleged bundled rebates have excluded Praluent® from the formularies of ESI Commercial, ESI Part D, and Optum Commercial, which respectively allegedly account for 15.27%, 7.7%, and 7.05%, or, in total, 30.02%, of PCSK9 inhibitor "prescriptions covered." Compl. ¶ 96. But correcting for the fact that Amgen's agreements with ESI Part D and Optum Commercial do *not* provide for a bundled rebate for exclusive coverage of Repatha®, Regeneron is left with only one contract, with alleged foreclosure of merely 15.27%. *See In re: EpiPen*, 2022 WL 3009140, at *24 (citing *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 330–33 (1961)). That leaves the vast majority of the market open and means that Amgen's conduct cannot possibly be considered anticompetitive.[13]

Moreover, even if the Court were to credit Regeneron's allegation that certain "smaller Third-Party Payors" also cover Repatha® exclusively," Compl. ¶ 96, Regeneron alleges no facts suggesting that including some of these smaller TPPs would take the degree of foreclosure from 15% to anything close to the "40% to 50% . . . usually required" for foreclosure to be "substantial." *ZF Meritor*, 696 F.3d at 286. Indeed, Regeneron does not plead that *every single one* of these "smaller TPPs" allegedly covers Repatha® as a result of the challenged bundled discounts, and only TPPs with the challenged contractual provisions would count towards the foreclosure level. *See id.* at 271 ("The legality of an exclusive dealing arrangement depends on whether *it* will

[13] Regeneron's theory of supposed "spillover" foreclosure, *see, e.g.*, Compl. ¶¶ 98–100, is meritless and fails. *See In re: EpiPen*, 2022 WL 3009140, at *24–25 ("refus[ing] to recognize [the] theory of spillover foreclosure").

foreclose competition in such a substantial share of the market." (emphasis added)).

Accordingly, Regeneron's allegations do not plausibly contend that the challenged bundled rebates foreclose it from 40–50% of the market, as required to demonstrate substantial foreclosure. *Id.* at 286; *In re: Epipen*, 2022 WL 3009140, at *20 (rejecting antitrust challenge to rebate contracts with only 31% foreclosure); *Barr Labs*, 978 F.2d at 111 (deeming 15% foreclosure unsubstantial).

3. Regeneron Has Failed To Allege That Amgen's Agreements With Optum And ESI Have Sufficient Durations To Exclude Competition, And The Contracts Themselves Show That They Do Not

Under applicable legal standards, contracts of three or fewer years are generally too short in duration to be exclusionary. The Third Circuit has stated that "short-term agreements . . . present little threat to competition." *ZF Meritor*, 696 F.3d at 286. As the Tenth Circuit recently explained in rejecting antitrust claims based on allegedly exclusive rebate agreements, "[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." *In re*: *EpiPen*, 2022 WL 3009140, at *21 (rejecting antitrust challenge to rebate agreements where "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."). *See also Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227, 237 (1st Cir. 1983) (contract of "about two years" too short to be anticompetitive); *Balaklaw v. Lovell*, 14 F.3d 793, 799 (2d Cir. 1994) (no injury to competition "since the contract . . . has a term of only three years").

Regeneron alleges that Amgen's bundled rebate contract with ESI Commercial lasts for only two years. *See* Compl. ¶ 80 (alleging "exclusive position" for two years). And it fails to assert *any* duration for Amgen's alleged bundled rebates with other customers. *See id.* ¶¶ 81–85. The Complaint thus, on its face, fails to allege anticompetitive duration for any contract.

Moreover, this Court can consider the fact that, as in *EpiPen*, Amgen's agreements with

ESI Commercial and Optum Commercial have no required duration at all for Repatha® coverage. The contract terms *do not require any particular formulary* coverage for Repatha®; they simply grant rebates during the period that the PBM chooses to cover Repatha® under the terms specified.[14] In other words, the contracts allow the PBMs to remove Repatha® from formularies *at any time and for any reason*. Once removed, the rebates provided for Repatha® coverage would cease.[15] Amgen's contracts thus do not require these PBMs to cover Repatha® (or not cover Praluent®) for any duration (or at all), which is wholly antithetical to the notion of an exclusive arrangement.

It is well-established that such "easily terminable" coverage decisions pose no threat to competition. *ZF Meritor*, 696 F.3d at 287; *In re*: *EpiPen*, 2022 WL 3009140, at *21. Indeed, at will termination is more competitively benign than other termination rights deemed too flexible to be exclusionary. *See, e.g.*, *Balaklaw*, 14 F.3d at 799 (rejecting challenge where the contracts "may be cancelled without cause upon six months' notice"); *In re: EpiPen*, 2022 WL 3009140, at *21 (rejecting challenge where "most of the contracts . . . included termination provisions allowing either party to terminate the agreements without cause on 90-days' written notice or less.").

In short, no contractual lock-in is plausibly alleged in the Complaint, and none is evidenced from the contracts themselves. The contracts leave the field wide open for Regeneron to compete.

4. Regeneron Fails To Allege Coercion

"Exclusive dealing will generally only be unlawful where . . . there is some element of coercion present." *ZF Meritor*, 696 F.3d at 284. Regeneron contends that Amgen's agreements offer supposedly "coercive rebates" that "leav[e] Payors with no viable choice but to exclude Praluent® from their formularies." Compl. ¶ 148; *see also, e.g.*, *id.* ¶¶ 72, 79. But courts are clear

[14] *See generally, e.g.*, Stock Decl., Ex. A; *id.*, Ex. B.

[15] *Id.*

that "the threat of a lost discount," including a rebate on pharmaceuticals, is "a far cry" from coercion. *Eisai*, 821 F.3d at 407; *In re: EpiPen*, 2022 WL 3009140, at *27 ("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."); *see also Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 79 (3d Cir. 2010) ("it is no more an act of coercion . . . to offer more money . . . than it is . . . to offer the lowest . . . prices").

Regeneron has not plausibly alleged coercion prompted by the loss of rebates as a result of unfavorable formulary treatment for Repatha®. As noted, no Otezla® rebates at all are conditioned on Repatha® coverage. *See supra* at Statement of Facts § II.B.1. And for Enbrel®, it is not plausible that Optum or ESI would be "coerced" by the loss of a small additional rebate on that drug because there are numerous alternatives to Enbrel® for the treatment of rheumatoid arthritis. Indeed, Enbrel® is not even the "preferred" rheumatoid arthritis treatment on Optum's formulary;[16] that designation instead belongs to Humira®.[17] [redacted][18]

Further, ESI, Optum, and other PBMs "clearly want" Amgen and Regeneron to "compet[e] to become the exclusive supplier," which "is a vital form of rivalry, and often the most powerful one," by forcing suppliers to offer the best deals they can. *Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 660 F. Supp. 2d 590, 605–06 (W.D. Pa. 2009) (quotation marks and citation omitted).

5. Regeneron Admits It Contracts For Exclusive Formulary Treatment

Courts also consider the "use of exclusive dealing by competitors of the defendant." *ZF*

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[16] *See* Stock Decl., Ex. I at 5 (listing Enbrel® as a Tier 3, i.e., non-preferred, drug).

[17] *See id.*, Ex. I at 5 (listing Humira® as a Tier 2, i.e., "preferred," drug); *see also* Section II (explaining why Enbrel® lacks market power)

[18] *See id.*, Ex. A, at Ex. A § 5A.iv.e. Here, we address Regeneron's claims of anticompetitive contractual provisions. Section I.B addresses Regeneron's claims based on Amgen's low pricing.

Meritor, 696 F.3d at 272. As the Tenth Circuit explained in *In re: EpiPen*: the plaintiff's "use of exclusive rebate agreements confirms what is otherwise abundantly clear in the record: PBMs used exclusivity to encourage price competition." *In re: EpiPen*, 2009 WL 3009140, at *25. Like the plaintiff in *In re: EpiPen*, Regeneron admits that it enters agreements for exclusive formulary placement for its product, i.e., Praluent®. Indeed, in touting its earlier "collaboration" with ESI, Compl. ¶ 70, Regeneron cites an ESI press release announcing that "Praluent . . . will be the exclusive PCSK9 inhibitor on our National Preferred Formulary beginning July 1, 2018." *See id.* ¶ 70 n.60 (citing ESI press release). Praluent® is also the only PCSK9 inhibitor listed on the formulary of CVS,[19] which Regeneron notes is "the second largest PBM." *Id.* ¶ 53, n.51.

Regeneron acknowledges that exclusive formulary placement is procompetitive because it is the result of "head-to-head competition" between Repatha® and Praluent® and "generate[s] price concessions, discounts, and rebates" that "lower[] . . . prices" for consumers. *Id.* ¶¶ 51, 62; *see also In re EpiPen Mktg., Sales Pracs. & Antitrust Litig.*, 545 F. Supp. 3d 922, 1011 (D. Kan. 2021) (noting that "use of exclusive dealing contracts is common in the pharmaceutical industry," and "PBMs use exclusive rebating practices as a way to negotiate lower prices . . . by offering preferred formulary placement in exchange for greater rebates."). Thus, while Praluent® once was, and Repatha® now is, the only PCSK9 inhibitor on ESI Commercial's formulary, that balance may shift again if Regeneron chooses to compete.

Regeneron has thus not pled exclusionary contract by Amgen under the rule of reason.

B. Regeneron Has Failed To Plausibly Allege That Amgen's Bundled Rebates Result In Anticompetitive Below-Cost Prices

Regeneron's antitrust claims based on anticompetitive pricing also fail because they do not

[19] *See* Stock Decl., Ex. J at 5 (listing Praluent® as sole PCSK9 inhibitor).

meet the stringent standards applicable to such a claim. To assert a claim based on anticompetitive pricing, a plaintiff must plead "that (1) the rival's low prices are below an appropriate measure of its costs and (2) the rival had a dangerous probability of recouping its investment in below-cost prices." *Eisai*, 821 F.3d at 408 (footnote omitted, citing *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 222–24 (1993)). Regeneron has failed to plausibly allege either.

Regeneron tries to allege that Amgen prices Repatha® below an appropriate measure of its costs by falsely assuming that for ESI Commercial, Amgen conditioned rebates "totaling $210 million . . . for Enbrel®, Otezla®, and Repatha®" on Repatha® coverage. Compl. ¶ 78. But as Amgen's actual agreement shows, Amgen does *not* condition Otezla® rebates on Repatha® coverage. *See supra* at Statement of Facts § II.B.1. Thus, the calculations in the Complaint—incorporating Otezla® rebates that are *not* lost if a customer switches from Repatha® to Praluent®—cannot support Regeneron's claim. Regeneron thus fails to plausibly allege below-cost pricing.

Regeneron also fails to allege a dangerous probability of recoupment, which is necessary to show that consumers would be harmed by any below-cost pricing. *See In re: EpiPen*, 2022 WL 3009140, at *17–19, *17 n.7. This requires plausible allegations that "given the aggregate losses caused by the below-cost pricing, the intended target would likely succumb." *Brooke Grp.*, 509 U.S. at 225. But Regeneron pleads only that Amgen's pricing "*could* be fatal to Praluent®," and that it is merely "*consider[ing]* . . . an exit from the PCSK9i market . . . or some other significant scaling back of the product." Compl. ¶¶ 159 (emphases added), 179. That is far from a dangerous probability of exiting, or "that exit from the market has occurred or is imminent." *R.J. Reynolds Tobacco Co. v. Cigarettes Cheaper!*, 462 F.3d 690, 695 (7th Cir. 2006).

Regeneron has not plausibly alleged that Praluent® is in dire straits or likely to exit the market. Its allegations show Praluent® has been, and remains, regularly considered by major

PBMs as a strong candidate for exclusive PCSK9 inhibitor status. Indeed, Praluent® currently is the only PCSK9 inhibitor on the formulary of CVS,[20] "the second largest PBM," Compl. ¶ 53, n.51. And the short-term, fleeting nature of these formulary decisions confirms Praluent® is fully able to compete—even for business from PBMs and TPPs that currently cover only Repatha®. *See id.* ¶¶ 55, 76. Moreover, Regeneron does not—and cannot—allege that it is unable to offer a bundle comparable to Amgen's—for example, with its $4.7 billion blockbuster drug Dupixent®.[21] *See ZF Meritor*, 696 F.3d at 274 n.11 (citing *LePage's*, 324 F.3d at 155).

Moreover, in a real below-cost pricing scenario, Amgen would need to recoup its alleged losses by charging supracompetitive prices after a Praluent® exit. But Regeneron has not adequately alleged Amgen could charge monopolistic prices for Repatha® after a Praluent® exit. Regeneron argues Leqvio® does not compete with Praluent® on price, but Regeneron lists Leqvio® as a "Competitor Product" to Praluent® in its Form 10-K.[22] "Although . . . courts generally must accept all factual allegations in the complaint as true," they need not do so for allegations "directly contradicted by . . . matters of which a court may take judicial notice, such as SEC filings." *Sapir v. Averback*, 2016 WL 554581, at *10 (D.N.J. Feb. 10, 2016). In light of that concession, it has not adequately pled that because Leqvio® is covered a different contract with drug buyers (i.e., a medical benefit plan) giant health insurance companies would be unable to use Leqvio® to create competitive pressure on Repatha®.[23]

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[20] *See* Stock Decl., Ex. J at 5 (listing Praluent® as sole PCSK9 inhibitor).

[21] 10-K, https://investor.regeneron.com/static-files/c9a14dfa-086f-4c2f-8a1b-ed5d018edacc

[22] *Id.*

[23] Regeneron's failure to allege substantial foreclosure, *see supra* Argument § I.A.2, is also fatal to its claims of anticompetitive pricing. Indeed, the threat of below-cost pricing is the exclusion of equally efficient rivals from the relevant market. *See Eisai*, 821 F.3d at 405; *see also Cascade Health Solutions v. PeaceHealth*, 515 F.3d 883, 897 (9th Cir. 2008) ("the principal anticompetitive danger of the bundled discounts offered by [the defendant] is that the discounts could freeze [the

II. Regeneron's Antitrust Claims Also Fail Because It Does Not Allege That Amgen Bundles Repatha® With Rebates On A Drug With Monopoly Or Market Power

Antitrust challenges to bundled rebates require that the defendant has foreclosed competition for a particular product (the "competitive product") by offering customers a price concession on a different product over which the defendant has monopoly power (the "monopoly product") on the condition that the customer purchase the competitive product from the defendant. *See SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1065 (3d Cir. 1978); *LePage's*, 324 F.3d at 154–56; *see also* Herbert Hovenkamp, *The Obama Administration and Section 2 of the Sherman Act*, 90 B.U. L. Rev. 1611, 1657–58 (2010). A sufficiently large rebate on a monopoly product could, theoretically, coerce a customer into purchasing the competitive product from the defendant, because if the customer does not do so, it forfeits the rebate on the "monopoly" product that has no substitutes. *See Shire US, Inc. v. Allergan*, Inc., 375 F. Supp. 3d 538, 555–56 (D.N.J. 2019).

Coercion can occur, however, only when the competitive product is bundled with, and the rebate is offered on, a product over which the defendant has a *monopoly*. In *Shire US, Inc. v. Allergan, Inc.*, for example, Shire argued Allergan's bundled rebates anticompetitively foreclosed Shire's dry eye disease drug, Xiidra, from the formularies of PBMs. *Id.* at 543. But Shire's claim failed because it "ha[d] not alleged that [Allergan] ha[d] a monopoly over the glaucoma drugs which it bundle[d] with Restasis, the product competing with . . . Xiidra." *Id.* at 557; *see also SmithKline*, 575 F.2d at 1065 (condemning conditioning of rebate on "products on which [the defendant] faced no competition" on customers also purchasing a "competitive product"); *LePage's*, 324 F.3d at 157 (condemning defendant "us[ing] monopoly in transparent tape . . . to squeeze out" plaintiff from competing on other products by "bundling" those products together).

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plaintiff] out of the market"). But excluding Regeneron from just a limited portion of the market—indeed, only a single contract—will not plausibly do so, or result in consumer harm.

Similarly, here, Regeneron does not plead ESI or Optum will lose rebates on a monopoly product if Repatha® is not covered. For Otezla®, the contracts show that Amgen does not condition Otezla® rebates on Repatha® coverage. Thus, to sustain its claims, Regeneron must plausibly allege that Enbrel® has a monopoly. But Regeneron concedes it does not. The Complaint repeatedly contrasts Otezla®'s supposed "*monopoly power* in the moderate-to-severe psoriasis market" with what it calls Enbrel®'s "*market power* in the rheumatoid arthritis market." Compl. ¶ 119 (emphases added); *see also, e.g.*, *id.* ¶ 146 (alleging "Ote[zla]® and Enbrel® . . . *possess monopoly power and market power, respectively*, in the relevant markets" (emphases added)). Regeneron has chosen its words carefully as there is a material difference between the two concepts. *See Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 481 (1992) ("Monopoly power . . . requires, of course, something greater than market power.")

Regeneron has not even plausibly pled "market power," which is "the ability to raise prices above those that would otherwise prevail in a competitive market." *FTC v. AbbVie Inc.*, 976 F.3d 327, 371 (3d Cir. 2020). "A court can infer market power from a market share significantly greater than 55 percent. Other germane factors include the size and strength of competing firms, freedom of entry, pricing trends and practices in the industry, ability of consumers to substitute comparable goods, and consumer demand." *Id.* at 371–72 (quotation marks and citation omitted).

Regeneron carefully *avoids* alleging the share of the alleged rheumatoid arthritis business attributable to Enbrel®. Nor does Regeneron make allegations concerning the "[o]ther germane factors" relevant to market power. *Id.* at 371. It alleges no facts regarding "the size and strength" of other manufacturers of rheumatoid arthritis treatments, relevant industry "pricing trends and practices," the ability of patients to "substitute" other rheumatoid arthritis treatments for Enbrel®, and patient "demand" for Enbrel®. *Id.* at 371–72. It thus pleads no facts that can sustain its claims

of market power. *See Globespanvirata, Inc. v. Tex. Instrument, Inc.*, 2006 WL 543155, at *4 (D.N.J. Mar. 3, 2006) (dismissing antitrust claim for failure to allege market power); *see also, e.g.*, *Brunson Commc'ns, Inc. v. Arbitron, Inc.*, 239 F. Supp. 2d 550, 570 (E.D. Pa. 2002) (dismissing claims where "[p]laintiff ha[d] not only failed to allege any facts regarding . . . market share, but also, none of the other factors associated with monopoly power."). Moreover, Enbrel® competes for multiple indications in addition to rheumatoid arthritis, and Regeneron does not allege that competitive treatments for those other indications do not also constrain Enbrel®'s pricing.

Regeneron's one factual pleading fails to plausibly suggest market power. It cites two charts from a Staff Report from the U.S. House of Representatives Committee on Oversight and Reform, depicting increased pricing for Enbrel® from 2003 through 2019. *See* Compl. ¶¶ 122–23. But those charts are irrelevant; they depict data through 2019 whereas the challenged conduct allegedly started in 2020. *See id.* ¶¶ 68, 123. Obviously, a plaintiff must allege market power at the time of the allegedly anticompetitive conduct because "[w]ithout market power, a manufacturer is not in a position to restrict competition regardless of the restraint imposed." *Inter-City Tire & Auto Center, Inc. v. Uniroyal, Inc.*, 701 F. Supp. 1120, 1123 (D.N.J. 1988). Moreover, to the extent the charts reflect anything relevant, it is that at least since 2016, vibrant competition in the rheumatoid arthritis business, especially from Humira®, has caused Amgen to *lose significant Enbrel® sales* to other competitive drugs. *See* Compl. ¶ 123 ($5.05 billion in 2019 Enbrel® net U.S. revenue); ¶ 122 ($4.85 billion in 2020 and $4.35 billion in 2021). Regeneron's allegations show that since 2016 Amgen's net U.S. Enbrel® revenue has fallen by $1.37 billion. *See id.* ¶ 123.

Regeneron admits Amgen's declining revenue from Enbrel® is the result of "Enbrel® . . . losing market share to Humira® starting in 2017." *Id.* ¶ 122. Humira® is an approved treatment

for rheumatoid arthritis and "the highest grossing drug in the world."[24] Regeneron concedes that Amgen has lost significant share of the rheumatoid arthritis business to Humira®—and that is the antithesis of market power. *See 42nd Parallel N. v. E St. Denim Co.*, 286 F.3d 401, 405 (7th Cir. 2002) ("A company has market power if it can raise prices above a competitive level *without losing its business*." (emphases added)); *Altitude Sports & Entm't, LLC v. Comcast Corp.*, --- F. Supp. 3d ---, 2020 WL 8255520, at *7 (D. Colo. Nov. 25, 2020) ("The Court agrees" that "los[ing] market share" is "the opposite of maintaining market power." (quotation marks omitted)).

And the Court need not turn a blind eye to the ample public evidence that Enbrel® faces fierce competition in the rheumatoid arthritis market from Humira® and others. "FDA approvals," which are "matters of public record . . . appropriate for judicial notice," *Clements v. Sanofi-Aventis, U.S., Inc.*, 111 F. Supp. 3d 586, 592 n.2 (D.N.J. 2015), as well as Amgen's contracts, demonstrate that Enbrel® competes with numerous FDA-approved treatments for rheumatoid arthritis, including the blockbusters Humira® and Remicade®, as well as Xeljanz®, Rinvoq®, Orencia®, and Simponi®, among numerous others.[25] The alleged market for FDA-approved rheumatoid arthritis treatments is rich with competitive alternatives to Enbrel®, and Regeneron fails to plead any market share levels. The Complaint thus does not plausibly allege market power.

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[24] *See* "Drug Pricing Investigation, AbbVie—*Humira and Imbruvica,*" Staff Report, at (i) (May 2021) (the "Humira Staff Report"), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Committee%20on%20Oversight%20and%20Reform%20-%20AbbVie%20Staff%20Report.pdf. The Humira Staff Report states that list prices of Enbrel® and Humira® increased by roughly the same proportion (5.6 or 5.7) between 2002 and 2020, but that during that period U.S. revenue for Enbrel® increased by around 3.88 times, whereas U.S. sales of Humira® increased by over 80 times. *Compare* Compl. ¶¶ 122–23 *with* Humira Staff Report at 2, 5. Between 2016 and 2020, Amgen's U.S. sales from Enbrel® allegedly *fell* by $870 million, Compl. ¶¶ 122–23, while Humira®'s sales *increased* by $5.7 billion, Humira Staff Report at 5.

[25] *See* Stock Decl., Ex. K (FDA approval letters); *see, e.g.*, *id.*, Ex. C, at Ex. C (listing products Optum considers competitors of Enbrel®).

III. Regeneron's Remaining Claims Fail

Regeneron's UCL claim is derivative of its antitrust claims and therefore must be dismissed for the same reasons. *See Eastman v. Quest Diagnostics Inc.*, 2016 WL 1640465, at *13 (N.D. Cal. Apr. 26, 2016). Regeneron's UPA claim fails because Regeneron has not "allege[d], in other than conclusionary terms, the defendant's sales price, costs in the product, and costs of doing business," as the UPA requires. *Fisherman's Wharf Bay Cruise Corp. v. Super. Ct. of San Francisco*, 114 Cal. App. 4th 309, 322 (Cal. Ct. App. 2003). Regeneron's tortious interference claim fails because Amgen had a "privilege to compete . . . in a fair and lawful manner," and absent an antitrust violation, there is no plausible claim that Amgen won that business unfairly or unlawfully. *U.S. Bank Nat'l Assn. v. Gunn*, 23 F. Supp. 3d 426, 436 (D. Del. 2014) (Andrews, J.). Moreover, Regeneron's assertion that "Amgen acted with dishonest, unfair, or improper means by utilizing its sales force to spread misleading facts regarding Praluent®," Compl. ¶ 259, cannot support an antitrust claim based on alleged exclusionary contracting with PBMs given its lack of particularity under Fed. R. Civ. P. 9(b) and given that the alleged statements were made "to nurses, physicians, and other medical practitioners" and not to ESI, Optum, or any other PBM, *id.* ¶ 66.

CONCLUSION

In sum, Counts 1–6, 9, and 10 of the Complaint must be dismissed for failure to allege anticompetitive conduct (*see* Section I), and for failure to allege that rebates on a monopoly product were conditioned on Repatha® coverage (*see* Section II). Counts 7, 8, and 11 must be dismissed because they depend largely on the Complaint's antitrust allegations, which fail to state a claim for the reasons discussed herein (*see* Section III).

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