

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

REGENERON PHARMACEUTICALS, INC.	)	
	)	
Plaintiff,	)	C. A. No.: 22-00697-RGA-JLH
	)	
v.	)	<b>JURY TRIAL DEMANDED</b>
	)	
AMGEN INC.,	)	
	)	
Defendant.	)	

**AMGEN INC.'S OBJECTIONS TO THE REPORT & RECOMMENDATION**

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**TABLE OF CONTENTS**

	<u>Page</u>
INTRODUCTION .....	1
STANDARD OF REVIEW .....	2
OBJECTIONS.....	2
I. The Court Should Reject the R&R’s Finding That 22% Foreclosure Is Sufficient To State a Claim Where a Plaintiff Pleads No Other Plausible Additional Indicia of Competitive Harm. ....	2
II. At Minimum, the Court Should Reject the R&R’s Recommendation Not To Dismiss Claims Based on Alleged Bundling with Enbrel <sup>®</sup> Due to Lack of Monopoly Power.....	7
III. The Court Should Consider The Contracts Amgen Submitted.....	10
CONCLUSION.....	10

**TABLE OF AUTHORITIES**

	<u>Page(s)</u>
<b>CASES</b>	
<i>42nd Parallel N. v. E St. Denim Co.</i> , 286 F.3d 401 (7th Cir. 2002) .....	9
<i>Altitude Sports &amp; Entm’t, LLC v. Comcast Corp.</i> , --- F. Supp. 3d ---, 2020 WL 8255520 (D. Colo. Nov. 25, 2020).....	9, 10
<i>American Holiday Inns v. Holiday Inns, Inc.</i> , 521 F.2d 1230 (3d Cir. 1975).....	5
<i>B &amp; H Med., L.L.C. v. ABP Admin., Inc.</i> , 526 F.3d 257 (6th Cir. 2008) .....	3
<i>Balaklaw v. Lovell</i> , 14 F.3d 793 (2d Cir. 1994).....	4
<i>Barry Wright Corp. v. ITT Grinnell Corp.</i> , 724 F.2d 227 (1st Cir. 1983).....	4
<i>Bell Atl. Corp. v. Twombly</i> , 550 U.S. 544 (2007).....	2, 9
<i>Brooke Grp. Ltd. v. Brown &amp; Williamson Tobacco Corp.</i> , 509 U.S. 209 (1993).....	7
<i>Brunson Commc’ns, Inc. v. Arbitron, Inc.</i> , 239 F. Supp. 2d 550 (E.D. Pa. 2002) .....	9
<i>Eisai, Inc. v. Sanofi Aventis U.S., LLC</i> , 821 F.3d 394 (3d Cir. 2016).....	7
<i>FTC v. AbbVie Inc.</i> , 976 F.3d 327 (3d Cir. 2020).....	8, 9
<i>Globespanvirata, Inc. v. Tex. Instrument, Inc.</i> , 2006 WL 543155 (D.N.J. Mar. 3, 2006) .....	8
<i>Int’l Constr. Prod. LLC v. Caterpillar Inc.</i> , 2016 WL 264909 (D. Del. Jan. 21, 2016).....	6, 7
<i>Jefferson Parish Hosp. Dist. No. 2 v. Hyde</i> , 466 U.S. 2 (1984).....	3
<i>Kidd v. Bass Hotels &amp; Resorts, Inc.</i> , 136 F. Supp. 2d 965 (E.D. Ark. 2000).....	3

*Pension Benefits Guar. Corp. v. White Consol. Indus.*,  
998 F.2d 1192 (3d Cir. 1993).....10

*PNY Techs., Inc. v. SanDisk Corp.*,  
2014 WL 1677521 (N.D. Cal. Apr. 25, 2014) .....4, 6

*Pro Search Plus, LLC v. VFM Leonardo, Inc.*,  
2013 WL 3936394 (C.D. Cal. July 30, 2013).....4, 6, 10

*SEI Global Servs., Inc. v. SS&C Advent*,  
496 F. Supp. 3d 883 (E.D. Pa. 2020) .....8

*Shire US, Inc. v. Allergan, Inc.*,  
375 F. Supp. 3d 538 (D.N.J. 2019) .....8

*Stop & Shop Supermarket Co. v. Blue Cross & Blue Shield of R.I.*,  
373 F.3d 57 (1st Cir. 2004).....3

*In re Surescripts Antitrust Litig.*  
2022 WL 2208914 (N.D. Ill. June 21, 2022) .....5

*U.S. v. Microsoft Corp.*,  
253 F.3d 34 (D.C. Cir. 2001) .....2, 4

*Vázquez-Ramos v. Triple-S Salud, Inc.*,  
55 F.4th 286 (1st Cir. 2022).....5

*ZF Meritor, LLC v. Eaton Corp.*,  
696 F.3d 254 (3d Cir. 2012)..... *passim*

**STATUTES**

28 U.S.C. § 636(b)(1)(C) .....2

**OTHER AUTHORITIES**

ABA Antitrust Section, Antitrust Law Dev. (1997) .....3

**RULES**

Fed. R. Civ. P. 72(b)(3).....2

**TABLE OF AUTHORITIES**Page(s)**INTRODUCTION**

Defendant Amgen Inc. (“Amgen”) respectfully objects to the February 10, 2023 Report and Recommendation (“R&R”) recommending denial of Amgen’s motion to dismiss. D.I. 49. Amgen requests that the Court not adopt the R&R, and instead dismiss the complaint for failure to plead substantial foreclosure. In the alternative, Amgen requests that the Court, at a minimum, dismiss all claims relating to alleged bundling with Amgen’s drug Enbrel<sup>®</sup>.

Plaintiff Regeneron Pharmaceuticals, Inc. (“Regeneron”) sells Praluent<sup>®</sup>, a drug that competes with Amgen’s drug, Repatha<sup>®</sup>. Regeneron alleges that Amgen has granted customers rebates on other Amgen drugs that are conditional on those customers covering Repatha<sup>®</sup> exclusively, and not Praluent<sup>®</sup>. The R&R found that Regeneron plausibly alleged this conduct foreclosed Regeneron from competing for about 22% of the market. But under well-established law in this Circuit, that is not enough. Regeneron must show it has been “substantially foreclosed” from the market, which generally requires foreclosure levels of 40 to 50%. *See ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 286 (3d Cir. 2012). Regeneron’s allegations do not do so, and its claims are particularly weak because they show the contracts are of short duration. And given that Regeneron alleges a market limited to two players, allegations that one competitor has used low prices to temporarily secure only 22% of that market do not state an antitrust claim.

The R&R also erred in not recommending dismissal of Regeneron’s claims relating to alleged anticompetitive bundling involving Enbrel<sup>®</sup>. To sustain its claim of alleged “bundled discounting,” Regeneron must plead that Amgen utilized bundled discounts on a product with monopoly power to secure exclusivity for Repatha<sup>®</sup>. Regeneron alleges that Amgen bundled two drugs with Repatha<sup>®</sup>—Enbrel<sup>®</sup> and Otezla<sup>®</sup>. The Enbrel<sup>®</sup> allegations do not state a claim because Regeneron has not adequately pled facts suggesting Enbrel<sup>®</sup> has a high market share, or any other indicia of monopoly power. And the allegations relating to Otezla<sup>®</sup> are not plausible because the

contracts Amgen submitted to the Court show no bundled rebates with Otezla<sup>®</sup>. Given the high expense of antitrust litigation, the R&R erred by declining to review Amgen’s contracts—which were integral to and the basis for Regeneron’s complaint—to verify the plausibility of Regeneron’s allegations relating to Otezla<sup>®</sup> prior to letting this case proceed to expensive antitrust discovery.

### STANDARD OF REVIEW

The R&R is reviewed *de novo*. Fed. R. Civ. P. 72(b)(3); 28 U.S.C. § 636(b)(1)(C). The Court may “accept, reject, or modify, in whole or in part, the findings or recommendations made by the magistrate judge.” 28 U.S.C. § 636(b)(1)(C); *see also* Fed. R. Civ. P. 72(b)(3). District courts should carefully scrutinize antitrust claims at the pleading stage to ensure that they pass the “threshold of plausibility” that “must be crossed at the outset before a[n] . . . antitrust case should be permitted to go into its inevitably costly and protracted discovery phase.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007) (citation omitted). Those considerations apply strongly here.

### OBJECTIONS

#### **I. The Court Should Reject the R&R’s Finding That 22% Foreclosure Is Sufficient To State a Claim Where a Plaintiff Pleads No Other Plausible Additional Indicia of Competitive Harm.**

“[E]xclusive contracts are commonplace—particularly in the field of distribution . . . and imposing upon a firm with market power the risk of an antitrust suit every time it enters into such a contract, no matter how small the effect, would create an unacceptable and unjustified burden upon any such firm.” *U.S. v. Microsoft Corp.*, 253 F.3d 34, 70 (D.C. Cir. 2001). For this reason, courts require an antitrust plaintiff challenging exclusive dealing to show, among other things, that the exclusive contracts resulted in foreclosure of the plaintiff from a “*substantial*” portion of the market, and for a “*sufficient duration*.” *ZF Meritor*, 696 F.3d at 271–72 (emphasis added). The Third Circuit has noted that foreclosure levels of “40 to 50%” are “usually” required to sustain such a claim, *id.* at 286, and it is not alone. “Since the early 1970’s ‘judicial decisions have

established a virtual safe harbor for market foreclosure of 20% or less.” *Kidd v. Bass Hotels & Resorts, Inc.*, 136 F. Supp. 2d 965, 969 (E.D. Ark. 2000) (citing ABA Antitrust Section, Antitrust Law Dev., 223 (1997)). And since the Supreme Court in *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 47 (1984) dismissed an exclusive dealing claim with 30% foreclosure, courts now routinely observe that “foreclosure levels are unlikely to be of concern where they are less than 30 or 40 percent.” *B & H Med., L.L.C. v. ABP Admin., Inc.*, 526 F.3d 257, 266 (6th Cir. 2008); *Stop & Shop Supermarket Co. v. Blue Cross & Blue Shield of R.I.*, 373 F.3d 57, 68 (1st Cir. 2004).

These precedents doom Regeneron’s claim, which relies on facts plausibly suggesting, at most, 22% foreclosure. D.I. 40 at 5–6. But in the R&R, the Magistrate Judge was “not prepared to say at this stage of the case that plausibly pleading contracts resulting in foreclosure of at least 22.32% is insufficient as a matter of law to state [a] . . . claim.” R&R at 11. The R&R provided three reasons: (1) *ZF Meritor* noted that 40-50% foreclosure was “usually” required, not always; (2) Repatha<sup>®</sup> allegedly had monopoly power; and (3) Regeneron’s drug, Praluent<sup>®</sup>, allegedly was “not covered” by customers representing 50% of the market. R&R at 11-12 & n.6. This was error.

The R&R noted that *ZF Meritor* holds only that substantial foreclosure is “usually” required, and that the decision also sets forth “a number of additional factors relevant to the analysis” under the rule of reason. *Id.* The R&R cites the D.C. Circuit in *Microsoft* for the proposition that there can be unusual circumstances where it is possible to state a monopolization claim with foreclosure levels lower than 40-50%. *See id.* The R&R also cites a few district court decisions allowing antitrust claims with allegations of less than 40-50% foreclosure. *See id.*

Even assuming that it is possible (under the case law, or otherwise) to plead facts regarding other “market conditions” that could support an exclusive dealing claim notwithstanding foreclosure levels of only 22%, Regeneron did not plead such facts. Indeed, its other allegations

make its foreclosure claims weaker, not stronger. As noted, under *ZF Meritor*, a key factor in evaluating an exclusive dealing claim is the *duration* of the allegedly exclusive contracts. Only long-term exclusive contracts can effect meaningful foreclosure, and “short-term agreements . . . present little threat to competition.” *ZF Meritor*, 696 F.3d at 286. Regeneron pled, however, that Amgen’s largest contract, with ESI, lasts for only two years. Compl. ¶ 80; D.I. 18 at 15. Such a limited duration has been consistently held insufficient to foreclose competition. *See, e.g., 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”). Indeed, cases hold that such a short duration justifies dismissal. *See, e.g., Pro Search Plus, LLC v. VFM Leonardo, Inc.*, 2013 WL 3936394, at \*4 (C.D. Cal. July 30, 2013) (dismissing claims based on contracts of two and three years due to their “relatively short duration”); *PNY Techs., Inc. v. SanDisk Corp.*, 2014 WL 1677521, at \*5–6 (N.D. Cal. Apr. 25, 2014) (similar). Moreover, for Amgen’s contract with Optum, Regeneron pleads no duration at all. Compl. ¶¶ 81–85. This, too, is independent grounds for dismissal, particularly when combined with the low percentage foreclosure.

Regeneron pleads nothing comparable to other cases where courts have found adequate allegations that foreclosure was “substantial” notwithstanding low quantitative levels of foreclosure. In *Microsoft*, upon which the R&R relied, the Department of Justice alleged that “Microsoft ha[d] exclusive deals with fourteen of the top fifteen [Internet] access providers in North America, [accounting] for a large majority of all Internet access subscriptions in this part of the world.” 253 F.3d at 70. That showed that, even if Microsoft’s competitor still had access to customers via different sales channels, the competitor had been substantially foreclosed from the most efficient means of distribution, and that played a strong role in protecting the monopoly. *Id.*

Here, Regeneron alleges nothing of the sort. It simply alleges that it has (temporarily) lost contracts with two major pharmacy benefit managers (“PBMs”) covering only 22% of the market but still has an *exclusive* relationship with the third major PBM. Compl. ¶ 70; D.I. 18 at 18. That in a two-player market, three top customers are split 2-1 does not plausibly suggest substantial foreclosure, nor that foreclosure of 22% of that market can result in concerns of meaningful anticompetitive exclusion warranting an exception to the general rule in *ZF Meritor*.<sup>1</sup>

The R&R suggests that 22% foreclosure should be considered together with the allegation that Praluent<sup>®</sup> was “not covered” by other customers constituting 50% of the market. R&R at 12. But that additional point makes no difference. Substantial foreclosure is measured not by the proportion of customers that chose Amgen’s product through the competitive process; it is instead measured by proportion of the market foreclosed by the *allegedly wrongful conduct*. D.I. 18 at 13. Other than, at most, the two contracts representing 22% of the market addressed in the R&R (ESI and Optum), Regeneron pleads (and the R&R identifies) no facts plausibly suggesting that Regeneron cannot compete on the merits for the remaining customers in the market—*i.e.*, those not subject to the alleged bundling. The R&R erred by allowing Regeneron to substitute the buying decisions of these other customers for actually alleging that the *challenged conduct* resulted in

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<sup>1</sup> The other cases that the R&R cites, where courts allowed claims to proceed with low foreclosure percentages, are either not analogous or reflect situations where the plaintiffs did establish “other market factors” that justified a departure from *ZF Meritor*. See R&R at 12 n.6. *American Holiday Inns v. Holiday Inns, Inc.* is a 48-year-old, pre-*Jefferson Parish* case. It also involved a very different industry—hotel franchising—and the cited language is dicta (yet still acknowledges the relevance of other factors). 521 F.2d 1230, 1252 (3d Cir. 1975). In *Vázquez-Ramos v. Triple-S Salud, Inc.*, the plaintiffs alleged *total* foreclosure, that they were “shut . . . out of a plausibly relevant market entirely.” 55 F.4th 286, 299 (1st Cir. 2022). And in *In re Surescripts Antitrust Litig.* 2022 WL 2208914 (N.D. Ill. June 21, 2022), the plaintiff alleged arrangements “imposed on nearly 80%” of the “doctor and pharmacy side of the e-prescribing market,” which the plaintiffs pled (like in *Microsoft*) was a particularly crucial distribution outlet; and those plaintiffs also alleged that the arrangements included “*long-term* exclusivity commitments,” such that “[t]he same conditions present in *ZF Meritor* [were found to be] present.” *Id.* at \*2, \*9–10.

substantial foreclosure. And the fact that—in a market allegedly limited to two drugs—roughly half of the market has chosen to cover Amgen’s drug exclusively raises no inference of exclusion.

Nor is substantial foreclosure a “factual” issue that is immune to scrutiny on the pleadings. R&R at 13. Courts regularly dismiss exclusive dealing cases *on the pleadings* where the plaintiffs do not plead substantial foreclosure or meaningful contract duration. D.I. 40 at 5–6; *see, e.g., Int’l Constr. Prod. LLC v. Caterpillar Inc.*, 2016 WL 264909, at \*6 (D. Del. Jan. 21, 2016) (dismissal for failure to allege “substantial foreclosure”); *Pro Search Plus*, 2013 WL 3936394, at \*4; *PNY Techs., Inc.*, 2014 WL 1677521, at \*5–6. As the court in *PNY Techs.* explained in rejecting an argument that “foreclosure is a fact issue,” “[f]oreclosure is a legal conclusion—[plaintiff’s] task is to provide the facts supporting it. It has not done so.” *Id.* at \*6. The same is true here.

This Court’s decision in *International Construction* is illustrative. At issue was an exclusive dealing claim dismissed at the pleading stage for “fail[ing] to demonstrate that the . . . exclusive dealing arrangements amount[ed] to substantial foreclosure in any alleged market.” 2016 WL 264909, at \*6. The plaintiff alleged that the defendants had “exclusive dealing arrangements with dealers,” that “new entrants [were] ‘unable to compete successfully for distribution,’” that the “imposition of exclusivity” was “coercive and contrary to the preference of the dealers,” and that “existing dealers” experienced “difficulty switching to new manufacturers.” *Id.* at \*6. This Court found the complaint deficient because it did not provide enough information to determine whether plaintiff met its “*prima facie* case,” which required consideration of the *ZF Meritor* factors, including, of course, “substantial foreclosure” and “sufficient duration.” *Id.*

The R&R attempts to distinguish *Int’l Construction* because the plaintiff there “allege[d] no facts about the nature of the exclusive dealing arrangements and their potentially anticompetitive effects.” R&R at 13 n.7; 2016 WL 264909, at \*6. But Regeneron, though

providing some detail on the “nature of the . . . arrangements,” utterly failed to plead facts showing a “*prima facie* case” of “potentially anticompetitive effects” as measured by *ZF Meritor*—*e.g.*, foreclosure from a substantial portion of the market, with contracts of significant duration. *Id.*

Regeneron’s failure to allege substantial foreclosure is also fatal to its price-based claims. The competitive threat of below-cost pricing is the exclusion of equally efficient rivals from the market. *See Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 405 (3d Cir. 2016); *see also* D.I. 18 at 20 n.23. But excluding Regeneron from a small portion (22%) of a two-player market—and for such a short duration—will not plausibly cause Regeneron to go out of business. D.I. 18 at 18. And that means there can be no consumer harm from allegedly below cost prices because if Regeneron does not exit, then consumers benefit from low prices, even if below cost.

Respectfully, the R&R erred when it found it was not necessary for Regeneron to plead it would “likely” exit, or that allegations of no profit or low sales were enough. R&R at 15. Under Supreme Court precedent—and to make plausible allegations of consumer harm—an antitrust plaintiff challenging low prices must plead that it “would *likely* succumb” and exit. *See Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 225 (1993) (emphasis added).

Accordingly, all of Regeneron’s claims should be dismissed due to its failure to allege substantial foreclosure, regardless of how the Court rules on any of the other issues raised herein.

## **II. At Minimum, the Court Should Reject the R&R’s Recommendation Not To Dismiss Claims Based on Alleged Bundling with Enbrel<sup>®</sup> Due to Lack of Monopoly Power.**

The R&R rejected Amgen’s arguments relating to the lack of monopoly power for Enbrel<sup>®</sup>, stating that “Amgen’s arguments regarding Enbrel<sup>®</sup> . . . involve factual disputes and invoke extra-Complaint evidence that the Court will not consider.” R&R at 13. But, respectfully, the R&R did not engage with Amgen’s arguments *based solely on the inadequacy of the pleadings*.

Monopolization claims require allegations of monopoly power and exclusionary conduct. Where an antitrust plaintiff’s claim of exclusionary conduct is based on bundled discounts, the

plaintiff must plead that the product (the “competitive product”) that competes with the plaintiff’s product was bundled with a separate product (the “bundled product”) that has monopoly power. D.I. 18 at 21. Illustrative of this principle is *Shire US, Inc. v. Allergan, Inc.*, where Shire claimed that Allergan’s bundled rebates on glaucoma drugs with its drug Restasis (the competitive product) foreclosed Shire’s competing drug, Xiidra<sup>®</sup>, from key customers. 375 F. Supp. 3d 538, 543 (D.N.J. 2019). Shire’s claim failed because it “ha[d] not alleged that [Allergan] ha[d] a monopoly over the glaucoma drugs [the bundled products] which it bundle[d] with Restasis [the competitive product], the product competing with . . . Xiidra<sup>®</sup>.” *Id.* at 557.

Regeneron’s allegations relating to Enbrel<sup>®</sup> are plainly insufficient. Regeneron alleges that Amgen unlawfully bundled rebates on Enbrel<sup>®</sup> (the bundled product) with Repatha<sup>®</sup>, but pleads nothing to show either monopoly power or even the lesser standard of “market power” for Enbrel<sup>®</sup>—a deliberate choice in light of its extensive allegations regarding Otezla’s “monopoly.” Compl. ¶¶ 113–18; D.I. 18 at 22–24. “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.” *FTC v. AbbVie Inc.*, 976 F.3d 327, 371–72 (3d Cir. 2020) (quotation marks and citation omitted). But Regeneron pleads neither high market share, nor any other “germane factors” like “size and strength of competing firms.” *Id.* In fact, Regeneron pleads no market share at all—the “most significant factor” in the analysis. *SEI Global Servs., Inc. v. SS&C Advent*, 496 F. Supp. 3d 883, 894 (E.D. Pa. 2020). That is inexcusable (and revealing) given the wide availability of market share data for pharmaceutical products.

These pleading failures, alone, are enough for the Court to find that Regeneron has not adequately pled that Enbrel<sup>®</sup> has market power. In *Globespanvirata, Inc. v. Tex. Instrument, Inc.*,

for example, the court dismissed monopolization claims for not making “[a]llegations concerning a defendant’s share of the relevant market . . . . While other factors are also relevant, they are typically considered alongside facts concerning market share, not in lieu of such facts.” 2006 WL 543155, at \*4 (D.N.J. Mar. 3, 2006); *see also 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 [relevant] factors”).

On these other germane factors, Regeneron made only a flawed attempt to plead “pricing trends and practices” through citations to charts from a Congressional Staff Report, which depict increased prices for Enbrel<sup>®</sup> from 2003-2019. Compl. ¶¶ 122–23. But those charts are irrelevant because the time period is outside of the relevant pleaded conduct—Regeneron alleges the bundled discounts did not start until 2020, and thus the data, at most, invite speculation as to Enbrel<sup>®</sup>’s market power. *See id.* ¶¶ 68, 123. And “[f]actual allegations must be enough to raise a right to relief above the *speculative* level.” *Twombly*, 550 U.S. at 555 (emphasis added). In any event, the charts show a *lack* of market power because the increased prices are associated with *decreased* revenue—a decline of \$1.37 billion since 2016. *Id.* ¶ 123. Amgen does not have the “ability to raise prices” on Enbrel<sup>®</sup> if doing so leads to declines in revenue. *AbbVie*, 976 F.3d at 371.

If this were not enough, Regeneron concedes that Amgen lost revenue as a result of “Enbrel<sup>®</sup> . . . losing market share to *Humira*<sup>®</sup> starting in 2017.” Compl. ¶ 122; *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.*” (emphasis 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)). *Humira*<sup>®</sup> is the best-selling drug in the world, and

Regeneron's pleading concedes that Humira<sup>®</sup> competes directly with Enbrel<sup>®</sup>. Yet Regeneron pleads *zero facts* suggesting that (1) Enbrel<sup>®</sup> has a higher market share than Humira<sup>®</sup> in the relevant market, or (2) Humira<sup>®</sup> is not an adequate substitute for Enbrel<sup>®</sup> for patients and customers, and that customers could not turn to Humira<sup>®</sup> in the face of an Enbrel<sup>®</sup> price increase.

Because these flaws are apparent on the face of the Complaint, it was error for the R&R to find that Amgen's arguments on this issue could not succeed based solely on the pleadings. Claims of alleged bundling of Repatha<sup>®</sup> with Enbrel<sup>®</sup> should be dismissed. That would streamline this case and allow it to focus only on the claims the Court finds adequately pled by Regeneron.

### **III. The Court Should Consider The Contracts Amgen Submitted.**

The R&R declined to consider the contracts Amgen submitted, stating that it “disagree[d] that the documents submitted by Amgen are integral to or relied upon by Regeneron such that the Court may consider them...” R&R at 10. Respectfully, that was error. Regeneron's claims are squarely based on what it calls Amgen's “illegal, anticompetitive bundled rebate agreements” with “two major Third-Party Payors.” D.I. 40 at 2. It is the well-established practice of federal courts to “consider an undisputedly authentic document that a defendant attaches ... to a motion to dismiss if the plaintiff's claims are based on the document.” *Pension Benefits Guar. Corp. v. White Consol. Indus.*, 998 F.2d 1192, 1196 (3d Cir. 1993). Other courts have examined such contracts in analogous situations. D.I. 18 at 9; *see Pro Search Plus*, 2013 WL 3936394, at \*4. Regeneron made no plausible allegation that the contracts were not authentic or that the material terms were in dispute. Because these agreements show no Otezla<sup>®</sup> bundling—or that the Optum agreement resulted in exclusivity—that is further reason why the Court should dismiss the complaint.

### **CONCLUSION**

The R&R should be rejected and the Court should dismiss all federal claims, as well as all of the state claims, which fail for the same reasons as the federal claims. *See* R&R at 16.

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