IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

Regeneron Pharmaceuticals, Inc.,

Plaintiff,

v.

C. A. No.: 1:22-cv-00697-RGA-JLH

Amgen Inc.,

Defendant.

PLAINTIFF REGENERON PHARMACEUTICALS, INC.'S RESPONSE TO DEFENDANT AMGEN INC.'S OBJECTIONS TO THE MAGISTRATE JUDGE'S REPORT AND RECOMMENDATION

Dated: March 10, 2023

David E. Wilks (DE Bar No. 2793)	Jonathan D. Polkes (admitted pro hac vice)
Scott B. Czerwonka (DE Bar No. 4844)	Elizabeth Stotland Weiswasser (admitted pro hac vice)
WILKS LAW, LLC	Eric S. Hochstadt (admitted pro hac vice)
4250 Lancaster Pike Suite 200	Jessica L. Falk (admitted pro hac vice)
Wilmington, DE 19805	Adam B. Banks (pro hac vice pending)
Telephone: (302) 225-0850	Robert Niles-Weed (admitted pro hac vice)
Fax: (302) 225-0851	WEIL, GOTSHAL & MANGES LLP
	767 Fifth Avenue
	New York, NY 10153-0119
	Telephone: (212) 310-8000
	Fax: (212) 310-8007
	Michael R. Moiseyev (admitted pro hac vice)
	Priyata Y. Patel (admitted pro hac vice)
	WEIL, GOTSHAL & MANGES LLP
	2001 M Street, NW
	Washington, D.C. 20036
	Telephone: (202) 682-7000
	Fax: (202) 857-0940

Attorneys for Regeneron Pharmaceuticals, Inc.

TABLE OF CONTENTS

Page

Introdu	action	1
Standa	rd of Review	4
Argum	ent	4
I.	Amgen concedes that its extra-complaint record cannot be considered and Otezla [®] is part of the unlawful bundle.	4
II.	Regeneron adequately alleged Enbrel [®] 's market power	5
III.	Regeneron adequately alleged substantial foreclosure in the PCSK9i market	8
Conclu	ision 1	0

TABLE OF AUTHORITIES

Page(s)

Cases

3Shape Trios A/S v. Align Tech., Inc., 2020 WL 6938054 (D. Del. Nov. 25, 2020) passim
<i>Allen-Myland, Inc. v. Int'l Bus. Machines Corp.</i> , 33 F.3d 194 (3d Cir. 1994)
<i>Am. Motor Inns, Inc. v. Holiday Inns, Inc.</i> , 521 F.2d 1230 (3d Cir. 1975)4, 9
Ashcroft v. Iqbal, 556 U.S. 662 (2009)4
<i>B&H Med., L.L.C. v. ABP Admin., Inc.,</i> 526 F.3d 257 (6th Cir. 2008)10
<i>Bell Atl. Corp. v. Twombly</i> , 550 U.S. 544 (2007)
<i>Broadcom Corp. v. Qualcomm Inc.</i> , 501 F.3d 297 (3d Cir. 2007)7
Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209 (1993)
<i>Brunson Commc'ns, Inc. v. Arbitron, Inc.,</i> 239 F. Supp. 2d 550 (E.D. Pa. 2002)
<i>Cont'l Ore Co. v. Union Carbide & Carbon Corp.</i> , 370 U.S. 690 (1962)
<i>Eisai, Inc. v. Sanofi Aventis U.S., LLC,</i> 821 F.3d 394 (3d Cir. 2016)
<i>FTC v. AbbVie Inc.</i> , 976 F.3d 327 (3d Cir. 2020)
Globespanvirata, Inc. v. Tex. Instrument, Inc., 2006 WL 543155 (D.N.J. Mar. 3, 2006)
<i>Ingevity Corp. v. BASF Corp.</i> , 2020 WL 1329604 (D. Del. Mar. 23, 2020)

<i>ZF Meritor, LLC v. Eaton Corp.</i> , 696 F.3d 254 (3d Cir. 2012)4, 6,	10
Rules	
Fed. R. Civ. P. 72(b)(3)	4
Other Authorities	
3A Areeda & Hovenkamp, Antitrust Law § 1703d1	9
10 Areeda & Hovenkamp, Antitrust Law § 1752e	6

INTRODUCTION

In a careful, well-reasoned 19-page opinion, Judge Hall correctly concluded that Regeneron's 102-page Complaint stated claims under the federal antitrust laws and state analogues. Regeneron's Complaint challenges Amgen's anticompetitive campaign to leverage bundled rebates involving blockbuster products in unrelated markets to drive Regeneron's Praluent[®] out of the much smaller PCSK9 inhibitor market. As Judge Hall explained, Regeneron's "core allegation" is that "Amgen is giving pharmacy benefit managers ('PBMs') rebates on other drugs-specifically, its blockbuster drugs Otezla® and Enbrel®-in return for exclusive or preferred formulary placement for [Amgen's PCSK9 inhibitor] Repatha[®]." D.I. 49 ("R&R") at 2. One of the three largest PBMs, ESI, told Regeneron that Amgen offered a bundled rebate "totaling \$210 million" and that Amgen "[']tied rebates for the three drug products together and conditioned these rebates on exclusivity for Repatha[®].[']" *Id.* at 3 (quoting Compl. ¶ 78). This rebate "results in Repatha[®] being priced 'far lower than any appropriate estimate of Amgen's corresponding costs" and "[t]o match Amgen's [rebates] Regeneron would have had to sell Praluent at a loss." Id. at 4-5 (quoting Compl. ¶ 89-94). Regeneron made "similar allegations regarding UHC/Optum" (another top three PBM) and alleged that, "[a]s of January 2022, Praluent was 'not covered' on formularies of Payors accounting for at least 50% of the [market],"¹ which is pushing "Praluent[®] below a critical mass of market share necessary to ... remain viable." *Id.*

Amgen's Motion to Dismiss hardly disputed that Regeneron's Complaint, taken as true, stated plausible claims under federal antitrust law and various state laws. Notably, Amgen did not

¹ Specifically, Regeneron alleged that Amgen's bundle at ESI Commercial foreclosed 15.3% of the market; Amgen's bundle at ESI Part D foreclosed 7.7%, *see* Compl. ¶¶ 81, 186; and Amgen's bundle at Optum foreclosed 7.1%. *Id.* ¶ 96. This 30.1% foreclosure, "[c]ombined with the formularies of other, relatively smaller Third-Party Payors" including "Humana, Cigna, and Prime," where Amgen likewise "made a broad portfolio offer," foreclosed Regeneron from "Payors accounting for *at least 50 percent* of the total prescriptions in the PCSK9i market." *Id.* ¶¶ 86, 96.

challenge the relevant market definitions and did not challenge that *both Otezla® and Repatha® are monopoly products*. Instead, Amgen hinged its Motion on "extra-Complaint evidence" in the form of nearly 400 heavily redacted pages of confidential contracts between Amgen and third parties. As Judge Hall explained, "Amgen's primary argument for dismissal—which Amgen devote[d] almost all of its briefing to—[was] essentially this: It didn't happen." *Id.* at 8. Judge Hall rejected Amgen's attempt to bend the rules and short-circuit discovery: "The problem with that argument, of course, is that we are at the motion to dismiss stage" and *"[a]t this stage, the Court does not get to decide who to believe*." *Id.* (emphasis added). Judge Hall appropriately did not consider Amgen's artificial record, determined that "[o]nce Amgen's extra-Complaint documents are removed from the analysis, most of its arguments fall away," and "reject[ed]" Amgen's remaining arguments "[t]o the extent that any … remain" since they "implicate factual disputes that cannot be resolved at this stage of the case." *Id.* at 10, 13, 15.

Amgen, in its Objections, simply repeats these arguments. Amgen again asks this court to address stray factual issues of Amgen's choosing on a record of its own design and interpretation, with the desperate hope of avoiding scrutiny of its commercial practices.

Start with how Amgen handles the extra-Complaint evidence that was the backbone of its Motion. Amgen has now all-but-abandoned the issue and, in one paragraph buried at the end of its Objections, D.I. 54 ("Obj.") at 10, asks the Court to consider—on a motion to dismiss—extrinsic evidence Regeneron could not possibly have relied upon when drafting the Complaint (because Regeneron did not have access to Amgen's confidential contracts) *and* conclusively interpret that disputed evidence in Amgen's favor to take Otezla[®] out of the bundle. This Court should follow Judge Hall's lead and refuse Amgen's procedurally and legally infirm invitation. R&R at 8-10.

As Judge Hall recognized, without extra-Complaint evidence, "most of [Amgen's]

2

arguments fall away." *Id.* at 10. That is the case for Amgen's argument that Regeneron has not alleged Enbrel[®]'s market power. Obj. at 7-10. As a threshold matter, that argument is irrelevant since *Otezla[®]* has monopoly power, which alone suffices to support Regeneron's allegations. But even were Regeneron required to allege Enbrel[®]'s market power, Regeneron did so. The Complaint's allegations about Enbrel[®]'s market power easily clear this bar and "Amgen's arguments ... involve factual disputes and invoke extra-Complaint evidence that the Court will not consider" at this stage. R&R at 13. Any belated attempt by Amgen to isolate "claims relating to alleged bundling with ... Enbrel[®]" but not Otezla[®], Obj. at 1, misreads both the Complaint, which alleged a three-product bundle, and Judge Hall's R&R, which credited that allegation.

Amgen's only remaining Objection questions whether the precise proportion of the market foreclosed by its anticompetitive bundle is "substantial." *Id.* at 2-7. But simply to state Amgen's Objection is to show why—as this Court has explained—substantial foreclosure demands a "factintensive inquiry that is not properly disposed of before fact discovery." *Ingevity Corp. v. BASF Corp.*, 2020 WL 1329604, at *2 (D. Del. Mar. 23, 2020). As Judge Stark put it in adopting Judge Hall's R&R in *3Shape*—a closely analogous case that Amgen's Objections do not cite, much less distinguish—"factual details required for quantitative and qualitative analyses of the degree of market foreclosure" are not "required at the motion to dismiss stage." *3Shape Trios A/S v. Align Tech., Inc.*, 2020 WL 6938054, *2 (D. Del. Nov. 25, 2020). Even so, Regeneron alleges that *Amgen has foreclosed more than 50% of the market* (an amount Amgen does not dispute is substantial). In any event, Judge Hall—considering only a subset of that foreclosure—correctly concluded that *even 22% foreclosure was not "insufficient as a matter of law.*" R&R at 11-12. To rule otherwise, this Court would have to *both* reject the well-pleaded allegations of foreclosure in Regeneron's complaint *and* hold that the 22% foreclosure is inadequate as a matter of law. Amgen's Objections offer no good reason for the Court to do either, much less both. They should be overruled.

STANDARD OF REVIEW

This Court reviews objections to an R&R *de novo*, Fed. R. Civ. P. 72(b)(3), but may rely on the magistrate judge's recommendations, *see Wright v. City of Wilmington*, 2016 WL 1275591, at *1 (D. Del. Mar. 31, 2016). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim for 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)). "[T]he same *Twombly* plausibility standard applies [in antitrust cases]" and "[i]t is inappropriate to apply *Twombly*'s plausibility standard with extra bite." R&R at 6 (citation omitted). It is for this reason that complex antitrust cases like this one—including every Third Circuit antitrust case Amgen cites²—can be resolved only *after* discovery, as Judge Stark's paragraph-long string citation of such cases in *3Shape* makes clear. *See 3Shape*, 2020 WL 6938054, at *2.

ARGUMENT

I. AMGEN CONCEDES THAT ITS EXTRA-COMPLAINT RECORD CANNOT BE CONSIDERED AND OTEZLA[®] IS PART OF THE UNLAWFUL BUNDLE.

Amgen does not dispute that Otezla[®]—one of the products in its anticompetitive bundle is a monopoly product. *See* Compl. ¶¶ 113-18. Amgen instead buries, in the very last paragraph of its Objections, its argument that the Court should consider the extra-Complaint evidence Judge Hall properly disregarded and hold that the evidence conclusively shows Otezla[®] is not part of the bundle. Obj. at 10. Amgen's argument fails at both steps.

As Judge Hall stated, "[t]o decide a motion to dismiss, courts generally consider only the

² See FTC v. AbbVie Inc., 976 F.3d 327 (3d Cir. 2020) (trial); Eisai, Inc. v. Sanofi Aventis U.S., LLC, 821 F.3d 394, 403 (3d Cir. 2016) (summary judgment); ZF Meritor, LLC v. Eaton Corp., 696 F.3d 254 (3d Cir. 2012) (trial); Am. Motor Inns, Inc. v. Holiday Inns, Inc., 521 F.2d 1230 (3d Cir. 1975) (trial).

allegations contained in the complaint, exhibits attached to the complaint and matters of public record" and "[t]he documents submitted by Amgen are none of those things." R&R at 8 (quoting *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014)). While there is a narrow "exception that allows courts to consider undisputedly authentic documents that are integral to or explicitly relied upon in the complaint," Judge Hall recognized that Amgen's confidential contracts with third parties are no such thing. *Id.* "Regeneron did not have access to [them]," Regeneron does not concede their authenticity, and "Regeneron's claims are not based on [them]" but upon "plausible allegations [that] could have been memorialized in [another] document ... or [not] written down at all." *Id.* at 9; *see* Compl. ¶ 78. Amgen says "that was error," Obj. at 10, but does not explain why and fails to challenge any of the points Judge Hall relied on to support her conclusion.³ Even if the documents could be considered, Amgen offers no reason to interpret them to conclusively establish the composition and magnitude of Amgen's bundled rebate—a fact-intensive inquiry Judge Hall appropriately did not resolve. R&R at 10-11. In short, the contracts cannot resolve the issue in dispute and, if anything, confirm that Otezla[®] *is* part of the bundle. *See* D.I. 37 at 10-15.

Simply put, "an antitrust defendant cannot get a case dismissed ... simply by submitting to the court a written document ... the defendant contends is its entire agreement with a third party, where the court and the plaintiff have no way of testing that contention." R&R at 9.

II. REGENERON ADEQUATELY ALLEGED ENBREL[®]'S MARKET POWER.

Amgen's Objections also focus on Enbrel[®]'s market power. But the Court need not address the issue of Enbrel[®]'s market power to overrule Amgen's Objections because (1) as Judge Hall explained, the Third Circuit has not required allegations of market power to support a bundling

³ Amgen does cite one inapposite, out-of-Circuit district court case that hardly addresses the issue. Obj. at 10. But Regeneron well distinguished that case in its Opposition to Amgen's Motion, as did Judge Stark in *3Shape. See* D.I. 37 at 9 n.9 (distinguishing *Pro Search Plus, LLC v. VFM Leonardo, Inc.*, 2013 WL 3936394 (C.D. Cal. July 30, 2013)); *3Shape*, 2020 WL 6938054, at *2 (same).

claim like Regeneron's,⁴ and (2) without its improper extra-Complaint evidence, Amgen cannot dispute that Otezla[®] is a monopoly product and part of the alleged bundle, *see supra* at 4-5.

But beyond that, Regeneron's allegations also plausibly establish Enbrel[®]'s market power, which is a highly fact-intensive inquiry ill-suited for resolution at this stage. *See* 10 Areeda & Hovenkamp, Antitrust Law § 1752e; *see, e.g., ZF Meritor*, 696 F.3d at 287 (putting the issue to a jury). Far from "plead[ing] nothing," Obj. at 8, Regeneron's Complaint plausibly alleges (in over a dozen paragraphs spanning seven pages) Enbrel[®]'s market power, *i.e.*, "the ability to raise prices above those that would otherwise prevail in a competitive market" considering, among other factors, "[b]arriers to entry." *FTC v. AbbVie*, 976 F.3d at 371 (citation omitted). Regeneron alleges that Enbrel[®] is a \$4 billion product and "one of the world's most profitable drugs" and that its list price increased 457 percent between 2002 and 2020 with sales continuing to grow significantly in that time. Compl. ¶¶ 122-23. Regeneron further describes (though Amgen's Objections nowhere mention) the high barriers to entry in the rheumatoid arthritis market. *Id.* ¶¶ 124-28, 131-33.

Amgen ignores Regeneron's allegations and instead offers a variety of stray rebuttals that suggest—at the very most—a competing inference about Enbrel[®]'s market power. Amgen mainly faults Regeneron, who does not compete in the rheumatoid arthritis market, for not pleading Enbrel[®]'s exact market share. Obj. 8-9. But market share is just one factor in the holistic and factintensive market power analysis. *See Allen-Myland, Inc. v. Int'l Bus. Machines Corp.*, 33 F.3d 194, 209 (3d Cir. 1994) ("Market share is just a way of estimating market power, which is the ultimate consideration.").⁵ Amgen further criticizes Regeneron for alleging Enbrel[®]'s year-over-year price

⁴ As Judge Hall noted, the Third Circuit in *LePage's* imposes "no such requirement" that a defendant "ha[s] to have monopoly power or market power on the[] other lines where they are giving discounts." Jan. 6, 2023 Hr'g Tr. at 34:1-5. Amgen cites *Shire US, Inc. v. Allergan, Inc.*, 375 F. Supp. 3d 538 (D.N.J. 2019), to argue otherwise. Obj. at 8. But, as Judge Hall explained in response to *Shire*, "[*LePage's*] didn't say that." Tr. at 35:19. *LePage's* instead involved rebates "on purchases spanning six of 3M's diverse product lines," and the Third Circuit did not address whether 3M had monopoly power in any line other than transparent tape. *LePage's Inc. v. 3M*, 324 F.3d 141, 154 (3d Cir. 2003). ⁵ *Cf. Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 319 (3d Cir. 2007) ("Although the complaint did not allege

increases only through 2019, since "the bundled discounts did not start until 2020." Obj. at 9. But Regeneron's Complaint in fact cited an October 2020 U.S. House Report quoting Enbrel[®]'s price "as of October 2020," after the alleged bundling began. Compl. ¶ 122. Finally, Amgen also argues that the mere existence of Humira[®] makes it implausible as a matter of law that Enbrel[®] could have market power. Obj. at 9-10. But more than one product in a market may possess market power and even "declining market share … does not foreclose [] a finding" of market power. *Le Page 's Inc. v. 3M*, 2000 WL 280350, at *11 (E.D. Pa. Mar. 14, 2000); *see, e.g., United States v. Visa U.S.A., Inc.*, 344 F.3d 229, 240 (2d Cir. 2003) (finding that MasterCard had "market power" with just a 26% share). Judge Hall was correct to conclude that "Amgen's arguments regarding Enbrel[®] … involve factual disputes … that the Court will not consider" at this stage. R&R at 13.

As a final matter, the Court should not countenance any attempt by Amgen to dismiss "[c]laims of alleged bundling of Repatha[®] with [only] Enbrel[®]." Obj. at 10. Amgen forfeited this argument by first raising it in Reply. D.I. 40 at 11; *see Teleconference Sys. v. Proctor & Gamble Pharms., Inc.*, 676 F. Supp. 2d 321, 331 n.13 (D. Del. 2009) ("Issues raised for the first time in a reply brief should not be heard."). In any case, Amgen's counter-factual "Enbrel[®]-only claims" do not exist: Regeneron's claims involve the three-product bundle of Otezla[®], Enbrel[®], and Repatha[®]. The bundle is the point, as Judge Hall recognized. *E.g.* R&R at 2-3. Amgen's attempt to disaggregate the anti-competitive bundle is improper as a matter of antitrust law. *See Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962) ("[P]laintiffs should be given the full benefit of their proof, without tightly compartmentalizing the various factual components

^{...} market share[,] determining whether a defendant has a 'dangerous probability' of successful monopolization is a fact-sensitive inquiry, in which market share is simply one factor." (citation omitted)). None of the cases Amgen cites is to the contrary. *See SEI Global Servs., Inc. v. SS&C Advent*, 496 F. Supp. 3d 883, 894 (E.D. Pa. 2020) ("No single factor is dispositive"); *Globespanvirata, Inc. v. Tex. Instrument, Inc.*, 2006 WL 543155, at *4 (D.N.J. Mar. 3, 2006) (similar); *Brunson Commc'ns, Inc. v. Arbitron, Inc.*, 239 F. Supp. 2d 550, 569 (E.D. Pa. 2002) (similar).

and wiping the slate clean after scrutiny of each ... the duty of the jury [will be] to look at the whole picture and not merely at the individual figures in it."). Further, Amgen's argument is a transparent attempt to, as Judge Hall put it, improperly "knock out theories" rather than claims and avoid scrutiny of the full scope of Amgen's anticompetitive conduct. Tr. at 37:20.

III. REGENERON ADEQUATELY ALLEGED SUBSTANTIAL FORECLOSURE IN THE PCSK9i MARKET.

Amgen's sole remaining argument is that Regeneron has not adequately alleged substantial foreclosure—yet another "fact-intensive inquiry that is not properly disposed of before fact discovery." *Ingevity Corp.*, 2020 WL 1329604 at *2.⁶ But here, too, Amgen distorts Regeneron's Complaint and Judge Hall's R&R and ignores key legal issues in favor of its preferred strawman.

First, substantial foreclosure is not an element of Regeneron's well-pleaded predatorypricing claims. *See* R&R at 14 ("Regeneron alleges facts that appear to meet even the stricter assessment" of below-cost pricing); Compl ¶¶ 163-82. Amgen's sole argument against Regeneron's predatory-pricing claims is that the alleged anticompetitive conduct "will not plausibly cause Regeneron to go out of business." Obj. at 7. But Judge Hall credited Regeneron's allegations "that Amgen's actions are 'pushing Praluent[®] below a critical mass of market share necessary to compete" in this two-player market and concluded that these allegations meet any requirement that Regeneron "plead something about … exiting the market." R&R at 15 (quoting Compl. ¶¶ 137-38). Taking the allegations as true and construing inferences in Regeneron's favor, Regeneron has sufficiently alleged Praluent[®] "would likely succumb" to Amgen's anticompetitive gambit. *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 225 (1993).

Second, Regeneron's Complaint plausibly alleges market foreclosure of over 50 percent,

⁶ See, e.g., 3Shape, 2020 WL 6938054, at *2 ("factual details" of market foreclosure are not "required at the motion to dismiss stage"); *Roxul USA, Inc. v. Armstrong World Indus., Inc.*, 2018 WL 810143, at *5 (D. Del. Feb. 9, 2018) ("Roxul is not required to allege a specific foreclosure percentage").

an amount Amgen does not dispute is substantial. *See supra* at 1 n.1; Obj. at 2-3. Judge Hall had no occasion to address this full extent of alleged foreclosure, finding, correctly, that foreclosure was substantial "[e]ven setting aside Regeneron's allegations about" foreclosure at ESI Part D (7.7% of the market) and other small payors (around 20%). R&R at 11; *see* Compl. ¶ 96.⁷ This Court should credit Regeneron's well-pleaded allegations and overrule the Objections.

Third, Judge Hall was correct to reject Amgen's extreme position that "plausibly pleading ... foreclosure of at least 22.32% is insufficient as a matter of law," especially in light of Regeneron's other allegations. R&R at 11-12. Whether foreclosure is in fact substantial is a holistic inquiry that cannot be reduced to a "fixed percentage." *Eisai*, 821 F.3d at 403; *see* 3A Areeda & Hovenkamp, Antitrust Law § 1703d1. Courts hold that foreclosure less than 20% can suffice,⁸ especially when dealing with a monopolist—as Amgen is in the PCSK9i market—for the good reason that monopolists need to foreclose only a relatively smaller amount of the market to a rival. Compl. ¶ 110; *see United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 187 (3d Cir. 2005) ("Behavior that otherwise might comply with antitrust law may be impermissibly exclusionary when practiced by a monopolist."); *United States v. Microsoft*, 253 F.3d 34, 70 (D.C. Cir. 2001) (same).

Amgen's advocacy for a *per se* rule that 22% foreclosure is insubstantial or that Regeneron's allegations are lacking only highlights why the issue cannot be resolved at this stage. The cases Amgen cites to support its novel *per se* rule all acknowledge that there are fact-specific situations that call for exceptions. Obj. 2-3.⁹ So Amgen is left to dispute the facts of Regeneron's

⁷ Judge Hall's comment that "Regeneron does not allege that Amgen gave ESI Part D a bundled rebate," R&R at 4 n.4, appears to overlook Regeneron's express allegation that Amgen "entered into agreements with at least ESI Commercial, ESI Part D, and [Optum], 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 [of] Repatha[®]." Compl. ¶ 186. ⁸ See, e.g., Am. Motor Inns, 521 F.2d at 1252 (14.7% foreclosure "may well offend the limitations [of] the Clayton Act," a violation of which Regeneron alleges, Compl. ¶¶ 194-204); In re Surescripts Antitrust Litig., 2022 WL 2208914, at *16–17 (N. D. Ill. June 21, 2022) (20% foreclosure is sufficient to survive dismissal of a claim under § 2 of the Sherman Act, which Regeneron also pleads, Compl. ¶¶ 152-62).

⁹ As Judge Hall explained, ZF Meritor "saying that at least 40% is 'usually' required to establish a violation is not the

alleged foreclosure (which by now has gone on for years), saying it is not substantial based on Amgen's own assertions of its contracts' duration, because Regeneron maintained coverage at another payor, and because Praluent[®]'s undisputed foreclosure from more than half the market "makes no difference." Id. at 4-5. But, as Judge Hall explained, factual disputes like these can be resolved only *after discovery*, not before, and Amgen cannot invent its own preferred record of what it says its contracts say and how long they last.¹⁰ It thus comes as little surprise that Amgen cites no pleading-stage dismissals anything like this case. Amgen falls back on Int'l Constr. Prods. LLC v. Caterpillar Inc., 2016 WL 264909 (D. Del. Jan. 21, 2016), which Judge Hall quickly and correctly dispatched as "unavailing" because "the Plaintiff [there] 'allege[d] no facts about the nature of the exclusive dealing arrangements and their potentially anticompetitive effects," which "is not the case here." R&R at 13 n.7 (citation omitted).¹¹ This Court should reject Amgen's bold and unsupported invitation to discredit Regeneron's well-pleaded allegations to resolve a "factintensive inquiry that is not properly disposed of before fact discovery" and rule as a matter of law (over Judge Hall's well-reasoned conclusion) that 22% foreclosure—considered in light of the facts of the case—cannot be substantial. Ingevity, 2020 WL 1329604 at *2.

CONCLUSION

Amgen's Objections to the R&R should be overruled. The R&R should be adopted in full and Amgen's Motion to Dismiss should be denied.

same thing as saying that it is required," and neither of the two out-of-Circuit cases Amgen cites imposes a *per se* threshold. R&R at 12; *see B&H Med., L.L.C. v. ABP Admin., Inc.*, 526 F.3d 257, 266 (6th Cir. 2008); *Kidd v. Bass Hotels & Resorts, Inc.*, 136 F. Supp. 2d 965, 969 (E.D. Ark. 2000).

¹⁰ See R&R at 12 ("[W]hether an exclusive dealing arrangement is lawful because it is of short-term in duration or easily terminable is another factual dispute." (citing *3Shape*, 2020 WL 6938054)); *id.* at 13 ("The Third Circuit says that the use of exclusive dealing by competitors of the defendant is only 'sometimes' considered and, even then, it is only one factor in the fact intensive analysis." (quoting *ZF Meritor*, 696 F.3d at 271-72)).

¹¹ Judge Stark, too, easily dispatched with Amgen's supposed on-all-fours case in *3Shape*: "In *Caterpillar*, unlike this case, the factual allegations pertaining to exclusive dealing were sparse." 2020 WL 6938054, at *2 (citation omitted). The two other out-of-circuit district court cases Amgen cites (Obj. at 6) were likewise readily distinguished by Judge Stark. *See 3Shape*, 2020 WL 6938054, at *2 n.2 (distinguishing *Pro Search Plus*, 2013 WL 3936394, at *3 and *PNY Techs., Inc. v. SanDisk Corp.*, 2014 WL 1677521 (N.D. Cal. Apr. 25, 2014)).

Case 1:22-cv-00697-RGA-JLH Document 56 Filed 03/10/23 Page 16 of 16 PageID #: 1030

Dated: March 10, 2023

/s/ <u>David E. Wilks</u> David E. Wilks (DE Bar No. 2793) Scott B. Czerwonka (DE Bar No. 4844) **WILKS LAW, LLC** 4250 Lancaster Pike Suite 200 Wilmington, DE 19805 Telephone: (302) 225-0850 Fax: (302) 225-0851

Jonathan D. Polkes (admitted *pro hac vice*) Elizabeth Stotland Weiswasser (admitted *pro hac vice*) Eric S. Hochstadt (admitted *pro hac vice*) Adam B. Banks (admitted *pro hac vice*) Jessica L. Falk (admitted *pro hac vice*) Robert Niles-Weed (admitted *pro hac vice*) **WEIL, GOTSHAL & MANGES LLP** 767 Fifth Avenue New York, NY 10153-0119 Telephone: (212) 310-8000 Fax: (212) 310-8007

Michael R. Moiseyev (admitted *pro hac vice*) Priyata Y. Patel (admitted *pro hac vice*) **WEIL, GOTSHAL & MANGES LLP** 2001 M Street, NW Washington, D.C. 20036 Telephone: (202) 682-7000 Fax: (202) 857-0940