IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. AMGEN INC., Defendant.	C.A. No. 22-697-RGA-JLH

REPORT AND RECOMMENDATION AND ORDER

Pending before the Court are two motions filed by Defendant Amgen Inc.: its Motion to Dismiss (D.I. 17) and its Motion to Stay (D.I. 27).[1] The motions are fully briefed (D.I. 18, 19, 28, 34, 35, 36, 40, 41, 43, 47, 48), and I heard oral argument on January 6, 2023 ("Tr. __"). For the reasons below, I recommend that Amgen's motion to dismiss be DENIED, and I order that Amgen's motion to stay is DENIED.

I. BACKGROUND

Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron") and Defendant Amgen Inc. ("Amgen") are pharmaceutical companies. They sell competing drugs in a class of drugs known as PCSK9 inhibitors. PCSK9 inhibitors are monoclonal antibody drugs that can help high-risk patients lower their LDL cholesterol, aka "bad cholesterol." Amgen's product is called Repatha®. Regeneron's rival product is Praluent®.

Each company has patents covering the specific amino-acid sequence in its product. Amgen also has patents with claims that cover a genus of antibodies that bind to specific residues

[1] Judge Andrews referred this case to me for all purposes through the case dispositive motion deadline. (D.I. 5.)

on PCSK9 and block it from binding to LDL receptors. In a separate litigation, Amgen alleged that Regeneron's Praluent infringed Amgen's genus claims. The Court of Appeals for the Federal Circuit held that Amgen's genus claims were invalid for lack of enablement. *Amgen Inc. v. Sanofi*, 987 F.3d 1080 (Fed. Cir. 2021). That case is now pending before the Supreme Court; oral arguments are scheduled for March 27, 2023. *Amgen Inc. v. Sanofi*, 143 S. Ct. 399 (2022) (granting petition for writ of certiorari).

This case also concerns Praluent and Repatha, but it is not a patent infringement case. In this case, Regeneron is the plaintiff, and it alleges that Amgen has violated the antitrust laws by undertaking an anticompetitive campaign to drive Praluent out of the PSCK9 inhibitor market. (D.I. 1 (Complaint) ¶ 13.) The core allegation—and the allegation that the parties' briefs focus on—is that Amgen is giving pharmacy benefit managers ("PBMs") rebates on other drugs—specifically, its blockbuster drugs Otezla® and Enbrel®[2]—in return for exclusive or preferred formulary placement for Repatha.[3] According to the Complaint, the size of the rebates on Otezla and Enbrel, and the fact that Otezla has monopoly power and Enbrel has market power, leave the PBMs with "no viable choice" but to accept Amgen's offer and to exclude Praluent from their formularies. (*Id.* ¶¶ 17, 113–123, 148.)

Regeneron's Complaint is 102 pages long. (D.I. 1.) This matter comes before me on a motion to dismiss, so I must accept the allegations in the Complaint as true and view them in the light most favorable to Regeneron. Because I write primarily for the parties and the District Judge,

[2] Otezla and Enbrel are not PSCK9 inhibitors. Otezla is a psoriasis treatment. (*Id.* ¶¶ 113–118.) Enbrel treats rheumatoid arthritis and other conditions. (*Id.* ¶¶ 119–123.)

[3] A formulary is a PBM's "official list of covered medications, which determines how much a patient will pay for them." (*Id.* ¶ 47.)

I assume general familiarity with the allegations and terminology used in the Complaint. The most pertinent allegations are as follows.

Amgen's Repatha has monopoly power in the PCSK9 inhibitor market. (*Id.* ¶ 110.) Amgen's Otezla has monopoly power in the moderate-to-severe psoriasis market. (*Id.* ¶¶ 113, 117.) Amgen's Enbrel has market power in the rheumatoid arthritis market. (*Id.* ¶¶ 122–23.)

"Express Scripts ('ESI'), United Healthcare/OptumRx ('UHC/Optum'), and CVS Caremark ('CVS') are the three most dominant Third-Party Payors for both the Commercial and Medicare Part D segments of the PCSK9 [inhibitor] market and collectively account for more than three quarters of all prescriptions filled in the United States." (*Id.* ¶ 53.) ESI Commercial accounts for 15.27% of the total PCSK9 inhibitor market. (*Id.* ¶ 96.) Regeneron's Praluent was on ESI Commercial's formulary prior to August 2020. (*Id.* ¶ 76.) In June 2020, however, ESI told Regeneron that Amgen had offered it "substantial rebates totaling $210 million over two years and four months for Enbrel®, Otezla®, and Repatha®." (*Id.* ¶ 78.) ESI further "acknowledged" that

> Amgen had tied rebates for the three drug products together and conditioned these rebates on exclusivity for Repatha® on ESI Commercial's National Preferred Formulary. For example, Regeneron was informed by ESI on a June 2020 call attended by senior level executives that Amgen's offer for Repatha® included "other products that would provide much more financial incentives to ESI." As a result, Regeneron was informed that Praluent® would be excluded from ESI Commercial's National Preferred Formulary unless it could match this $210 million rebate.

(*Id.*)

A rebate of $210 million over two years and four months comes out to approximately $90 million per year. (*Id.* ¶ 89.) If that $90 million in annual rebates is attributed only to sales of Repatha, it results in Repatha being priced "far lower than any appropriate estimate of Amgen's corresponding costs." (*Id.* ¶¶ 89–94.) To match Amgen's $90 million annual rebates to ESI

Commercial, Regeneron would have had to sell Praluent at a loss. (*Id.* ¶ 79.) "Nor [was] Regeneron able to match Amgen's bundled rebate by offering an equivalent bundle across its portfolio, which lacks the massive products subject to PBM rebating that could offset Amgen's coercive rebates for Otezla® or Enbrel®." (*Id.*) Because Regeneron did not match Amgen's rebate offer, ESI Commercial made the deal with Amgen, and, "[s]ince January 1, 2021 and through at least January 1, 2023, ESI Commercial's National Preferred Formulary . . . allow[ed] only Repatha® to be covered for consumers whose plans follow ESI Commercial's National Preferred Formulary."[4] (*Id.* ¶ 80.)

Regeneron makes similar allegations regarding UHC/Optum, which has 7.05% of the PCSK9 inhibitor market. (*Id.* ¶ 96.) Prior to September 2021, UHC/Optum's Commercial Formulary allowed members covered by UHC/Optum to be prescribed either Repatha or Praluent. (*Id.* ¶¶ 83–84.) "Starting on September 1, 2021, UHC Commercial moved to an exclusive relationship with Repatha®, and, starting on January 1, 2022, Optum Commercial also moved to an exclusive relationship with Repatha®." (*Id.* ¶ 84.) "Regeneron was . . . informed by UHC/Optum in May 2021 during negotiations for formulary access that there were further negotiations happening behind the scenes with Amgen," and Regeneron believes that "Amgen opted to structure its rebate offer to UHC/Optum similar to its offer to ESI Commercial, using a portfolio of drugs across multiple therapeutic drug classes to secure Repatha®'s exclusive position, where the effective price of Repatha® in the bundle was below cost." (*Id.*)

[4] Repatha also has an exclusive position with ESI Part D, which has 7.7% of the PCSK9 inhibitor market. (*Id.* ¶¶ 81, 96.) Regeneron does not allege that Amgen gave ESI Part D a bundled rebate. Rather, Regeneron alleges, "[u]pon information and belief, [that] Amgen's conduct directed at ESI Commercial drove ESI's Part D formulary decision to exclude Praluent®" 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 and efficiency." (*Id.* ¶ 81.)

Regeneron has also been told in "negotiations with other Third-Party Payors that Amgen made a broad portfolio offer for Repatha® that would allow for a higher absolute rebate value with the anti-inflammatory therapeutic class, *i.e.*, Otezla® and Enbrel®." (*Id.* ¶ 86.) As of January 2022, Praluent was "'not covered' on formularies of Payors accounting for at least 50% of the total prescriptions in the PCSK9 [inhibitor] market." (*Id.* ¶ 96.) Regeneron says that, "starting in 2022, [it] will no longer even be able to make a profit selling Praluent®" and that it is being "forc[ed] . . . to consider investing its resources elsewhere with an exit from the market altogether." (*Id.* ¶¶ 101, 137, 138 ("Amgen's below-cost pricing and conditional bundled rebate scheme is already pushing Praluent® below a critical mass of market share necessary to compete for access and remain viable . . . ."), 149.)

II. LEGAL STANDARDS

A. Motion to Dismiss

A defendant may move to dismiss a complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim. "To survive a motion to dismiss, 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)). A claim is plausible on its face when the complaint contains "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* A possibility of relief is not enough. *Id.* "Where a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" *Id.* (quoting *Twombly*, 550 U.S. at 557). In determining the sufficiency of the complaint under the plausibility standard, all "well-pleaded facts" are assumed to be true, but legal conclusions are not. *Id.* at 679.

"[W]hen the allegations in a complaint, however true, could not raise a claim of entitlement to relief, 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 (internal marks omitted). "Antitrust claims in particular must be reviewed carefully at the pleading stage because false condemnation of competitive conduct threatens to 'chill the very conduct the antitrust laws are designed to protect.'" *In re Keurig Green Mt. Singleserve Coffee Antitrust Litig.*, 383 F. Supp. 3d 187, 218 (S.D.N.Y. 2019) (quoting *Verizon Commc'ns. Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 414 (2004)). However, the same *Twombly* plausibility standard applies. *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 98 (3d Cir. 2010) ("[I]t is inappropriate to apply *Twombly*'s plausibility standard with extra bite in antitrust and other complex cases.").

B. Motion to Stay

A district court has broad discretion to grant or deny a motion to stay. *Apotex, Inc. v. Senju Pharma Co.*, 921 F. Supp. 2d 308, 313 (D. Del. 2013). In exercising their discretion, courts in this district generally consider (1) whether a stay will simplify the issues for trial, (2) whether discovery is complete and a trial date has been set, and (3) whether a stay would cause the non-movant to suffer undue prejudice from any delay or allow the movant to gain a clear tactical advantage. *Id.*

III. RECOMMENDATION ON THE MOTION TO DISMISS

Counts One through Six of the Complaint allege that Amgen violated Sections 1 and 2 of the Sherman Act and Section 3 of the Clayton Act. In order to establish an antitrust violation under any of those three statutes, a plaintiff must show (among other things) that (1) the defendant

engaged in anticompetitive conduct, and (2) the plaintiff suffered antitrust injury as a result.[5] *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 403 (3d Cir. 2016); *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 269 n.9 (3d Cir. 2012). Amgen says that the federal antitrust claims should be dismissed because it did not engage in anticompetitive conduct.

"'Anticompetitive conduct' can come in too many different forms, and is too dependent on context, for any court or commentator ever to have enumerated all the varieties." *LePage's Inc. v. 3M*, 324 F.3d 141, 152 (3d Cir. 2003) (citation omitted). Examples of agreements that may constitute anticompetitive conduct include exclusive dealing arrangements, *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 187 (3d Cir. 2005), and tying agreements, *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 482 (1992). Certain types of pricing behavior can also constitute anticompetitive conduct. For example, setting prices below one's costs can constitute anticompetitive predatory pricing (if other requirements are met). *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 222–23 (1993). The Third Circuit (but not the Supreme Court) has also held that offering bundled discounts can constitute anticompetitive conduct. *LePage's*, 324 F.3d at 154–58.

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[5] As the Third Circuit has explained,

> Sections 1 and 2 of the Sherman Act and Section 3 of the Clayton Act each include an anticompetitive conduct element, although each statute articulates that element in a slightly different way. Under Section 1 of the Sherman Act, a plaintiff must establish that the defendant was a party to a contract, combination or conspiracy that "imposed an unreasonable restraint on trade." Under Section 2, a plaintiff must demonstrate that the defendant willfully acquired or maintained its monopoly power in the relevant market. . . . Finally, Section 3 of the Clayton Act makes it unlawful for a person to enter into an exclusive dealing contract where the effect of such an agreement is to substantially lessen competition or create a monopoly.

ZF Meritor, LLC v. Eaton Corp., 696 F.3d 254, 269 n.9 (3d Cir. 2012) (internal citations omitted).

There are legal rules that govern the assessment of each of these theories of anticompetitive conduct. Still, challenged conduct "may be susceptible to more than one court-defined category." *Viamedia, Inc. v. Comcast Corp.*, 951 F.3d 429, 453 (7th Cir. 2020). "At bottom, the purpose of identifying these categories of conduct is to help determine 'the presence or absence of harmful effects, which are both the reason for any antitrust concern and often the simplest element to disprove.'" *Id.* (quoting Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application* ¶ 1701d, at 33 (4th ed. 2015)).

A. The Court should not consider Amgen's extra-Complaint evidence.

As mentioned above, Regeneron's core allegation is that Amgen gave PBMs big rebates on Otezla and Enbrel in return for Praluent being excluded (or getting less preferable placement) on the formularies. Amgen's primary argument for dismissal—which Amgen devotes almost all of its briefing to—is essentially this: It didn't happen.

The problem with that argument, of course, is that we are at the motion to dismiss stage. At this stage, the Court does not get to decide who to believe. The law requires the Court to credit Regeneron's version of the facts and to view them in the light most favorable to it. And the factual allegations in Regeneron's Complaint make it plausible that Amgen gave ESI and UHC/Optum rebates on Otezla and Enbrel that were conditioned on exclusive formulary placement for Repatha.

Amgen submitted with its motion to dismiss documents that it asserts are the agreements between it and ESI and UHC/Optum. But "[t]o decide a motion to dismiss, courts generally consider only the allegations contained in the complaint, exhibits attached to the complaint and matters of public record." *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014) (citations omitted). The documents submitted by Amgen are none of those things.

Amgen rightly points out that there is an exception that allows courts to consider undisputedly authentic documents that are integral to or explicitly relied upon in the complaint. *Id.* But that exception doesn't apply here, for a couple of reasons. For one thing, Regeneron does not concede that the documents supplied to the Court are authentic or that they represent the entire agreements between Amgen and the PBMs. An antitrust defendant cannot get a case dismissed before discovery simply by submitting to the court a written document (over the plaintiff's objection) that the defendant contends is its entire agreement with a third party, where the court and the plaintiff have no way of testing that contention.

Moreover, permitting Amgen to introduce extra-Complaint material at the motion to dismiss stage doesn't jibe with the purpose of the integral documents exception, which is to "avoid the situation where a plaintiff 'selected only portions of documents that support their claims, while omitting portions of those very documents that weaken—or doom—their claims.'" *Tomaszewski v. Trevena, Inc.*, 482 F. Supp. 3d 317, 328 (E.D. Pa. 2020) (quoting *Khoja v. Orexigen Therapeutics, Inc.*, 899 F.3d 988, 1002 (9th Cir. 2018)); *see also Schmidt*, 770 F.3d at 250 ("[T]he justification for the integral documents exception is that it is not unfair to hold a plaintiff accountable for the contents of documents it must have used in framing its complaint, nor should a plaintiff be able to evade accountability for such documents simply by not attaching them to his complaint."). Prior to filing this case, Regeneron did not have access to the documents Amgen has now submitted to the Court. And Regeneron's claims are not based upon the documents submitted by Amgen. Regeneron's claims are based upon its plausible allegation that Amgen agreed with PBMs that Repatha would get exclusive formulary position in exchange for rebates on other drugs; such an agreement could have been memorialized in a document not presently before the Court, or it might not have been written down at all.

In sum, I disagree that the documents submitted by Amgen are integral to or relied upon by Regeneron such that the Court may consider them when resolving Amgen's motion to dismiss. Those documents are not considered further below.

B. Amgen's remaining arguments for dismissing the federal antitrust claims implicate factual matters not suitable for resolution on a motion to dismiss.

Once Amgen's extra-Complaint documents are removed from the analysis, most of its arguments fall away, as the documents are repeatedly referenced throughout Amgen's briefing. (*See* D.I. 18 (Amgen Opening Br.) at 8 (Standard of Review), 9–24 (Argument); D.I. 40 (Amgen Reply Br.) at 2–11 (Argument)). To the extent that any of Amgen's arguments remain, I recommend rejecting them and denying its request to dismiss the federal antitrust claims.

1. Exclusive dealing

Amgen says that the Complaint fails to plausibly allege anticompetitive conduct under an exclusive dealing theory. In an exclusive dealing arrangement, "a buyer agrees to purchase certain goods or services only from a particular seller for a certain period of time." *ZF Meritor*, 696 F.3d at 270. While an exclusive dealing claim requires a showing of an agreement between the buyer and seller, an express exclusivity provision is not necessary. *Id* at 282. "*De facto* exclusive dealing claims are cognizable under the antitrust laws" where the effect of the agreement "in the real world" demonstrates that competitors are excluded from a substantial share of the relevant market. *Id.* at 270–72, 282–83.

The legality of an exclusive dealing arrangement is judged under the rule of reason. *Id.* at 271. Whether an arrangement is legal "depends on whether it will foreclose competition in such a substantial share of the relevant market so as to adversely affect competition." *Id.* The Third Circuit has explained the analysis as follows:

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

Id. at 271–72 (cleaned up); *see also In re EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litig.*, 44 F.4th 959, 988 n.9 (10th Cir. 2022).

Amgen offers five reasons why Regeneron's antitrust claims fail when assessed under an exclusive dealing theory. First, Amgen says that its rebate agreements with some PBMs do not condition rebates on Repatha exclusivity. But the Complaint plausibly alleges, at a minimum, that Amgen's deals with ESI Commercial and UHC/Optum do condition rebates on other drugs in exchange for Repatha exclusivity.

Second, Amgen argues that the Complaint fails to allege that its agreements with PBMs result in Praluent being "substantially foreclosed" from the market. Even setting aside Regeneron's allegations about ESI Part D and so-called "spillover" foreclosure at the payor and prescriber levels, Regeneron has pleaded exclusive dealing arrangements with ESI Commercial and UHC/Optum, which have 15.27% and 7.05% of the market, respectively, for a total of 22.32%. I am 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 an antitrust claim, particularly since the Complaint also alleges that Repatha has monopoly power and is "not

covered" on the formularies of payors accounting for at least 50% of the total prescriptions in the PCSK9 inhibitor market.[6]

Third, Amgen argues that the Complaint fails to plead that its contracts are of sufficient duration to be anticompetitive. But whether an exclusive dealing arrangement is lawful because it is of short-term in duration or easily terminable is another factual dispute that is "ill suited for the pleadings stage." *FTC v. Surescripts, LLC*, 424 F. Supp. 3d 92, 104 (D.D.C. 2020) (rejecting argument that exclusive dealing claim should be dismissed where the pertinent contracts were easily terminable and of short duration); *see also 3Shape Trios A/S v. Align Tech., Inc.,* No. 18-1332-LPS, 2020 WL 6938054, at *2 (D. Del. Nov. 25, 2020) ("[T]he Third Circuit has declined to take the position that the short duration and ease of termination of exclusive dealing contracts mean such agreements cannot violate the antitrust laws.").

[6] Contrary to Amgen's suggestion, the Third Circuit's opinion in *ZF Meritor* does not say that a complaint must plead specific contracts resulting in 40% to 50% foreclosure in order to survive a motion to dismiss. (Tr. 21, 65–66.) That case does say that "40% to 50% foreclosure is usually required to establish an exclusive dealing violation under Section 1 of the Sherman Act," but it doesn't purport to establish a pleading standard for all types of antitrust claims. *ZF Meritor*, 696 F.3d at 286. Moreover, saying that at least 40% is "usually" required to establish a violation is not the same thing as saying that it is required, and the case sets forth a number of additional factors relevant to the analysis. *Id.* at 271–72. Indeed, other courts have suggested that a smaller percentage of market foreclosure could be sufficient in combination with other relevant market conditions. *See, e.g.*, *United States v. Microsoft*, 253 F.3d 34, 70 (D.C. Cir. 2001) ("[W]e agree with plaintiffs that a monopolist's use of exclusive contracts, in certain circumstances, may give rise to a § 2 violation even though the contracts foreclose less than the roughly 40% or 50% share usually required in order to establish a § 1 violation."); *Am. Motor Inns, Inc. v. Holiday Inns, Inc.*, 521 F.2d 1230, 1252 (3d Cir. 1975) (explaining that foreclosure of 14.7% "may well offend the limitations which the Clayton Act places on exclusive contracts" when considered in combination with other market factors). Because the legality of an exclusive dealing arrangement is judged under the rule of reason, it "usually requires some fairly detailed facts, the ascertainment of which is often beyond the scope of a Rule 12(b)(6) inquiry." *Vazquez-Ramos v. Triple-S Salud, Inc.*, 55 F.4th 286, 299 (1st Cir. 2022); *see also In re Surescripts Antitrust Litig.*, No. 19-6627, 2022 WL 2208914, at *16–17 (N. D. Ill. June 21, 2022) (holding that allegation of 20% foreclosure was sufficient to withstand a motion to dismiss).

Fourth, Amgen argues that the Complaint fails to allege coercion. Amgen's argument, however, is premised on its factual assertion that "no Otezla® rebates at all are conditioned on Repatha® coverage" (D.I. 18 at 17), which, as noted above, is contrary to the plausible allegations in the Complaint. Amgen's arguments regarding Enbrel likewise involve factual disputes and invoke extra-Complaint evidence that the Court will not consider.

Fifth, Amgen points out that Regeneron itself engages in exclusive dealing arrangements for Praluent. Even if true, that's not enough to get Amgen off the hook at this stage. 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. *ZF Meritor*, 696 F.3d at 271–72. And nothing in the record properly before the Court suggests that Regeneron has itself offered the kind of multi-product bundled discount arrangement alleged in the Complaint.

In sum, Amgen's arguments about exclusive dealing all implicate factual disputes that cannot be resolved at this stage of the case.[7] Further factual development may reveal that Amgen is right, but Regeneron has alleged enough to move forward.

2. Bundled discounts

Amgen next says that the Complaint fails to plausibly allege anticompetitive conduct under a bundling theory. "Bundling is the practice of offering, for a single price, two or more goods or services that could be sold separately. A bundled discount occurs when a firm sells a bundle of

[7] Amgen's emphasis at oral argument on *International Construction Products LLC v. Caterpillar Inc.*, No. 15-108-RGA, 2016 WL 264909 (D. Del. Jan. 21, 2016) is similarly unavailing. In that case, Judge Andrews dismissed an exclusive dealing claim in part on substantial foreclosure grounds because there the Plaintiff "allege[d] no facts about the nature of the exclusive dealing arrangements and their potentially anticompetitive effects . . . ." *Id.* at *6. As explained above, that is not the case here.

goods or services for a lower price than the seller charges for the goods or services purchased individually." *Cascade Health Sols. v. PeaceHealth*, 515 F.3d 883, 894 (9th Cir. 2008).

In *LePage's Inc. v. 3M*, the Third Circuit held that offering bundled discounts could constitute anticompetitive conduct, even when the goods are sold above cost. 324 F.3d 141, 154–57. Under *LePage's*, an antitrust plaintiff must show that the effect of the discounts is to "foreclose portions of the market to a potential competitor who does not manufacture an equally diverse group of products and who therefore cannot make a comparable offer." *Id.* at 155.

Although the Third Circuit's assessment of bundled discounts in *LePage*'s has not been widely adopted, other courts have adopted a stricter formulation that says that offering bundled discounts can constitute anticompetitive conduct when allocation of the entire discount to the single product at issue in the case results in below-cost pricing. *See, e.g.*, *Cascade*, 515 F.3d at 903 (allocating the entire bundled rebate to the single product at issue to test the impact of a multi-product bundle).

Here, Regeneron alleges facts that appear to meet even the stricter assessment of bundled discounts used by courts outside the Third Circuit. In particular, the Complaint plausibly alleges that, when Amgen's approximately $90 million annual bundled rebate to ESI Commercial is attributed only to sales of Repatha (which has monopoly power), it results in Repatha being priced below cost. (D.I. 1 ¶¶ 90–93.) It further alleges that Regeneron does not manufacture Otezla (which allegedly has monopoly power) or Enbrel (which allegedly has market power), or comparable products, and that Regeneron cannot make a comparable rebate offer.[8] (*Id*. ¶¶ 18, 155.)

[8] Regeneron alleges that it markets only three drugs in addition to Praluent and that all three are "overwhelmingly not dispensed as prescription drug [sic] via pharmacies and, thus, are not subject to significant coverage or reimbursement by Third Party-Payors." (D.I. 1 ¶ 18.)

Amgen contends that Regeneron's bundling theory isn't plausible because Amgen does not condition Otezla rebates on Repatha coverage. As explained above, however, Regeneron pleads a different version of the facts, and I must accept its version as true at this stage.

Amgen next argues that Regeneron's bundling allegations are deficient because it has not specifically alleged that there is a dangerous probability of it exiting the market or that exit from the market has occurred or is imminent. I don't think that those specific allegations are required at the pleading stage, and Amgen has not cited a case saying otherwise. To the extent Regeneron needs to plead something about it exiting the market (so that Amgen can recoup its discounts), I find sufficient at this stage Regeneron's allegations that it will no longer make a profit on Praluent starting in 2022 and that Amgen's actions are "pushing Praluent® below a critical mass of market share necessary to compete." (*Id.* ¶¶ 137–38.)

Finally, Amgen says that, even if Praluent exited the market, Amgen would not be able to recoup its discounts because another product, Novartis's Leqvio®, would put "competitive pressure" on Repatha. (D.I. 18 at 20.) Regeneron's Complaint, however, plausibly alleges that Leqvio is not in the same relevant market as Praluent and Repatha (because Leqvio is not dispensed through pharmacies and is not covered by PBM formularies) (D.I. 1 ¶¶ 104–108), and I must accept that as true at this stage.

Here again, Amgen's arguments about bundled discounts implicate factual disputes that cannot be resolved at this stage of the case. For all of the reasons set forth above, Amgen's request to dismiss Regeneron's federal antitrust claims should be denied.

C. Regeneron's state law claims should not be dismissed.

Counts Seven through Eleven allege violations of state law. Amgen says that the state law claims should also be dismissed. The parties give the state law claims only cursory treatment; each brief devotes only a single paragraph to all five claims. I too will consider them only briefly.

Essentially, Amgen says that Regeneron's antitrust claim under California's Unfair Competition Law, California Business and Professions Code §§ 1700, *et seq.* (Count Seven), its predatory pricing claim under the Unfair Practices Act, California Business and Professions Code §§ 17043, *et seq.* (Count Eight), its claim under the Cartwright Act, California Business and Professions Code §§ 16700 (Count Nine), and its claim under the Donnelly Act, § 340 of New York's General Business Law (Count Ten), should be dismissed for the same reasons that the federal antitrust claims should be dismissed. I recommend denying Amgen's request to dismiss the federal antitrust claims, so I likewise recommend denying its request to dismiss those state law claims.[9] While I have reservations about the basis for Regeneron's claim for tortious interference with prospective business relations (Count Eleven), Amgen argues only that it should be dismissed because there is no antitrust violation, and Regeneron has pleaded that there is. Regeneron's state law claims may all move forward.

[9] I reject Amgen's contention that the Complaint fails to allege sufficient details about the price and costs of Repatha.

IV. ORDER ON THE MOTION TO STAY

Amgen also moves to stay this case pending further proceedings by the Supreme Court in the parties' patent dispute. *Amgen Inc. v. Sanofi*, 143 S. Ct. 399 (2022) (granting petition for writ of certiorari). After considering the totality of the circumstances, including the stay factors, I am unpersuaded that the Court should exercise its discretion to stay the case at this time.

I agree with Amgen that the stage of this case does not weigh against a stay. No discovery has been conducted and the trial date has not been set.

However, I am skeptical about the potential for the Supreme Court's decision to simplify the issues in this case. There is no simplification if the Supreme Court affirms the Federal Circuit's holding that Amgen's patents are invalid for lack of enablement. And the parties dispute whether there will be any simplification if the Supreme Court vacates or reverses the Federal Circuit's decision. Amgen argues that, if its patents are ultimately held to be valid (by the Supreme Court or by a lower court on remand), then Regeneron's antitrust claims will necessarily fail because Regeneron should never have had the ability to legally sell its competing product in the PCSK9 inhibitor market. Amgen alternatively contends that an ultimate holding of validity would, at a minimum, result in Regeneron having to pay Amgen a substantial royalty rate, which could prevent Regeneron from being able to compete profitably in the market and render it unable to prove its antitrust claims. Amgen also points out that Regeneron may decide not to litigate this case if Amgen wins at the Supreme Court.

For its part, Regeneron points out that the Supreme Court might not decide the ultimate issue of validity and may instead remand for further proceedings, and that a final judgment in the patent case could be years away. Regeneron also disputes that an eventual holding of patent

validity will moot the antitrust case or that an order requiring it to pay a reasonable royalty will prevent it from proving its antitrust claims.

It seems to me that, while it is possible that a Supreme Court ruling for Amgen will moot or simplify this case, there is more than a reasonable likelihood that a ruling for Amgen will actually complicate the case even more than it already is. Of course, the possibility that the case will become even more complicated is not a good reason to plow ahead blindly with discovery. There is much to be said for Amgen's suggestion that we should at least wait until the Supreme Court rules and then see how the parties' positions start to shake out. But I am persuaded that the potential for simplification by staying the case pending the Supreme Court's ruling is outweighed by the prejudice to Regeneron. This is a competitor case involving pharmaceutical products. Regeneron alleges that it is being driven out of the market as a result of Amgen's conduct. The potential prejudice to Regeneron by delaying the ultimate resolution of this case is significant.[10]

Under the circumstances, having carefully considered all of the parties' arguments and the relevant factors, I will exercise my discretion as follows. Amgen's motion to stay is denied without prejudice to renew after the Supreme Court issues its ruling in a few months, which will likely be

[10] The cases cited by Amgen in support of a stay are distinguishable. For example, Amgen cites a number of cases in which courts stayed antitrust claims that alleged sham patent litigation. *See, e.g.*, *Apotex*, 921 F. Supp. 2d at 314–16. The argument for a stay is much stronger in that type of case, since the success of the antitrust claim necessarily hinges on the merits of the patent case and the antitrust plaintiff is often not subject to an alleged restraint separate from the patent litigation itself. That is not the situation here. The Hatch-Waxman cases are further distinguishable because the operation of the statute usually prevents the generic drug alleged to infringe from entering the market until after the patent litigation is resolved. There is no additional prejudice to the generic by staying the antitrust case because it is unable to enter the market until it wins the patent dispute. Here, in contrast, Regeneron is subject to prejudice if resolution of this case is delayed.

Amgen also cites a number of cases in which courts stayed infringement actions pending reexamination proceedings, which is also not the situation here. *See, e.g.*, *Vehicle IP, LLC v. Wal-Mart Stores, Inc.*, No. 10-503, 2010 WL 4823393, at *1–3 (D. Del. Nov. 22, 2010).

long before the parties complete fact discovery or begin expert discovery. The Court can reevaluate the situation at that time. Any renewed request for a stay should comply with my discovery dispute procedures.

V. CONCLUSION

For the reasons set forth above, I recommend that Defendant's Motion to Dismiss (D.I. 17) be DENIED. Defendant's Motion to Stay (D.I. 27) is DENIED.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), (C), Federal Rule of Civil Procedure 72(b)(1), and District of Delaware Local Rule 72.1. Any objections to the Report and Recommendation shall be filed within fourteen days and limited to ten pages. Any response shall be filed within fourteen days thereafter and limited to ten pages. The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. The parties are directed to the Court's "Standing Order for Objections Filed Under Fed. R. Civ. P. 72," dated March 7, 2022, a copy of which can be found on the Court's website.

Dated: February 10, 2023

The Honorable Jennifer L. Hall
UNITED STATES MAGISTRATE JUDGE