IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MYLAN PHARMS. INC. ET AL, Plaintiffs, v. SANOFI-AVENTIS U.S. LLC ET AL, Defendants.	)	2:23-cv-00836

OPINION

Mark R. Hornak, United States District Judge

This case involves a dispute between two large players in the pharmaceutical industry over the injectable insulin glargine market. Plaintiffs Mylan Pharmaceuticals Inc., Mylan Specialty L.P., and Mylan Inc. (collectively "Mylan"[1] or "Plaintiffs") brought suit against Sanofi S.A., Sanofi-Aventis U.S. LLC, Aventis Pharma S.A., and Sanofi-Aventis Puerto Rico Inc. (collectively "Sanofi" or "Defendants") in May 2023 alleging various violations of antitrust law. (ECF No. 1).

Counts I and II of the Complaint alleges violations of Section 2 of the Sherman Act, 15 U.S.C. § 2, via monopolization and attempted monopolization. Count III of the Complaint alleges violations of Section 4 of the Clayton Act, 15 U.S.C. § 15, via conditional sales resulting in reduction of competition. Count IV of the Complaint alleges violations of the New Jersey Antitrust Act. N.J. Stat. Ann. 56:9-4. And Count V of the Complaint alleges the common law tort of tortious inducement of refusal to deal.

Sanofi moved to dismiss Mylan's Complaint, alleging two preliminary pleading/jurisdictional defects and a host of reasons as to why Mylan allegedly did not state a

[1] The Court notes that as of November 2020 Mylan became part of Viatris, Inc.

claim upon which relief may be granted. (ECF No. 49). Mylan then filed a response opposing that Motion, (ECF No. 59), which Sanofi countered with a Reply in Support of its Motion to Dismiss, (ECF No. 66). Both parties have filed notices of supplemental authority and responded to those of the other party over the course of the litigation. (*See* ECF Nos. 65, 67, 68, 69, 70, 71, 74, 75, 80, 81). Those matters are ripe for disposition.

As to Sanofi's preliminary pleading/jurisdictional defenses, the Court denies dismissal relative to Sanofi's assertion of impermissible "shotgun pleading." Regarding Sanofi's claim that the Court lacks personal jurisdiction over Sanofi S.A.,[2] the Court authorizes the parties to engage in a 120-day period of jurisdictional discovery in order to better inform the record as to such matters. The Court DENIES Sanofi's Motion to Dismiss the Complaint on all grounds except as applied to Mylan's allegation of a Sherman Section 2 violation based solely on a "product hop" theory. The Court GRANTS Sanofi's Motion to Dismiss Mylan's allegations of a Sherman Section 2 violation based solely on a "product hop" theory but will allow Mylan an opportunity to amend its pleading concerning that matter.[3]

I. Background

Like many pharmaceutical matters involved in antitrust litigation, the background of this case is factually complex. This section of the Opinion therefore provides a 10,000-foot view of the factual background of the present dispute in the context of the analytical and procedural posture of the case. At a baseline level, Mylan alleges that it is entitled to money damages under the

[2] The Court acknowledges that "S.A." ("société anonyme," a French corporate designation) is not technically part of the French corporation's name. (ECF No. 50, at 37 n.14). Because both the Plaintiffs and Defendants refer to the corporate defendants collectively as "Sanofi" (ECF No. 1, at 4; ECF No. 50, at 10), the Court refers to the French company "Sanofi" as "Sanofi S.A." to avoid confusion.

[3] Granting Sanofi's Motion to Dismiss this allegation does not necessarily preclude Mylan from using the product hop allegation as a *component* of an overarching theory of anticompetitive behavior, whether it chooses to amend or not. Whether and in what context that may come to pass and would be permitted as an evidentiary matter will be a matter more fully addressed at the appropriate procedural juncture.

applicable federal and state antitrust and related laws for lost sales of Mylan's injectable insulin glargine product that would have occurred but for Sanofi's allegedly illegal exclusionary conduct regarding Sanofi's injectable insulin glargine products, branded in the United States as Lantus SoloSTAR and Toujeo. (ECF No. 1, ¶ 1). Via patented technology, Sanofi held a lawful monopoly over the injectable insulin glargine market from approximately 2000 to 2015. (*Id.* ¶¶ 83–85, 93). Mylan alleges that Sanofi intentionally worked to *extend* its monopoly over the drug — the injectable form of the diabetes drug insulin glargine — beyond its lawful period of exclusivity, to the detriment of other drug manufacturers, including Mylan, from roughly 2015 to 2020. (*Id.* ¶¶ 114–16, 137–38). Mylan alleges that it wanted to but could not — due to Sanofi's actions — introduce its biosimilar[4] injectable insulin glargine drug, Semglee, to the U.S. market sometime between 2015 and 2020.

Needless to say, there is a complex regulatory scheme, which Mylan details in its Complaint, that attempts to encourage at the same time the development of safe and effective drugs and also market competition in vital pharmaceuticals. An important element of that regulatory scheme is the granting of patent exclusivity to new pharmaceutical formulations. Time periods for exclusivity vary. In the present case, Sanofi had a patent over insulin glargine from around 1997 to 2014, based on Patent No. 5,656,722 ("the '722 patent"). (*Id.* ¶¶ 82–84). It used the '722 patent to formulate Lantus, which was approved by the FDA in 2000 and was launched in U.S. markets in May 2001. (*Id.* ¶¶ 83, 86, 92). Due to patent protection, Sanofi had lawful exclusivity over

[4] The FDA defines a biosimilar as a biologic medication that is "highly similar to a biologic medication already approved by the FDA — the original biologic (also called the reference product). Biosimilars also have no clinically meaningful differences from the reference product." Biosimilars and generics are not the same thing. While biosimilars are highly similar to branded drugs, generics are exactly the same. *See* U.S. Food & Drug Administration, *What is a biosimlar medication?*, http://fda.gov/drugs/biosimilars/biosimilars-basics-patients (last visited Jan. 26, 2026).

injectable insulin glargine from approximately 2001 to 2014, with an additional period of pediatric exclusivity extending through 2015. (*Id.* ¶¶ 84–85, 93–94).

Mylan alleges that starting in 2013, Sanofi began "improperly listing in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the 'Orange Book') a thicket of invalid and/or uninfringed patents with endless sham litigation to exploit the automatic stay derived from the improper Orange Book listings." (*Id.* ¶ 3). According to the Federal Trade Commission ("FTC"), which submitted an *amicus curiae* brief in this case (which is accepted into the record by the Court) but took no position as to the disposition of the pending Motion, "improper Orange Book listings like those alleged here can cause significant harm to competition." (ECF No. 64, at 4). Such improper listings "take advantage of the FDA's long-standing position that it has a purely ministerial role in the [Orange Book] listing process." (*Id.* at 5). Within a four-year period, Mylan alleges that Sanofi submitted 16 patents to the Orange Book, many of which were allegedly found invalid for reasons of obviousness or unpatentability. (ECF No. 1, ¶¶ 125, 140, 148, 154, 159, 165, 171, 177, 184).

The legislative backdrop to the present case is a longstanding statute entitled the Drug Price Competition and Patent Term Restoration Act of 1984 — more commonly known as the Hatch-Waxman Act. Pub. L. No. 98-417, 98 Stat. 1585. Under Hatch-Waxman, pharmaceutical brands must list all patents in the Orange Book "for which infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug" so long as the patent is for the drug substance, product, or "a method of using [the] drug." (FTC's Brief as Amicus Curiae, ECF No. 64, at 9 (first quoting *Jazz Pharms., Inc. v. Avadel CNS Pharms.*, LLC, 641 F. Supp. 3d 85, 89 (D. Del. 2022), then quoting *Caraco Pharm. Lab'ys., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012)). As mentioned above, the FTC does not take a position on

the overall merits in this case, but it does note that in 2020, the First Circuit reinstated a complaint alleging an improper 2013 listing by Sanofi in the Orange Book concerning Lantus. (*Id.* at 10 (citing *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 8 (1st Cir. 2020)).

The problem with allegedly invalid Orange Book listings is that they substantially delay market entry by competitors. If a branded drug manufacturer initiates an infringement action against a would-be competitor pursuant to a patent listing in the Orange Book, the FDA will not grant approval to a generic until either (1) the passage of thirty (30) months, or (2) the issuance of a decision by a court that the patent is invalid or insufficiently related to the product. (ECF No. 1, ¶¶ 76–77). Because FDA does not play a "referee" role regarding the Orange Book, antitrust law is essential to protecting consumers and competition from impermissible anticompetitive conduct. (FTC's Brief as Amicus Curiae, ECF No. 64, at 15–16). As the FTC states:

> By listing a patent in the Orange Book and then filing an infringement suit, a brand can block competition for up to two-and-a-half years regardless of the scope or validity of the patent and regardless of whether it meets the statutory listing criteria. . . . Additionally, an improper listing may work a more subtle harm by deterring potential competitors or distorting their decision-making. Faced with a 30-month lag on receiving a return on investment, a generic company may elect to pursue an alternative generic drug product. This means that unwarranted Orange Book claims may deprive consumers of lower-priced competing drugs even long after any 30-month stay would expire.

(*Id.* (citation and footnote omitted)).

At some time point at or around the approval of Lantus by the FDA in 2000, Sanofi listed the '722 patent in the Orange Book. (ECF No. 1, ¶¶ 86–87). In 2009 and 2010, Sanofi allegedly filed two additional patents in the Orange Book under the name "Lantus" — Nos. 7,476,652 and 7,713,930. (*Id.* ¶ 109). Mylan contends that because the '652 and '930 patents "only claim the vial formulation of Lantus," those patents "should *not* have been identified in the Orange Book as applicable to the two cartridge formulations of Lantus." (*Id.* ¶ 111). Mylan further alleges that

Sanofi constructed "a patent thicket" by "collect[ing] a series of injector pen patents," which were filed between 2011 and late 2017. (*Id.* ¶ 114). Mylan contends that these patents were filed in the Orange Book "for the sole purpose of delaying competition" after Sanofi's period of lawful exclusivity lapsed. (*Id.* ¶ 117).

According to Mylan, abuse of the Orange Book was not the only means by which Sanofi engaged in unlawful anticompetitive conduct to delay the entry of competitors into the injectable insulin glargine market. Mylan also asserts that Sanofi strategically launched a comparable injectable insulin glargine product, Toujeo, in March 2015 to incentivize a switch from Lantus to Toujeo in consumers. (*Id.* ¶¶ 195–99). Toujeo has the same ingredients as Lantus but it is three times more concentrated and releases insulin more slowly. (*Id.* ¶ 195). The FDA approved Toujeo for sale in February 2015, and Sanofi launched the product in March 2015, a month after the '722 patent expired. (*Id.* ¶ 198).

According to purported internal Sanofi documents referenced in the Complaint, Sanofi created a strategy of providing rebates so that Toujeo could gain a considerable market share before generic entrants began to compete in the insulin glargine market. Sanofi achieved this allegedly "coercive switch" by steering "pharmaceutical supply chain intermediaries called Pharmacy Benefit Managers, or PBMs, . . . away from Lantus and to Toujeo." (*Id.* ¶ 11). Specifically, Mylan alleges that Sanofi created a strategy of "bundling" rebates for Lantus and Toujeo, so that payers could only receive rebates for one of the drugs if they offered both. (*Id.* ¶ 206). Mylan alleges that Sanofi "leverage[ed] Lantus in its contracts with customers to 'unlock preferred access for Toujeo' on covered drug formularies, with '100% of [its] Toujeo contracts . . . tied to Lantus.'" (*Id.* ¶ 203 (quoting House Cmte. on Oversight & Reform, *Drug Pricing Investigation: Majority Staff Report*

115 (Dec. 10, 2021)). In other words, Mylan alleges that Sanofi coerced a market shift by conditioning Lantus rebates on the inclusion of Toujeo by commercial formularies.[5]

The third way that Sanofi allegedly engaged in anticompetitive conduct also has to do with the tying of Toujeo to Lantus. Once other entrants broke through to the market, Mylan alleges that the tying of rebates "[b]ecame Sanofi's [p]rotection [a]gainst [b]iosimilar [c]ompetition for Lantus." (ECF No. 1, at 58). Payers were allegedly unwilling to switch from Lantus to a generic or biosimilar injectable insulin glargine product because doing so would result in the payer having to pay more for *both* Lantus and Toujeo, not just one of them, as a result of the tied rebates. (*Id.* ¶ 210). Because Mylan did not have a product that competes with Toujeo, it asserts that it could not make up the value of Sanofi's rebates on both Toujeo and Lantus by selling its sole product in the insulin glargine market, Semglee. (*Id.*).

For its part, Mylan asserts that it began preparing in or around 2013 to compete with Sanofi for when Sanofi's '722 patent and exclusivity period expired. (*Id.* ¶¶ 123–25). Soon, however, it alleges that "Sanofi began deploying its injector pen patents to delay Mylan's ability to enter the market." (*Id.* ¶ 127). Mylan was therefore nearly guaranteed to face a 30-month delay, so it considered other strategies. On April 27, 2017, Mylan submitted a section 505(b)(2) New Drug Application ("NDA") for Semglee, its insulin glargine biosimilar. (*Id.* ¶ 129). Section 505(b)(2) applications, under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq.*, must "contain[] full reports of investigations of safety and effectiveness," but "some of the information required for approval comes from studies not conducted by or for the applicant." (*Id.* ¶ 44). This stands in contrast to section 505(j) applications, which "contain[] information to show

[5] For the pharmaceutically uninitiated among us, a commercial formulary is "[a] list of prescription drugs covered by a prescription drug plan or another insurance plan offering prescription drug benefits." "Formulary," Glossary, Healthcare.gov, https://www.healthcare.gov/glossary/formulary/#:~:text=A%20list%20of%20prescription%20drugs,Also%20called%20a%20drug%20list (last visited Jan. 26, 2026).

that the proposed product is identical" to a previously approved product. (*Id.*). Mylan's April 2017 application triggered the 30-month delay due to the Orange Book listings. (*Id.* ¶ 129). The FDA approved Mylan's application on June 11, 2020. (*Id.* ¶ 136). The FDA initially approved Mylan's NDA as a biologic product[6] and then as an interchangeable biosimilar on July 28, 2021. (*Id.* ¶¶ 136–38). Semglee was launched in late 2020, but Mylan allegedly did not attain "any measurable sales at all" for Semglee until late 2021. (*Id.* ¶¶ 210–11).

While Mylan pursued regulatory approval of its biosimilar, Sanofi began to sue Mylan in federal court as well as bringing claims before the Patent Trial and Appeal Board (PTAB). (*Id.* ¶ 140). In the patent proceedings, Mylan pleads that Sanofi lost nearly every claim. "Of the challenges to over 50 claims in Sanofi's patents brought through *inter partes* reviews, *only two* claims have survived." (*Id.* ¶ 143) (emphasis in original). In federal court, Sanofi sued Mylan in the District of New Jersey in 2017 alleging patent infringement. (*Id.* ¶ 145). In March 2020, that court issued an Opinion finding that Mylan's insulin glargine product had not infringed Sanofi's '844 patent and finding that patent invalid. (*Id.* ¶ 181). After the Federal Circuit affirmed, the Supreme Court denied certiorari. (*Id.* ¶ 183); *see also Sanofi-Aventis Deutschland GmbH v. Mylan Pharms. Inc.*, No. 19A886, 2020 WL 13853390 (U.S. Feb. 14, 2020). As alluded to above, the Complaint here notes that the PTAB has found — and the Federal Circuit has affirmed — other of Sanofi's patents also invalid. (*See, e.g.*, ECF No. 1, ¶ 153 ("On December 12, 2018, the PTAB found that all 25 claims of the '652 patent were invalid. The Federal Circuit affirmed, and the mandate issued February 18, 2020. Sanofi petitioned the Supreme Court for review of the decision,

[6] Mylan notes that its NDA was approved as a "biologics license application" on June 11, 2020. (ECF No. 1, ¶ 136). A biologics license application, according to the FDA, is "a request for permission to introduce, or deliver for introduction, a biologic product into interstate commerce (21 CFR 601.2)." U.S. Food & Drug Administration, *Biologics License Application (BLA) Process (CBER)*, https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber (last visited Jan. 26, 2026). Mylan does not explain the significance of its initial approval as a "biologic"; the Court thus infers that this was a step along the way to becoming an interchangeable biosimilar, which Mylan had hoped would have occurred sooner.

which the Supreme Court denied on October 5, 2020."); *id.* ¶ 158 ("On December 12, 2018, the PTAB found the '930 patent invalid. The Federal Circuit affirmed, and the mandate issued February 18, 2020. Sanofi petitioned the Supreme Court for review of the decision, which the Supreme Court denied on October 5, 2020.")).

The combination of Sanofi's alleged practices in and power over the injectable insulin glargine market give rise to Mylan's present Complaint.

II. Pleading Standards/Jurisdiction Over Defendants

As a preliminary matter, Defendants raise two preliminary issues, one relating to whether the Complaint provides sufficient notice of the discrete claims asserted as to each Defendant, and a second concerning the exercise of jurisdiction over Sanofi. First, they claim that Mylan's grouping of the Sanofi corporate Defendants together across the Complaint constitutes impermissible "shotgun pleading." Second, they claim that the Court lacks personal jurisdiction over Sanofi S.A., the parent company of the pharmaceutical conglomerate based out of France. The Court will not dismiss the action based on the former argument and will pause disposition of the latter argument on the terms described below.

A. Shotgun Pleading

Rule 8 requires that a complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). So-called shotgun pleading occurs when a plaintiff asserts multiple claims against multiple defendants and fails to appropriately disaggregate the claims as they apply to each of the independent defendants. *Bartol v. Barrowclough*, 251 F. Supp. 3d 855, 859 (E.D. Pa. 2017). Here, Defendants contend that grouping the corporate affiliates together and not disaggregating the claims made against them constitutes shotgun pleading.

The key purpose of the Rule 8 pleading standard is to provide fair notice to defendants about allegations made against each of them. Whether a complaint provides fair notice to defendants is a "context-dependent exercise," in which the court must consider "nature of the action, the sort of relief being sought, the availability of information, and other practical considerations." *Garrett v. Wexford Health*, 938 F.3d 69, 93 (3d Cir. 2019) (citation omitted). In some contexts — for example where it is implausible that all defendants engaged in all of the alleged conduct — fair notice might require specific allegations as to specific individual defendants. *See, e.g.*, *Bartol*, 251 F. Supp. 3d at 859–60. In other contexts, less specificity may be required. Where, for example, the defendants are related corporate entities and the content of the complaint suggests that each allegation is made against every defendant, referring to all defendants collectively may be permissible. *See, e.g.*, *Hotaling & Co., LLC v. Berry Sols. Inc.*, No. 20-CV-18718, 2021 WL 4860096, at *7 (D.N.J. Oct. 19, 2021).

Here, the Plaintiffs provided the Defendants with sufficient notice of the claims leveled against each of them. The Defendants are related corporate entities, (ECF No. 1, ¶¶ 27–30, 30 n.13), and they are represented by common counsel. *See In re Riddell Concussion Reduction Litig.*, 77 F. Supp. 3d 422, 431–32 (D.N.J. 2015) (rejecting a shotgun pleading defense in part because defendants were "represented by the same counsel, accepted service as a single entity, and all joined in the instant motion to dismiss"). Plaintiffs stipulated at the outset that they would refer to Defendants collectively as "Sanofi" and then used the term "Sanofi" in subsequent assertions and allegations throughout the Complaint. (*See, e.g.*, ECF No. 1, ¶¶ 200 ("Sanofi understood that the same logic applied to protect Medicaid sales"); *id.* ¶ 203 ("Sanofi succeeded in increasing Toujeo sales by over 25% within the first year")). By referring to Defendants collectively, "it can be reasonably inferred that each and every allegation is made against each individual defendant."

Nasdaq, Inc. v. IEX Grp., Inc., No. CV 18-3014-BRM-DEA, 2019 WL 102408, at *14 (D.N.J. Jan. 4, 2019); *see also Hotaling & Co., LLC*, No. 20-CV-18718, 2021 WL 4860096, at *7. "To the extent more specificity regarding the role of each Defendant is required, beyond the bar that Plaintiffs provide them proper notice, that is an issue more appropriate for discovery." *JD Glob. Sales, Inc. v. Jem D Int'l Partners, LP*, No. 221CV19943BRMMAH, 2023 WL 4558885, at *9 (D.N.J. July 17, 2023). So the Court will not grant dismissal at this juncture on that basis and such action is without prejudice to the position any Defendant may take as to its own alleged culpability, or at a later procedural stage, as to whether Mylan can prevail on a particular claim as to it.

B. Personal Jurisdiction Over Sanofi S.A.

The jurisdictional issue Defendants assert is whether the Court properly has personal jurisdiction over Sanofi S.A. Personal jurisdiction must be demonstrated for each individual defendant. *Nicholas v. Saul Stone & Co. LLC*, 224 F.3d 179, 184 (3d Cir. 2000). "[M]ere ownership of a subsidiary does not justify the imposition of liability on the parent," *Pearson v. Component Tech. Corp.*, 247 F.3d 471, 484 (3d Cir. 2001), and likewise, ownership of a local subsidiary generally does not create personal jurisdiction over the parent corporation, *In re Enterprise Rent-A-Car Wage & Hour Emp. Pracs. Litig.*, 735 F. Supp. 2d 277, 317 (W.D. Pa. 2010), *aff'd*, 683 F.3d 462 (3d Cir. 2012); *L.T. Overseas, Ltd. v. Dabur India, LTD.*, No. 17-CV-4863, 2017 WL 5707531, at *3 (D.N.J. Nov. 27, 2017).[7]

Mylan contends that the Court has specific jurisdiction over Sanofi S.A. (*See* ECF No. 59, at 44 ("Specific jurisdiction exists here.")). The Defendants contend that such is not the case. Courts engage in a three-part inquiry to determine whether specific jurisdiction exists. First, courts

[7] This general rule notwithstanding, a subsidiary's contacts with the forum may be imputed to the parent where the subsidiary is an "alter ego" of the parent corporation or where the parent otherwise controls the subsidiary. *Shuker v. Smith & Nephew, PLC*, 885 F.3d 760, 781 (3d Cir. 2018); *Fisher v. Teva PFC SRL*, 212 Fed. App'x. 72, 76 (3d Cir. 2006). Mylan does not argue that either of these analytical tools apply here.

ask whether the defendant has "'purposefully directed [its] activities' at the forum." *O'Connor v. Sandy Lane Hotel Co.*, 496 F.3d 312, 317 (3d Cir. 2007) (quoting *Burger King Corp. v. Rudzewicz*, 471 U.S.462, 472 (1985)). In other words, courts ask whether the defendant has taken some act or series of acts by which it "purposefully avail[ed] itself of the privilege of conducting activities within the forum State." *Ford Motor Co. v. Montana Eighth Jud. Dist. Ct.*, 592 U.S. 351, 359 (2021) (citation omitted). In antitrust cases, the relevant forum is the United States as a whole, rather than any specific state or judicial district. *In re Auto. Refinishing Paint Antitrust Litig.*, 358 F.3d 288, 298 (3d Cir. 2004). Second, the court asks whether the litigation "arise[s] out of or relate[s] to" the defendant's activities in the forum state. *O'Connor*, 496 F.3d at 318. "[T]here must be an affiliation between the forum and the underlying controversy, principally, an activity or an occurrence that takes place in the forum [] and is therefore subject to the [forum's] regulation." *Ford Motor Co.*, 592 U.S. at 359–60 (cleaned up). And third, if the first two requirements are met, the court considers whether exercising jurisdiction would comport with "fair play and substantial justice." *O'Connor*, 496 F.3d at 325 (quoting *Burger King*, 471 U.S. at 476).

At the pleading stage, if "the plaintiff's claim is not clearly frivolous, the district court should ordinarily allow discovery on jurisdiction" to determine whether personal jurisdiction exists. *Compagnie Des Bauxites de Guinee v. L'Union Atlantique S.A. d'Assurances*, 723 F.2d 357, 362 (3d Cir. 1983). "If a plaintiff presents factual allegations that suggest 'with reasonable particularity' the possible existence of the requisite 'contacts between [the party] and the forum' . . . the plaintiff's right to conduct jurisdictional discovery should be sustained." *Toys "R" Us, Inc. v. Step Two, S.A.*, 318 F.3d 446, 456 (3d Cir. 2003) (quoting *Mellon Bank (E.) PSFS, Nat'l Ass'n v. Farino*, 960 F.2d 1217, 1223 (3d Cir. 1992)). Jurisdictional discovery is particularly appropriate

where the defendant is a corporation. *Metcalfe v. Renaissance Marine, Inc.*, 566 F.3d 324, 336 (3d Cir. 2009).

Mylan's allegations show with reasonable particularity that Mylan's claims against Sanofi S.A. are not frivolous. Mylan asserts a number of alleged contacts between Sanofi S.A. and the United States:

1) Sanofi S.A. has been listed as a party in interest in *inter partes reviews* before the U.S. Patent Board, (ECF No. 59-1, ¶ 4);
2) Sanofi S.A. has brought a number of lawsuits in federal court, (*id.* ¶ 5);
3) "Sanofi" has released a number of press releases regarding its activities in the United States with its location marked "Paris," (*id.* ¶¶ 6–8, 10);
4) Sanofi's regulatory filings with the U.S. Securities and Exchange Commission from the 2016 fiscal year list France as its jurisdiction of incorporation and Paris as its principal office, while also discussing the Lantus rebate strategy in the U.S., (*id.* ¶ 9); and
5) On at least two occasions, Sanofi S.A. executives have testified in front of Congress, (*id.* ¶¶ 11–12).

Mylan alleges that the Sanofi corporate family engaged in a multipronged anticompetitive scheme to preserve its monopoly over injectable insulin glargine. Sanofi S.A.'s filing of a Form 20-F[8] and the congressional testimony of its executives is some plausible demonstration that Sanofi S.A. was aware of its sales in the U.S., and that its leaders purposefully directed business activities to the American stream of commerce. (*See* ECF No. 59-8, at 3–4; ECF No. 59-10). These

[8] The SEC's Form 20-F is an annual report filed by foreign businesses that trade securities in the United States.

pieces of evidence demonstrate "with reasonable particularity the possible existence of the requisite contacts between [Sanofi S.A.] and the forum." *Toys "R" Us*, 318 F.3d at 456.

Accepting Mylan's well-pled allegations as true, Mylan has sufficiently shown that Sanofi S.A. likely has the requisite minimum contacts with the United States. The remaining questions are therefore whether the "plaintiff's cause of action is related to or arises out of the defendant's contacts" with the U.S., *Pinker v. Roche Holdings Ltd.*, 292 F.3d 361, 368 (3d Cir. 2002), and whether subjecting Sanofi S.A. to this Court's jurisdiction comports with "traditional notions of fair play and substantial justice," *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945). Because Mylan's allegations in these regards are not clearly frivolous, and neither are the Defendant's arguments in opposition, the Court will allow for a period of jurisdictional discovery of 120 days on the issue of Mylan's assertion of the presence of personal jurisdiction by this Court over Sanofi S.A.

III. Legal Standard-Balance of the Motion to Dismiss

Rule 12(b)(6) of the Federal Rules of Civil Procedure permits a defendant to move to dismiss a complaint on the grounds that the complaint fails to state a claim upon which relief can be granted. To survive such a motion, the complaint must "raise a right to relief above the speculative level" and "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 570 (2007). To state a plausible claim, the complaint must contain sufficient factual allegations, which, taken as true and construed in the light most favorable to the plaintiff, would support a "reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "Determining whether a complaint states a plausible claim to relief [is] a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679. While relevant to the plausibility analysis, the

mere existence of innocent alternative explanations for a defendant's conduct is not fatal to a plaintiff's claim. *See Doe v. Princeton Univ.*, 30 F.4th 335, 344 (3d Cir. 2022).

Importantly, the complaint need not allege a complete prima facie case. *Martinez v. UPMC Susquehanna*, 986 F.3d 261, 266 (3d Cir. 2021) (citing *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 508 (2002)). "The complaint need only allege enough facts to 'raise a reasonable expectation that discovery will reveal evidence of [each] necessary element.'" *Id.* (quoting *Fowler v. UPMC Shadyside*, 578 F.3d 203, 213 (3d Cir. 2009)). In deciding motions to dismiss, courts are generally limited to the content of the complaint. *Princeton Univ.*, 30 F.4th at 342. "But where a document is 'integral to or explicitly relied upon in the complaint,' it 'may be considered without converting the motion to dismiss into one for summary judgment.'" *Id.* (quoting *Doe v. Univ. of Scis.*, 961 F.3d 203, 208 (3d Cir. 2020)). The Court may also consider information and documents subject to judicial notice. *See Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 322 (2007).

It bears noting that our Court of Appeals has determined that "it is inappropriate to apply *Twombly*'s plausibility standard with extra bite in antitrust and other complex cases." *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 98 (3d Cir. 2010). The relevant inquiry is whether the claims alleged are plausible, not probable. In fact, because of the complexity and fact-dependent nature of complex cases, this Court has held that "[w]hen addressing antitrust claims, the standard for dismissal is somewhat higher" than in other cases. *Premier Comp Sols. LLC v. UPMC*, 163 F. Supp. 3d 268, 275 (W.D. Pa. 2016). This is because "summary procedures should be used sparingly in complex antitrust litigation where motive and intent play leading roles, the proof is largely in the hands of the alleged [defendants], and hostile witnesses thicken the plot." *Id.* (quoting *Poller v. Columbia Broad Sys.*, 368 U.S. 464, 473 (1962)); *see also Hosp. Bldg. Co. v. Trustees of Rex Hosp.*, 425 U.S. 738, 746 (1976) ("[I]n antitrust cases . . . dismissals prior to

giving the plaintiff ample opportunity for discovery should be granted very sparingly."). In the Court's view, this case law does not create a special standard for evaluating this Motion, but it does counsel the Court exercising more exacting confidence that a plausible claim has not been stated before the Court pulls the dismissal trigger.

IV. Plaintiffs' Claims

Plaintiffs assert five causes of action. Defendants move to dismiss each of them. The Court combines its discussion as to Counts I and II because both are asserted under Sherman Section 2. The Court also combines its analysis of Counts III and IV, which fall under the Clayton Act and New Jersey's Antitrust Act, respectively. Then Count V, which asserts a state law tort claim of tortious inducement of refusal to deal, is addressed. At the outset, the Court notes that the bulk of the following analysis is spent discussing the Sherman § 2 claims, as the viability of Plaintiffs' subsequent claims are at least in part tied to the viability of the Sherman claims.

A. Counts I and II: Monopolization and Attempted Monopolization (Sherman Act § 2)

At Count I of the Complaint, Mylan accuses Sanofi of illegally maintaining a monopoly in violation of Section 2 of the Sherman Act. In relevant part, Section 2 of the Sherman Act states:

> Every person who shall monopolize, or attempt to monopolize . . . any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation.

15 U.S.C. § 2. A violation of Section 2 of the Sherman Act has two elements: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966). Private parties injured by a corporation's violation of Section 2 may bring suit in federal

court. 15 U.S.C. §§ 15(a), 26. An antitrust plaintiff must plausibly show that it "suffered antitrust injury as a result" of the defendant's conduct. *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 402 (3d Cir. 2016). As applied to the present case, Mylan must plausibly assert that Sanofi had monopoly power; that it obtained or maintained that monopoly through anticompetitive or exclusionary conduct; and that its conduct caused Mylan to suffer an antitrust injury.

At Count II, Mylan alleges that Sanofi engaged in *attempted* monopolization in violation of Section 2 of the Sherman Act. "In order to establish a claim of attempted monopolization, a plaintiff must show that the defendant (1) had specific intent to monopolize the relevant market, (2) engaged in anti-competitive or exclusionary conduct, and (3) possessed sufficient market power to come dangerously close to success." *Barr Lab'ys, Inc. v. Abbott Lab'ys*, 978 F.2d 98, 112 (3d Cir. 1992). The second and third prongs of this cause of action — anticompetitive conduct and market power — mirror elements of an actual monopolization offense under Section 2.

The first element of attempted monopolization — specific intent by the defendant to monopolize the market — departs slightly from the elements of an actual monopolization offense. The "mere intent to prevail over rivals or to improve market position is insufficient" to establish this first element of attempted monopolization; instead, a "'specific intent to destroy competition or build monopoly'" is required. *Hum. Res. Inst. of Norfolk, Inc. v. Blue Cross of Virginia*, 498 F. Supp. 63, 67 (E.D. Va. 1980). "Even an intent to perform acts that can be objectively viewed as tending toward the acquisition of monopoly power is insufficient, unless it also appears that the acts were not 'predominantly motivated by legitimate business aims.'" *BanxCorp v. Bankrate Inc.*, No. CIV.A. 07-3398 ES, 2011 WL 6934836, at *22 (D.N.J. Dec. 30, 2011) (quoting *Penn. Dental Ass'n v. Med. Serv. Ass'n of Penn.*, 745 F.2d 248, 260–61 (3d Cir.1984)). But the plaintiff need not show direct evidence of specific intent; such intent "may be inferred from predatory or

exclusionary conduct." *Id.* (quoting *Penn. Dental*, 745 F.2d at 261). Various forms of evidence can be used to establish an inference of specific intent, including statements by corporate executives, *BanxCorp*, No. CIV.A. 07-3398 ES, 2011 WL 6934836, at *23, as well as "tie-in sales, corporate acquisitions and other activities," *United States v. Jerrold Elecs. Corp.*, 187 F. Supp. 545, 567 (E.D. Pa. 1960), *aff'd*, 365 U.S. 567 (1961). As such, much of the evidence used to allege a monopolization offense under Section 2 can also be used to allege attempted monopolization.

Because of the marked similarity in elements and relevant evidence, the Court analyzes Mylan's monopolization and attempted monopolization claims jointly. The conclusions in the below analysis thus apply to both Count I and Count II.

1. Monopoly Power

The first question is whether Mylan has shown sufficient facts to plausibly support its assertion that Sanofi had monopoly power during the relevant time period. "While merely possessing monopoly power is not itself an antitrust violation, it is a necessary element of a monopolization charge." *United States v. Microsoft Corp.*, 253 F.3d 34, 51 (D.C. Cir. 2001) (citations omitted). Monopoly power is the "power to control prices or exclude competition." *United States v. E. I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956). "More precisely, a firm is a monopolist if it can profitably raise prices substantially above the competitive level." *Microsoft Corp.*, 253 F.3d at 51.

Monopoly power can be proven via direct or indirect evidence. Sanofi argues that Mylan has not sufficiently alleged monopoly power through either direct or indirect evidence. Mylan argues that it has adequately alleged Sanofi's monopoly through both direct and indirect evidence. Direct evidence consists of "supracompetitive pricing and restricted output," whereas indirect evidence can "be inferred from the structure and composition of the relevant market." *Broadcom*

Corp. v. Qualcomm Inc., 501 F.3d 297, 307 (3d Cir. 2007). A logician might take issue with these definitions of indirect and direct evidence. Not only is the line between the two types of evidence blurred, but the reliance of direct evidence on "restricted output" would — at least in some instances — put the cart (whether a monopolist engaged in anticompetitive conduct) before the horse (whether a firm has "monopoly power" in the first place).

Direct evidence of monopoly power is (not surprisingly) rare, particularly at the pre-discovery pleading stage. *Harrison Aire, Inc. v. Aerostar Int'l, Inc.*, 423 F.3d 374, 381 (3d Cir. 2005). Because of that reality, and because the Court concludes that Mylan has sufficiently pleaded that Sanofi plausibly had monopoly power via asserted *indirect* evidence, we do not and need not grapple in this Opinion with the question of *direct* evidence.

Proving monopoly power via indirect evidence requires a plaintiff to "plead and prove that a firm has a dominant share in a relevant market, and that significant 'entry barriers' protect that market." *Broadcom*, 501 F.3d at 307 (quoting *Harrison Aire*, 423 F.3d at 381). Proving monopoly power through indirect evidence thus consists of showing that the allegedly offending party had (1) market power (2) in the relevant market and (3) that there are high barriers to enter that market. In line with other courts in this Circuit, we first analyze what the relevant market is in this dispute. *See Bayer Healthcare LLC v. Second Stone Enters. LLC*, No. CV 24-7618, 2025 WL 1531237, at *6 (D.N.J. May 29, 2025).

a. *Relevant Market*

Plausibly alleging monopoly power through indirect evidence requires the plaintiff to define the scope of the relevant market. Mylan defines the relevant market as "the injectable form of diabetes drug insulin glargine." (ECF 1, ¶ 1; *see also id.* ¶ 212 ("At all relevant times, Sanofi had monopoly power in the market for injectable insulin glargine because it had the power to raise

or maintain the price of injectable insulin glargine at supracompetitive levels without losing enough sales to make supracompetitive sales unprofitable and the power to exclude competitors."); ECF No. 59, at 33–35). Sanofi asserts that Mylan's definition of the relevant market fails because injectable insulin glargine products compete with non-injectable and non-glargine-based forms of basal (i.e., long-acting) insulin. (ECF No. 50, at 21–22). Sanofi thus asserts that Mylan "fails to allege a relevant market" because it does not account for such competitors. (*Id.* at 22).

The plaintiff bears the burden of proving the scope of the relevant market. *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 436 (3d Cir. 1997). A relevant market is generally defined by both the product market and geographic market. *Fed. Trade Comm'n v. AbbVie Inc.*, 976 F.3d 327, 372 (3d Cir. 2020). Here, it is not disputed that the relevant geographic market is the United States. It is disputed, however, what the relevant *product* market is. To determine what constitutes the relevant product market, courts ask if products are "readily substitutable for one another." *Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 435 (3d Cir. 2016) (citation omitted). This means considering "the extent to which [d]efendants' product is interchangeable with alternative products in the field." *Id.* at 436. "'Interchangeability' implies that one product is roughly equivalent to another for the use to which it is put." *Allen-Myland, Inc. v. Int'l Bus. Machines Corp.*, 33 F.3d 194, 206 (3d Cir. 1994). Our Court of Appeals has held that the relevant product market is comprised of "those groups of producers which, because of the similarity of their products, have the ability actual or potential to take significant amounts of business away from each other." *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1063 (3d Cir. 1978).

Importantly, "[c]ourts are reluctant to find single-product markets" because "every manufacturer in a single-product market will have monopoly power." *Mylan Pharms., Inc. v.*

Warner Chilcott Pub. Co., No. CIV. 12-3824, 2015 WL 1736957, at *8 (E.D. Pa. Apr. 16, 2015), *aff'd*, 838 F.3d 421 (3d Cir. 2016). For that reason, courts typically reject definitions of relevant markets that consist only of a single supplier's products. *Id.* For instance, in one case, the Third Circuit rejected a plaintiff's attempt to define a relevant market as new Chrysler cars manufactured in the United States because "[t]he relevant product market include[d] Chrysler cars *and* cars that are reasonably interchangeable with Chrysler cars." *Town Sound & Custom Tops, Inc. v. Chrysler Motors Corp.*, 959 F.2d 468, 480 (3d Cir. 1992).

Mylan states what it says is the relevant market many times throughout its Complaint. (*See, e.g.*, ECF No. 1, ¶ 21 ("Sanofi's monopolization of the *injectable insulin glargine market* . . ."); *id.* ¶ 212 ("At all relevant times, Sanofi had monopoly power in the *market for injectable insulin glargine* . . ."); *id.* ¶ 224 ("But for Sanofi's conduct, Mylan would have been able to enter the *injectable insulin glargine market* . . .")). Lantus, Toujeo, and Semglee are each injectable insulin glargine products. Mylan's product Semglee was approved by the FDA as interchangeable with Lantus on July 28, 2021. (*Id.* ¶¶ 137–38). Toujeo is also an injectable basal insulin drug with the active ingredient insulin glargine. (*Id.* ¶ 195). The only consequential difference between Toujeo and Lantus is that Toujeo lasts four hours longer. (*Id.*). By its own documents, it would plausibly appear that Sanofi engaged in various strategies to transfer a portion of its patient base from Lantus to Toujeo, plausibly illustrating the drugs' interchangeability. Internal Sanofi documents allegedly state that the "Lantus to Toujeo switch is required to maximize the glargine family and defend our leadership position." (*Id.* ¶ 208). Sanofi's categorization of some of its products belonging to the "glargine family" bolsters Mylan's definition of the relevant market as the injectable insulin glargine market.

As the Defendants remind the Court, the Court can take notice of publicly available records from the FDA. (ECF No. 50, at 28). According to the FDA's "Purple Book," Lantus has two "interchangeables," which the FDA defines as "biological product[s] that meet[] the requirements for [] biosimilar product[s] and [are] approved based on information that is sufficient to show that [they] can be expected to produce the same clinical result as the reference product in any given patient." "Lantus," U.S. Food & Drug Administration, *Purple Book: Database of Licensed Biological Products*. Those two products are Semglee, Mylan's product originally approved as interchangeable with Lantus on July 28, 2021, and Rezvoglar, an Eli Lilly and Company product originally approved as interchangeable on December 17, 2021.[9]

Sanofi lists several additional products with which it states injectable insulin glargine drugs compete. These include Levemir and Tresiba, as well as the premixed analog insulin products Humalog Mix and Novolog Mix. But Sanofi does not facially defeat the Plaintiffs' relevant market definition by alleging, in essence, that competition may exist at varying levels of market particularity. For comparison, Chrysler cars compete not only with "cars that are reasonably interchangeable with Chrysler cars" but also with cars that are unlike Chrysler cars in the broader car market. *Town Sound*, 959 F.2d at 480. In the present case, each of the products Sanofi references have different active ingredients than Lantus, Toujeo, and Semglee, each of which have the active ingredient insulin glargine. Levemir has the active ingredient insulin detemir; Tresiba has insulin degludec; Humalog Mix has insulin lispro; and Novolog Mix has insulin aspart. Active ingredients are an important factor in how PBMs determine coverage. That could plausibly mean,

[9] The entrance of Rezvoglar in the injectable insulin glargine market is not dispositive of this Motion because Mylan's allegations of antitrust violations presumably concern the period between approximately February 2015, (ECF No. 1, ¶ 93), through "late 2021, after Mylan secured interchangeability [of Semglee] for Lantus," (*id.* ¶ 211).

as Mylan alleges, that formularies cover injectable insulin glargine products as interchangeable with Lantus but not products with other active ingredients. (ECF No. 59, at 34–35).

Sanofi points to the figure at paragraph 194 of Mylan's Complaint as evidence of Sanofi's competition with other basal insulins, a category significantly broader than the injectable insulin glargine market. Again, Sanofi's theory that Lantus was in competition with all basal insulins — not just injectable insulin glargine — *may* be true, but it does not necessarily upend Mylan's asserted definition of the relevant market. In fact, the figure at paragraph 194 of the Complaint, which appears to depict an internal Sanofi PowerPoint slide, features a table divided into two rows of drugs that were "[a]lready in the market" as of 2014. The first row is labeled "Glargine," and points to the Lantus logo. The second row is labeled "Other Long-acting" and points to the logo for a different Sanofi product, Levemir. In the Court's view, this document plausibly shows that Sanofi did *not* consider all insulin products in its lineup completely equivalent; it placed its glargine product, Lantus, in a category separate from "[o]ther [l]ong-acting" insulin products. (ECF No. 1, ¶ 194).

Finally, it is for the Plaintiff, not the Defendant, to first plausibly define the relevant market in its pleading. Lantus, Toujeo, and Semglee are all injectable insulin glargine products with the same active ingredients. And this market — the injectable insulin glargine market — is not a minor subset of the insulin market. In 2014, when Sanofi had lawful exclusivity over the injectable insulin glargine market, it realized €4.225 billion in revenue from Lantus sales in the United States (*Id.* ¶ 18). At the pleading stage of an antitrust complaint, it is not the province of the Court to become mired in the "economic task put to the uses of the law" of conclusively determining the relevant market. *SmithKline*, 575 F.2d at 1063 (citation omitted). Whether the injectable insulin glargine market too narrowly defines the relevant market is therefore a prime matter for discovery and

follow along motion practice, as is whether such a definition constitutes an impermissible single-product market. For now, the pleading threshold has been met. The Court accepts Mylan's plausible categorization of the relevant market as the injectable insulin glargine market for pleading purposes.

b. *Market Power*

Market power — an element of monopoly power — is a firm's "ability to raise prices above those that would otherwise prevail in a competitive market." *AbbVie*, 976 F.3d at 371 (quoting *Gordon v. Lewistown Hosp.*, 423 F.3d 184, 210 (3d Cir. 2005)). If a firm controls more than 55 percent of the relevant market, a court can infer that the firm has market power. *Id.* At this stage, Mylan need not specifically plead that Sanofi has a market share greater than 55 percent pursuant to *AbbVie,* 976 F.3d at 371, because a complaint is not required to assert a complete prima facie case, *Martinez*, 986 F.3d at 266. Rather, Mylan's allegations need only "raise a reasonable expectation that discovery will reveal evidence" that Sanofi had a dominant share of the market. *Id.* "A predominant share of the market, or a lesser market share combined with other relevant factors, may suffice to demonstrate monopoly power." *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 201 (3d Cir. 1992).

With this in mind, the Court concludes that Mylan has done enough at the pleading stage to plausibly show that Sanofi had market power. Lantus was the first injectable insulin glargine drug, originally approved by the FDA in April 2000. (ECF No. 1, ¶ 83). It is undisputed that Sanofi had lawful exclusivity over the injectable insulin glargine market in the U.S. from approximately May 2001, when Sanofi began to sell Lantus in the U.S., through February 2015, when Lantus's period of patent exclusivity expired. (*Id.* ¶¶ 93–94). Presumably during that period, Sanofi had near one-hundred percent market share of the injectable insulin glargine market. After its period

of lawful exclusivity, Sanofi presumably still had significant market share.[10] For pleading purposes, such an inference is both reasonable and sufficient for the Court to conclude that Sanofi plausibly had "a dominant share in [the] relevant market." *Qualcomm*, 501 F.3d at 307.

Additional support for the inference that Sanofi had market dominance from approximately 2015 to 2020 comes from internal Sanofi documents included in the pleadings. At various times, Sanofi allegedly boasted of market dominance in internal PowerPoint slides. For instance, in 2015, Sanofi allegedly acknowledged the need for it to "'defend [its] leadership position' by switching patients to Toujeo 'before biologic follow on entry.'" (ECF No. 1, ¶ 9). It also allegedly stated that "Lantus is the preferred 1st generation basal insulin. We have succeeded at leveraging the size of Lantus to unlock preferred access for Toujeo." (*Id.* ¶ 10). These statements about Sanofi's "leadership position" and "size" in the injectable insulin glargine market came just after Sanofi's lawful exclusivity period ended. (*Id.* ¶ 14). Mylan also pleads that for one year after getting Semglee to market, from 2020 to 2021, it was not able to achieve "measurable sales" in the market, purportedly because of Sanofi's market power. (*Id.* ¶ 211). Taken as true, as they must be at this stage, these statements bolster the plausible inference that Sanofi had the requisite market power during the relevant period.

c. *Barriers to Entry*

The third element under Third Circuit law to plausibly allege that a party had monopoly power is the existence of high barriers to enter the relevant market. "Barriers to entry include 'regulatory requirements, high capital costs, or technological obstacles, that prevent new

[10] Mylan's Complaint does not assert factual allegations regarding Sanofi's market share in the injectable insulin glargine market after its period of lawful exclusivity ended. It may have been wise to include such facts in the pleadings but doing so is not necessary to survive this Rule 12(b)(6) motion.

competition from entering a market in response to a monopolist's supracompetitive prices.'" *AbbVie*, 976 F.3d at 372 (quoting *Broadcom*, 501 F.3d at 307).

Mylan has adequately pleaded that there are significant barriers to enter the injectable insulin glargine market. "[A] generic drug has significant capital, technical, regulatory, and legal barriers to overcome" to get to market. *Id.* at 373 (citation omitted). Would-be competitors must go through complex and onerous regulatory processes before bringing their products to market. (ECF No. 1 ¶¶ 43–59); *Ethypharm S.A. France v. Abbott Lab'ys*, 707 F.3d 223, 236 (3d Cir. 2013) (describing the FDA's "stringent requirements" for pharmaceutical companies as a "high legal barrier to entry"). As a result of regulatory hurdles and others, Mylan alleges that it took eight years to bring its product to market, (ECF No. 1, ¶¶ 15–16, 210), and after reaching the market, another year to achieve measurable sales, (*id.* ¶ 211). Sanofi attributes much of the delay to Mylan's own action and inaction. (ECF No. 50, at 17–21). At this juncture in the litigation, though, the delay Mylan describes supports a reasonable inference that there are high barriers for competitors to enter the injectable insulin glargine market.

Accordingly, the Court concludes that Mylan has adequately alleged that there are significant entry barriers that protect the market for injectable insulin glargine. *See Sandoz, Inc. v. United Therapeutics, Corp.*, No. 3:19-CV-10170-BRM-LHG, 2020 WL 697137, at *12 (D.N.J. Feb. 4, 2020) ("Certainly it is a commonplace that the marketplace for pharmaceutical treatments has significant entry and expansion barriers."). The combined effect of Mylan asserting sufficient facts to allege that Sanofi had dominant market share in the relevant market of injectable insulin glargine products and that there were high barriers to enter that market is that the first element of a Sherman Section 2 violation has been plausibly pleaded.

2. Anticompetitive or Exclusionary Conduct

The conclusion that Mylan has adequately pleaded monopoly power is hardly the end of the inquiry. To survive the Motion to Dismiss the Sherman Section 2 claims, Mylan must also plausibly allege anticompetitive conduct through the willful acquisition or maintenance of monopoly power. *In re Lipitor Antitrust Litig.*, 855 F.3d 126, 147 (3d Cir. 2017), *as amended* (Apr. 19, 2017). "[A] firm engages in anticompetitive conduct when it attempts 'to exclude rivals on some basis other than efficiency,' or when it competes 'on some basis other than the merits.'" *W. Penn Allegheny Health Sys.*, 627 F.3d at 108 (first quoting *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 605 (1985); then quoting *LePage's Inc. v. 3M*, 324 F.3d 141, 147 (3d Cir. 2003)). But, as our Court of Appeals and other courts in this Circuit have noted, "there is no clear formula for what is unlawful anticompetitive behavior." *Castro v. Sanofi Pasteur Inc.*, No. 11-7178, 2012 WL 12516572, at *8 (D.N.J. Aug. 6, 2012) (citing *LePage's*, 324 F.3d at 152).

Mylan alleges that Sanofi engaged in a three-part monopolization scheme to improperly protect its insulin glargine products from generic competition. (ECF No. 1, ¶ 3). First, according to Mylan, Sanofi delayed FDA approval of generic and biosimilar competition "though a pattern of regulatory abuse" that involved improperly listing patents in the FDA's Orange Book and engaging in sham litigation. (*Id.*). Second, according to Mylan, "Sanofi wielded its Lantus market power to coerce payors to shift demand from Lantus to Toujeo" by conditioning rebates on Lantus on the inclusion of Toujeo by commercial formularies while at the same time marketing Toujeo to Lantus customers. (*Id.*). And third, once Toujeo achieved sufficient market shares, Sanofi allegedly used the same bundled rebates to protect Lantus from biosimilar competition. (*Id.*). Mylan urges the Court to view the alleged conduct cumulatively, as part of an overarching anticompetitive scheme.

Sanofi takes a different approach in advancing its dismissal Motion. It argues that, viewed individually, each of Mylan's theories of anticompetitive conduct fails. Given that each theory fails on its own, says Sanofi, Mylan cannot combine them to create a viable antitrust claim. Relevant case law favors Mylan's analytical approach.

The Supreme Court and our Court of Appeals have held that courts evaluating anticompetitive conduct must take a holistic view of defendants' conduct. *See, e.g.*, *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 and wiping the slate clean after scrutiny of each."). "The relevant inquiry," our Court of Appeals has counseled, "is the anticompetitive effect of [the defendant's] exclusionary practices considered together." *LePage's*, 324 F.3d at 162; *accord In re Suboxone (Buprenorphine Hydrochlorine & Naloxone) Antitrust Litig.*, 967 F.3d 264, 270 (3d Cir. 2020) ("[W]e look at all the acts taken together to determine whether they show the willful acquisition or maintenance of a monopoly." (cleaned up)). As such, independently lawful conduct may combine into an overarching illegal anticompetitive scheme. *See, e.g.*, *Am. Tobacco Co. v. United States*, 328 U.S. 781, 809 (1946) ("It is not of importance whether the means used to accomplish the unlawful objective are in themselves lawful. . . . [I]f they are part of the sum of the acts which are relied upon to effectuate the conspiracy which the state forbids, they come within its prohibition."); *accord In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 622 F. Supp. 3d 22, 61 (E.D. Pa. 2022) ("[T]he Third Circuit has explicitly recognized that independently lawful conduct — i.e., discount programs, rebates, exclusive dealing contracts — can have an anticompetitive effect that is actionable under antitrust law.").

However, as a practical matter, courts "have found that it is appropriate to consider the individual components of the scheme and whether those components can substantiate a claim of anticompetitive conduct on their own." *In re Revlimid & Thalomid Purchaser Antitrust Litig.*, No. CV 19-7532, 2024 WL 2861865, at *39 (D.N.J. June 6, 2024). The Supreme Court has also held that in certain circumstances plaintiffs cannot "alchemize" two legally deficient claims into a viable aggregate antitrust claim. *Pacific Bell Telephone Co. v. linkLine Communications, Inc.*, 555 U.S. 438, 457 (2009). "Two wrong claims," the Court has commented, "do not make one that is right." *Id.* For that reason, in the present case, the Court first evaluates the viability of each anticompetitive practice individually: the alleged regulatory abuse and sham litigation, product hop, and bundling schemes. Then, the Court evaluates the anticompetitive effect of Sanofi's cumulative conduct.

a. *Regulatory Abuse and Sham Litigation*

According to Mylan, the first prong of Sanofi's anticompetitive scheme was a campaign of regulatory abuse and sham litigation. According to Mylan, from 2011 to 2017, Sanofi amassed a "thicket" of patents that it improperly listed in the Orange Book. (ECF No. 1, ¶ 114). Mylan also alleges that Sanofi further delayed Mylan's entry into the injectable insulin glargine market by bringing a patent infringement action against Mylan in October 2017. (*Id.* ¶ 145). Sanofi argues that these claims fail because Mylan has not adequately pleaded causation, because they are time barred, and because Mylan does not plausibly plead that Sanofi's patent infringement action was objectively baseless. Because causation is tied to what Mylan is alleging to be its antitrust injury, the Court will discuss that later in this Opinion. Here, the Court addresses Sanofi's assertion that Mylan's claim is time barred and the question of whether Mylan adequately pleaded the nature of the New Jersey patent litigation as being "baseless."

The statute of limitations period for antitrust claims under the Sherman Act is four years. 15 U.S.C. § 15b. Since Mylan filed the instant lawsuit on May 17, 2023, its Sherman Act claims are time-barred unless their causes of action accrued after May 17, 2019. According to Sanofi, the listing of patents in the Orange Book and filing of the patent infringement suit occurred before May 2019. Mylan says not so fast, and contends that Sanofi's Orange Book abuse and sham litigation were part of an overarching anticompetitive scheme that extended into the limitations period. Mylan also argues that the limitation's period did not expire on its claims because it is not clear when Mylan could have learned about the extent and nature of its damages. Lastly, in a very cursory fashion, Mylan argues that the statute of limitations was tolled because Sanofi concealed its anticompetitive behavior.

Ordinarily, an antitrust claim accrues and the limitations period begins to run "when a defendant commits an act that injures a plaintiff's business." *Zenith Radio Corp. v. Hazeltine Rsch., Inc.*, 401 U.S. 321, 338 (1971). But there are times when injury is not immediately ascertainable. *Id.* at 339–40. In such cases, the statute of limitations begins to run once damages are inflicted and those damages are ascertainable. *Id.* at 338–39; *Cont'l-Wirt Elecs. Corp. v. Lancaster Glass Corp.*, 459 F.2d 768, 770 (3d Cir. 1972); *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, No. 13-MD-2445, 2017 WL 4910673, at *18 (E.D. Pa. Oct. 30, 2017) (noting that "the limitations period does not begin to run until the damages are inflicted and ascertainable" and that this generally means the statute of limitations defense cannot be decided in the context of a Rule 12 motion).

The relevant question is whether a plaintiff can discern the fact that they have been injured, not whether they can discern the amount of damages. *See Perrigo Co. v. AbbVie Inc.*, No. 21-3026, 2022 WL 2870152, at *5 (3d Cir. July 21, 2022). And while in the Third Circuit a defendant can

indeed raise the statute of limitations in a Rule 12 motion under what is known as the "Third Circuit rule," a court will only grant dismissal at the pleadings stage on statute of limitations grounds if it is apparent on the face of the complaint that the claim is time-barred as a matter of law. *Robinson v. Johnson*, 313 F.3d 128, 135 (3d Cir. 2002). In the present case, the Court cannot conclusively hold that based on the pleadings of record, Mylan's claims are barred by the statute of limitations, but Sanofi is of course not barred from raising and litigating this defense in later proceedings in this case. *See In re Suboxone*, No. 13-MD-2445, 2017 WL 4910673, at *18.

It is also not clear on the face of the Complaint when Mylan's injury was ascertainable. Mylan alleges that it was injured because Sanofi delayed Semglee's market entry. Accordingly, in this analytical lane, Mylan's injury was ascertainable — and Mylan's claim accrued — only when Mylan could discern that Sanofi's conduct had allegedly caused the delay. When Sanofi added patents to the Orange Book or filed its patent infringement action in 2017, it may not have been clear that such conduct was allegedly anticompetitive or would cause additional delay to Mylan's entry to the market. When Sanofi triggered the thirty-month stay in 2017, it may not have been clear that, but for the stay, Mylan may have secured FDA approval sooner. *See Azurity Pharms., Inc. v. Bionpharma Inc.*, 650 F. Supp. 3d 269, 277 (D. Del. 2023). Because it is not conclusively apparent on the face of Mylan's Complaint that its claims are time-barred, *Robinson*, 313 F.3d at 135, the Court should not grant Sanofi's Motion to Dismiss on this basis.

Next, Sanofi raises the defense of the *Noerr-Pennington* doctrine, asserting that Mylan has not adequately alleged that Sanofi's 2017 infringement action was a sham. (ECF No. 50, at 31–32). Mylan responds that it need not demonstrate that Sanofi's infringement suit was a sham because Sanofi engaged in "*serial* petitioning," which is assessed using a different standard than *Noerr-Pennington*. (ECF No. 59, at 21–22). Mylan also argues that determining whether *Noerr-*

Pennington applies is fact-intensive, so the issue is not suitable for resolution on the pleadings, at least not in this case. (*Id.* at 23–24).

The *Noerr-Pennington* doctrine provides that "a party who petitions the government for redress generally is immune from antitrust liability." *Perrigo*, No. 21-3026, 2022 WL 2870152, at *3 (quoting *Cheminor Drugs, Ltd. v. Ethyl Corp.*, 168 F.3d 119, 122 (3d Cir. 1999)). But *Noerr-Pennington* immunity is not absolute. "Activity ostensibly directed toward influencing governmental action does not qualify for First Amendment immunity if it is a mere sham to cover an attempt to interfere directly with the business relationships of a competitor." *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 148 (3d Cir. 2017).

In general, a lawsuit can only be characterized as a sham if it is (1) objectively baseless and (2) motivated by a subjective attempt to directly interfere with a competitor. *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 272 (3d Cir. 2017). A lawsuit is objectively baseless if "no reasonable litigant could realistically expect success on the merits." *Id.* (citation omitted). If an antitrust plaintiff has "probable cause to institute legal proceedings," a court is precluded from finding that the defendant has engaged in sham litigation as to those proceedings. *Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc.* ("*PRE*"), 508 U.S. 49, 62 (1993). Courts may inquire into the litigant's subjective intent "[o]nly if [the] challenged litigation is objectively meritless." *Id.* at 60. In other words, courts must conclude that the record establishes that the first prong of the exception exists — that the litigation was objectively baseless — before proceeding to the second prong.

When a litigant engages in what has become known as "serial petitioning," however, courts apply a more flexible test than the two-prong "sham litigation" test. *Hanover 3201 Realty, LLC v. Vill. Supermarkets, Inc.*, 806 F.3d 162, 180 (3d Cir. 2015). Serial petitioning is the allegation that

a party filed "a series of legal proceedings . . . . without regard to merit and for the purpose of using the governmental process (as opposed to the outcome of that process) to harm a market rival and restrain trade." *Id.* Mylan contends that the serial petition standard should apply here because, even though Sanofi brought only one lawsuit, Sanofi asserted eighteen causes of action against Mylan and because Sanofi "continued to advance its validity arguments in separate *inter partes* review proceedings before the Federal Circuit for several patents." (ECF No. 59, at 23).

The Court concludes that the serial petitioning standard does not apply in this case, but that it also cannot resolve, at this stage, whether Sanofi engaged in "sham litigation." First, Mylan cannot rely on the proceedings in front of PTAB and the Federal Circuit concerning the Orange Book listings because those proceedings were initiated by Mylan, not Sanofi, when Mylan submitted notice letters to Sanofi regarding twenty-one of Sanofi's patents. (ECF No. 1, ¶ 5). Sanofi only actually *initiated* one lawsuit against Mylan, the one brought in the District of New Jersey. (*Id.* ¶ 145). The Third Circuit has rejected the contention that two lawsuits constitute serial petitioning, much less one. "The test for serial petitioning . . . explicitly applies to a series of legal proceedings or a pattern of petitioning, and two proceedings . . . does not constitute a pattern.'" *In re Wellbutrin*, 868 F.3d at 157 (citation omitted). In line with that precedent, Mylan's contention that multiple causes of action in a single petition should be construed as serial petitioning for *Noerr-Pennington* purposes does not cut the mustard for these purposes.

Mylan must therefore plausibly plead that the 2017 lawsuit was objectively baseless to survive the application of *Noerr-Pennington*. Mylan's allegations about "sham" infringement litigation boil down to:

1) allegations that the patent litigation "was brought without any reasonable chance at prevailing," (ECF No. 1 ¶142);
2) allegations that Mylan explained its positions with respect to Sanofi's patents when it sent its paragraph IV certification, (*id.* ¶ 144);

3) allegations that the patents in question were invalid, (*see, e.g.*, *id.* ¶ 148);
4) allegations that almost all of Mylan's challenges to Sanofi's patents through *inter partes* reviews were successful, (*id.* ¶ 143);
5) allegations that the PTAB and the Federal Circuit ultimately held that the patents were invalid, (*see, e.g.*, *id.* ¶ 153);
6) allegations that the patents were improperly listed in the Orange Book, (*see, e.g.*, *id.* ¶ 149);
7) allegations that Sanofi granted Mylan covenants not to sue for a number of its patents, (*id.* ¶ 147).

Without more, the above assertions could amount to little more than a claim that Sanofi's underlying patent case in the District of New Jersey was unsuccessful. *See PRE*, 508 U.S. at 60 n.5 ("When the antitrust defendant has lost the underlying litigation, a court must resist the understandable temptation to engage in *post hoc* reasoning by concluding that an ultimately unsuccessful action must have been unreasonable or without foundation." (cleaned up)); *In re Wellbutrin*, 868 F.3d at 148 ("[T]he essential question is not whether the suit succeeds, but whether the suit was a sham at the time it was filed."). But, plausibly, such assertions upon further development could lead to more. Considering the overarching standard in this Circuit for resolving motions to dismiss, the Court is to consider whether further factual development via discovery is appropriate to determine whether the litigation was in fact objectively baseless and motivated by anticompetitive intent. The Court concludes that it is.

Beyond all of that, the Court agrees with a sister court long and well experienced in litigation of just this sort that the application of *Noerr-Pennington* is "generally not suitable for resolution at the pleading stage." *Indivior Inc. v. Dr. Reddy's Lab'ys S.A.*, No. CV177106KMCLW, 2020 WL 4932547, at *8 (D.N.J. Aug. 24, 2020). Sanofi's Motion to Dismiss Mylan's claims of anticompetitive conduct premised on sham litigation and regulatory abuse arguments will not carry the day, at least not at the moment.

b. *Product Hop*

According to Mylan, the second prong of Sanofi's anticompetitive scheme was a coercive "product hop" or "market switch." Mylan asserts that Sanofi engaged in coercive tactics to switch the injectable insulin glargine market from Lantus (for which Sanofi expected it would lose exclusivity by 2017) to the therapeutically indistinguishable Toujeo. (ECF No. 1, ¶ 9). Sanofi allegedly effectuated this plan for PBMs "to steer prescribers and patients away from Lantus and to Toujeo." (*Id.* ¶ 11). Sanofi priced Toujeo at parity with Lantus and conditioned rebates for Lantus on the inclusion of Toujeo on PBM formularies. (*Id.*). At the same time, Sanofi allegedly engaged in a "marketing blitz," spending "millions [of dollars] to market Toujeo to patients and doctors and mostly stopped promoting Lantus." (*Id.* ¶ 207).

Sanofi argues that Mylan's "product hop" claim fails because Mylan insufficiently alleges that Sanofi actually withdrew Lantus from the market, and this, says Sanofi, is a prerequisite for a product hop claim. (ECF No. 50, at 18). Mylan responds that a product hop claim does not require compete withdrawal of the first product from the market. Rather, Mylan argues, "[w]hat is required is some form of coercion that constrains the free choice of consumers," not a "hard switch." (ECF No. 59, at 30). While the Court agrees with Mylan that product withdrawal is not required, the Court concludes that Mylan has not adequately alleged that Sanofi *coerced* consumers to switch from Lantus to Toujeo.

"As a general rule, courts are properly very skeptical about claims that competition has been harmed by a dominant firm's product design changes." *Microsoft Corp.*, 253 F.3d at 65. Far from stifling competition, innovation and the accompanying introduction of new products is a principal mechanism of competition. *Id.* That said, in certain circumstances, a product redesign

may be anticompetitive. *New York ex rel. Schneiderman v. Actavis PLC* ("*Namenda*"), 787 F.3d 638, 652 (2d Cir. 2015). A "product hop" is one such circumstance.

"'Product hopping' is 'conduct by a monopolist to perpetuate patent exclusivity through successive products.'" *Blue Cross & Blue Shield of Vermont v. Teva Pharm. Indus., Ltd.*, 712 F. Supp. 3d 499, 520 (D. Vt. 2024) (quoting *Namenda*, 787 F.3d at 643). Federal patent law is designed to give patent holders a lawful temporary monopoly on individual drugs, but it is not meant to give patent holders "a right to use their patents as part of a scheme to interfere with competition 'beyond the limits of the patent monopoly.'" *Namenda*, 787 F.3d at 660 (quoting *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948)). In a product hop, a monopolist facing imminent generic competition will introduce a new but similar product. It will then coerce its existing customer base to switch to the new product, which often has an extended exclusivity period. *See Namenda*, 787 F.3d at 653–58. This hinders generic competition by preventing automatic substitution.

There is also often a high cost to consumers switching from the monopolist's second-generation proprietary drug to a first-generation generic drug. *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 683–84 (E.D. Pa. 2014). The most obvious way a monopolist can coerce its customers to switch from one product to the other is by withdrawing the former product from the market before generic entry. *Namenda*, 787 F.3d at 654. Where there is no meaningful alternative to the monopolist's first-generation drug, customers are forced to switch to the newer product. But customer coercion may also take subtler forms. "The key question is whether the defendant combined the introduction of a new product with some other wrongful conduct, such that the comprehensive effect is likely to stymie competition, prevent consumer choice and reduce the market's ambit." *In re Suboxone*, 64 F. Supp. 3d at 682.

Here, Mylan does not adequately allege that Sanofi "coerced" customers to switch from Lantus to Toujeo. Mylan alleges that Sanofi priced the two drugs at parity, required PBMs to place both drugs on their formularies, aggressively marketed Toujeo, and, for the most part, stopped marketing Lantus. But none of these actions necessarily cross the line from permissible persuasion to impermissible coercion. Customers remained free to choose either product. Mylan does not allege that Sanofi pulled Lantus off the market, *Namenda*, 787 F.3d at 654-55, threatened to pull it off the market, *In re Suboxone*, 64 F. Supp. 3d at 682, or increased the price of Lantus, *Blue Cross & Blue Shield of Vermont*, 712 F. Supp. 3d at 520. Rather, Mylan alleges that Sanofi made both products available to PBMs and tried to persuade them to buy Toujeo. Accordingly, when viewed in isolation, Mylan's product hopping allegations do not amount to anticompetitive conduct.

As stated above, while "simply introducing a new product on the market, whether it is a superior product or not, does not, by itself, constitute exclusionary conduct[,] [t]he key question is whether the defendant *combined* the introduction of a new product with some other wrongful conduct, such that the comprehensive effect is likely to stymie competition." *In re Suboxone*, 64 F. Supp. 3d at 682 (emphasis added). Accordingly, as currently pleaded, the Court will allow Mylan's product hop allegation to proceed only as a subpart of Mylan's *aggregate* theory of Sanofi's allegedly anticompetitive conduct. As a standalone claim of anticompetitive conduct, Mylan's product hop theory does not pass muster on the state of the papers before the Court. That being said, the Third Circuit has instructed courts that "if a complaint is vulnerable to 12(b)(6) dismissal, a district court must permit a curative amendment, unless an amendment would be inequitable or futile." *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 236 (3d Cir. 2008). The Court

will therefore grant Sanofi's motion to dismiss Mylan's "product hop" allegation but without prejudice, and will give Mylan a period of 30 days to amend if it elects to do so.

c. *Bundled Rebates*

Finally, Mylan claims that Sanofi acted deliberately to create a monopoly over the injectable insulin glargine market by conditioning discounts for Lantus and Toujeo on the purchase of both — in its words, "depriv[ing] Mylan of the sales and profits it would have realized had Sanofi not illegally tied rebates between its two insulin glargine products." (ECF No. 1, ¶ 228). According to Sanofi, "Mylan's theory boils down to allegations of exclusive dealing based on 'bundled rebates.'" (ECF No. 50, at 12).

Exclusive dealing, bundling, and unlawful tying are overlapping legal theories of anticompetitive conduct. Each of these arrangements can, in some circumstances, constitute antitrust violations; in other circumstances, each of these arrangements are perfectly legal and procompetitive. Sanofi urges the Court to analyze its bundling practices under the price-cost test of the exclusive dealing doctrine. (*Id.* at 14). Mylan urges the Court to analyze Sanofi's bundling under the theory of the unlawful practice of tying. (ECF No. 59, at 25).

Bundled rebates could be a vehicle of exclusive dealing *or* of unlawful tying. "Bundling is the practice of offering, for a single price, two or more goods or services that could be sold separately." *Eisai*, 821 F.3d at 405 n.32 (quoting *Cascade Health Sols. v. PeaceHealth*, 515 F.3d 883, 894 (9th Cir. 2008)). Not all bundling practices are exclusive dealing arrangements or unlawful tying; some bundled rebates may not require that a buyer purchases products exclusively from a single seller.

"An exclusive dealing arrangement is an agreement in which a buyer agrees to purchase certain goods or services only from a particular seller for a certain period of time." *ZF Meritor,*

LLC v. Eaton Corp., 696 F.3d 254, 270 (3d Cir. 2012). In general, these arrangements "pose little threat to competition." *Id.* Such arrangements become problematic under antitrust law when they "foreclose rival suppliers from a large enough portion of the market to deprive such rivals of the opportunity to achieve the minimum economies of scale necessary to compete." *Id.* at 271.

Unlawful tying, for its part, arises in certain circumstances when a seller markets and sells a product that is conditioned on the buyer purchasing a second, "tied" product. *N. Pacific Ry. v. United States*, 356 U.S. 1, 5 (1958). Not all tying arrangements constitute antitrust violations. *Illinois Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28, 36–37 (2006). For that reason, exclusive dealing arrangements are "judged under the rule of reason," which requires courts to assess "the likely or actual anticompetitive effects of the exclusive dealing arrangement, including whether there was reduced output, increased price, or reduced quality in goods or services." *Eisai*, 82 F.3d at 403. In some cases, courts have required the plaintiff to show that the defendant had the economic power to restrain competition in the product market and that a non-negligible amount of the relevant commerce was affected for the exclusive dealing arrangement to be considered unlawful tying. *SmithKline*, 575 F.2d at 1061 n.3.

Sanofi contends that its alleged conduct cannot constitute unlawful tying because unlawful tying "cannot exist unless two separate product markets have been linked," (ECF No. 50, at 13 (quoting *ZF Meritor*, 696 F.3d at 274 n.11)), and Lantus and Toujeo were part of the *same* product market. Sanofi asserts that its alleged bundling practices should be assessed under the price-cost test of the exclusive dealing doctrine, which is one of the two antitrust tests associated with exclusive dealing arrangements. The default antitrust test for exclusive dealing arrangements is the

rule of reason test.[11] The price-cost test applies when pricing is the predominant exclusionary conduct alleged.[12] At this stage, the Court believes that it is improvident to determine if or whether the price-cost test or the rule of reason test apply instead of Mylan's proffered theory because, accepting the facts asserted in Mylan's Complaint as true, Mylan satisfies the Third Circuit's test for plausibly alleging unlawful tying.

Although other Courts of Appeals have "stricter formulation[s]" regarding when bundled discounts constitute anticompetitive conduct, the Third Circuit has broadly held that plaintiffs can show that bundled discounts constitute anticompetitive conduct when such discounts "'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.'" *Regeneron Pharms., Inc. v. Amgen Inc.*, No. CV 22-697-RGA-JLH, 2023 WL 1927544, at *6 (D. Del. Feb. 10, 2023) (quoting *LePage's*, 324 F.3d at 155). Plausibly alleging that bundling constitutes an unlawful tying scheme involves a showing that "(1) a defendant seller tied two distinct products, conditioning sale of one product on the purchase of a different tied product; (2) the seller possesses market power in the tying product market; and (3) a substantial amount of interstate commerce is affected." *Marchese v. Cablevision Sys. Corp.*, No. CIV.A. 10-2190 JLL, 2012 WL 78205, at *2 (D.N.J. Jan. 9, 2012) (citing Town Sound, 959 F.2d at 477).

Mylan plausibly asserts facts that meet that threshold. First, Mylan makes several allegations of bundled contracts between Sanofi and PBMs to purchase Lantus and Toujeo at a

[11] The rule of reason requires courts to "consider not only the percentage of the market foreclosed, but also take into account 'the restrictiveness and the economic usefulness of the challenged practice in relation to the business factors extant in the market.'" *ZF Meritor*, 696 F.3d at 271 (citation omitted).

[12] Under the price-cost test, Sanofi asserts that its conduct would not constitute an antitrust violation because it priced Lantus and Toujeo *above* cost. (ECF No. 50, at 16). "[W]hen price is the clearly predominant mechanism of exclusion, the price-cost test tells us that, so long as the price is above-cost, the procompetitive justifications for, and the benefits of, lowering prices far outweigh any potential anticompetitive effects." *ZF Meritor*, 696 F.3d at 275.

reduced price, conditioning those reduced prices on the purchase of both at the exclusion of biosimilar insulin glargine products. (ECF No. 1, ¶¶ 11, 17). Mylan specifically alleges that those agreements required buyers to purchase Lantus and Toujeo or else rebates on *both* products would be reduced. Second, Mylan repeatedly alleges that Sanofi had market power of the insulin glargine market. (*See, e.g., id.* ¶ 199 (citing Sanofi's internal drug pricing documents); *id.* ¶¶ 212–22; *see also* discussion above on market power). And third, the Complaint discusses the alleged effect of Sanofi's anticompetitive scheme on interstate commerce. (*See, e.g.*, *id.* ¶ 226 ("Sanofi's anticompetitive scheme has harmed the competitive process and allowed Sanofi to perpetuate supracompetitive prices against wholesalers, retailers, payers, and consumers. But for Sanofi's anticompetitive conduct, consumers and federal, state, and private payers would have enjoyed the benefits of lower-priced 'generic' or biosimilar competition years earlier.")).

The relevant caselaw supports the notion that district courts routinely allow this type of claim to survive at the pleading stage. *See, e.g.*, *UniStrip Techs., LLC v. LifeScan, Inc.*, 153 F. Supp. 3d 728, 741 (E.D. Pa. 2015) (holding that the plaintiff sufficiently pled a plausible claim against the defendant with regard to an alleged illegal bundling arrangement and denying defendant's motion to dismiss); *In re Remicade Antitrust Litig.*, 345 F. Supp. 3d 566, 577–78 (E.D. Pa. 2018) (finding that the plaintiff's complaint sufficiently alleged anticompetitive conduct in the form of allegations that the defendant's contracts and rebate bundles made it impossible for competitors to compete); *Castro*, No. 11-7178, 2012 WL 12516572, at *9–10 (holding that the plaintiff's claim against the defendant regarding its bundled rebate scheme survived a motion to dismiss). In line with those decisions, the Court denies Sanofi's Motion to Dismiss Mylan's claims on the basis that the bundled rebates were lawful as a matter of law.

d. *Aggregate Anticompetitive Scheme*

The Court has concluded that Mylan has alleged viable theories of anticompetitive conduct based on individual tactics of Sanofi, namely via alleged regulatory abuse and rebate bundling. Given the individual sufficiency of these practices to establish plausible Sherman Section 2 violations, it follows, at least in this context, that the aggregate conduct of the firm satisfies the pleading standard as well.

In its Complaint, Mylan alleges that Sanofi engaged in an overarching scheme to delay Mylan's entry into the market for injectable insulin glargine, and then to diminish uptake once Mylan entered. Mylan plausibly alleges that Sanofi delayed Mylan's market entry by delaying the time frame for FDA approval of Semglee. Mylan alleges that Sanofi did so by improperly listing patents in the Orange Book and allegedly initiating sham litigation, which altered Mylan's decision-making and triggered a thirty-month stay on the FDA approval process. Mylan also sufficiently pleads that Sanofi's bundled rebate scheme constituted unlawful tying.

As noted above, Mylan can assert its product hop theory as a component of an aggregate allegation of anticompetitive conduct (as opposed to it being a standalone basis for liability as things now stand). Mylan alleges that Sanofi introduced Toujeo, a follow-on product to Lantus, to strategically transition consumers from Lantus to Toujeo after Sanofi's period of lawful patent exclusivity ended. While the Court has determined that, independently, the product hop strategy was not anticompetitive as pled, when viewed in light of the other practices alleged by Mylan, it worsens the picture for Sanofi. Mylan alleges that Sanofi entered into *de facto* exclusive dealing arrangements by conditioning rebates on Toujeo and Lantus on the inclusion of both on PBM formularies. Mylan alleges that, functionally, this made rebates on Toujeo and Lantus conditional on the exclusion of generic insulin glargine products like Mylan's. It is adequately asserted that

these bundled or conditioned rebates successfully excluded Mylan from the market, as Mylan was not able to make meaningful sales until a year after market entrance, and that these practices also harmed the competitive process because customers did not have access to a generic alternative to Lantus.

Read holistically, the Complaint plausibly alleges that Sanofi engaged in a multi-part scheme to "exclude rivals on some basis other than efficiency" and compete "on some basis other than the merits." *W. Penn Allegheny Health Sys., Inc*, 627 F.3d at 108 (citations omitted).

3. Antitrust Injury

In antitrust actions, the plaintiff must plead and then establish an antitrust injury, which is an injury that (1) is "of the type the antitrust laws were intended to prevent and (2) [] flows from that which makes defendants' acts unlawful." *A.D. Bedell Wholesale Co. v. Philip Morris Inc.*, 263 F.3d 239, 247 (3d Cir. 2001) (quoting *Brunswick Corp. v. Pueblo Bowl-O-Mat*, 429 U.S. 477, 489 (1977)). It is not enough for the antitrust injury to be "causally linked" to the defendant's behavior. Rather, the alleged antitrust injury must be "the type of loss that the claimed violations . . . would be likely to cause." *Brunswick*, 429 U.S. at 489 (quoting *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 125 (1969)). The plaintiff "need not allege proximate cause or antitrust injury separately for each component of the alleged scheme . . . [rather] [t]he injuries inflicted by [the defendant's] allegedly anticompetitive activities should, instead, be viewed as a whole." *In re Suboxone*, No. 13-MD-2445, 2017 WL 4910673, at *11 (citation omitted).

The plaintiff also need not allege that the defendant's actions were the *only* cause of its injury, nor must the plaintiff discredit all possible intervening causes. *Id.* Rather, the plaintiff need only show that the defendant's actions are a "material cause" of the alleged injury. *Id*. (quoting *Zenith*, 395 U.S. at 114 n.9). Given the fact intensive nature of this analysis, antitrust injury and

causation are rarely resolved at the pleading stage. *Brader v. Allegheny Gen. Hosp.*, 64 F.3d 869, 876 (3d Cir. 1995). The Court will stick to that general principle here.

The Court concludes that Mylan has adequately pleaded that Sanofi's conduct caused antitrust injury to Mylan. Mylan generally asserts that Sanofi's conduct resulted in the delay of Mylan entering the injectable insulin glargine market, which cost both Mylan and consumers significant sums of money. For one, Mylan has adequately pleaded that Sanofi's Orange Book practices caused an antitrust injury in the form of the delay in getting its product to market. Mylan asserts that Sanofi's slew of new patents, including its injector pen patents, forced Mylan to contend with an assured 30-month delay beginning in late 2013, (ECF No. 1, ¶¶ 126–29); many of those patents were later dismissed as invalid for obviousness or unpatentability, (*id.* ¶¶ 148–184); and the FDA "would have approved Mylan's product more quickly in the absence of the 30-month stay," (*id.* ¶ 193). As a result, Mylan alleges, Mylan changed its conduct. Instead of immediately seeking FDA approval, Mylan sought guidance from the FDA about which pathway was proper so that, in the event of a thirty month stay, their efforts would not be for naught. In other words, they allege that Sanofi's allegedly improper conduct shaped their own decision-making, which resulted in the injury of the delay in getting their product to market.

Sanofi says that it is "absurd[]," (ECF No. 50, at 26), and "nonsensical," (ECF No. 66, at 18), for Mylan to blame Sanofi for the delay in getting Semglee to market. According to Sanofi, Mylan's own actions caused it to delay its application until 2017, and Mylan delayed its application to take advantage of "the cheaper and faster ANDA [Abbreviated New Drug Application] route." (ECF No. 50, at 26–27). According to Sanofi, "[it] was this negotiation with FDA — not Sanofi's patents — that delayed Mylan's filing of its Semglee 505(b)(2) application until 2017." (*Id.* at 27).

Perhaps. But perhaps not. As the FTC states in its *amicus* brief, "an improper [patent] listing may work a more subtle harm by deterring potential competitors or distorting their decision-making." (ECF No. 64, at 15). Taking the allegations in the Complaint as true, Sanofi's Orange Book listings were more like a cocked fist: any would-be competitor knew they would face a thirty-month delay in the FDA-approval process after application. Rather than be struck unprepared, it is plausible at this stage that Mylan attempted to mitigate the effect of that thirty-month stay by engaging in extensive pre-filing negotiation with the FDA. The decision to engage in such negotiations plausibly could have been in part or in full based on Mylan's knowledge of the guaranteed 30-month stay. None of that reasoning strikes the Court as absurd or nonsensical. There is nothing implausible about the allegation that "a legal prohibition on the FDA granting final approval would delay launch of the product." *Azurity Pharms., Inc. v. Bionpharma Inc.*, 650 F. Supp. 3d 269, 279 (D. Del. 2023) ("[The] allegation that the 30-month stay delayed [market] entry must be accepted as true at the pleadings stage.").

Sanofi also argues that "Mylan's delay from 2013 to 2017 is entirely irrelevant because FDA rejected the application in 2017" and subsequently denied approval again in 2018 and 2019. (ECF No. 66, at 18). But the operative question is whether Sanofi's conduct delayed Mylan's market entry — that is, whether Mylan would have been able to enter the market sooner absent Sanofi's conduct. As discussed above, Mylan plausibly pleads that Sanofi's Orange Book practices caused Mylan to delay submitting its application for Semglee and that its other conduct delayed Mylan achieving market success. *Accord In re Suboxone*, No. 13-MD-2445, 2017 WL 4910673, at *11 (concluding that the plaintiff need not "completely discredit in its initial pleadings all possible intervening causes" of its injury (citation omitted)). Even if there were other deficiencies with Mylan's application, it is still plausible that Mylan would have been able to enter the market

sooner *but for* Sanofi's practices. Mylan's failure to discredit intervening causes of its delay to enter the market does not require a contrary conclusion. *In re Neurontin Antitrust Litig.*, No. 02-1390, 2009 WL 2751029, at *12 (D.N.J. Aug. 28, 2009) ("Nor are Plaintiffs required at this stage of the proceeding to adduce proofs discrediting all possible intervening causes of the delayed launch of generic products, such as the failure to obtain tentative generic approval from the FDA before the expiration of the 30-month stays at issue.").

In the absence of the 30-month stay, Mylan may well have acted differently. Where a 30-month stay has been triggered, "generic manufacturers have had little practical incentive to pursue even conditional agency approval." *Bristol-Myers Squibb Co. v. Ben Venue Lab'ys*, 90 F. Supp. 2d 540, 545 (D.N.J. 2000). "[B]ecause FDA approval would be meaningless in the absence of a favorable court ruling on infringement or validity, the generic companies are better served to direct their resources toward defense of the infringement action." *Id.*; *accord In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 757 (E.D. Pa. 2003). Similarly, the stay may well have affected the FDA's processing of Mylan's application. *See Blue Cross & Blue Shield of Vermont v. Teva Pharm. Indus., Ltd.*, 712 F. Supp. 3d 499, 534 (D. Vt. 2024) ("[I]t is reasonable to infer that the stay resulting from the patent infringement litigation led the FDA to divert its resources away from' Sandoz's 20 mg ANDA." (citation omitted)).

Sanofi's proposed intervening cause — Mylan's lack of FDA approval between 2013 and 2017 — does not necessarily break the causal chain between Sanofi's conduct and Semglee's delayed entry because, viewing the Complaint in the light most favorable to Mylan, the FDA's non-approval of Semglee during this period may still not have been independent of Sanofi's conduct. *See In re Flonase Antitrust Litig.*, 798 F. Supp. 2d 619, 629 (E.D. Pa. 2011) ("Intervening conduct does not sever the chain of causation, however, where that conduct was in turn

proximately caused by the defendant's antitrust violation."); *In re Suboxone*, No. 13-MD-2445, 2017 WL 4910673, at *13. For these reasons, and consonant with the Third Circuit's repeated observation that "the existence of antitrust injury is not typically resolved through motions to dismiss," *Schuylkill Energy Res., Inc. v. Pennsylvania Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997), the Court concludes that Mylan has adequately pleaded antitrust injury to survive the Motion to Dismiss.

In sum, the Complaint adequately alleges that Sanofi has monopoly power in the market for injectable insulin glargine and that it has maintained this monopoly through exclusionary conduct. *See Broadcom*, 501 F.3d at 306–08. Accordingly, the Court concludes that Mylan has adequately alleged its claims under Section 2 of the Sherman Act. Sanofi's Motion to Dismiss Counts I and II will be denied.

B. Counts III and IV: Clayton Act § 3 and New Jersey Antitrust Act

The parties appear to agree that Mylan's claims under Section 3 of the Clayton Act and the New Jersey Antitrust Act should be analyzed under the same standards as its claims under Section 2 of the Sherman Act. In its Motion, Sanofi states that, for all of the reasons stated throughout the section analyzing the Complaint under the Sherman Act, the Complaint also fails to state a claim under the Clayton Act under which the applicable law is the same as under Section 2 of the Sherman Act. (ECF No. 50, at 25 (citing *Eisai*, 821 F.3d at 402 & n.11)). And as to Mylan's claim under New Jersey state law, Sanofi concedes that New Jersey courts "follow federal antitrust law in interpreting [New Jersey's] antitrust statute." (*Id.* at 35 (quoting *Sickles v. Cabot Corp.*, 877 A.2d 267, 270-71 (N.J. Super. Ct. App. Div. 2005))). In its response, Mylan simply states that "Mylan's exclusive dealing claims, New Jersey Antitrust Act claims, and Section 3 of the Clayton

Act claims survive for the same reasons Mylan's Sherman Act Section 2 claims survive." (ECF No. 59, at 41).

The relevant caselaw supports the parties' understanding that the applicable law is the substantively the same for Mylan's claims under the Sherman Act, Clayton Act, and New Jersey Antitrust Act. *See, e.g.*, *Eisai*, 821 F.3d at 402 n.11 (stating that the applicable law is the same for claims under the Sherman Act, Clayton Act, and New Jersey Antitrust Act); *ZF Meritor*, 696 F.3d at 269 n.9 (analyzing claims under Sections 1 and 2 of the Sherman Act and Section 3 of the Clayton Act under same framework); *State v. N.J. Trade Waste Ass'n*, 472 A.2d 1050, 1056 (N.J. 1984) ("[T]he New Jersey Antitrust Act shall be construed in harmony with ruling judicial interpretations of comparable federal antitrust statutes."). As such, Sanofi's Motion to Dismiss Mylan's Clayton Act and New Jersey Antitrust Act claims is also denied consistent with the analysis set forth above.

C. Count V: State Law Tortious Inducement of Refusal to Deal

The final count of Mylan's complaint charges Sanofi with "tortious inducement of refusal to deal." (ECF No. 1, ¶ 257). The parties assume that Pennsylvania substantive law applies as to this claim, and the Court sees no reason to differ. (ECF No. 50, at 35; ECF No. 59, at 41–42). Under Pennsylvania law, "[t]he tort of inducing . . . refusal to deal is defined as inducing or otherwise causing a third person . . . not to enter into or continue a business relation with another, without a privilege to do so." *Glazer v. Chandler*, 200 A.2d 416, 418 (Pa. 1964). To prevail at trial, the plaintiff must prove the following:

1) the existence of a prospective contractual relationship between the plaintiff and a third party;

2) improper action by the defendant that is specifically intended to prevent a prospective relationship from occurring;

3) the absence of privilege or justification for the defendant's actions; and

4) actual damage flowing from the defendant's conduct.

Advent Sys. Ltd. v. Unisys Corp., 925 F.2d 670, 673 (3d Cir. 1991); *McLaughlin v. Int'l Bhd. of Teamsters, Loc. 249*, 641 F. Supp. 3d 177, 220 (W.D. Pa. 2022). Sanofi argues that Mylan has not adequately alleged the requisite prospective contractual relationships. (ECF No. 50, at 35–36; ECF No. 66, at 21–22).

The term "prospective contractual relation[s]" has an "evasive quality, eluding precise definition." *Thompson Coal Co. v. Pike Coal Co.*, 412 A.2d 466, 471 (Pa. 1979). The Pennsylvania Supreme Court has defined the term — admittedly ambiguously — as "something less than a contractual right, something more than a mere hope." *Id.* Our Court of Appeals has held that a prospective contract "exists if there is a reasonable probability that a contract will arise from the parties' current dealings." *Alvord-Polk, Inc. v. F. Schumacher & Co.*, 37 F.3d 996, 1015 (3d Cir. 1994). Due to the ambiguous definitions, it is unsurprising that "district courts have struggled to articulate clear standards for what plaintiffs must allege on this claim to satisfy their pleading obligations under *Twombly* and *Iqbal*." *Wurth Baer Supply Co. v. Strouse*, 627 F. Supp. 3d 422, 435 (M.D. Pa. 2022).

That uncertainty notwithstanding, lower courts have tended to agree that "the complaint need not allege with certainty particular potential contractual relationships that would in fact have been consummated in the absence of defendant's wrongful conduct." *Advanced Power Sys., Inc. v. Hi-Tech Sys., Inc.*, No. CIV. 90-7952, 1992 WL 97826, at *11 (E.D. Pa. Apr. 30, 1992). Other courts in this Circuit have also held that plaintiffs need not list "specific contracts which it alleges

have been harmed" in order to make out a claim of tortious inducement of refusal to deal at the pleading stage, as doing so would be "an extreme and unnecessary burden." *E. Frank Hopkins Seafood, Co. v. Olizi*, No. 2:17-CV-01558-JCJ, 2017 WL 2619000, at *3 (E.D. Pa. June 16, 2017); *see also Wurth Baer Supply Co. v. Strouse*, 627 F. Supp. 3d 422, 436 (M.D. Pa. 2022) ("[F]or tortious interference with prospective contractual relations claims, a plaintiff's failure to identify a potential contractual partner by name does not necessitate dismissal; the claim may proceed if supported by specific allegations about the universe of prospective counterparties and predicate actions indicating interference.").

Here, the Court concludes that Mylan has adequately pleaded the existence of prospective contractual relationships. Mylan alleges — plausibly — that Sanofi's rebating practices kept Semglee off commercial formularies and out of reach of "thousands of purchasers, pharmacies, and diabetic patients across the country." (ECF No. 1, ¶ 258). Mylan alleges that, if offered the choice, some purchasers would have chosen Semglee. (*Id.*). And this allegation is plausible because Mylan alleges that Semglee was nearly identical to, but less expensive than, Sanofi's drug Lantus, (*see id.* ¶¶ 3, 13, 15), and because Mylan alleges that "the launch of a generic product can result in the rapid shift of purchasers from brand to generic," (*id.* ¶ 81). Reading these allegations together, Mylan has plausibly alleged that there is "a 'reasonable probability' that a contract would have arisen absent [Sanofi's] interference." *Sandoz Inc. v. Lannett Co., Inc.*, 544 F. Supp. 3d 505, 512 (E.D. Pa. 2021) (citation omitted).

Therefore, the Court will deny Sanofi's Motion with respect to Count V.

V. Conclusion

For the reasons stated above, the Court concludes the following:

- Sanofi's Motion to Dismiss on the basis of shotgun pleading is DENIED.

- There shall be a period of jurisdictional discovery of 120 days concerning Sanofi's contention that the Court lacks personal jurisdiction over Sanofi S.A. Disposition of that contention, for the period of jurisdictional discovery, shall be HELD IN ABEYANCE.
- The Court DENIES Sanofi's Motion to Dismiss the Complaint on all grounds except as applied to Mylan's allegation of a Sherman Section 2 violation based solely on a "product hop" theory. As to that specific argument, the Motion is GRANTED WITHOUT PREJUDICE. The Court grants Mylan a period of 30 days for leave to amend or to file a Notice that it does not intend on doing so.
- All Defendants, other than Sanofi S.A., shall file their Answers within 45 days of the date of this Order.
- The parties shall confer and file a Joint Status Report within 21 days of this Order setting forth their detailed plan for the referenced jurisdictional discovery.
- The Court will enter a separate Order relative to the Initial Case Management report and Order.

An appropriate Order will issue.

s/ Mark R. Hornak
Mark R. Hornak
United States District Judge

Dated: January 27, 2026