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

MYLAN PHARMACEUTICALS INC., MYLAN SPECIALTY L.P., and MYLAN INC., *Plaintiffs*, v. SANOFI-AVENTIS U.S. LLC, SANOFI S.A., AVENTIS PHARMA S.A., and SANOFI-AVENTIS PUERTO RICO INC. *Defendants*.	No. 2:23-cv-00836-MRH

REPLY MEMORANDUM IN SUPPORT OF
DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' COMPLAINT

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INTRODUCTION

Mylan offers no serious response to at least three dispositive arguments. *First*, the bundled-discounts claim fails as a matter of law because the complaint does not allege that Sanofi bundled discounts on products in "separate product markets." Mot.6 (quoting *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 274 n.11 (3d Cir. 2012)). Mylan never contests this legal standard or its failure to meet it. Mylan instead tilts at windmills, arguing that Lantus and Toujeo are not identical products, while never contesting that Lantus and Toujeo compete in the *same product market*.

Second, all of the patent-related conduct (Orange Book listings and sham litigation) is concededly outside the limitations period. Mylan's response is to misapply the continuing-violation doctrine, an argument squarely foreclosed by *Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 189 (1997). The claim based on patent-related conduct must be dismissed on this simple basis.

Third, that claim also fails because Mylan does not plausibly allege causation—i.e., that Sanofi's patent-related conduct caused FDA to delay approval of Semglee. The key point is this: FDA *denied approval* for Semglee—twice—based on Mylan's own manufacturing defects, and Semglee *never obtained even tentative approval* until *after* the 30-month Hatch-Waxman stay expired. Lacking any merits response, Mylan asks this Court to ignore FDA's denials with a spurious argument that the Court cannot take judicial notice of government records. Opp.28. For these and the additional reasons discussed below, the entire complaint must be dismissed.

ARGUMENT

I. MYLAN FAILS TO STATE A MONOPOLIZATION CLAIM UNDER THE SHERMAN ACT

To state a monopolization claim, a plaintiff must plausibly allege anticompetitive conduct and possession of monopoly power. *Pac. Bell Tel. Co. v. linkLine Commc'ns, Inc.*, 555 U.S. 438, 447-48 (2009). Mylan alleges two theories of anticompetitive conduct: (1) exclusive dealing

through bundled discounts leading to market foreclosure and (2) improper Orange Book listings and sham patent litigation to delay FDA approval of Semglee.[1] Neither theory is plausibly alleged.

A. Mylan Must Plead A Legally Sufficient Theory Of Anticompetitive Conduct Even If It Alleges A "Multifaceted Anticompetitive Scheme"

Mylan insists that the Court may not separately examine the "individual components" of the alleged "overall anticompetitive scheme." Opp.8. That is incorrect. A complaint alleging multiple types of anticompetitive conduct must separately satisfy the legal standards governing each type, and a plaintiff is not free to "alchemize them into a new form of antitrust liability." *linkLine*, 555 U.S. at 457. When exclusionary conduct does not fit a "single paradigm," "courts disaggregate the exclusionary conduct into its component parts before applying the relevant law" and only then evaluate whether any "'synergistic effect' saves [the] case." *In re EpiPen*, 44 F.4th 959, 982 (10th Cir. 2022); *accord 3Shape Trios A/S v. Align Tech., Inc.*, 2019 WL 4686614 (D. Del. Sept. 26, 2019) (alleged scheme must be evaluated "as separate parts" and then as "sum of those parts"); Daniel Crane, *Does Monopoly Broth Make Bad Soup?*, 76 Antitrust L.J. 663, 668 (2010) ("Where there are developed tests…, a plaintiff must first satisfy the test as to each species of allegedly anticompetitive conduct before measuring the cumulative or 'synergistic' effect.").

Mylan's theories implicate separate, established legal standards. Its bundling theory is governed by *Eisai*, *ZF Meritor*, and *LePage's*, and requires tying across markets, inability to make a comparable deal, and market foreclosure. Its sham-litigation theory, by contrast, requires objective baselessness of litigation and causation of regulatory delay. Only if those legal standards

[1] Mylan lists three theories in its complaint, but the second and third both rest on allegations of exclusionary bundled discounts. *See* Compl. ¶ 3; Opp.8. Insofar as Mylan attempts to allege a standalone third theory of product hopping, it must be dismissed for the reasons stated in Sanofi's Motion (at 9). Mylan has not alleged a hard switch, and it cannot plausibly allege that Sanofi coerced consumers into switching from Lantus to Toujeo by using bundled discounts to provide consumers with formulary access to *both drugs*. Providing consumers with *more choice* is not an anticompetitive product hop, even under Mylan's cited case. *See In re HIV Antitrust Litig.*, 656 F. Supp. 3d 963, at 975-80 (N.D. Cal. 2023) (discussing "the element of consumer coercion" and rejecting product hopping claim).

are met should the Court examine whether any "'synergistic effect' saves [the] case." *EpiPen*, 44 F.4th at 982; *see Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 694-700 (1962) (viewing evidence of causation as a whole only after determining that the alleged conduct was unlawful). In any event, Mylan points to no synergy. For instance, its sham-litigation allegations cannot help overcome that its bundling theory fails to allege separate product markets, nor can its bundling allegations show that Sanofi's patent suit delayed FDA approval of Semglee.

B. Mylan's Bundled-Discount Theory Fails to Allege Exclusionary Conduct Or Substantial Foreclosure of the Relevant Market

An exclusive-dealing claim requires an exclusive-dealing arrangement plus "substantial foreclosure" of the market. *ZF Meritor*, 696 F.3d at 270-71. Mylan plausibly alleges neither.

1. *Mylan's bundled-discount theory contravenes binding precedent.*

Mylan alleges that Sanofi entered into exclusive-dealing arrangements by bundling discounts on Lantus and Toujeo to exclude Semglee from pharmacy benefit manager (PBM) formularies. Opp.14-15. The bundling theory fails as a matter of law for three independent reasons.

First, Mylan does not allege bundling of products across separate product markets. Mot.5-6. Like tying, bundling "cannot exist unless two separate product markets have been linked." *ZF Meritor*, 696 F.3d at 274 n.11 (quoting *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 21 (1984)); *see* Opp.15 n.12 (bundling derives from "the unlawful practice of tying"). The rationale is, if one company offers bundled discounts on "multiple different product lines," while another produces only one product line, the latter "cannot make a comparable offer" matching the total discounts without manufacturing entirely new product lines. *ZF Meritor*, 696 F.3d at 274 n.11.

Mylan acknowledges its own allegations that Lantus, Toujeo, and Semglee are "readily substitutable" and thus compete in the same product market. Opp.23-24. Mylan can therefore make a "comparable offer" without entering a new market. If Sanofi bundles discounts on 100 units each

of Lantus and Toujeo, Mylan can match by offering the same discount on 200 units of Semglee, because Semglee can replace *both drugs* on a formulary. Mylan's response that Semglee and Toujeo are not identical products is irrelevant. Opp.17. All that matters is that Semglee competes with both of Sanofi's drugs in the same product market.[2]

Intent on highlighting this deficiency, Mylan submitted supplemental authority (ECF No. 65) emphasizing that a bundling claim exists only where "two separate product markets have been linked," and referring to *"LePage's* central holding that linking a product market with no competition to a product market with competition poses antitrust concerns." *Baltimore v. Merck Sharp & Dohme Corp.*, 2023 WL 8018980, at *4 (E.D. Pa. Nov. 20, 2023). There, Merck bundled discounts across at least "five" markets and "was the sole supplier in three of the markets." *Id.* at *1. Here, Mylan fails to allege bundling across "two separate product markets." *Id.* at *4.

Second, even if Lantus and Toujeo were in separate markets, a bundling claim fails if the competitor (Mylan) also sells multiple product lines and can therefore "make a comparable offer" by bundling its discounts, too. *ZF Meritor*, 696 F.3d at 274 n.11. In that case, a bundled discount is *pro-competitive*. *See Cascade Health Sols. v. PeaceHealth*, 515 F.3d 883, 895 (9th Cir. 2008) ("bundled discounts generally benefit buyers").

Mylan does not dispute that it produces hundreds of products. It instead contends that even a multi-product producer could be excluded if it did not produce "the same diverse array of products" as in the bundle. Opp.18-19 & n.15. But, unlike in *LePage's*, Sanofi's bundle involves just *two products*, so Mylan sells "the same diverse array" if it sells just *two products*. Mylan has not alleged it cannot offer bundled discounts to PBMs on Semglee and other products to compete

[2] Mylan also suggests that competition happens "at the pharmacy counter," after a patient already has a prescription in hand. Opp.17. That contradicts Mylan's complaint, which alleges that Mylan and Sanofi compete over placement on PBMs' formularies. Compl. ¶¶ 11-12, 15.

with Sanofi's bundled rebates, which is healthy price competition. *See Shire US, Inc. v. Allergan, Inc.*, 375 F. Supp. 3d 538, 557 (D.N.J. 2019) ("Plaintiff—a large pharmaceutical company—has also not asserted that it did not have other available products that it could offer … as part of a bundled rebate."). Mylan gets antitrust law backwards by arguing that dueling bundled discounts would mean a "race to the bottom." Opp.18-19. Bundled discounts are "price cut[s]"—the kind of "vigorous price competition" that courts "strenuously protect." *EpiPen*, 44 F.4th at 999-1000.

Third, Mylan does not plausibly allege that Sanofi conditioned discounts on exclusively purchasing from Sanofi. Mot.8-9. It is true that, instead of express exclusivity, a seller might impose *de facto* exclusivity by conditioning discounts on filling most or all of a customer's need for the product. Opp.17; *ZF Meritor*, 696 F.3d at 265 ("rebates were conditioned on International purchasing 87% to 97.5% of its requirements from Eaton"); *LePage's Inc. v. 3M*, 324 F.3d 141, 154, 160 (3d Cir. 2003) (en banc) ("customer-specific target[s]" effectively "forced" customers to "drop any non-Scotch products"). But Mylan does not plausibly allege that Sanofi imposed any such *de facto* conditions, either. Mot.8-9.

2. *Mylan fails to allege substantial foreclosure of the relevant market.*

Exclusive-dealing arrangements "are often entered into for entirely procompetitive reasons." *EpiPen*, 44 F.4th at 983. They pose antitrust concern only when such a large percentage of available buyers is locked up that competitors have no "market for their goods." *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 403 (3d Cir. 2016). Therefore, an exclusive-dealing claim requires the plaintiff to plead "substantial foreclosure" of the relevant market. *Id.*

Mylan's complaint fails to allege any degree of foreclosure. Mylan responds that it need not plead an exact percentage because it may rely on "qualitative evidence," such as whether the defendant "tied up key dealers." Opp.29. But Mylan points to no such "qualitative evidence" in the complaint. *Compare Smart Commc'ns Holding, Inc. v. Glob. Tel-Link Corp.*, 638 F. Supp. 3d

430, 440 (M.D. Pa. 2022) (finding "sole allegation" gave "no indication of the portion of the nationwide market held" and did not "contain sufficient factual content" to infer foreclosure), *with Baltimore*, 2023 WL 8018980, at *8 ("eight lengthy paragraphs" on market foreclosure). Mylan also admits that Eli Lilly launched a competing glargine product but declines to allege whether Eli Lilly was foreclosed. Opp.30; *see Eisai*, 821 F.3d at 403 ("the challenged practices must bar a substantial number of rivals" (cleaned up)). This is insufficient to plausibly allege foreclosure.[3]

C. Mylan Fails To Plausibly Define A Relevant Market Or Allege Market Power

Market definition. Mylan must allege a relevant market to support its allegation of indirect evidence of market power, its claim of attempted monopolization, and its allegation that Sanofi's bundled rebates substantially foreclosed the relevant market to competition. Mot.11. A relevant market must include all products that are functionally interchangeable and share cross-elasticity of demand. *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 437 (3d Cir. 1997). Mylan's alleged market limited to insulin glargine is not plausible because Mylan ignores potential substitutes that are apparent from the face of the complaint and incorporated documents. Mot.12.[4]

To plausibly allege a relevant market limited to insulin glargine, Mylan would have to allege why glargine is "unique" and not "part of the larger market" of basal insulin. *Id.* Mylan

[3] Separately, *Noerr-Pennington* immunity bars the subset of Mylan's claims based on rebates to state Medicaid agencies. Mot.7; *In re EpiPen*, 2017 WL 6524839, *10-12 (D. Kan. Dec. 21, 2017). Mylan responds with the inapposite point that *EpiPen* "concerned the use of a 'single-product loyalty discount,'" which is "not a coercive tying arrangement liked *bundled* rebates." Opp.18 n.14. But *EpiPen*'s conclusion that *Noerr-Pennington* immunity applied had nothing to do with the price-cost test or the presence or absence of coercion. *EpiPen* held that Mylan could not be liable for "using the outcome of a government process," as opposed to "the process itself to harm a competitor." *EpiPen*, 2017 WL 6524839, at *11. The other case Mylan cites is inapposite because it involved "coercion" in the form of actual "threats" and "intimidation" of government officials, not negotiations offering big discounts. *Sacramento Coca-Cola Bottling Co. v. Chauffeurs, Etc. Loc. 150*, 440 F.2d 1096, 1099 (9th Cir. 1971). Finally, *Suboxone's* conclusion that *Noerr-Pennington* did not warrant dismissal of "the *entirety* of Plaintiffs' antitrust claim," *In re Suboxone*, 622 F. Supp. 3d 22, 77 (E.D. Pa. 2022) (emphasis added), is unavailing because Sanofi only seeks to apply *Noerr-Pennington* and dismiss the part of the claim involving government contracts.

[4] Sanofi does not ask this Court to determine the relevant market as a factual matter. Opp.23. It is Mylan's burden to plausibly plead a relevant market. If—as here—it is not plausible, "a motion to dismiss may be granted." *Queen City Pizza*, 124 F.3d at 436.

responds that other insulin products have "different active ingredients." Opp.24. But that is not the test; the test is whether the products are "reasonably interchangeable" and have cross-elastic demand. Opp.24; *see In re Intuniv Antitrust Litig.*, 496 F. Supp. 3d 639, 666 (D. Mass. 2020) (concluding that drug at issue potentially competed with drugs containing different active ingredients). Here, the complaint contains a single, conclusory allegation regarding cross-elasticity. Compl. ¶ 214. The complaint is devoid of any well-pleaded facts regarding whether the market—here, PBMs putting together drug formularies, *see* Compl. ¶¶ 17, 204—treats various basal insulins as interchangeable. Indeed, Mylan undermines its own position by arguing *the opposite*: it contends that that PBMs "do not include all [basal insulins] on their formularies," and a PBM may or may not "choose[] insulin glargine." Opp.25. But if that is true, it means that basal insulins *are* interchangeable and *should* be included in the relevant market.

Market power. Mylan fails to allege market power using either direct or indirect evidence.

No direct evidence. It is theoretically possible to prove market power by means of "direct evidence of supercompetitive prices and restricted output." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 307 (3d Cir. 2007). But direct evidence is "rarely available." *Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 434 (3d Cir. 2016) ("*Doryx*"). Measuring market power directly requires technical data about a firm's price and cost curves that can "seldom" be acquired. *See* Areeda & Hovenkamp ¶ 504. Not surprisingly, Mylan cites *not one case* upholding a complaint based on allegations of direct evidence. Opp.21-22. Nor does Mylan's complaint allege that Mylan has that "rare" data. Mylan points to net revenue for Lantus in 2004-2019. Opp.21. But that figure says nothing about the price and cost curves that Sanofi faced, and Mylan fails to identify any case relying on a simple net-revenue figure.

Mylan also misunderstands what "restricted output" means. Mylan argues that Sanofi restricted *Mylan's* output by delaying Semglee. Opp.22. That argument inappropriately "blend[s] the power inquiry with the question of whether the defendant(s) obtained market power through improper exclusionary conduct." Areeda & Hovenkamp ¶ 501. The question is whether the defendant restricted *its own* output to maintain higher prices. *See Doryx*, 838 F.3d at 434-35 ("Mylan also fails to show that Defendants restricted Doryx output to maintain monopoly profits"). The complaint's failure to allege that Sanofi restricted its own output is fatal. Mot.14.

No indirect evidence. To rely on indirect evidence of market power, "a plaintiff typically must 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. Alleging the defendant's share of the relevant market is among the most basic requirements of an antitrust complaint. *Synthes, Inc. v. Emerge Med., Inc.*, 2012 WL 4473228, at *19 (E.D. Pa. Sept. 28, 2012) (even a "cookie cutter antitrust claim" alleges "rudimentary elements" like "market share"). But Mylan does not allege Sanofi's share, even approximately. Its brief tries to contend that Sanofi's share was "huge," Opp.25, pointing to Paragraph 10, which contains a Sanofi document stating Lantus is the "preferred 1st generation" basal insulin and Toujeo had "76% coverage." These statements are meaningless without context, and Mylan does not attempt to explain or quantify how being "preferred" among a subset of basal insulins or having some unspecified "coverage" translates into market share. Opp.25, 30. And Paragraph 18, listing Lantus and Toujeo sales relative only to *each other*, says nothing about market share. Opp.25.

D. Mylan's Sham-Litigation Claim Is Time-Barred And Fails For Lack Of Causation

Mylan's second theory of anticompetitive conduct—that Sanofi improperly listed patents in FDA's Orange Book and asserted those patents in sham litigation to delay FDA approval of Semglee—is clearly time barred and fails for lack of causation.

1. *Mylan's claim based on Orange Book listings and sham litigation is time-barred.*

Sanofi's Orange Book listings and the filing of the alleged sham patent suit occurred before May 2019, so the four-year limitations period has run on that conduct. Mot.21-22. In response, Mylan invokes the "continuing violation" doctrine, seeking to tie the sham litigation conduct (outside the limitations period) together with the bundling conduct (inside the limitations period). Opp.9-10. But the Supreme Court squarely foreclosed this approach in *Klehr*, 521 U.S. at 189. In "[a]ntitrust law," although the "continuing violation" doctrine provides that "each overt act … starts the statutory period… again," that principle allows claims *only for those new acts*. *Id.* "[A] separate new overt act generally does not permit the plaintiff to recover for the injury caused by old overt acts outside the limitations period," even where the old overt acts are not only part of the same scheme, but are (unlike here) *identical* to the recent acts. *Id.* (illustrating with a "price-fixing conspiracy" where the defendants' conduct includes "a series of unlawfully high priced sales over a period of years"). Thus, "the plaintiff cannot use an independent, new [overt] act as a bootstrap to recover for injuries caused by other [overt] acts that took place outside the limitations period." *Id.* at 190; *Heraeus Med. GmbH v. Esschem, Inc.*, 927 F.3d 727, 740 (3d Cir. 2019) (applying *Klehr* and the "separate accrual rule"). That is exactly what Mylan seeks to do here.[5]

Mylan's other argument relies on the same bootstrapping trick. Mylan claims that its damages were "speculative" "until at least 2021," when it gained "full visibility into Sanofi's monopolization scheme" because the Senate Finance Committee issued its insulin pricing report. Opp.11. Here again, Mylan seeks to rely on its bundling allegations to evade the limitations period

[5] Mylan attempts to support its version of "continuing violation" theory with two inapposite cases. Opp.9-10. One of them announced a specific rule for hostile-work-environment claims that, as the four-justice dissent pointed out, does not apply in antitrust cases. *Nat'l R.R. Passenger Corp. v. Morgan*, 536 U.S. 101, 127 (2002) (O'Connor, J. dissenting) (discussing *Klehr*). The other primarily relied on *Keystone Ins. Co. v. Houghton*, 863 F.2d 1125 (3d Cir. 1988), for its articulation of the "continuing violation" theory. *Brenner v. Loc. 514, United Bhd. of Carpenters & Joiners of Am.*, 927 F.2d 1283 (3d Cir. 1991). But *Klehr* expressly abrogated *Keystone*. *See* 521 U.S. at 186-87.

for the older alleged conduct of Orange Book listing and sham litigation. The Senate Finance Report, Opp.2, has nothing to do with that older conduct, and only discusses insulin rebates and bundling, insofar as it is relevant at all. Insulin Rep. 78-79. Other than bootstrapping the bundling allegations, Mylan makes no argument that its claim based on patent listings and sham litigation did not accrue when the alleged sham lawsuit was filed. *See* Mot.22 (citing cases rejecting arguments that damages from sham litigation are too speculative on the date the suit is filed). Finally, Mylan's allegation of fraudulent concealment is wholly conclusory and has nothing to do with Orange Book listing or sham litigation, which was obviously not concealed. Compl. ¶ 229; *see Fuqua v. Bristol-Myers Squibb Co.*, 926 F. Supp. 2d 538, 549 (D.N.J. 2013) ("Plaintiffs have not pled the elements, nor the circumstances of, fraudulent concealment"). Mylan's claim based on Orange Book listing and sham litigation must be dismissed on this very simple basis.

2. *Mylan fails to plausibly allege that Sanofi's Orange Book listings or Hatch-Waxman litigation caused a delay in FDA approval of Semglee.*

Separately, the regulatory-delay theory fails as a matter of law under *Twombly* because the complaint does not plausibly allege a causal connection between Sanofi's patents and the timing of FDA approval of Semglee. Mot.16-21; *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2007). Although Mylan quibbles with the standard for causation, it concedes it must plausibly allege that Sanofi's conduct was "a material cause" of delayed FDA approval. Opp.26.

a. Mylan has not plausibly alleged (Compl. ¶¶ 129-33) that Sanofi's 30-month stay was a material cause of delay in FDA approval because FDA never granted tentative approval during the stay, and instead rejected the application in 2017 and twice denied approval in 2018 and 2019 for reasons *independent of* the 30-month stay. Mot.19-20 & nn.7-11.[6] By regulation, if FDA had

[6] FDA refuses to file a drug application that is not "sufficiently complete to permit a substantive review," 21 C.F.R. § 314.101(a), and it issues a complete response letter after determining that it "will not approve the application … in its present form," *id.* § 314.110(a). In both instances, the regulations specify a list of deficiencies on which FDA

determined that Mylan's application "would otherwise be ready for final approval were it not for the regulatory 30-month stay" (Compl. ¶ 78), it would have issued a tentative approval for Semglee, which it *did* for Eli Lilly's Basaglar in August 2014 and Merck's Lusduna in July 2017. Mot.18 & n.5.[7] Thus, as a matter of law, Mylan cannot plausibly allege that the "30-month stay," alone or "in conjunction with the … transition date created by the BPCIA" (Compl. ¶ 133), was a material cause of delay, because there was an independent regulatory barrier to approval that "break[s] the chain of causation." *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 152 (3d Cir. 2017) (holding that plaintiff's inability to launch its product "even in the absence of the 30-month stay" was "an independent problem with … causation"); *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 268-69 (3d Cir. 1998) (affirming dismissal for lack of causation).

With no response to this on the merits, Mylan contests judicial notice of FDA's government records and argues that the Court cannot "draw inferences and make credibility determinations that judicial notice will not permit." Opp.28. This is doubly wrong.

First, Sanofi's argument does not ask the Court to make credibility determinations or to draw inferences beyond *Twombly*'s plausibility requirement—*i.e.*, a complaint must contain "plausible grounds to infer" the truth of its allegations. *Twombly*, 550 U.S. at 556 (2007); *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (allegations must support a "reasonable inference" of liability).

Second, courts regularly take judicial notice of FDA records that are "indisputably authentic" when ruling on motions to dismiss. *Freed v. St. Jude Med., Inc.*, 2017 WL 4102583, at *2 & n.13 (D. Del. Sept. 15, 2017) (collecting cases). Mylan does not challenge authenticity, as

may rely, which does not include the existence of a 30-month stay. *See id.* §§ 314.101(d)-(e), 314.125(b).

[7] "FDA will issue a tentative approval letter … if a 505(b)(2) application otherwise meets the requirements for approval … but cannot be approved until the conditions in § 314.107(b)(3) are met." 21 C.F.R. § 314.105(a); *id.* § 314.107(b)(3) (concerning "[d]isposition of patent litigation").

the records are available on FDA's website, a "source[] whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(2). Instead, Mylan tries to differentiate between the existence of the records and the truth of the matters asserted therein. But, whether the "facts" in the records are true or not (*e.g.*, whether there really were violations of good manufacturing practices), the *mere issuance* of these records constitutes FDA's official determination that Mylan's application did not meet the regulatory requirements for approval during the 30-month stay.

b. Separately from the 30-month stay, Mylan alleges (Compl. ¶ 128) that the mere existence of Sanofi's patents in the Orange Book in 2013 caused Mylan to delay filing its drug application until 2017. *See* Mot.16-17. This fails *Twombly* for at least two reasons.

First, whatever its cause, Mylan's delay from 2013 to 2017 is entirely irrelevant because FDA rejected the application in 2017 and denied approval in 2018 and again in 2019 based on Mylan's own defects that had nothing to do with Sanofi's patents. Mot.19-20 & nn.7-11. Mylan cannot plausibly allege that FDA would have granted approval anytime between 2013 and 2017 when, as a matter of public record, FDA denied approval in 2019.

Second, the allegation that Sanofi's patents caused Mylan's delay from 2013 to 2017 is conclusory and nonsensical. Compl. ¶ 128. Mylan alleges in a single, conclusory sentence having no relation to the rest of the paragraph that the delay somehow "would have been avoided" but for Sanofi's patents "because Mylan would have obtained FDA approval … earlier." *Id.* This is incoherent and unsupportable. For one thing, FDA denied the application in 2019, so Mylan cannot plausibly allege that FDA would have granted approval "earlier" than 2017. For another, based on the legal standards for filing drug applications, Sanofi's patents were irrelevant as a matter of law to Mylan's discussions with FDA about the type of drug application to file. Mot.17-18 & n.4. Critically, *all* of the available regulatory paths required Mylan to certify to the patents, so the

patents were not a distinguishing factor between the types of applications. *Id.*[8] Mylan thus has no basis for its argument that the patents "artificially prolonged" its discussions with FDA. Opp.28.[9]

Tellingly, Mylan tries to defend its conclusory allegation with factual assertions not in the complaint. *See Voneida v. Pennsylvania*, 508 F. App'x 152, 155 (3d Cir. 2012) ("[S]tatements in a brief are not a substitute for the allegations in the complaint."). According to its brief, "Mylan alleged that it could and would have immediately sought FDA approval for Semglee had Sanofi not improperly listed a thicket of sham patents in the Orange Book." Opp.28. Nothing close to that allegation appears in the complaint. *See* Compl. ¶ 128. Mylan also asserts that FDA "would have voided Mylan's application" if it changed its classification between "generic" and "biologic." Opp.28. Again, the complaint alleges nothing of the sort, and even if it did, any "voiding" would be caused by an intervening FDA decision, not by Sanofi's patents. Finally, Mylan asserts that the "critical" fact is that FDA could have granted "expedited final approval" if not for Sanofi's patents, but the complaint alleges nothing about "expedited final approval." Opp.28; Compl. ¶¶ 128-39. And, expedited approval is implausible because FDA rejected Mylan's application in 2019.

E. Mylan's Sham Litigation Allegations Must Be Dismissed Under *Noerr-Pennington*

The sham litigation allegations must also be dismissed for failure to plead facts sufficient to overcome *Noerr-Pennington*. Mot.22-24. Mylan has not cleared the "high hurdle" of plausibly alleging that Sanofi's patent infringement lawsuit was "objectively baseless." *See Wellbutrin*, 868 F.3d at 148-49; *see Pro. Real Est. Inv'rs, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 63

[8] Both 505(b)(2) NDAs and 505(j) ANDAs are required to include patent certifications, which can give rise to a 30-month stay. *See* 21 U.S.C. § 355(b)(2)(A) & (j)(2)(A)(vii). And, Mylan's own complaint concedes that filing a biologics license application, which would not require certifications to Sanofi's patents, "would only be available as a pathway *after* March 23, 2020 (after the transition of the reference product)." Compl. ¶ 132 (emphasis added).

[9] Even assuming that patents "may work a more subtle harm by deterring potential competitors or distorting their decision-making" (FTC Amicus Br. at 12), and that some unspecified "subtle" harm is sufficient to state an antitrust claim, Mylan's complaint is devoid of any facts making this theoretical possibility *plausible* in this case.

(1993) ("court may decide probable cause as a matter of law"); *La. Health Serv. & Indem. Co. v. Janssen Biotech, Inc.*, 2021 WL 4988523, at *7 (D.N.J. Oct. 27, 2021) ("A court may decide the applicability of the *Noerr–Pennington* doctrine on a motion to dismiss" (collecting cases)).

Mylan does not argue that its complaint satisfies the standard of alleging objective baselessness, but instead claims that *Professional Real Estate* is inapplicable because "this case concerns a pattern of *serial* petitioning." Opp.11-12. Mylan is wrong, and its reliance on *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 513 (1972), is misplaced. These cases "apply to different situations: *California Motor* to a series of sham petitions and *Professional Real Estate* to a single sham petition." *Hanover 3201 Realty, LLC v. Vill. Supermarkets, Inc.*, 806 F.3d 162, 179-80 (3d Cir. 2015). Mylan's claim falls squarely into the latter category because it concerns a *single patent infringement lawsuit* filed by Sanofi. Compl. ¶ 145. One lawsuit does not constitute a pattern or series of petitions. *See, e.g.*, *Wellbutrin*, 868 F.3d at 157 ("The test for serial petitioning announced in *Hanover* explicitly applies to 'a series of legal proceedings' or 'a pattern of petitioning,' and two proceedings … does not constitute a pattern." (cleaned up)). Moreover, a "serial petitioning charge is particularly inapt" in the Hatch-Waxman context because it "would punish behavior that Congress sought to encourage." *Id.* at 157-58.

Mylan engages in a tortured analysis to convert Sanofi's single petition into a series of petitions based on the number of claims asserted and Sanofi's arguments in "separate *inter partes* review proceedings" (IPRs) *brought by Mylan.* Opp.13. But Mylan invents its claim-by-claim standard out of whole cloth, and the Third Circuit has twice rejected attempts to dissect petitions based on the number of claims asserted in a single petition.[10] And Mylan itself was the petitioner

[10] *See, e.g.*, *Wellbutrin*, 868 F.3d at 156 n.34 ("The flaw is in viewing the Petition as four independent requests, rather than as a single petition. When considering whether a petition is entitled to immunity, courts should consider whether the petition as a whole is objectively baseless."); *Avaya Inc., RP v. Telecom Labs, Inc.*, 838 F.3d 354, 413-14 (3d Cir. 2016) (rejecting argument that "the sham exception should be applied … claim-by-claim").

who brought the IPRs seeking to invalidate Sanofi's patents. *See* Compl. ¶¶ 151, 156, 162, 168, 174, 180, 187. The Court should reject Mylan's effort to transform *its own petitions*—for which Sanofi had a statutory and due process right to defend itself and to appeal any unfavorable ruling—into a pattern of petitioning behavior by Sanofi. *Noerr-Pennington* "equally applies to the right to defend against a petition," *Kamdem-Ouaffo v. Colgate Palmolive Co.*, 2023 WL 7151580, at *6 n.7 (D.N.J. Oct. 31, 2023), and whether there was a "sham defense" turns on *Professional Real Estate*'s "two-part test." *Freeman v. Lasky, Haas & Cohler*, 410 F.3d 1180, 1184-85 (9th Cir. 2005). To hold otherwise would be to permit a plaintiff to manufacture a serial petitioning claim by filing numerous lawsuits and waiting for the defendant to respond. Thus, just as *California Motor* is "particularly inapt" in the Hatch-Waxman context, *Wellbutrin*, 868 F.3d at 157, so too is it unsuitable in the context of defending against IPRs.

In short, regardless of whether Sanofi's petitioning activity includes defending the IPRs or is limited to filing a single patent infringement lawsuit against Mylan, the analysis is governed by *Professional Real Estate*, not *California Motor*. Since the complaint does not plausibly allege that Sanofi's conduct was objectively baseless, *Noerr-Pennington* applies, and Mylan's sham litigation claim must be dismissed on this basis as well.

II. MYLAN'S BACKUP CLAIMS ALSO MUST BE DISMISSED

Mylan does not dispute that its claims in Counts II-IV rise or fall based on the merits of Mylan's main monopolization claim. *See* Mot.25-26; Opp.30-31. Because that claim must be dismissed for the reasons explained above, the others must be as well.

Count V for tortious inducement must be dismissed for failure to plead a prospective contractual relationship. Mot.26-27. "[E]ven at the pleading stage, a plaintiff may not rest a claim for tortious interference with prospective contractual relations on a mere hope that additional contracts or customers would have been forthcoming but for defendant's interference." *Advanced*

Power Sys., Inc. v. Hi-Tech Sys., Inc., 1992 WL 97826, at *11 (E.D. Pa. Apr. 30, 1992). Mylan cobbles together allegations about Sanofi's Lantus-Toujeo bundle "effectively exclud[ing]" Semglee from formularies. Opp.32. Yet the complaint pleads no facts giving rise to a "reasonable probability" that, absent Sanofi's bundling, PBMs would have contracted with *Mylan* to place Semglee on formulary. The complaint, for example, alleges no "mechanism" through which Mylan would secure contracts. *Sandoz Inc. v. Lannett Co.*, 544 F. Supp. 3d 505, 512-13 (E.D. Pa. 2021).

III. MYLAN FAILS TO ALLEGE PERSONAL JURISDICTION OVER SANOFI S.A.

Mylan fails to meet its burden to "establish a prima facie case of personal jurisdiction" over Sanofi S.A. *Hardwick v. Consumer Guardian Specialists, LLC*, 2021 WL 1152739, *2 (W.D. Pa. Mar. 26, 2021). Mylan relies on specific jurisdiction (Opp.34), which means it must allege "suit-related conduct" by Sanofi S.A. to "create a substantial connection" with the forum. *Id.* at *3. Mylan must allege the "nature and extent" of these suit-related contacts "with reasonable particularity." *Gehling v. St. George's Sch. of Med., Ltd.*, 773 F.2d 539, 542 (3d Cir. 1985).

The vague, scatter-shot allegations of the complaint come nowhere close to supporting a prima facie case. Mot.29-32. And Mylan's declaration in response to Sanofi's motion does not change this calculus. Decl. of Melissa Mills, ECF No. 59-1. According to Mylan, the "most striking example" supporting jurisdiction are statements from Sanofi S.A.'s Form 20-F that "we have increased the level of rebates granted for Lantus in order to maintain favorable formulary positions" in the United States, and that Lantus was a leading product for Sanofi globally. Opp.34; Ex. 6, ECF No. 59-8. Mylan does not even attempt to explain how these two statements establish the required minimum contacts for Sanofi S.A., specifically, as opposed to any of its subsidiaries. *See, e.g.*, *Heartrepreneur, LLC v. Jones*, 2020 WL 2839102, at *3 (E.D. Pa. June 1, 2020) ("Plaintiffs may not simply lump Defendants together to establish jurisdiction.").

Mylan's remaining documents fare no better. The press releases relating to Toujeo's testing, approval, and performance (Ex. 3-4, 7, ECF Nos. 59-5, -6, -9) and to settlement of the litigation between Sanofi U.S. and Eli Lilly (Ex. 5, ECF No. 59-7) are not related at all to the "suit-related conduct" challenged in the complaint and are therefore insufficient to establish specific jurisdiction. *See Hardwick*, 2021 WL 1152739, at *8-9; *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 919 (2011) ("[S]pecific jurisdiction is confined to adjudication of issues deriving from, or connected with, the very controversy that establishes jurisdiction." (cleaned up)). Moreover, none of the press releases provide any information regarding *Sanofi S.A.'s* conduct that would specifically suggest it purposefully availed itself of jurisdiction in the United States. Similarly, testimony Sanofi S.A. officers have provided to Congress regarding insulin pricing (Ex. 8-9, ECF Nos. 59-10, -11) and the IPRs and intellectual property lawsuits that Sanofi S.A. has filed involving *other drugs* and *other patents* (Ex. 1-2, ECF Nos. 59-3, -4) are entirely unlinked from suit-related conduct and therefore irrelevant to the specific jurisdictional inquiry.

Despite this deficiency, Mylan makes a last-ditch effort to keep Sanofi S.A. tied up in this litigation by requesting jurisdictional discovery. But jurisdictional discovery is only permitted if the plaintiff established its prima facie case for specific jurisdiction "with reasonable particularity." *Eurofins Pharma US Holdings v. BioAlliance Pharma SA*, 623 F.3d 147, 157 (3d Cir. 2010).[11] Mylan has completely failed to satisfy this burden, and it should not be allowed to embark on a "fishing expedition … under the guise of jurisdictional discovery." *Id.*

CONCLUSION

For the foregoing reasons, the Court should dismiss the complaint.

[11] Mylan's reliance on *Toys "R" Us* is misplaced because the plaintiff there made particularized allegations of the defendant's specific transaction and internet-based contacts with the forum. *Toys "R" Us, Inc. v. Step Two, S.A.*, 318 F.3d 446, 448-51 (3d Cir. 2003). Mylan has not made any such particularized allegations against Sanofi S.A.

Dated: December 11, 2023

Respectfully submitted,

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