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 and SANOFI-AVENTIS PUERTO RICO INC. *Defendants*.	No. 2:23-cv-00836-MRH

POST-HEARING MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION

Sanofi submits this post-hearing memorandum on its pending motion for reconsideration (ECF 105). Nothing Mylan offered at the May 19, 2026 hearing changes the conclusion that reconsideration should be granted. *See* May 19, 2026 Transcript ("Tr.").

I. MYLAN AGAIN FAILS TO DEFEND A SINGLE-MARKET BUNDLING THEORY, AND ITS TOUJEO "SUBMARKET" FINDS NO SUPPORT IN THE COMPLAINT.

Sanofi's motion for reconsideration rests on a straightforward proposition of law: a bundling claim "cannot exist unless two separate product markets have been linked." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 274 n.11 (3d Cir. 2012) (citation omitted); *accord Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 405 n.32 (3d Cir. 2016); *see* ECF 106 ("Mot.") at 7–8.

Mylan has never defended the viability of a single-market bundling theory, ECF 113 ("Reply") at 5–7, and did not do so at the hearing. Instead, it doubled down on the conclusory assertion that Toujeo implicitly occupies its own "submarket" distinct from Lantus and Semglee. Tr. 45:11–48:4. That position contradicts both Mylan's complaint and this Court's order. Reply 8–9. Mylan has pleaded—repeatedly—a single "injectable insulin glargine market" comprising all three drugs. ECF 1 ("Compl.") ¶¶ 21, 212, 214–15, 224. The entire premise of Mylan's case is that Lantus, Toujeo, and Semglee are "therapeutically indistinguishable," "exhibit significant, positive

cross-elasticity of demand," and that Sanofi sought to "switch the market" from Lantus to Toujeo. *Id.* ¶¶ 3, 8, 195–97, 214. Mylan failed, even during the hearing, to articulate any purported "submarket" occupied solely by Toujeo. Mylan cannot amend its complaint through its brief, or oral argument, much less in a manner that contradicts its own pleadings. Reply 8.

Nor can Mylan cure its pleading failure by invoking "notice pleading," asking the Court to "look at these things holistically and allow the complaint to move to discovery," or claiming that its deficient allegations put Sanofi "on notice of the conduct" at issue. Tr. 39:12–17, 47:4, 51:24. There is a real pleading requirement for product markets in this Circuit: Mylan bears the burden of pleading a plausible market encompassing "all interchangeable substitute products." *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 436 (3d Cir. 1997). Where a proposed market "clearly does not encompass all interchangeable substitute products …, the relevant market is legally insufficient and a motion to dismiss may be granted." *Id.*[1] As this Court recognized, "there's no reference to submarkets" in Mylan's complaint. Tr. 47:7. And Mylan's own allegations of interchangeability between Toujeo, Lantus, and Semglee foreclose a Toujeo "submarket" as a matter of pleading. Reply 8–9. Mylan cannot, consistent with Rule 8, expose Sanofi to "the potentially enormous expense of [antitrust] discovery" on an antitrust theory it has never pleaded—and that contradicts the theory it did plead. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 559 (2007).[2]

[1] "Numerous courts have applied this standard to dismiss complaints insufficiently pleading a relevant product market." *Synthes, Inc. v. Emerge Med., Inc.*, 2012 WL 4473228, at *10 (E.D. Pa. Sept. 28, 2012) (collecting cases); *see also, e.g.*, *Ragner Tech. Corp. v. Berardi*, 324 F. Supp. 3d 491, 509–10 (D.N.J. 2018). That is especially so where, as here, the plaintiff's market definition "create[s] conflict within its own allegations." *Satnam Distribs. LLC v. Commonwealth-Altadis, Inc.*, 140 F. Supp. 3d 405, 420 (E.D. Pa. 2015); *see also Risner v. L. Sch. Admission Council, Inc.*, 2026 WL 1161443, at *13 (E.D. Pa. Apr. 28, 2026) ("inconsistent pleading warrants dismissal").

[2] In this vein, the only new authority Mylan offered at the hearing (Tr. 4:25–6:3)—*Louisiana Wholesale Drug v. Becton Dickinson & Co.*, 2007 U.S. Dist. LEXIS 47437 (D.N.J. June 29, 2007)—confirms Mylan's pleading defect. That case relied on the now-displaced *Conley* "fair notice" pleading standard and the pre-*Iqbal* rule that antitrust complaints should be "liberally construed." *Id.* at *17, *44 (citations omitted). It also predates *ZF Meritor* and *Eisai.* Regardless, it cuts against Mylan on the merits: the parties there agreed that plaintiffs had pleaded bundling across at least *four* "distinct" product markets. *Id.* at *21 & n.13, *28, *41. Mylan, by contrast, has pleaded a *single* product market in which all three drugs compete—and has pleaded no facts that would carve Toujeo out of it. Reply 8–9.

II. DISMISSAL OF MYLAN'S BUNDLING THEORY NARROWS THE CASE SUBSTANTIALLY.

If the Court agrees that Mylan's bundling theory is not cognizable as pleaded, this case would be streamlined significantly: First, no independent exclusive-dealing claim survives, because bundling Lantus and Toujeo rebates is the only "vehicle of exclusive dealing" Mylan actually pleads. Reply 11; *see* ECF 84 ("Op.") at 38. Once the bundling theory falls, there is no *separate* exclusive-dealing claim left in the complaint.

The only allegation Mylan points to (Tr. 38:16–39:5)—that Sanofi "conditioned rebates for Toujeo on PBMs' agreement to exclude biosimilar insulin glargine products from formularies," Compl. ¶ 11—is precisely the kind of "formulaic recitation" unsupported by factual allegations that is insufficient. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Indeed, Mylan acknowledged in opposition to Sanofi's motion to dismiss that it had not pleaded any contractual exclusivity provision. ECF 59 at 25 & n.10. And Mylan has pleaded itself out of an exclusive-dealing claim under the price-cost test by alleging that "Sanofi sold Lantus and Toujeo at prices well in excess of marginal costs." Compl. ¶ 216; *see ZF Meritor*, 696 F.3d at 274 n.11; Tr. 25:2–28:6.

The demise of Mylan's bundling theory sinks Counts III and V. Mylan's Clayton Act § 3 claim (Count III) depends on the existence of an exclusive-dealing arrangement. Compl. ¶¶ 246–47. So does Mylan's tortious-inducement claim (Count V), which is premised entirely on "Sanofi's rebating practices." Op. 50. The only claims left standing would be Mylan's Sherman Act § 2 claims (Counts I and II) and its parallel New Jersey Antitrust Act claim (Count IV), but based only on the improper Orange Book listing and sham-litigation allegations that Mylan contends delayed FDA approval of Semglee until June 2020. Op. 33–34, 44–48.

Moreover, bundling should not survive even as background for the remaining claims. The Court previously permitted Mylan's dismissed product-hop allegations to remain in the case because, "viewed in light of" the bundling theory, they "worsen[] the picture for Sanofi." Op. 42–

43. That made sense: product hop and bundling both concern conduct directed to the *post-Semglee-market-entry* period—the introduction of Toujeo to "strategically transition consumers from Lantus to Toujeo after Sanofi's period of lawful patent exclusivity ended" and the use of bundled rebates to allegedly entrench that transition. *Id.* But the surviving Orange Book and sham-litigation allegations are fundamentally different. They concern an alleged "campaign of regulatory abuse and sham litigation" aimed at "delay[ing] FDA approval"—*pre-Semglee market entry*. Op. 27, 29, 42; Compl. ¶¶ 95–122, 140–92. There is no comparable nexus between the conduct that was allegedly undertaken *to delay* FDA approval of Semglee and the conduct that was allegedly taken to prevent Mylan from obtaining a foothold in the market *after* FDA approval of Semglee. Mot. 12–13; Tr. 43:8–44:22. And permitting sweeping discovery into Sanofi's *lawful* conduct during the post-Semglee-entry period to buttress a distinct scheme directed at delaying Semglee's market entry is precisely the kind of aggregation of "independently lawful" conduct that the Supreme Court has rejected. *Pacific Bell Tel. Co. v. linkLine Commc'ns, Inc.*, 555 U.S. 438, 455, 457 (2009).

A recent decision confirms the point. In *Mylan Pharmaceuticals Inc. v. Teva Pharmaceuticals Industries Ltd.*, 2025 WL 756793 (D.N.J. Feb. 27, 2025), *R&R adopted*, 2026 WL 982946 (D.N.J. Apr. 13, 2026), the District of New Jersey rejected Mylan's similar effort to aggregate pre- and post-market-entry conduct into a single scheme. *Id.* at *39–40. After surveying Third Circuit precedent, the court held that independently non-viable claims may be included in an overall scheme "only if the independently lawful acts … *augment the exclusionary effect of the conduct that has been properly alleged to be exclusionary.*" *Id.* at *13–14. Applying that principle, the court rejected Mylan's attempt to aggregate its pre-market-entry petitioning and sham litigation allegations with its post-market-entry theories targeting "hindrance of [Mylan's] generic uptake *after* FDA approval," holding the two theories "lack[ed] a temporal nexus." *Id*. at *36–37, 39–40.

The same logic forecloses Mylan's argument here.[3]

At a minimum, Rule 26 proportionality requires that discovery regarding conduct allegedly directed to impairing Mylan's ability to compete *after* Semglee was approved be sharply curtailed given its tangential relevance to the alleged activity to *delay* Semglee's approval. Tr. 21:15–22:13.

III. ALTERNATIVELY, THE COURT SHOULD CERTIFY AN INTERLOCUTORY APPEAL.

Even if this Court does not grant reconsideration, it should certify its order for immediate appeal under 28 U.S.C. § 1292(b) and stay discovery pending the Third Circuit's review, for the reasons set forth in Sanofi's prior briefs. Mot. 14–16; Reply 11–14.

CONCLUSION

The Court should grant reconsideration or interlocutory appeal and stay the proceedings.

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Respectfully submitted,

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[3] The *Mylan* court recognized that both *Suboxone* decisions on which this Court relied to aggregate Sanofi's conduct (Op. 28, Tr. 11:6–9, 41:22–42:11) were of limited relevance. 2025 WL 756793, at *13, *35–36 & nn.25–26. The Third Circuit's 2020 *Suboxone* decision arose in the Rule 23 class-certification context and "did not reach" whether inactionable conduct may be aggregated into an "overall antitrust scheme." *Id.* And the 2022 district court *Suboxone* decision allowed certain inactionable conduct to remain in the overall scheme only because that conduct was plausibly "part of a single alleged strategy" in a way that Mylan's temporally distinct allegations are not. *Id.*