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

REPLY MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR RECONSIDERATION OR CERTIFICATION OF INTERLOCUTORY APPEAL AND TEMPORARY STAY

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INTRODUCTION

Tellingly, in response to Sanofi's motion for reconsideration, Mylan declines to defend the viability of its single-market bundling theory as a matter of law. That alone is good grounds for reconsideration. Mylan tries to reshape its factual allegations, *now* claiming that Sanofi's products, Lantus and Toujeo, *are* in separate markets, but the actual complaint alleges the opposite, as the Court's order explained. Mylan cannot save its bundling allegations by attempting to amend its complaint through a brief.

Taken as pleaded, and whether characterized as "exclusive dealing" or "tying," Mylan's claim hinges on whether Mylan may plead a claim based on bundled discounts within the same product market. Precedent and logic dictate that there is no impediment to competition when a firm bundles discounts on interchangeable products in the same product market. Indeed, every case cited by the Court in denying Sanofi's motion to dismiss concerned bundling across product markets. The Court should reconsider this issue now—or, in the alternative, certify that its order merits interlocutory appeal—before the parties engage in expensive discovery.

None of Mylan's objections to Sanofi's motion has merit: the viability of Mylan's bundling allegations is a controlling question of law; Mylan does not try to reconcile its theory with Third Circuit precedent; and immediate appeal, before the case proceeds to discovery and summary judgment, may advance the ultimate termination of the case by disposing of a major portion of it. And Mylan's protest that Sanofi's negotiation of the dismissal of unnecessary defendants is somehow at odds with its request for certification is unfounded and beside the point.

Mylan's objection to staying expensive and time-consuming discovery, which would be entirely wasteful if Mylan cannot state a claim, fares no better. Such stays are routine, contrary to Mylan's inapposite caselaw. And a stay pending Third Circuit review of a petition for interlocutory review would be de minimis if denied given the expedited briefing schedule for such petitions

(10 days for Sanofi to file and 10 days for Mylan to respond) and the Third Circuit's practice of acting expeditiously on such motions. If the Third Circuit grants the request for interlocutory review, that is all the more reason to postpone costly discovery.

ARGUMENT

I. THE COURT SHOULD RECONSIDER WHETHER MYLAN'S ADMITTED FAILURE TO ALLEGE SEPARATE PRODUCT MARKETS PRECLUDES ITS BUNDLING THEORY.

A. Mylan must plead that Sanofi bundled discounts across product markets.

As Sanofi has explained, 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 also* ECF 106 ("Mot.") at 7-8. That linkage is the crux of the claim. A firm may be able to avoid competition in one market by offering "a discount aggregated across multiple products," because a competitor "may find it impossible to compensate for lost discounts on products that it does not produce." *LePage's Inc. v. 3M*, 324 F.3d 141, 155 (3d Cir. 2003) (citation omitted). That logic falls apart for products in the *same* product market. Because each product in the market is, by definition, interchangeable for any other, a competitor making just a single product can compete with any other product or combination of products in the market and match any aggregate discount.

Under this precedent and reasoning, Mylan's bundling theory fails. If, as Mylan alleges, Semglee is a substitute for *both* Lantus and Toujeo and all three drugs compete in the same "injectable insulin glargine" market and exhibit "positive cross-elasticity of demand" with each other (ECF 1 ("Compl.") ¶¶ 214-15), a drug formulary could replace *both* Lantus and Toujeo with Semglee. Sanofi gains no structural advantage over Mylan by bundling discounts on the two drugs. Thus, Mylan can compete with *both* Lantus and Toujeo with Semglee; it does not need another product.

Although the Court acknowledged Sanofi's argument, it did not render an express holding on whether a single-market bundling claim is cognizable. ECF 84 ("Op.") at 39-41. But allowing Mylan's bundling claim to proceed implicitly contravenes the precedent above and amounts to a clear error of law, especially given that every case cited by the Court involves bundling or tying across multiple product markets. *See* Mot. 9-11.

Moreover, there is good cause for the Court to reconsider its order before the case progresses further. If the Court agrees that a single-market bundling claim is not cognizable, deciding so now will save the parties and the Court significant time and expense by streamlining discovery and, eventually, summary judgment. Discovery into Mylan's bundling claim involves different conduct, by different actors, over a different time period than discovery into Mylan's patent-related allegations. *See id.* at 12-13.

B. Mylan fails to defend the viability of its single-market bundling theory.

In opposition, one would expect Mylan to contest the merits of Sanofi's legal argument, either by pointing to cases allowing bundling claims within the same product market or at least by explaining how a firm could use same-market bundles to avoid competition. But Mylan offers no case and makes no argument. Indeed, Mylan disavows that the Court's order even contemplates single-market bundling claims: "this Court made no such holding." ECF 108 ("Opp.") at 9-10.

Instead of mounting any defense, Mylan offers a handful of deficient responses. First, Mylan's contention that motions for reconsideration should not be used to "relitigate issues that the court previously resolved" (*id.* at 7 (citation omitted)) misses the point. Respectfully, the Court did not "resolve" the issue. Although the Court referenced the argument (Op. 39), it never expressly ruled on it. As Mylan's own case explains, motions for reconsideration are proper where "the court overlooked arguments that were previously made." *Nyamekye v. Mitsubishi Elec. Power Prods., Inc.*, 2018 WL 3933504, at *3 (W.D. Pa. Aug. 16, 2018).

Mylan's second argument—that *ZF Meritor* and *LePage's* are not limited to "competitors that literally only offer one product" (Opp. 9)—is irrelevant to the motion at hand. In its motion to dismiss, Sanofi *separately* argued that Mylan failed to allege that it could not match Sanofi's aggregate discount on Lantus and Toujeo by bundling discounts on Semglee with discounts on its other products. ECF 50 at 16-17. Mylan's argument may be responsive to *that* point, but it has no bearing on the sole issue presented in Sanofi's motion for reconsideration.

Finally, Mylan's attempt to reshape its allegations by now arguing that Lantus and Toujeo are actually in *separate* product markets (Opp. 10-11) is impossible to square with Mylan's complaint, so it cannot save Mylan's claim. "It is axiomatic that a complaint may not be amended by a plaintiff through a brief." *Ghrist v. CBS Broad., Inc.*, 40 F. Supp. 3d 623, 630 n.4 (W.D. Pa. 2014) (citing *Pennsylvania ex rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d 173, 181 (3d Cir. 1988)).

A product market includes all products that are "readily substitutable for one another," meaning that their respective producers "have the ability actual or potential to take significant amounts of business away from each other." Op. 20 (citations omitted). Mylan alleged "many times throughout its complaint" that the relevant product market is the "injectable insulin glargine market," which includes "Lantus, Toujeo, and Semglee." *Id.* at 21 (citing Compl. ¶¶ 21, 212, 224). Mylan took pains to minimize any functional difference between Toujeo and Lantus, alleging that "Toujeo offered no unique therapeutic value or advantage" and that "Toujeo is **slightly** longer lasting." Compl. ¶¶ 196-97 (Mylan's emphasis). In economic terms, Mylan alleged that the products "exhibit significant, positive cross-elasticity of demand" with each other. *Id.* ¶ 214. This emphasis on interchangeability served Mylan's narrative that Sanofi was trying to "switch the market" from Lantus to Toujeo. *Id.* ¶ 8. Based on these allegations, the Court found Mylan plausibly alleged that Lantus and Toujeo are in the same product market. Op. 21.

Now, however, it serves Mylan to argue the opposite—that "Toujeo is in a distinct product market" and that there may be factors that "restrict the cross-elasticity of demand" between Lantus and Toujeo. Opp. 10, 11 n.4 (citation omitted). But that argument directly contradicts Mylan's complaint and the Court's order. It is not merely a matter of "labeling" over "substance." *Contra* Opp. 10 n.3. To state separate submarkets, a complaint must allege "such practical indicia as industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors," *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962)—allegations that are glaringly absent from Mylan's complaint.

And alleging such a market would be an uphill battle, given that Mylan would be segregating Toujeo into its own single-product market, which "[c]ourts are reluctant to find." Op. 20 (citation omitted).[1] Mylan suggests that discerning whether Toujeo is in its own market is a "fact-intensive exercise" better suited to discovery. Opp. 10-11, 13-14. But this puts the cart before the horse. Before the parties confront "the potentially enormous expense of discovery," Mylan must meet Rule 8's plausibility requirement. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 559 (2007). As it stands, Mylan has failed to state a cognizable bundling claim as a matter of law, and Sanofi urges the Court to take this opportunity to resolve the issue.

II. ALTERNATIVELY, THE COURT SHOULD CERTIFY THE ISSUE FOR APPEAL.

Should the Court decline to reconsider its order, Sanofi respectfully requests that the Court certify its order for appeal under 28 U.S.C. § 1292(b). There is no basis to find this request untimely, and the issue presented by the Court's order merits the Third Circuit's intervention.

[1] Mylan prefers the term "submarket," but that label does not change the inquiry, which still turns on whether the products are "interchangeable." *Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421, 441 n.90 (3d Cir. 2016) (rejecting Mylan's argument that competitor's branded drug was its own "submarket").

A. Sanofi's motion is not untimely.

Mylan's lead argument is that Sanofi's request is untimely. But there is no deadline for such a request in § 1292(b) itself; in any of the Federal Rules of Civil Procedure; in any local rule; or in Federal Rule of Appellate Procedure 5(a)(3), which provides that "the district court may amend its order" to include language required under § 1292(b). Mylan cites two cases from another district that rely on Seventh Circuit caselaw for the idea that there is some unwritten deadline. Opp. 11. But how the Seventh Circuit "chooses to exercise its discretion[]" under § 1292(b) "has nothing to do with whether this Court should permit [a movant] to seek an interlocutory appeal to the U.S. Court of Appeals for the Third Circuit." *Lutch v. Huffy Corp.*, 2006 WL 2546945, at *5 n.2 (W.D. Pa. Sept. 1, 2006). The Third Circuit has adopted no such artificial limit. Indeed, it has observed that the lack of any deadline in Rule 5 "substantially undercut[s]" the notion that even "considerable delay" would deprive the court of discretion to certify its order. *Braden v. Univ. of Pittsburgh*, 552 F.2d 948, 952 (3d Cir. 1977); *cf. JPMorgan Chase Bank, N.A. v. Argus Info. & Advisory Servs. Inc.*, 802 F. Supp. 3d 733, 736 (D. Del. 2025) (Bibas, J., sitting by designation) ("District courts are not free to create" a requirement that "lacks a basis in the text of the civil rules.").

In any event, there has been no unreasonable delay. Sanofi did not "simply st[and] silent" since the Court issued its decision. *Contra* Opp. 12. To the contrary, in addition to answering the complaint, Sanofi devoted considerable attention to the expedited 120-day "period of jurisdictional discovery" ordered by this Court (*see* Op. 51)—including meeting and conferring and negotiating by email with Mylan throughout February and March. *See* ECF 97 ¶ 2 (documenting meetings and correspondence). That effort culminated in an agreement to dismiss two unnecessary foreign defendants, thereby obviating the need to complete jurisdictional discovery or address the applicability of the Hague Convention on Discovery. There is no doubt that this agreement will

"*speed up* discovery," as promised. Opp. 12. So, too, would resolution of the present motion, which was timely filed under the rules and caselaw of this Circuit, well before the initial case management conference.

B. The issue presented merits interlocutory review.

The Court should certify its order under § 1292(b) because it meets all of the statute's requirements, and Mylan's arguments to the contrary are unavailing.

Controlling question of law. Whether bundling discounts on products in the same relevant product market can give rise to a cognizable antitrust claim is a question of pure law that the Third Circuit could answer without reference to any facts. And it is controlling here, because it is "serious to the conduct of the litigation," both "practically" and "legally." *Davis v. Albert M. Higley Co., LLC*, 2025 WL 1094138, at *2 (W.D. Pa. Apr. 11, 2025) (citation omitted). Should the Third Circuit hold that bundling must link multiple markets to be actionable, that would cut down one of the two main pillars of Mylan's case, leaving only its patent-related allegations.

Mylan responds (without explanation) that even if its "tying theory" fails, its "exclusive dealing theory would independently keep its claim alive." Opp. 12. But the complaint alleges that Sanofi "conditioned rebates for Toujeo on PBMs' agreement to exclude biosimilar insulin glargine products from formularies" (Compl. ¶ 11); "bundle[d] Toujeo with Lantus" (*id.* ¶ 13); and "maintain[ed] its market power over insulin glargine by tying [Lantus and Toujeo] together through rebates" (*id.*). In other words, bundling Lantus and Toujeo rebates is the only "vehicle of exclusive dealing" that Mylan alleges. Op. 38. If those bundling allegations are legally insufficient, there is no separate claim of exclusive dealing left in the complaint, which defeats not just Mylan's Sherman Act, Clayton Act, and New Jersey Antitrust Act claims, *see id.* at 48, but also its tortious inducement claim, which is premised entirely on "Sanofi's rebating practices," *id.* at 50.

Mylan also argues that the question might not control the outcome of its claim because it

"alleges plausible submarkets," so Sanofi's bundling of Lantus and Toujeo may actually have linked separate markets. Opp. 13-14. But as explained above (*supra* 4-5), Mylan's complaint nowhere alleges that Lantus and Toujeo are in separate markets or separate submarkets.

Substantial ground for difference of opinion. The issue presents a substantial ground for a difference of opinion because the Court's order, which allows Mylan to proceed to discovery on a theory of bundled discounts within the same product market, conflicts with the Third Circuit's explanation that bundling requires "two separate product markets." *ZF Meritor*, 696 F.3d at 274 n.11. Mylan attempts to invent a new requirement by arguing that, even if Sanofi is correct that its allegations are defective, Sanofi has not cited any case "requiring dismiss[al]" for that reason. Opp. 14. But if Mylan's allegations do not state a claim, Rule 12(b)(6) itself requires dismissal. In any case, § 1292(b) merely requires "genuine doubt as to the correct legal standard." *Davis*, 2025 WL 1094138, at *2 (citation omitted).

Materially advance termination of the litigation. Whether a single-product-market bundling claim is cognizable is a "'gateway' issue" for a substantial portion of Mylan's case. *Ellis v. Westinghouse Elec. Co., LLC*, 2020 WL 4499931, at *19 (W.D. Pa. Aug. 5, 2020). Thus, allowing the Third Circuit to address that pure legal question at the outset "may materially advance the ultimate termination of the litigation," as § 1292(b) requires. Should the Third Circuit agree, Mylan's case will narrow significantly, obviating any need for discovery into years of negotiations among the PBMs and Sanofi, Mylan, and third-party manufacturers.

In response, Mylan argues that interlocutory appeal would not advance termination because this is a "multi-theory, multi-claim case." Opp. 14-15. But Mylan cannot seriously contest that the loss of its bundling claim would dramatically reduce the case's scope. The Court has dismissed Mylan's product-hop claim, so only Mylan's patent-related claims would remain. Mylan suggests

those claims are nonetheless "significant," based on "the District of Massachusetts' recent entry of summary judgment *against* Sanofi as to the impropriety of its Orange Book listings." *Id.* at 15. But that litigation is not controlling here as a matter of law or fact and, in any case, the court *did not hold* that Sanofi's Orange Book listings violated the antitrust laws. Rather, the court held "Purchasers are entitled to summary judgment on one narrow issue—that Sanofi improperly submitted the Pen Patents to the FDA for listing in the Orange Book—an issue that Sanofi did not contest on summary judgment." *In re Lantus Direct Purchaser Antitrust Litig.*, 2026 WL 939793, at *1 n.4 (D. Mass. Mar. 24, 2026). After acknowledging that "the [First] Circuit recognized … that 'the defenses to antitrust liability as a result of such an improper submission include proving that the submission was the result of a reasonable, good-faith attempt to comply with the Hatch-Waxman scheme,'" the court held that "the summary-judgment record is mixed" and *denied* plaintiffs' motion for summary judgment in that regard. *Id.* at *2-4.[2]

The Court's discretion. Finally, Mylan's request that the Court exercise its discretion to reject certification is flawed. First, Sanofi engaged in no "gamesmanship" when negotiating the dismissal of unnecessary foreign defendants. That dismissal will "speed discovery" by making it more efficient, whether it commences now or after interlocutory appeal. *Supra* 6-7. Second, the only "full record" (Opp. 15) necessary under Rule 12(b)(6) is the complaint. Again, there are no "market definition issues" (*id.*) presented by Mylan's actual complaint—which alleges a single

[2] Moreover, Mylan's claims are factually distinct from those at issue in Massachusetts—indeed, the *Lantus* plaintiffs abandoned any claim that "Sanofi's conduct caused FDA to delay approval for Mylan's product" after discovery, proceeding only with their claims as to delay of two other pharmaceutical companies' insulin glargine products (Lilly and Merck). *See In re Lantus*, No. 1:16-cv-12652 (D. Mass.), ECF No. 585 at 11 n.4; *see also id.*, ECF No. 657 at 6-7 (R&R referring only to Lilly and Merck in factual background). Here, by contrast, Mylan will have to prove that Sanofi's patent-related conduct caused FDA approval of Semglee to be delayed, a seemingly impossible feat given that FDA did not approve Semglee until several months *after* the expiration of the 30-month stay stemming from Sanofi's patent infringement suit against Mylan. *Compare* Compl. ¶ 132 (30-month stay expired March 19, 2020), *with id.* ¶ 136 ("FDA approved Mylan's application on June 11, 2020."). Mylan itself acknowledges that "[w]hen the 30 months have expired, the patent ceases to be a barrier to final FDA approval." *Id.* ¶ 76.

relevant product market—that could cure the defect in Mylan's bundling theory. *Supra* 4-5.

III. THE COURT SHOULD STAY PROCEEDINGS DURING RECONSIDERATION OR APPEAL.

If the Court is inclined to reconsider or certify, it should stay proceedings pending its order on reconsideration or the Third Circuit's resolution of Sanofi's § 1292(b) petition (and, if granted, the appeal). A stay of discovery is proper where a pending motion "may result in a narrowing or an outright elimination of discovery" and where the burden of extra delay is "minimal." *N. Am. Commc'ns v. InfoPrint Sols. Co.*, 2011 WL 4571727, at *2, 4 (W.D. Pa. July 13, 2011). And Section 1292(b) expressly grants the Court the authority to "so order" a stay, which would spare the parties and the Court any wasted effort while "permit[ting] the process contemplated by 28 U.S.C. § 1292(b) to play out." *Ellis*, 2020 WL 4499931, at *20.

Mylan wrongly attempts to impose the traditional stay factors on Sanofi's request, but none of Mylan's cases concerns a stay under the Court's statutory authority in § 1292(b). A major purpose of that statute is "avoiding the wasted effort" of potentially unnecessary litigation. *Katz v. Carte Blanche Corp.*, 496 F.2d 747, 754 (3d Cir. 1974). To avoid such waste, "courts have routinely granted a stay where they have certified an order for interlocutory appeal." *Consumer Fin. Prot. Bureau v. Navient Corp.*, 522 F. Supp. 3d 107, 120 (M.D. Pa. 2021); *see, e.g.*, *Rankin v. PTC All. LLC*, 2023 WL 8438604, at *4 (W.D. Pa. Dec. 5, 2023); *Ellis*, 2020 WL 4499931, at *20 (Hornak, J.); *G.L. v. Ligonier Valley Sch. Dist. Auth.*, 2013 WL 6858963, at *6 n.14 (W.D. Pa. Dec. 30, 2013) (Hornak, J.). The Court should do the same here.

CONCLUSION

The Court should grant reconsideration or certify its order for interlocutory appeal and stay proceedings pending either form of relief.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a copy of this document was served on all counsel of record via ECF filing on May 6, 2026.

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