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

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| MYLAN PHARMACEUTICALS INC., MYLAN SPECIALTY L.P., and MYLAN INC.<br><br>Plaintiffs,<br><br>v.<br><br>SANOFI-AVENTIS U.S. LLC and SANOFI-AVENTIS PUERTO RICO INC.<br><br>Defendants. | Civil Action No. 2:23-cv-836-MRH |

**PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION FOR RE-CONSIDERATION OR CERTIFICATION OF INTERLOCUTORY APPEAL AND TEMPORARY STAY**

## INTRODUCTION

Defendants (collectively, "Sanofi") have not begun to show that this Court's Rule 12 Order is the rare and clearly erroneous ruling that warrants reconsideration, let alone that it presents the sort of exceptional circumstances warranting interlocutory review and a stay of discovery.

Sanofi begins with a request for reconsideration of just one aspect of this Court's January 2026 order: the Court's holding that Mylan adequately alleged that Sanofi unlawfully bundled rebates. Sanofi does not cite any new authority or evidence in support of its request; instead, it says this Court erroneously issued an "implicit" holding that violates Third Circuit precedent. But Sanofi's reconsideration request is a thinly veiled rehash of the same arguments that this Court already considered and rejected, and numerous authorities recognize that such disagreement with a court's ruling provides no basis for reconsideration. In any event, the Court did not err: it correctly applied Rule 12(b)(6)'s pleading standard and Third Circuit precedent in holding that Mylan adequately stated a claim. The Court's careful analysis does not require reconsideration.

Sanofi's belated attempt to seek interlocutory appellate review of Mylan's bundling claim fares no better. For starters, Sanofi's 63-day delay renders the motion untimely. And even if the Court were to consider the motion's substance, there is no controlling question of law or substantial difference of opinion that would justify interlocutory appellate review. Indeed, because a large part of this case will necessarily proceed—a fact that Sanofi freely concedes—Sanofi's motion is an unjustified request for piecemeal and inefficient adjudication of Mylan's claims.

Finally, Sanofi makes no effort to carry its burden to justify a stay of discovery in this action; nor is one warranted. Sanofi's motion should be denied in full.

## FACTUAL AND PROCEDURAL BACKGROUND

***This Action and Sanofi's Motion to Dismiss.*** Three years ago, Mylan sued Sanofi for

anticompetitive conduct. Mylan alleged that, from 2001 to 2015, Sanofi held a multi-billion-dollar monopoly over insulin glargine, which it sold under the brand name Lantus, by virtue of a patent protecting its composition. ECF 1 (Compl.) ¶¶ 18, 82, 93. When that patent expired, competitors should have been free to enter the market with lower-priced insulin. *Id.* ¶ 93. That did not happen. Instead, Sanofi unlawfully maintained its monopoly well past the expiration date, continuing to raise prices, restrict supply, block competition, and accrue billions in profits. *E.g.*, *id*. ¶ 2. It did so by weaponizing the FDA approval process, forcing the market to adopt a second insulin glargine product (Toujeo), enacting an improper exclusionary rebating scheme to protect itself from competition while it made the switch to the second product, and punishing any customer who tried to make purchases outside the Lantus/Toujeo rebate bundle. *E.g.*, *id.* ¶ 3. Mylan alleged that these efforts foreclosed its generic alternative, Semglee, and other competing insulin glargine products from the market, in violation of the Sherman Act, the Clayton Act, and state law. *Id*. ¶¶ 140-265.

In September 2023, Sanofi moved to dismiss Mylan's Complaint. ECF 49-50. As relevant to the sole issue presented here—the component of Mylan's Sherman Act claim based on impermissible bundling of rebates—Sanofi conceded that "'bundled rebates and discounts' can 'operate as exclusive dealing arrangements,'" but argued that this principle applied only when "'a *single-product producer* is excluded through a bundled rebate program offered by a producer of multiple products.'" ECF 50 at 4 (citation omitted). According to Sanofi, "Mylan's bundling claim fail[ed] . . . because Mylan fail[ed] to allege bundling of products in 'separate products markets'" (*id.* at 6 (citation omitted)) and Mylan was not "a 'single-product competitor.'" *Id.* at 7.

Mylan's response explained that it was alleging not "that Sanofi committed a discrete series of separate anticompetitive acts," but rather "that Sanofi orchestrated a comprehensive plan to maintain a 20-year+ monopoly" via "interconnected anticompetitive acts." ECF 59 at 6. As to

Sanofi's bundled rebates, Mylan explained that under binding Third Circuit precedent, "[o]ne way to 'break the competitive mechanism,' is by tying different products together for the purpose of bundling rebates across products, foreclosing the market to a competitor who does not 'manufacture an equally diverse group of products.'" *Id.* at 15 (citations omitted). Mylan also explained that Sanofi's own cases and the FTC reject Sanofi's view that precedent requires tying claims to "refer to competitors that *literally* offer only a single product." *Id.* at 19 & n.15.

***The Court's Order.*** On January 27, 2026, this Court denied most of Sanofi's motion to dismiss, ECF 84,[1] ordering 120 days of discovery as to personal jurisdiction over Sanofi S.A. ECF 85. On the merits, the Court noted that, at the pleading stage, Mylan need only "allege enough facts to 'raise a reasonable expectation that discovery will reveal evidence'" of its claims. ECF 84 at 15. Further, "because of the complexity and fact-dependent nature" of the claims, the Court stressed that "summary procedures should be used sparingly in complex antitrust litigation where motive and intent play leading roles [and] the proof is largely in [Sanofi's] hands." *Id.*

Applying that standard, the Court specifically analyzed Sanofi's position that "unlawful tying 'cannot exist unless two separate product markets have been linked,' and Lantus and Toujeo were part of the *same* product market." *Id.* at 39. The Court found it "improvident" to dismiss Mylan's claim at the pleading stage "because, accepting the facts asserted in Mylan's Complaint as true, Mylan satisfies the Third Circuit's test for plausibly alleging unlawful tying," under which bundled discounts can constitute anticompetitive conduct when they foreclose portions of the market to a potential competitor that does not have an "equally diverse group of products." *Id.* at 40 (quoting *Regeneron Pharms., Inc. v. Amgen Inc.*, 2023 WL 1927544, *6 (D. Del. Feb. 10, 2023)).

[1] The Court dismissed Mylan's claim based on a product hop theory but permitted it to use product hopping allegations to support its other claims of anticompetitive behavior. ECF 84 at 2.

As the Court recognized, Mylan made "several allegations of bundled contracts between Sanofi and PBMs to purchase Lantus and Toujeo at a reduced price" that were conditioned on "the exclusion of biosimilar insulin glargine products," and it alleged that "those agreements required buyers to purchase Lantus and Toujeo or else rebates on *both* products would be reduced." *Id.* at 40-41. The Court held that those allegations satisfied Rule 12(b)(6). *Id.*

***Events Leading to This Motion.*** The parties then began jurisdictional discovery. Mylan served its first written discovery requests in February 2026 (Seite Decl. ¶ 4), and the parties also negotiated the required jurisdictional discovery schedule, engaging in meet and confers. *Id.* ¶ 5. During one such meeting, Sanofi told Mylan that it intended to argue that Hague Convention procedures applied to all discovery directed at Aventis Pharma S.A. ("Aventis") and Sanofi S.A. and any documents that were owned by those entities and in the possession of the other defendants. Sanofi represented that it had negotiated dismissal of foreign Sanofi entities in other actions by guaranteeing that Sanofi U.S. could satisfy any judgment, and it asked "to discuss a similar resolution here." *Id.* ¶ 7. Mylan agreed to consider Sanofi's proposal.

Notably, during negotiations, Sanofi continually asked Mylan to dismiss Aventis—even though Aventis was concededly subject to personal jurisdiction. *Id.* ¶ 8. Sanofi's counsel tried to justify this request by claiming that they were "trying to make discovery easier" because the Hague Convention would govern discovery served on Aventis. *Id.* ¶ 9. Ultimately, Mylan stipulated to dismissing Sanofi S.A. and Aventis without prejudice. The stipulation expressly provided Sanofi S.A. would provide certain discovery without forcing Mylan to invoke the Hague Convention.

On March 26, 2026, the parties filed their stipulation and a status report stating that they "[we]re prepared to move forward" with the initial case management process contemplated by Local Civil Rule 16.1. ECF 102 ¶ 4; *see also* LCvR 16.1.A.1. Notably, although Sanofi's counsel

later admitted that they had been contemplating the instant motion since the Court's Order (Seite Decl. ¶ 11), at no point during negotiations over the stipulation did Sanofi mention that it might seek reconsideration or an interlocutory appeal, much less a stay of all discovery. *Id.* ¶ 10.

This is not the only case against Sanofi over anticompetitive conduct related to its insulin products: represented by the same counsel, it faces parallel claims in a class action in Massachusetts. *See In re Lantus Direct Purchaser Antitrust Litig.*, No. 1:16-cv-12652 (D. Mass.). And, on March 24, 2026—the *same day* the parties here reached an agreement in principle to forgo jurisdictional discovery and proceed with the case—that court there entered summary judgment against Sanofi, holding its "submission of a Pen Patent for Orange Book listing . . . improper" as a matter of law. *Id.*, ECF 679 at 3. The parties have since requested an October 2026 trial. *Id.*, ECF 682.

On March 31, 2026—just four days after the Court entered the parties' stipulation (*see* ECF 103), but *some 63 days* after the Order on the motion to dismiss—Sanofi notified Mylan for the first time that it intended to seek reconsideration or, alternatively, interlocutory review of that Order. Seite Decl. ¶ 10. Defendants filed this motion on April 7, 2026. *See* ECF 106.

## ARGUMENT

Sanofi presents three motions: (1) a motion for reconsideration; (2) an "alternative" motion for interlocutory appellate review; and (3) a motion to stay all discovery. All are without merit.

### I. Sanofi's motion for reconsideration lacks merit.

Sanofi's motion falls woefully short of the strict standard for reconsideration. "To preserve the court's interest in finality, motions for reconsideration . . . should be granted sparingly." *Carnevale v. Digiovanni*, 2026 WL 346207, *2-3 (W.D. Pa. Feb. 9, 2026). When a party asks to reconsider an interlocutory order, Rule 54(b) governs. *Id* at *3. Thus, the movant "must establish good cause for why the court should revisit its prior decision." *Id.* at *2. That analysis is guided

by the factors governing reconsideration of final orders under Rules 59(e) and 60(b), namely: (1) an intervening change in controlling law; (2) the availability of new evidence; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice. *Id.* at *3-4. Sanofi does not suggest that there has been an intervening change in the law or that new evidence has been discovered, and indeed neither is true. Instead, it proceeds on a theory of clear error—namely, that the Court wrongly issued an "implicit holding" that Mylan may assert a bundling claim based on products in the same market. ECF 106 at 3.[2] Sanofi is mistaken, for at least two independent reasons.

***First,*** a motion for reconsideration "is not an opportunity for the parties to relitigate issues that the court previously resolved or to present arguments or evidence that the movant could have offered prior to the issuance of the order for which reconsideration is sought." *Carnevale*, 2026 WL 346207, at *2. Nor is reconsideration "properly founded on a request that the Court 'rethink what [it] had already thought through—rightly or wrongly.'" *Pollock v. Energy Corp. of Am.*, 665 F. App'x 212, 218 (3d Cir. 2016) (alteration in original) (citations omitted). Yet Sanofi's motion is a rehash of a single argument made in its motion to dismiss—i.e., that Plaintiffs must plead, and ultimately prove, that Sanofi bundled discounts on products in separate product markets. *Compare* ECF 106 at 3-5, *with* ECF 50 at 4-7. Indeed, Sanofi's arguments in support of reconsideration directly track—often nearly verbatim—the points it made before. This chart tells the story:

| **Sanofi's Motion to Dismiss (ECF 50) & Reply in Support (ECF 66)** | **Sanofi's Motion for Reconsideration (ECF 106)** |
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| "Mylan fails to allege bundling across two separate product markets." (ECF 50 at 5)<br>"Mylan does not allege bundling of products across separate product markets." (ECF 66 at 3) | "As Sanofi argued in its motion to dismiss, a bundling claim, like a tying claim, 'cannot exist unless two separate product markets have been linked.'" (ECF 106 at 3) |

[2] Any arguments based on the first two factors are therefore waived. *E.g.*, *Calhoun v. Invention Submission Corp.*, 2019 WL 154372, *4 (W.D. Pa. Apr. 9, 2019).

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| "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 with Sanofi's bundled rebates, which is healthy price competition." (ECF 66 at 4-5) | "the fact that Sanofi offers two products does not somehow enable it to offer a higher aggregate discount that Mylan cannot match. Because Mylan's product can replace both, Mylan can achieve the same aggregate sales." (ECF 106 at 5) |
| "Mylan acknowledges its own allegations that Lantus, Toujeo, and Semglee are 'readily substitutable' and thus compete in the same product market." (ECF 66 at 3) | "Mylan's complaint alleges again and again that Lantus, Toujeo, and Semglee are all substitute products in the same product market." (ECF 106 at 4) |
| "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." (ECF 66 at 1)<br>"All that matters is that Semglee competes with both of Sanofi's drugs in the same product market." (ECF 66 at 4) | "Instead, Mylan garbled Sanofi's argument, claiming Sanofi was arguing 'that Lantus and Toujeo are the same products.' That is incorrect. The point is that, by Mylan's own telling, they are in the same *product market*." (ECF 106 at 5) |

Even Sanofi's cheeseburgers analogy is a rerun. *Compare* ECF 106 at 4, *with* ECF 66 at 3.

Given that Sanofi argued these issues at length in its motion to dismiss, it is not surprising that this Court expressly addressed Sanofi's argument in its Order. ECF 84 at 39-40. In fact, the Court devoted several pages to analyzing Mylan's bundling claim under Third Circuit precedent, including nearly every case that Sanofi now invokes. *Id.* at 38-41. Sanofi's displeasure with the result does not justify reconsideration (*Pollock*, 665 F. App'x at 218), and courts routinely deny reconsideration where, as here, the movant merely rehashes points in its motion to dismiss. *E.g.*, *Echols v. Premiere Credit of N. Am., LLC*, 2021 WL 5444771, *1 (E.D. Pa. Mar. 9, 2021) ("Plaintiff here seeks to relitigate issues already resolved against her without . . . demonstrating a clear error of law"); *Bowlen v. Coloplast A/S*, 2019 WL 4597570, *1-2 (W.D. Pa. Sept. 23, 2019) (reconsideration should not "sanction[] the relitigation of matters already considered and decided"), *In re Diisocyanates Antitrust Litig.*, 2026 WL 522845, *4-5 (W.D. Pa. Feb. 25, 2026) (plaintiffs failed to show clear legal error where they relitigated dismissal points). That alone warrants denial.

***Second***, Sanofi's motion misunderstands both the clear error standard and the underlying law. Clear error only exists "if after reviewing the evidence, the Court is left with a definite and firm conviction that a mistake has been committed." *Black Bear Energy Servs., Inc. v. Youngstown Pipe & Steel, LLC*, 2017 WL 2985432, *5 (W.D. Pa. July 13, 2017) (citation modified). Such a mistake must be "plain and indisputable"—"a complete disregard of the controlling law." *Diiso-cyanates*, 2026 WL 522845, *4 (citations omitted). This Court committed no error at all, let alone a plain and indisputable one.

For starters, as Mylan explained in response to Sanofi's Motion to Dismiss, ECF 59 at 18-19, Sanofi's reading of *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254 (3d Cir. 2012), as applying only to competitors that literally only offer one product is nonsensical. First, it sidesteps explicit language recognizing that the reason LePage's could not compete with 3M was not because it sold only one product, but because "it did not sell *the same* diverse array of products as 3M." *Id.* at 274 n.11 (emphasis added). Second, LePage's *itself* sold more than one product, so the holding of that decision cannot be so limited, *see* Second Am. Compl. ¶ 1, *LePage's Inc. v. 3M*, No. 97-cv-3983 (E.D. Pa. Sept. 2, 1998). As Sanofi reads it, *ZF Meritor* effectively overruled *LePage's*, which the *ZF Meritor* panel did not purport to do (nor could it, *see In re Aleckna*, 13 F.4th 337, 344 n.38 (3d Cir. 2021)). Sanofi thus lacks *any* binding authority barring claims like Mylan's—confirming that there could not be a "clear error" of law here. *In re Abbott Lab'ys*, 96 F.4th 371, 380 (3d Cir. 2024).

Even taken at face value, moreover, Sanofi's claim of error does not rest on any explicit holding of this Court—only a purported "implicit holding" "that Mylan may assert a bundling claim based on products in the same product market." ECF 106 at 3. According to Sanofi, this violates "express" teaching that "*LePage's*' does not extend to 'rebates offered by suppliers within a single-product market.'" *Id*. (quoting *ZF Meritor*, 696 F.3d at 274 n.11). But this Court made no

such holding. Rather, it recognized that "[b]undled rebates could be a vehicle of exclusive dealing *or* of unlawful tying" (ECF 84 at 38) and held that, "[a]t this [motion to dismiss] stage"—where it accepts "Mylan's Complaint as true"—Mylan "satisfie[d] the Third Circuit's test for plausibly alleging unlawful tying." *Id.* at 40. The Court then recited *LePage's* binding holding "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," *id.* (citing *LePage's, Inc. v. 3M*, 324 F.3d 141, 155 (3d Cir. 2003) (citation modified)), and applied that law to Mylan's specific allegations. *See id.* at 40-41. A court does not commit clear error by carefully applying binding precedent. *See Shoop v. Pa. Bd. of Parole*, 2025 WL 2178422, *7 (M.D. Pa. July 31, 2025).

In addition, even under Sanofi's unsupported test, Mylan has alleged a valid bundling claim. Mylan's allegations support a finding that, despite similar indications, Sanofi's anticompetitive conduct established that Toujeo is in a distinct product market in a separate submarket from the broader insulin glargine market—namely, a higher concentration drug that releases insulin more slowly. *E.g.*, ECF 1 ¶ 195.[3] A jury could find, as Mylan alleges, that Sanofi anticompetitively extended its regulatory exclusivity, thereby gaining market power, as evidenced in part by Sanofi's ability to avoid substituting products on the sell-side (i.e., its ability to continue selling both Lantus and Toujeo). Then, Sanofi exploited that market power to set prices so as to avoid any incentive to switch products on the buy-side (i.e., avoid purchasers switching to generic alternatives, such as Semglee). *E.g.*, *id.* ¶¶ 13, 208. Because properly defining submarket boundaries is a complex and "fact-intensive exercise that often must be refined through discovery," the issue is ill-suited

[3] Although Mylan's Complaint did not specifically use the term "submarket," the absence of such "labeling" is "not controlling"—it is "the substance of the allegations" that "are of paramount importance." *Downs v. Andrews*, 639 F. App'x 816, 819 (3d Cir. 2016) (citation omitted).

for resolution on a motion to dismiss. *Multiple Energy Techs., LLC v. Under Armour, Inc.*, 2021 WL 807722, *2 (W.D. Pa. Mar. 3, 2021). Thus, as the Order noted, courts routinely allow this type of claim to survive not only at the pleading stage, but beyond. *See* ECF 84 at 41; *see* Order at 1, *Regeneron Pharms., Inc. v. Amgen Inc.*, No. 22-697-JLH (D. Del. Apr. 10, 2025), ECF 419 (denying defendant summary judgment, as "a jury could find that [it] offered bundled discounts that restricted [the plaintiff's] access to portions of the market because it did not have an equally diverse drug portfolio," even though neither party was a single-product company).[4] That Sanofi dislikes this Court's approach does not show clear error. *In re Energy Future Holdings Corp.*, 904 F.3d 298, 312 (3d Cir. 2018) (movant must show "more than mere disagreement with the earlier ruling").

## II. Sanofi's motion for Section 1292(b) review lacks merit.

### A. Sanofi's motion is untimely.

Sanofi does not mention Section 1292(b)'s timeliness requirement, but it cannot meet it. Section 1292(b) motions must be filed within a "reasonable time" after the challenged order issued. *E.g.*, *Liberty Salad, Inc. v. Groundhog Enters., Inc.*, 2019 WL 1303829, *3 (E.D. Pa. Mar. 20, 2019). The courts have repeatedly "held that a delay of two months or more is unreasonable." *Id.*; *see Chijioke-Uche v. AmeriCredit Fin. Servs., Inc.*, 2025 WL 3567180, *1 n.1 (E.D. Pa. Mar. 6, 2025) (collecting cases). Here, Sanofi let *63 days* lapse between the Court's Order and notifying Plaintiffs of its intent to file this motion.[5] Sanofi offers no reason for the delay, let alone a "good

[4] This Court's Order is also consistent with antitrust law's recognition that while two products may be "functional[ly] interchangeable" (i.e., as with Semglee and Toujeo), "other economic factors may nonetheless restrict the cross-elasticity of demand between two products and confine them to different product markets"—as is the case here, as a result of Sanofi's anticompetitive conduct. *Regeneron Pharms., Inc. v. Novartis Pharma AG*, 96 F.4th 327, 340 (2d Cir. 2024) (comparing to *FTC v. AbbVie Inc.*, 976 F.3d 327, 372-73 (3d Cir. 2020)).

[5] Sanofi first told Mylan of its intent to file on March 31, 2026. Seite Decl. ¶ 10. During the parties'

reason." Nor could it, given that Sanofi's counsel freely acknowledged it had been considering the motion *since the Court's opinion came out.* Seite Decl. ¶ 11. Sanofi simply stood silent, waiting until (1) it negotiated a stipulated dismissal of two defendants, suggesting that this would *speed up* discovery, and (2) the Court signaled discovery would begin. *See* ECF 103. This Court should not countenance Sanofi's behavior, let alone treat it as a "good reason" for delay.

**B. Even if Timely, Sanofi's Motion for Interlocutory Appeal is Meritless.**

"Even had [Sanofi] requested certification under § 1292(b) sooner, it is nonetheless inappropriate here." *Liberty Salad*, 2019 WL 1303829, *3. "[T]he burden is on the movant to demonstrate that a 1292(b) appeal is warranted." *Animal Legal Def. Fund v. Lucas*, 2022 WL 17668796, *1 (W.D. Pa. Dec. 14, 2022) (citation omitted). "Each of the elements must be satisfied for certification, and even if all the elements are satisfied, the ultimate decision to grant certification is within the district court's sole discretion." *Glover v. Udren*, 2013 WL 3072377, *1 (W.D. Pa. June 18, 2013). Sanofi cannot satisfy Section 1292(b)'s mandates here.

***No Controlling Question of Law:*** First, Sanofi identifies no controlling question of law. A controlling question must ordinarily "result in a reversal of a judgment," *Katz v. Carte Blanche Corp.*, 496 F.2d 747, 755 (3d Cir. 1974) (en banc), and does not exist where plaintiffs' "alternative theories" could keep a claim alive, *Coleman v. Commonwealth Land Title Ins. Co.*, 2013 WL 12155806, *1 n.1 (E.D. Pa. Dec. 12, 2013). That is the case here. First, Sanofi seeks review of Mylan's tying theory, but Mylan's exclusive dealing theory would independently keep its claim alive. ECF 84 at 39-40. Because it is "conceivable that the Court of Appeals could reverse the

April 1, 2026, meet and confer, Defendants' counsel agreed to provide Plaintiffs an extension through Monday, April 6, 2026, to provide their position, given certain religious holidays. Plaintiffs' counsel agreed not to cite the extra days—i.e., April 2 through April 6—as support for an untimeliness argument. *Id*. But a 63-day-delay is itself untimely as a matter of law.

Court's conclusion" on tying "but still affirm" based on exclusive dealing, Sanofi's motion "does not present a controlling question of law." *Acosta v. Pace Loc. I-300 Health Fund*, 2007 WL 1074093, *1 (D.N.J. Apr. 9, 2007). Second, as Sanofi concedes, the portion of Mylan's case based on Sanofi's improper listing of patents in the Orange Book and sham patent litigation will proceed irrespective of Sanofi's belated challenge here. ECF 106 at 1. And given that the District of Massachusetts recently entered summary judgment *against* Sanofi as to the impropriety of its Orange Book listings, *In re Lantus Direct Purchaser Antitrust Litig.*, No. 1:16-cv-12652 (D. Mass.), ECF 679, there can be no suggestion that this is somehow an insignificant part of this case.

For similar reasons, Sanofi cannot show that its question is so "serious to the conduct of the litigation," *Katz*, 496 F.2d at 755, as to "overcome[] the concerns of confusion and delay caused by protracted, piecemeal litigation." *MLB Players, Inc. v. DraftKings, Inc.*, 2025 WL 1462547, *6 (E.D. Pa. May 21, 2025). However the tying issue is resolved, Mylan will still press (1) its exclusive dealing theory; (2) its Sherman Act and New Jersey antitrust claims that Sanofi monopolized the insulin glargine market; and (3) its claim that Sanofi tortiously induced a refusal to deal. Sanofi *asserts* "serious consequences" on discovery (*id.*), but does nothing to explain how "[t]he discovery then undertaken would . . . be materially affected by the legal theory of liability." *Figueroa v. Point Park Univ.*, 2021 WL 4975196, *4 (W.D. Pa. Oct. 26, 2021). These conclusory assertions cannot carry Sanofi's "burden of demonstrating that certification . . . is warranted." *Id.* at *2.

There is also no "controlling question of law" when "the dispute turns on the court's application and interpretation of the facts." *Johnson v. PG Publ'g Co.*, 2021 WL 4171420, *2 (W.D. Pa. Sept. 14, 2021). Sanofi's (incorrect) theory hinges on eventual market and submarket definitions. But "[m]arket definition is a question of fact," *Weiss v. York Hosp.*, 745 F.2d 786, 825 (3d Cir. 1984), as is "whether a submarket exists," *Yeager's Fuel, Inc. v. Pa. Power & Light Co.*, 953

F. Supp. 617, 645 (E.D. Pa. 1997). As explained above, Mylan alleges plausible submarkets (*see supra* at 8-9), and discovery will illuminate the exact market delineations. Those fact issues mean there is no "controlling question of law." *Johnson*, 2021 WL 4171420, *2.

***No Substantial Ground for Difference of Opinion:*** Second, there is no substantial ground for difference of opinion. All Sanofi offers is "disagreement with the district court's ruling," which "does not suffice." *Glover*, 2013 WL 3072377, *3. Most notably, Sanofi cites *no* decisions reading *LePage*'s and *ZF Meritor* to require dismissing bundling allegations under Rule 12(b)(6)—it simply rehashes its misreading of the law, which this Court has already rejected. ECF 106 at 40.[6]

***Will not Materially Advance the Termination of the Litigation:*** Third, Sanofi cannot show that § 1292(b) review would materially advance the termination of the litigation. Even when (unlike here) an appeal might "obviate a significant . . . claim presented by the Plaintiffs and might well alter the arc of the litigation, including but not limited to the discovery and pretrial process," certification is not warranted when "the balance of the litigation that would remain is also significant." *Howard v. Arconic Inc.*, 2022 WL 3021549, *2 (W.D. Pa. July 29, 2022). After all, "in every complex, multi-claim civil case, interlocutory [review] would likely . . . truncat[e] the scope of the action," but "that broadly applicable truism is not the test." *Id.* Rather, § 1292(b) certification "is generally reserved for 'exceptional cases where an intermediate appeal would avoid protracted and expensive litigation.'" *D.C. ex rel. A.T. v. Pittsburgh Pub. Schs.*, 2020 WL 4670378, *2 (W.D. Pa. Aug. 12, 2020) (quoting *Forsyth v. Kleindienst*, 599 F.2d 1203, 1208 (3d Cir. 1979)).

Sanofi cannot clear that hurdle. It asks the Court to certify one theory of one claim in a

[6] Sanofi also says an "absence of precedent" can itself "amount[] to substantial grounds for difference of opinion" (ECF 106 at 11), but "the fact that an action raises a question of first impression is not alone sufficient to support certification." *Complaint of Imperial Towing Inc.*, 2012 WL 6460068, *2 (W.D. Pa. Dec. 13, 2012) (Hornak, J.). And in any case, decisions cited by the Court, *e.g.*, *Regeneron*, 2023 WL 1927544, confirm that precedent supports its holding.

multi-theory, multi-claim case, much of which will proceed. As in *Arconic*, "the balance of the litigation that would remain is . . . significant." 2022 WL 3021549, *2. Piecemeal adjudication would thus "significantly delay the resolution of this case," without corresponding benefits. *Pa. Skill Games, LLC v. Action Skill Games, LLC*, 2021 WL 243038, *4 (W.D. Pa. Jan. 25, 2021). And again, the District of Massachusetts' recent entry of summary judgment *against* Sanofi as to the impropriety of its Orange Book listings, *see supra* at 5, demonstrates that the only plausible outcome of Sanofi's request, if granted, would be piecemeal adjudication and further delay.

***The Court Should Exercise its Discretion Not to Certify.*** Even apart from the foregoing analysis, the Court should exercise its discretion not to certify. *Glover*, 2013 WL 3072377, *3. As discussed, Sanofi negotiated dismissal of its foreign entities on the premise that dismissal would speed discovery, then *belatedly sought reconsideration, § 1292(b) review, and a stay* delaying the very discovery it promised. That alone justifies denying relief—as does the importance of ensuring "a full record before considering the disputed legal issue." *Katz*, 496 F.2d at 754. Denying relief is especially warranted due to the fact-intensive nature of the market definition issues.

## III. Sanofi's motion for a discovery stay lacks merit.

Sanofi's failure to address the criteria for a discovery stay itself warrants denying relief. *United States v. Breyer*, 41 F.3d 884, 893 (3d Cir. 1994). Nor can it satisfy them. *See Nken v. Holder*, 556 U.S. 418, 433-34 (2009). Most glaringly, Sanofi never tries to show irreparable harm—it says only that a stay "would avoid potentially unnecessary discovery." ECF 106 at 12. But "litigation expense," even if "substantial and unrecoupable," is not "irreparable injury." *Renegotiation Bd. v. Bannercraft Clothing Co*., 415 U.S. 1, 24 (1974). The lack of such harm is "on its own, fatal." *S.S. Body Armor I., Inc. v. Carter Ledyard & Milburn LLP*, 927 F.3d 763, 775 (3d Cir. 2019). And, as discussed, this case will require discovery however the issue that Sanofi presses

here is resolved.[7]

Finally, although this Court "need not … assess" the "remaining factors" (*id.*), Sanofi cannot satisfy them either. As to likelihood of success, Sanofi's reconsideration motion merely rehashes its unsuccessful motion to dismiss, and its § 1292(b) request is both untimely and deficient—independently "fatal" flaws. *Id*. at 772. As to the balance of private interests, Mylan will be prejudiced by delay, and by the risk of losing evidence as witnesses' memories fade. *See Parker v. Haynes*, 2025 WL 1396343, *2 (D. Del. May 14, 2025). To boot, substantial claims will remain no matter what, and Sanofi has engaged in gamesmanship on discovery. *See Huffman v. Prudential Ins. Co.*, 2018 WL 1281901, *3 (E.D. Pa. Mar. 12, 2018) (stay would prejudice plaintiffs because Third Circuit ruling would not resolve all claims). And the public interest is furthered by "effective enforcement of the antitrust laws," *FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 352 (3d Cir. 2016), which Sanofi is routinely violating, *see In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 10 (1st Cir. 2020) (holding that it was "improper for Sanofi to have submitted [its patent] for listing in the Orange Book as a drug claiming . . . insulin glargine").

**CONCLUSION**

For the foregoing reasons, Sanofi's motions should be denied.

Dated: April 21, 2026

/s/ *Evan L. Seite*
Evan L. Seite (admitted *pro hac vice*) (CA 274641)

[7] Contrary to Sanofi's claim (at 12), this case is unlike *Ellis v. Westinghouse Elec. Co.*, 2020 WL 4499931, *1 (W.D. Pa. Aug. 5, 2020), *rev'd on other grounds*, 11 F.4th 221 (3d Cir. 2021), which "present[ed] a Gordian Knot of bankruptcy law entangled with an employment discrimination claim, spanning different courts in two jurisdictions." And the notion that a stay is warranted simply to "permit the [review] process" to "play out" (Mot. 12) is foreclosed by the text of § 1292(b), which states that certification "*shall not stay proceedings in the district court*" unless separately ordered. Courts routinely certify orders without entering a stay. *In re Chocolate Confectionary Antitrust Litig.*, 607 F. Supp. 2d 701, 709 (M.D. Pa. 2009).

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*Counsel for Plaintiffs Mylan Pharmaceuticals Inc., Mylan Specialty L.P., and Mylan Inc.*

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

| | |
|---|---|
| MYLAN PHARMACEUTICALS INC., MYLAN SPECIALTY L.P., and MYLAN INC.<br><br>Plaintiffs,<br><br>v.<br><br>SANOFI-AVENTIS U.S. LLC and SANOFI-AVENTIS PUERTO RICO INC.<br><br>Defendants. | Civil Action No. 2:23-cv-836-MRH |

**DECLARATION OF EVAN L. SEITE IN SUPPORT OF PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION FOR RECONSIDERATION OR CERTIFICATION OF INTERLOCUTORY APPEAL AND TEMPORARY STAY**

I, Evan L. Seite, declare as follows:

1. I am an attorney licensed to practice law in California.

2. I am a partner of the law firm Wilson Sonsini Goodrich & Rosati, P.C., and counsel of record for Plaintiffs Mylan Pharmaceuticals Inc., Mylan Specialty L.P., and Mylan Inc. (collectively "Plaintiffs") in the above-captioned action.

3. I submit this Declaration in support of Plaintiffs' Response in Opposition to Defendants' Motion for Reconsideration or Certification of Interlocutory Appeal and Temporary Stay. Unless otherwise stated, I have personal knowledge of the matters set forth herein and, if called a witness, could and would testify competently thereto.

4. On February 10, 2026, Plaintiffs served their first set of written jurisdictional discovery requests on Sanofi S.A., Aventis Pharma S.A., Sanofi-Aventis U.S., LLC, and Sanofi-Aventis Puerto Rico Inc.

5. Following the Court's January 27, 2026 order, counsel for the Parties negotiated a jurisdictional discovery schedule, including by exchanging drafts and meeting and conferring via teleconference.

6. During a February 16, 2026 meet and confer call, Defendants informed Plaintiffs that Defendants intended to take the position that Hague Convention procedures applied to (a) all discovery directed at Sanofi S.A. and Aventis Pharma S.A. and (b) any documents that were owned by those entities and in the possession of the other Defendant entities.

7. Defendants memorialized their intended position via email on February 18, 2026. Defendants also stated that they had negotiated dismissal of foreign Sanofi entities in other actions, representing that Sanofi Aventis US LCC could satisfy any judgment and was willing to provide assurances in that regard, and asked "to discuss a similar resolution here."

8. Mylan agreed to consider a negotiated resolution, and the Parties met and conferred regarding the issue throughout February and March of 2026. Throughout those negotiations, Defendants repeatedly proposed that Plaintiffs agree to include Aventis Pharma S.A. in the dismissal.

9. Defendants' counsel represented that they included Aventis Pharma S.A. in the dismissal because they were "trying to make discovery easier" because, in their view, the Hague Convention would otherwise govern discovery served on Aventis Pharma S.A.

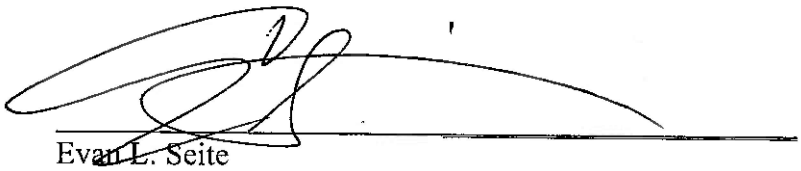
10. On March 31, 2026, the remaining Defendants notified Plaintiffs for the first time that they intended to seek reconsideration or, alternatively, interlocutory review of the Court's

January 27, 2026 Order on Defendants' Motion to Dismiss. At no point during the Parties' negotiations throughout February and March of 2026 regarding the potential stipulation dismissing Sanofi S.A. and Aventis S.A. did Defendants mention they might seek reconsideration, interlocutory appeal, or a discovery stay.

11. On April 1, 2026, the Parties met and conferred regarding the remaining Defendants' intent to seek reconsideration, or, alternatively, interlocutory review. During that meeting, I asked counsel for Defendants how long Defendants had intended to file the motion. Counsel for Defendants responded that they had been considering it since the Court issued its January 27, 2026 Order on the Motion to Dismiss.

I declare under penalty of perjury under the laws of the United States that the above is true and correct.

Executed: April 21, 2026
Palo Alto, CA



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