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

MYLAN PHARMS. INC., ET AL., Plaintiffs, v. SANOFI-AVENTIS U.S. LLC, ET AL., Defendants.	Civil Action No. 2:23-cv-836-MRH

PLAINTIFFS' POST-HEARING SUBMISSION

Mylan Adequately Pled a Section 2 Monopolization Claim. Sanofi has not and cannot meet its high burden to establish good cause for the Court to revisit its detailed, cogent ruling on Sanofi's motion to dismiss. Opp. at 6–7; Tr. at 20:6–10.[1] Sanofi claims that the Court's "implicit[]" holding that "Mylan can plead a bundled-discount theory of exclusion based on a bundle of products in the same product market" (ECF No. 106 at 5), somehow amounts to "manifest injustice." But, in addition to not meeting the exacting standards for reconsideration (Opp. at 6–7), Sanofi misapprehends ***what*** is necessary to plead a Section 2 monopoly claim, and ***when*** the Court should resolve complicated factual questions about the scope of relevant product markets.

First, in arguing that the Court erred in "implicitly" holding that anticompetitive bundling need not involve products in separate markets, Sanofi improperly conflates a ***Section 1*** tying claim and a ***Section 2*** monopolization claim supported by tying allegations. *See, e.g.*, Tr. at 17:13–18:10 (counsel asserting "the first inquiry in ***any Section 1 tying case*** is whether the defendant has sufficient market power of the tying product which requires a finding that two separate product markets exist"). The distinction is critical. In a Section 1 tying claim, where the per se illegality rule typically applies, the strict requirement for separate product markets "serves a valuable screening function" because the "per se rule . . . has a significant potential to overreach,

[1] "Opp." refers to ECF No. 108. "Tr." refers to the May 19, 2026 Transcript. "Order" refers to the Court's Order at ECF No. 84. Unless noted, all emphasis is added and all citations are omitted.

particularly when applied to ***nondominant*** firms." Areeda & Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles & Their Application ¶ 777 (2025). But in a Section 2 monopolization case, "mandatory bundling by the monopolist may be unlawful ***even if the items in the bundled package would not constitute separate products***." *Id.* Thus, where, as here, "'the defendant is a dominant firm' . . . the 'special screening function' of the tying factors is 'largely unnecessary, and the more general standards of § 2 become relevant.'" *Viamedia, Inc. v. Comcast Corp.*, 951 F.3d 429, 468–69 (7th Cir. 2020). As a result, "the question is whether, ***viewing the monopolist's conduct as a whole***, it has unreasonably maintained or enhanced its monopoly position." Areeda & Hovenkamp ¶ 777. That is the precise question the Court correctly addressed, allowing the case to proceed to be decided with a full factual record. Order at 38–41.

Binding Third Circuit jurisprudence—as set forth primarily in *LePage's, Inc. v. 3M*, 324 F.3d 141 (3d Cir. 2003) as well as other decisions—is entirely consistent with these principles.[2] Notably, in evaluating 3M's anticompetitive rebates, the *LePage's* court expressly relied on its earlier decision in *SmithKline v. Eli Lilly & Co.*, 575 F.2d 1056 (3d Cir. 1978). *SmithKline* involved a post-trial appeal of a Section 2 monopolization case where the defendant, Lilly, offered a bonus rebate to any hospital purchasing "specified quantities of any three of Lilly's five cephalosporin

[2] Sanofi's argument that footnote 11 of the panel decision in *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 274 n.11 (3d Cir. 2012), reflects a "holding as a formal limitation on liability under *LePage's*" (Tr. at 23:18–20) lacks any basis in law or fact. Footnote 11 merely addressed an *amicus* argument that *LePage's* foreclosed use of the price-cost test to alleged exclusionary conduct involving pricing practices. 696 F.3d at 274 n.11; *see also* Brief of Amicus Curiae Am. Antitrust Institute in Support of Plaintiffs-Appellees, *ZF Meritor LLC v. Eaton Corp.*, Nos. 11-3301 & 11-3426, 2012 WL 475864, at *6 (3d Cir. Feb. 7, 2012). In rejecting that bright-line rule, the court found *LePage's* "inapplicable" under the facts presented, i.e., "where . . . only one product is at issue and the plaintiffs have not made any allegations of bundling or tying." *Id.* To the extent that the footnote elsewhere discussed *LePage's*, it is quintessential dictum. *United States v. Mallory*, 765 F.3d 373, 381 (3d Cir. 2014). Moreover, it is black-letter law that the panel decision in *ZF Meritor* could not have imposed a "formal limitation" on the *en banc* decision in *LePage's*, nor could it have *sub silentio* abrogated *SmithKline*. ECF No. 108 at 9.

[products]," *LePage's*, 324 F.3d at 156, all products alleged to be in the ***same product market***. *Id*. at 157. The "effect of the rebate program was to induce hospitals to conjoin their purchases" in order "[t]o preserve [Lilly's] market position" in a higher-priced, patented product and "discourage sales" of the plaintiff's generic product that competed with it, an economic predicament remarkably similar to Mylan's position here. *Id.* at 155–56.[3] In a unanimous decision, the Third Circuit held that Lilly's bundling rebate "blatantly" violated the "economic laws of [the] competitive market" making it "a transgressor under § 2 of the Sherman Act." *LePage's*, 324 F.3d at 156–57. *LePage's*, in turn, held that *SmithKline* was "equally applicable" to 3M's rebate programs and, therefore, "3M's conduct was at least as anticompetitive as the conduct which this court held violated § 2 in *SmithKline*." *Id.* Other courts have likewise permitted Section 2 monopolization claims to proceed without a showing of market separateness.[4]

Second, Sanofi's motion fails to account for clear Third Circuit precedent, cited by the Court (Order at 23, 40–41), that strongly counsels against the legal resolution of complicated factual inquiries into relevant product markets at the pleading stage. Sanofi has not cited any

[3] Indeed, the *SmithKline* court noted that the generic product was a "therapeutic equivalent of the market leader" patented product—*i.e.*, precisely the same situation presented by Lantus and Semglee. 575 F.2d at 1061. The question of substitutability is even more acute in the instance of insulin glargine than in *SmithKline* because, while Semglee is an AB-rated bioequivalent generic for Lantus, and therefore subject to automatic substitution, it was not so rated for Toujeo and therefore was not substitutable for Toujeo.

[4] *See, e.g.*, *United States v. Microsoft Corp.*, 253 F.3d 34, 96 (D.C. Cir. 2001) (en banc) (explaining that "there is no need for [the] screening device" of the "separate-products inquiry" in evaluating a Section 2 tying violation); *C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1379, 1382 (Fed. Cir. 1998) (Section 2 liability based on product tying upheld; no separate tying and tied products necessary); *Eastman Kodak Co. v. Image Technical Servs., Inc.*, 504 U.S. 451, 462 (1992), *on remand*, 125 F.3d 1195 (9th Cir. 1997) (tying arrangement found to be Section 2 violation without separate product market requirement), *cert. denied*, 523 U.S. 1094 (1998); *Multistate Legal Studies, Inc. v. Harcourt Brace Jovanovich Legal & Pro. Publ'ns, Inc.*, 63 F.3d 1540, 1543, 1549–52 (10th Cir. 1995) (Section 2 monopolization claim based on tying did not require finding of "separate products"); *see also* Areeda & Hovenkamp ¶ 777a (discussing authorities).

decision applying the strict pleading-stage requirement of product market separateness that it now advances. Rather, the Third Circuit cases Sanofi cites were allowed to proceed well beyond the pleading stage[5] and all of the decisions cited involved Section 1 claims or claims of tying different types of customer demand.[6] Again, the Court was correct in holding that "district courts routinely allow this type of claim to survive at the pleading stage." Order at 41.

Mylan Adequately Pled Submarkets. Even assuming *arguendo* that pleading separate product markets was required to state a Section 2 monopolization claim based on a tying theory (it was not), the Complaint still states a viable claim. The Complaint provides detailed allegations regarding the differences among Lantus, Toujeo, and Semglee, quoting Sanofi's own internal documents and outlining the tactics Sanofi used to force patients and doctors to switch from Lantus to Toujeo, a drug for which Mylan did not offer a competitor product. *E.g.*, ¶¶ 13–15, 195–197, 201–202, 208–211. This Court—as with others considering similar issues[7]—should continue to

[5] *See Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 405 (3d Cir. 2016) (summary judgment); *ZF Meritor*, 696 F.3d at 263 (post-trial appeal including Section 1 tying claims); *see also Mayor & City Council of Balt. v. Merck Sharp & Dohme Corp.*, 2023 WL 8018980, at *5 n.8 (E.D. Pa. Nov. 20, 2023) ("It bears mention that both *Eisai* and *Meritor* were decided on fully developed records . . . . Whether conduct is anti-competitive is heavily fact dependent, and so long as the allegations of an antitrust complaint are plausible, discovery is warranted"); *FTC v. Syngenta Crop Prot. AG*, 711 F. Supp. 3d 545, 578 (M.D.N.C. 2024) (similar).

[6] *See, e.g., In re Remicade Antitrust Litig.*, 345 F. Supp. 3d 566, 576 & n.3 (E.D. Pa. 2018) (noting parties' agreement that plaintiffs' claims under "Section 1 and 2 of the Sherman Act [we]re 'effectively the same'"); *UniStrip Techs., LLC v. LifeScan, Inc.*, 153 F. Supp. 3d 728, 735 (E.D. Pa. 2015) (bundling under Sections 1 and 2); *Regeneron Pharms., Inc. v. Amgen Inc.*, 2023 WL 1927544, at *3 (D. Del. Feb. 10, 2023) (Sections 1 and 2), *report & recommendation adopted*, 2023 WL 2587809 (D. Del. Mar. 21, 2023); *Castro v. Sanofi Pasteur Inc.*, 2012 WL 12516572, at *5 (D.N.J. Aug. 6, 2012) (same); *Marchese v. Cablevision Sys. Corp.*, 2012 WL 78205, at *2 (D.N.J. Jan. 9, 2012) (same).

[7] *See, e.g., Viamedia*, 951 F.3d at 470 (dispute regarding whether two services were "a single 'unified market'" was "at minimum a question to 'be resolved by the trier of fact.'"); *In re Hypodermic Prods. Antitrust Litig.*, 2007 WL 1959224, at *6 n.13 (D.N.J. June 29, 2007) ("[T]he determination of a relevant product market or submarket ('market') is a highly factual one best allocated to the trier of fact.").

avoid Sanofi's invitation to "become mired in . . . conclusively determining the relevant market" at the pleading stage. Order at 23 (quoting *SmithKline*, 575 F.2d at 1063).

Mylan Adequately Pled Exclusive Dealing. Because Sanofi seeks reconsideration based only on Mylan's "bundled-discount theory" (ECF No. 106 at 5), Mylan's separate exclusive dealing allegations are outside of the scope of reconsideration. Nevertheless, at the hearing, counsel for Sanofi claimed that "[i]f there is no bundled rebate claim . . . then there is no exclusive dealing claims." Tr. at 8:13–14. Not so. The Complaint expressly alleges that Sanofi "conditioned rebates for Toujeo on PBMs' agreement to exclude biosimilar insulin glargine products from formularies" (¶ 11); that Sanofi's exclusive dealing lasted for years (¶¶ 204, 244); and that it created an "insurmountable barrier to competition" because Semglee was "excluded from commercial and noncommercial formularies" (¶¶ 15, 17). And, although Sanofi claims otherwise (Tr. 13:19–25), Mylan did not abandon these allegations in the motion to dismiss; it merely noted that it need not "prove such a[n exclusivity] clause exists" at the pleading stage. ECF No. 59 at 25 n.10.

Amendment. For the reasons set forth in Mylan's prior submissions and above, Mylan submits that Sanofi's requests for reconsideration, interlocutory appeal, and/or a discovery stay should be denied in full. However, if the Court is inclined to grant any form of Sanofi's requested relief, Mylan respectfully requests leave to amend to cure any alleged deficiency in the Complaint, including with respect to product-hopping allegations to the extent the Court credits Sanofi's assertion that those allegations did not survive the prior motion to dismiss (which they did).

Dated: June 1, 2026

By: */s/ Julia Tarver Wood*

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