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

DEFENDANTS' MOTION FOR RECONSIDERATION OR CERTIFICATION OF INTERLOCUTORY APPEAL AND TEMPORARY STAY

Defendants Sanofi-Aventis U.S. LLC and Sanofi-Aventis Puerto Rico Inc. (collectively, "Defendants"), by and through undersigned counsel, hereby move for reconsideration of the Court's Order (ECF No. 85) on Defendants' Motion to Dismiss Plaintiffs' Complaint (ECF No. 49) pursuant to Federal Rule of Civil Procedure 54(b). In the alternative, Defendants move for certification of an interlocutory appeal to the U.S. Court of Appeals for the Third Circuit pursuant to 28 U.S.C. § 1292(b). In addition, Defendants respectfully request that the Court stay proceedings in this action during the pendency of its review or the Third Circuit's review. The grounds are set forth in the accompanying memorandum of law. Defendants have conferred with Plaintiffs, who oppose this motion.

WHEREFORE, Defendants respectfully request that the Court grant reconsideration or, alternatively, certify the Order for interlocutory appeal, and stay proceedings pending its reconsideration or the Third Circuit's resolution of the interlocutory appeal. A proposed order is attached.

Dated: April 7, 2026

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 April 7, 2026.

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INTRODUCTION

Before this case proceeds into what will inevitably be a lengthy and expensive period of discovery, this Court should take the opportunity to reconsider a single issue of pure law: whether Mylan can plead a bundled-discount theory of exclusion based on a bundle of products in the same product market. Sanofi's very first argument in its motion to dismiss was that, under binding Third Circuit precedent, bundling must link separate product markets to be actionable. ECF No. 50 ("Ds' Mot.") at 13-16. The Court's order on Sanofi's motion acknowledged Sanofi's argument but did not expressly resolve it. ECF No. 84 ("Op.") at 39-41. Implicitly, the order suggests it is enough that Lantus and Toujeo are distinct products, even if they are in the same product market. *See id.* But every single case cited in the order involves bundling *across* product markets. That limitation makes sense: the exclusionary mechanism of bundling, like tying, is the avoidance of competition in one market by linking sales in that market to sales in other markets. But when the products at issue are substitutes in the same product market, competition is unhindered.

The Court should reconsider the issue before the case proceeds further. The issue is one of law, and if the Court does not dispose of it now, the same question will recur at summary judgment, entirely unaffected by intervening discovery. If the correct rule is that Mylan must plead and ultimately prove bundling across distinct product markets, then a substantial fraction of discovery, summary judgment briefing, and any other future proceedings will have been for naught, because Mylan does not and cannot allege that Lantus and Toujeo are in separate product markets. Deciding the issue now, by contrast, would radically streamline this suit, because Mylan's only remaining theory would rest on Sanofi's alleged improper listing of patents in the Orange Book and sham patent litigation.

In the alternative, the Court should certify that its order merits interlocutory appeal. The question of whether Mylan must plead bundling across markets has serious ramifications for this

litigation, given that it is one of the two main pillars of Mylan's case. The Court's order shows that there are substantial grounds for difference of opinion, either because the order conflicts with Third Circuit precedent on the issue or because the order reveals that there is a lack of precedent answering the precise question at issue. And having the Third Circuit sort out the issue now, before the case proceeds to discovery, could ultimately advance the termination of the case by significantly paring down the allegations at issue.

Should the Court agree to reconsider this issue or certify its order for interlocutory appeal, it should also stay proceedings in this action during the pendency of its review, or the Third Circuit's review, to avoid potentially wasteful discovery regarding bundling conduct for which Mylan cannot state a claim.

ARGUMENT

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

A district court has "the inherent power to reconsider prior interlocutory orders" and may do so whenever "it is consonant with justice." *State Nat'l Ins. Co. v. Cnty. of Camden*, 824 F.3d 399, 406, 406 n.14 (3d Cir. 2016) (citation omitted); *see* Fed. R. Civ. P 54(b) (providing that interlocutory orders "may be revised at any time" before final judgment); *Reinig v. RBS Citizens, N.A.*, 2024 WL 5443175, at *3 (W.D. Pa. Feb. 2, 2024) (finding "no legal or factual basis" to hold Rule 54(b) motion untimely after eight weeks).

A party seeking reconsideration must "establish good cause for why the court should reconsider its prior decision." *Gorgonzola v. Ahuja*, 2022 WL 796922, at *11 (W.D. Pa. Mar. 16, 2022) (Hornak, J.) (quoting *Qazizadeh v. Pinnacle Health Sys.*, 214 F. Supp. 3d 292, 295 (M.D. Pa. 2016)). Good cause to reconsider an interlocutory order may be present even if the traditional

bases for reconsidering final orders—a change in law, new evidence, correcting clear errors of law or fact, or preventing manifest injustice—are not present. *Qazizadeh*, 214 F. Supp. 3d at 295.

In this case, the Court's implicit holding that Mylan may assert a bundling claim based on products in the same product market amounts to a clear error of law. *See* Op. 39-41. Neither Mylan nor the Court has highlighted any precedent for such a claim.

A. Mylan must plead, and ultimately prove, that Sanofi bundled discounts on products in separate product markets.

As Sanofi argued in its motion to dismiss, a bunding claim, like a tying 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) (quoting *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 21 (1984)); *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 405 n.32 (3d Cir. 2016) (same); *see also* Ds' Mot. 13-14. It is the express "holding" of the Third Circuit that "[t]he reasoning of *LePage's*" does not extend to "rebates offered by suppliers within a single-product market." *ZF Meritor*, 696 F.3d at 274 n.11.

That limitation is inherent to how tying and bundling claims work. In both cases, a firm is alleged to have sought to "foreclose[] competition on the merits in a product market" by conditioning purchases or discounts on "a distinct product market." *Jefferson Parish*, 466 U.S. at 21-22; *see Mayor & City Council of Baltimore v. Merck Sharp & Dohme Corp.*, 2023 WL 8018980, at *4 (E.D. Pa. Nov. 20, 2023) ("*LePage's* central holding [is] that linking a product market with no competition to a product market with competition poses antitrust concerns."). In the case of bundling, the firm offers a higher *aggregate* discount across purchases in both markets: the customer buys the firm's offering in one product market not because it "is better or even cheaper" but "in order to receive a greater discount" in other product markets. *LePage's Inc. v. 3M*, 324 F.3d 141, 155 (3d Cir. 2003) (quoting Phillip E. Areeda & Herbert Hovenkamp, Antitrust

Law ¶ 794, at 83 (Supp. 2002)). In that way, bundled discounts "may 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.* For example, in *LePage's*, the plaintiff could not compete with 3M's aggregate discount on tape and health care products because the plaintiff made only tape. *Id.* at 144-45.

The logic of a bundling claim falls apart when the bundle involves products in the *same* product market, where all of the products are substitutes for one another. In that case, no matter how many products are in a bundle, a single product can substitute for them all, so a single-product producer can compete with any aggregate discount. For example, assume that McDonald's offers two products in the same fast-food-burger market (the Big Mac and the Quarter Pounder) while Burger King offers only one (the Whopper). If McDonald's offers a bundled discount on purchases of both products, does Burger King have an antitrust claim? No. Its product is a substitute for either of McDonald's, so it can compete with any bundle McDonald's offers. If McDonald's offers a bundle of one Big Mac and one Quarter Pounder for five dollars, Burger King can offer a bundle of two Whoppers for five dollars. Burger King does not need a more "diverse" stable of products to make a "comparable offer." *Id.* at 155.

The same is true here. Mylan's complaint alleges again and again that Lantus, Toujeo, and Semglee are all substitute products in the same product market. Sanofi's Lantus and Toujeo products are "therapeutically indistinguishable," and indeed Sanofi itself allegedly attempted to "shift demand" away from Lantus to Toujeo. ECF No. 1 ("Compl.") ¶¶ 3, 8, 22. Semglee is a generic or "biosimilar" version of Lantus, meaning it is an "equivalent" drug. *Id.* ¶¶ 3, 8, 15, 23, 80, 215. Consequently, all three drugs are substitutes with "positive cross-elasticity of demand" within the same "injectable insulin glargine market." *Id.* ¶¶ 214-15. In this light, Mylan's

allegation that it "does not offer a competing product to Toujeo" is inconsistent and absurd. *Id.* ¶ 210. By definition, in order to be in the same product market, Semglee and Toujeo must compete.

Because Semglee is a substitute for both Lantus and Toujeo, Mylan's bundled-discount theory makes no sense. In Mylan's own telling, a Pharmacy Benefit Manager ("PBM") can replace *both* Lantus *and* Toujeo on a formulary with Semglee alone—either way, patients have access to at least one "therapeutically indistinguishable" injectable insulin glargine product. Consequently, 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.

In response to Sanofi's motion to dismiss, Mylan entirely failed to address Sanofi's argument that a bundling claim must link separate markets or to explain why *ZF Meritor* or *Eisai* are not binding here. ECF No. 59 ("Ps' Opp.") at 27-28. Instead, Mylan garbled Sanofi's argument, claiming Sanofi was arguing "that Lantus and Toujeo are the same *products*." *Id.* at 27; *see also* ECF No. 66 ("Ds' Reply") at 9-10. That is incorrect. The point is that, by Mylan's own telling, they are in the same *product market*. Nor did Mylan cite a single case for the idea that a bundling theory requires only distinct products, rather than distinct product markets. To the contrary, Mylan's own citation of *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451 (1992), supports Sanofi's point. There, Kodak was accused of tying its offerings in two distinct markets related to its copier products—the market for repair parts and the "*separate market* for service." *Id.* at 462 (emphasis added).

B. The Court's implicit holding that Mylan need not plead and prove bundling across product markets lacks any support.

The Court acknowledged Sanofi's argument that Mylan must allege (and ultimately prove) bundling across separate product markets. Op. 39. But the Court never expressly determined

whether that proposition is correct or, correspondingly, whether Mylan had met that requirement. Instead, the Court held that Mylan sufficiently alleged that Sanofi "tied two distinct products," by conditioning rebates on including "*both* products" on a formulary. Op. 40-41 (quoting *Marchese v. Cablevision Sys. Corp.*, 2012 WL 78205, at *2 (D.N.J. Jan. 9, 2012)).

The Court's implicit holding—that a bundling claim need not tie distinct product markets so long as it ties "distinct products"—is not only contrary to binding precedent in *ZF Meritor* and *Eisai* but is also inconsistent with all of the precedent cited in the Court's opinion. Most notably, the Court drew the standard for bundling claims from the decision in *Marchese*, but *Marchese* itself explains that "the danger of tying" is "when a seller leverages economic power *from one market to another*." 2012 WL 78205, at *15 (emphasis added) (citing *Jefferson Parish*, 466 U.S. at 12). That is why *Marchese* contains dozens of references to both a "tying product market" and a "tied product market." *See generally id.* In that case, the tying product market was television cable services, and the separate tied product market was for cable set-top boxes. *Id.* at *5.

Consistent with *Marchese*, every single case identified by the Court involves bundling or tying across distinct product markets. Op. 40-41. In *Regeneron Pharms., Inc. v. Amgen Inc.*, 2023 WL 1927544 (D. Del. Feb. 10, 2023), the defendant allegedly bundled its drug in the "PSCK9 inhibitor market" with another drug in the "moderate-to-severe psoriasis market" and another drug in the "rheumatoid arthritis market." *Id.* at *2. In *UniStrip Techs., LLC v. LifeScan, Inc.*, 153 F. Supp. 3d 728 (E.D. Pa. 2015), the defendant allegedly bundled its products in "two sub-markets—one for electronic meters and one for accompanying test strips." *Id.* at 734, 741-42. In *In re Remicade Antitrust Litig.*, 345 F. Supp. 3d 566 (E.D. Pa. 2018), the defendant allegedly bundled its drug with "other [] drugs and medical devices." *Id.* at 575. Finally, in *Castro v. Sanofi Pasteur*

Inc., 2012 WL 12516572 (D.N.J. Aug. 6, 2012), the defendant allegedly bundled vaccines in "five product markets"—meningitis, DTaP, DTaP boosters, polio, and Hib. *Id.* at *2.

In sum, none of the cases identified by the Court (or Mylan) involve a bundling claim where the products in the bundle are substitutes in the same product market. That pattern fits with the logic underlying bundling and tying claims. Only by linking distinct markets can a firm avoid competition on the merits from "a potential competitor who does not manufacture an equally diverse group of products." *LePage's*, 324 F.3d at 155. Here, Mylan's glargine product *is* as "diverse" as Sanofi's two glargine products, because, according to Mylan's own allegations, it can substitute for both. There is no need for Mylan to enter an entirely new product market just to compete.

C. There is good cause for the Court to reconsider its order at this juncture.

The Court should reconsider its implicit holding before this litigation progresses further. The question is one of pure law that discovery will not affect, and a correct application of the law to Mylan's complaint would dramatically streamline discovery and future motions practice.

The question of whether Mylan can assert a cognizable bundling claim within a single product market is an issue of law that will recur at summary judgment and beyond. As explained above, the antitrust concern with bundling is that a party offers "a discount aggregated across multiple products" to avoid competition on the merits within a single product market. *LePage's*, 324 F.3d at 155 (quoting Areeda & Hovenkamp ¶ 794 (Supp. 2002)). That logic falls apart here, where all of the products at issue are substitutes in the same product market, so there is no structural impediment to Mylan making "a comparable offer." *Id.*

Nothing in discovery will solve this logical hole in Mylan's case, so there is no sense in waiting until summary judgment to decide the issue. The only way out would be to show that Toujeo is actually in its own single-product market, distinct from Lantus and Semglee. But that

could not happen without Mylan rewriting its entire theory of the case. Whether products are in the same product market depends on whether they are "interchangeable substitute[s]." *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 436 (3d Cir. 1997). Here, Mylan takes great pains to allege that Lantus (and generic Semglee) and Toujeo are "therapeutically indistinguishable" products competing in the same "injectable insulin glargine" market to fill the exact same demand. Compl. ¶¶ 3, 8, 195, 197, 201, 208, 244. Indeed, Mylan alleges that Sanofi actively attempted to convert patients from Lantus to Toujeo—a feat that would be impossible if the drugs were not substitutes. *Id.* ¶¶ 201-07.[1] If Mylan wants to try to rewrite its complaint to allege that Toujeo is in its own single-product market, Mylan should have to show it can meet Rule 8's plausibility requirement right now, before the parties confront the "potentially enormous expense of discovery" with no "reasonably founded hope" that Mylan can save its case. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 559 (2007) (citation omitted).

Deciding the issue now would also dramatically streamline the proceedings in this case. Mylan's complaint asserts two overarching theories of anticompetitive conduct. First, it alleges that Sanofi improperly listed patents in the FDA's Orange Book and filed a sham patent suit against Mylan based on those patents. Compl. ¶¶ 95-122, 142-46. Second, the complaint alleges that Sanofi introduced Toujeo, which it bundled together with Lantus, to negotiate for formulary placement. *Id.* ¶¶ 201-11.[2] These two theories, however, center on different conduct in different

[1] This argument assumes that "injectable insulin glargine" is the relevant market, as Mylan alleges. But the market may be even broader. As Sanofi explained in moving to dismiss, the complaint and its incorporated documents suggest that other basal insulins may also be substitutes. Ds' Mot. 21-22. In opposition, Mylan itself suggested that PBMs do not need to include any insulin glargine product on a formulary, but may choose to include only other basal insulins. Ps' Opp. 35.

[2] Mylan also alluded to a "product hop" from Lantus to Toujeo. Compl. ¶ 223. In tension with this theory, however, Mylan alleged that Sanofi used Toujeo to maintain Lantus's *continued* presence in the market. Compl. ¶¶ 209-10. The Court dismissed Mylan's product-hop theory as

time periods with different effects. Discovery into Mylan's patent allegations will center on the propriety of listing patents in the Orange Book for Lantus from 2009 through 2017; whether Sanofi's 2017 patent suit was "objectively baseless"; and whether Sanofi's conduct was the actual cause of Mylan's delay in entering the market, as opposed to Mylan's own protracted negotiations with the FDA, or Mylan's deficient New Drug Application, or Mylan's failed manufacturing inspections. By contrast, discovery into Mylan's bundled-rebate allegations will center on, for instance, Sanofi's Toujeo launch in 2015; negotiations by, at least, Sanofi, Mylan, and Eli Lilly[3] with various PBMs to secure formulary placement for their insulin glargine products; and Mylan's ability to offer its own multi-product bundle to match Sanofi's aggregate discount after it obtained FDA approval in June 2020. *See Shire US, Inc. v. Allergan, Inc.*, 375 F. Supp. 3d 538, 557 (D.N.J. 2019) (finding no harm to competition where plaintiff could offer own bundle).

If at summary judgment the Court concludes as a matter of law that Mylan cannot assert a bundling claim based on products in the same product market, all of the discovery in the second bucket—including any discovery complications or disputes that may entail and discovery from non-party Eli Lilly—will have been for nothing because it will not be relevant to any live issue in the case. Deferring this question of law is inconsistent with *Twombly*, which recognizes that "proceeding to antitrust discovery can be expensive" and holds that careful enforcement of Rule 8's plausibility standard is the only practical guard to "avoid the potentially enormous

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an independent basis for liability, but invited Mylan to amend its Complaint. Op. 35-38. Mylan declined to do so. ECF No. 90.

[3] Eli Lilly launched a "competing insulin glargine product," Basaglar, in 2016, four years before Mylan brought Semglee to market in 2020, but the complaint does not attempt to explain whether Sanofi's rebates had any impact on Lilly's ability to compete. *See* Compl. ¶ 214. Discovery would include even more manufacturers and drugs if the relevant market is in fact broader than injectable insulin glargine.

expense of discovery in cases with no 'reasonably founded hope that the discovery process will reveal relevant evidence.'" *Twombly*, 550 U.S. at 559 (citation omitted).

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

Should the Court decline to reconsider its order, Sanofi respectfully requests that the Court certify this specific issue for immediate appeal to the Third Circuit. As explained above, a decision that Mylan must plead and prove bundling across distinct product markets would pare down Mylan's case significantly.

Under 28 U.S.C. § 1292(b), a party may take an appeal from an interlocutory order if the district court certifies that the order "involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation." All of those factors are met here.

Controlling question of law. Whether Mylan must plead a bundling claim linking multiple product markets is a question of law. There is no factual dispute at this juncture, because Mylan's factual allegations must be "accepted as true" for purposes of Sanofi's motion to dismiss. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). That question is also a controlling one, 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) (quoting *Katz v. Carte Blanche Corp.*, 496 F.2d 747, 755 (3d Cir. 1974)). As explained above, a substantial portion of Mylan's case against Sanofi rests on the allegation that Sanofi bundled products in the same product market, so dismissal of that theory would have serious consequences for discovery and future motions practice. The question is also controlling because, if Mylan were to win a judgment against Sanofi premised on bundled discounts within the same product market and that bundling theory turns out not to be cognizable as a matter of law, it "would require reversal of the final

judgment." *G.L. v. Ligonier Valley Sch. Dist. Auth.*, 2013 WL 6858963, at *6 (W.D. Pa. Dec. 30, 2013) (Hornak, J.) (citing *Katz*, 496 F.2d at 755).

Substantial ground for difference of opinion. The issue presents substantial ground for a difference of opinion because it involves either "conflicting precedent" or "the absence of controlling law." *Davis*, 2025 WL 1094138, at *2. The Third Circuit has explained that tying and bundling require "two separate product markets," *ZF Meritor*, 696 F.3d at 274 n.11, and the cases cited by the Court all involve distinct product markets. In light of that precedent, the Court's implicit holding to the contrary that Mylan need only plead "distinct products" (Op. 40) is subject to "genuine doubt or conflicting precedent as to the correct legal standard." *Complaint of Imperial Towing Inc.*, 2012 WL 6460068, at *2 (W.D. Pa. Dec. 13, 2012) (Hornak, J.). To the extent the Court believes that those cases do not answer the "precise question" regarding distinct products in the same market, that absence of precedent likewise amounts to substantial grounds for difference of opinion. *G.L.*, 2013 WL 6858963, at *6.

Materially advance termination of the litigation. The answer to whether Mylan may plead a bundling claim within a single product market is dispositive for a substantial portion of Mylan's case against Sanofi. In that sense, it is a "'gateway' issue in this civil action," and therefore ripe for immediate adjudication. *Ellis v. Westinghouse Elec. Co., LLC*, 2020 WL 4499931, at *19 (W.D. Pa. Aug. 5, 2020) (Hornak, J.). If the Third Circuit decides that Mylan is required to allege and prove separate product markets, contrary to the current complaint, the scope of Mylan's case would be greatly reduced during discovery and summary judgment such that immediate appeal may in fact speed up the *ultimate* resolution of Mylan's claims, especially if Mylan's remaining patent-based claims fail at summary judgment for their own independent reasons (*e.g.*, lack of causation, *see* Ds' Mot. 25-30; Op. 43-47). In other words, an immediate

appeal "would clearly and finally define the scope of Plaintiff['s] claims," allowing the parties to proceed to the merits of Mylan's claims "without remaining doubt as to their validity." *G.L.*, 2013 WL 6858963, at *7.

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

If the Court agrees to reconsider this legal issue or certifies that interlocutory appeal of the issue is warranted, the Court should stay proceedings pending its decision on reconsideration or pending the Third Circuit's determination on Sanofi's application for leave to appeal (due within just ten days, under 28 U.S.C. § 1292(b)). Such a temporary stay would "permit the process contemplated by 28 U.S.C. § 1292(b) to play out" for the benefit of the parties and the Court, *Ellis*, 2020 WL 4499931, at *20, and it would avoid potentially unnecessary discovery regarding the Lantus and Toujeo rebating conduct. And, for the same reasons, if the Third Circuit grants the application for interlocutory appeal, proceedings in this Court should be stayed pending the Third Circuit's resolution of the appeal.

CONCLUSION

For the foregoing reasons, the Court should grant reconsideration or, alternatively, certify the order for interlocutory appeal, and stay proceedings pending its decision on reconsideration or the Third Circuit's resolution of the interlocutory appeal.

Dated: April 7, 2026

Respectfully submitted,

/s/ *Aaron Healey*

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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 April 7, 2026.

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