THE 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, SANOFI S.A., AVENTIS PHARMA S.A., and SANOFI-AVENTIS PUERTO RICO INC. *Defendants*.	No. 2:23-cv-00836-MRH

DEFENDANTS' RESPONSE TO PLAINTIFFS'
SECOND NOTICE OF SUPPLEMENTAL AUTHORITY

Mylan's 100-page second notice of supplemental authority (ECF 67) consists of highlighted copies of two out-of-circuit district court cases, plus a District of Delaware case decided over a year ago, which Mylan vaguely asserts support its arguments for no fewer than ten issues. If this Court considers these cases at all, Defendants ("Sanofi") respectfully request that the Court consider the brief points below, which show why the cases are inapposite and do not make the grounds for dismissing this case any less compelling.

1. ***FTC v. Syngenta Crop Protection AG***, 2024 WL 149552 (M.D.N.C. Jan. 12, 2024).

Market definition. Unlike the plaintiffs in *Syngenta*, whom the court found "plausibly alleged facts that show that there is limited cross-elasticity between the products inside and outside of Plaintiffs' alleged markets," 2024 WL 149552, at *11, including "characteristics that make each [product] unique in the marketplace, that alternatives are not considered by farmers as suitable, and that farmers prefer specific [products]," *id.*, Mylan does not plausibly allege that other basal insulins are not ready substitutes for insulin glargine. Sanofi Br. 11-13; Sanofi Reply 6-7.

Judicial notice of FDA records. In contrast to the EPA labels the *Syngenta* court declined to judicially notice because they were ambiguous and thus would not "materially alter the court's analysis," 2024 WL 149552, at *11, the FDA records Sanofi asks this Court to judicially notice *unambiguously* show that FDA denied Mylan's Semglee application at specific times and for specific reasons *unrelated* to Sanofi's alleged conduct. Sanofi Br. 19-21; Sanofi Reply 10-12.

Price/cost test. *Syngenta*'s price/cost test discussion is irrelevant to the core problems with Mylan's bundling claim, i.e., (1) the failure to allege bundling across separate product markets, (2) the fact that Mylan sells multiple products lines and can offer a comparable bundled discount, (3) the failure to allege that Sanofi conditioned discounts on PBMs exclusively (or mostly) purchasing from Sanofi, and (4) the failure to allege market foreclosure. Sanofi Reply 3-6.

2. *BCBS of Vermont v. Teva Pharm. Indus., Ltd.*, 2024 WL 323775 (D. Vt. Jan. 22, 2024).

Sham litigation. *BCBS* cannot be reconciled with Third Circuit precedent requiring plaintiffs to plead and prove the elements of sham litigation, *see* 2024 WL 323775, at *13 & n.16, or with Third Circuit courts that routinely dismiss sham litigation claims on the pleadings, *see* Sanofi Reply 13-14. And the conclusion that BCBS sufficiently pleaded objective baselessness, 2024 WL 323775, at *14-16, is irrelevant because Mylan *waived* this argument, asserting that it need not plead objective baselessness because Sanofi's single lawsuit somehow constituted serial petitioning. Sanofi Reply 14-15.

Product hop. The court allowed a product-hopping claim to survive because the complaint alleged that "patients were subjected to coercion" when defendant "irrationally pric[ed]" a new drug below the legacy drug and then sharply raised the price of the legacy drug, all while "pressing prescribers to exclude new generic entrants from their orders." 2024 WL 323775, at *27-29. Mylan's complaint does not allege any such conduct. *See* Sanofi Reply 2 n.1; Sanofi Br. 9.

Scheme. The court allowed the case to go forward because the plaintiff sufficiently alleged anticompetitive conduct as to *each* of the plaintiff's two theories. *Id.* at *11, 12, 23-29. Here, Mylan asserts three theories: (1) FDA regulatory delay, (2) bundled discounts as exclusive dealing, and (3) bundled discounts as product hopping. Mylan must plausibly allege anticompetitive conduct as to each theory for that theory to survive a motion to dismiss, and it has not done so. *See* Sanofi Reply 2-3.

Causation of delayed FDA approval. Teva filed multiple citizen petitions and lawsuits against FDA demanding that the agency reject generic drug applications. The court concluded that the complaint plausibly alleged that Teva's conducted caused a delay of FDA approval because "citizen petitions," in particular, "consumed FDA resources and slowed the FDA's evaluation" of generic drug applications. 2024 WL 323775, at *22. Here, Mylan does not allege that Sanofi filed

citizen petitions or lawsuits against the FDA. Nor does Mylan allege or argue in its brief that FDA diverted resources away from Mylan's application because of Sanofi's conduct. Indeed, FDA's public records show that FDA continued processing and repeatedly rejected Mylan's application for reasons having to do with Mylan's own application and nothing to do with Sanofi's alleged conduct. Sanofi Reply 10-11.

3. ***Azurity Pharm., Inc. v. Bionpharma Inc.***, 650 F. Supp. 3d 269 (D. Del. Jan. 2023).

Statute of limitations. The opinion suggests in dicta that sham litigation claims "might not" accrue until some unspecified time after they are filed, *id.* at 277, but does not address the string of authorities Sanofi cited concluding the opposite. Sanofi Br. 22 & n.13. Nor did Mylan raise this argument in its brief, relying instead on the continuing violation doctrine. Sanofi Reply 9-10.

Serial petitioning. *Azurity* does not support Mylan's invocation of the serial petitioning rule for Sanofi's *single* lawsuit against Mylan. Unlike Sanofi, the defendant in *Azurity* "filed seven lawsuits over the same generic product." 650 F. Supp 3d at 282; *id.* at 274-75 (describing five lawsuits against the same company and two against its contract manufacturer).

Objective baselessness. *Azurity* illustrates the types of allegations sufficient to support the element of objective baselessness, none of which are included in Mylan's complaint. *Id.* at 279-281 (analyzing two of the "numerous reasons" alleged for objective baselessness, including allegations about "infringement, validity, licensing, and jurisdiction"). *See* Sanofi Reply 14-15.

Causation. *Azurity* does not suggest that *implausible* allegations of delay from the 30-month stay must be taken as true. *See* 650 F. Supp. 3d at 279. And it does not address circumstances like those here, where FDA itself had rejected a drug application multiple times based on grounds wholly independent of a 30-month stay or the defendant's alleged conduct. *See id.*; *see also* Sanofi Reply 10-11.

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Respectfully submitted,

/s/ *Aaron Healey*

Aaron Healey (Pa. 310803)
JONES DAY
250 Vesey Street
New York, NY 10281
Phone: (212) 326-3939
ahealey@jonesday.com

John M. Majoras (*pro hac vice*)
Rosanna K. McCalips (*pro hac vice*)
Robert N. Stander (*pro hac vice*)
Brett J. Wierenga (*pro hac vice*)
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001.2113
Telephone: (202) 879-3939
jmmajoras@jonesday.com
rkmccalips@jonesday.com
rstander@jonesday.com
bwierenga@jonesday.com

Counsel for Defendants Sanofi-Aventis U.S. LLC, Sanofi-Aventis Puerto Rico Inc., Sanofi S.A., and Aventis Pharma S.A.

Jonathan J. McCreary (Pa. 326071)
Katherine E. Eayre (Pa. 328825)
JONES DAY
500 Grant Street, Suite 4500
Pittsburgh, PA 15219
Telephone: (412) 391-3939
jmccreary@jonesday.com
keayre@jonesday.com