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

MYLAN PHARMACEUTICALS INC. ET AL, Plaintiffs, v. SANOFI-AVENTIS U.S. LLC ET AL, Defendants.	2:23-cv-00836-MRH Chief Judge Mark R. Hornak Oral Argument Requested

PLAINTIFFS' REPLY IN SUPPORT OF NOTICE OF SUPPLEMENTAL AUTHORITY

Mylan respectfully submits this brief reply in support of its Notice of Supplemental Authority (ECF No. 67) and in response to Sanofi's brief in opposition thereto (ECF No. 68).

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

Market definition. Sanofi misses the point. *Syngenta*'s clear holding was that plaintiffs need not explain why certain products are outside the relevant market. 2024 WL 149552, at *10. In any event, Mylan *has* provided an explanation mirroring the explanation in *Syngenta*. As Mylan explained in its brief, the products Sanofi hopes to include in the relevant market "provided no pricing constraint on Sanofi's Lantus or Toujeo" (limited cross-elasticity) and all "have different active ingredients than Lantus, Toujeo, and Semglee" (unique characteristics). Opp. at 24.

Judicial notice of FDA records. *Syngenta* properly understood that while courts may take judicial notice of facts that are matters of public record they may not "accept [defendant's] interpretation of [those] facts." 2024 WL 149552, at *11; *see also* Opp. at 28 (making this same point). But that is exactly what Sanofi invites this court to do when it asks the court to read into its cited FDA documents the inference that Sanofi in no way delayed Mylan.

Price-cost test. Sanofi ignores *Syngenta*'s holding that whether non-price mechanisms of exclusion predominate over price "will depend on the development of the record." 2024 WL 149552, at *18. Further, Sanofi's myopic focus on whether Mylan properly alleges bundling (it does, *see* Opp. at 15-19 and Mylan's First Notice of Supplemental Authority (ECF No. 65)) overlooks the fact that *Syngenta* viewed agreements that only "share some features with bundling" as containing non-price means of coercion. 2024 WL 149552, at *18.

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

Sham litigation. Sanofi's assertion that *BCBS* cannot be reconciled with Third Circuit precedent is facially incorrect. The Vermont court explicitly noted that its conclusion that Blue Cross had plausibly alleged sham petitioning would be the same under Third Circuit law. 2024 WL 323775, at *13 & n.16. Nor has Mylan waived its allegation that "Sanofi's suit was objectively baseless." Compl. ¶ 146; *cf.* Opp. at 11-14 (never conceding that Sanofi's suit had an objective basis).

Product hop. *BCBS* recognized that a market shift may be effected by means other than complete withdrawal of the legacy product, because withdrawal is not the only method of coercion. 2024 WL 323775, at *26-27. Sanofi coerced a market shift by tying rebates on Lantus and Toujeo and other methods similar to those at issue in *BCBS*. *Compare* Compl. ¶ 207 (Sanofi's marketing blitz) *with* 2024 WL 323775, at *27 (Teva's "intense outreach campaign" targeting prescribers).

Scheme. Once the Vermont court concluded that Blue Cross's allegations as to market shift were sufficient to substantiate its allegation that Teva unlawfully diminished generic uptake, there was no need to address the remaining allegations of unlawful conduct to allow Blue Cross's overall scheme claim to go forward. 2024 WL 323775, at *29. By analogy, this Court could find that either Sanofi's market shift or its exclusive contracts suffice to plausibly explain Mylan's diminished uptake. *See* Opp. at 14-22.

Causation of delayed FDA approval. Contrary to Sanofi's assertions, Mylan was under no obligation to plead that FDA diverted resources away from Mylan's application. Nevertheless, Mylan alleged that the stay caused by Sanofi's Orange Book abuse "complicated the FDA's review and approval of Mylan's application." Compl. ¶ 133. Mylan also alleges that

"[t]he FDA . . . would have approved Mylan's product more quickly in the absence of the 30-month stay." Compl. ¶ 193. Like *BCBS*, *Azurity* also held that there was no fatal causation problem in plaintiffs' delay theory when a 30-month stay expired before the FDA approved the generic product and did so without speculating as to the specific explanation for delay after expiration of the stay. *Compare* 2024 WL 323775, at *21-22 *with* 650 F. Supp. 3d at 278-79 ("allegation that the 30-month stay delayed its entry must be accepted as true at the pleading stage.").

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

Statute of limitations. *Azurity* faithfully applied Supreme Court precedent, which of course trumps the lower court decisions Sanofi cited in its brief. 650 F. Supp. 3d at 277 (quoting *Zenith Radio Corp. v. Hazeltine Research Inc.*, 401 U.S. 321, 339 (1971)). In any event, one of those cases, *Perrigo*, is perfectly consonant with *Azurity*. *See Perrigo Co. v. AbbVie Inc.*, 2022 WL 2870152, at *5 & n.12 (3d Cir. July 21, 2022) (recognizing that the *Zenith* speculative damages rule would have postponed accrual of an antitrust claim until tentative or final approval of an ANDA had the plaintiff shown "it was uncertain *whether* they would suffer damages" but (unlike Mylan) the plaintiff had only alleged uncertainty as to "*when* the FDA would approve the [] generic"). This is not a new argument. *See* Opp. at 10-11 (discussing unascertainability of damages at the time Sanofi filed suit).

Serial petitioning. *Azurity* (and *BCBS* for that matter) directly undermines Sanofi's assertion that "a serial petitioning charge is particularly inapt in the Hatch-Waxman context." Reply at 14 (quotation omitted). Sanofi attempts to sidestep this important proposition about when the serial rule applies with the non sequitur that *Azurity* does not address when multiple patent claims constitute a series, an issue Mylan fully addressed in its brief. Opp. at 13 & n.7.

Objective baselessness. Despite Sanofi's insinuations, *Azurity* does not provide a checklist of objective baselessness allegations a plaintiff must include. Mylan has sufficiently alleged that "at no time did Sanofi have a reasonable expectation of winning litigation pertaining to any patent" it asserted against Mylan. Compl. ¶ 140. Regardless, Mylan's complaint covers two of the four categories Sanofi cites. *See* Compl. ¶ 146 (addressing non-infringement and invalidity). And the other two (licensing and jurisdiction) are hardly necessary to plausibly allege objective baselessness.

Causation. Of course *Azurity* does not say that "implausible" allegations must be taken as true. Nor could it. But that is beside the point, which is that *Azurity* stands for the proposition that allegations of delay beyond expiration of a 30-month stay are not implausible, as a matter of law. 650 F. Supp. 3d at 278-79; *see also BCBS*, 2024 WL 323775, at *21-22. Sanofi has no response to this.

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Respectfully submitted,

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