

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

JAZZ PHARMACEUTICALS, INC.,

Plaintiff,

v.

AVADEL CNS PHARMACEUTICALS,
LLC,

Defendant.

C.A. No. 21-691-GBW

REDACTED - PUBLIC VERSION

JAZZ PHARMACEUTICALS, INC., et al.,

Plaintiffs,

v.

AVADEL CNS PHARMACEUTICALS,
LLC,

Defendant.

C.A. No. 21-1138-GBW

REDACTED - PUBLIC VERSION

JAZZ PHARMACEUTICALS, INC., et al.,

Plaintiffs,

v.

AVADEL CNS PHARMACEUTICALS,
LLC,

Defendant.

C.A. No. 21-1594-GBW

REDACTED - PUBLIC VERSION

MEMORANDUM ORDER

Before the Court is Plaintiff Jazz Pharmaceuticals, Inc.’s (“Jazz”) Motion to Strike (the “Motion”) Defendant Avadel CNS Pharmaceuticals LLC’s (“Avadel”) Second Supplemental Response to Interrogatory No. 8 (the “Interrogatory Response”). D.I. 175.¹ The Motion has been fully briefed. D.I. 176, 189, 191. The Court held oral argument on November 15, 2022. For the reasons set forth below, the Motion is granted-in-part and denied-in-part.

I. BACKGROUND

In these coordinated actions, Jazz alleges infringement of seven patents. Near the outset of litigation, on August 25, 2021, Jazz served Interrogatory No. 8 seeking “the complete factual and legal bases for Avadel’s contention that [each] claim is allegedly invalid under 35 U.S.C. §112.” D.I. 176-1, Ex. A at 4; D.I. 44. Avadel responded on September 24, 2021, D.I. 52, and March 16, 2022, D.I. 86.

On November 29, 2021, the Court ordered the three above-captioned actions to proceed on the same schedule. D.I. 65. The Court further ordered the parties to “serve their final contentions (i.e., final infringement and invalidity contentions, as well as final non-infringement and validity contentions) at least three weeks before Plaintiff serves its opening claim construction brief . . . Final contentions shall include a party’s contentions under its proposed construction(s), as well as under the opposing construction(s) (if such an alternative contention exists).” *Id.* The Court then entered a stipulated order that required the parties to serve their respective infringement and invalidity contentions by April 29, 2022, D.I. 72, a deadline later amended to May 6, 2022, D.I. 97. Avadel served its Final Invalidity Contentions on May 6, 2022. D.I. 104. Jazz served its opening claim construction brief on May 27, 2022, D.I. 111, and the parties submitted their Joint Claim Construction Brief to the Court on July 29, 2022. D.I. 132.

¹ Docket numbers identified herein refer to C.A. No. 21-691-GBW unless otherwise noted.

On September 1, 2022, approximately four months after the deadline for final invalidity contentions, after claim construction briefing closed, but nearly two months before the close of fact discovery, Avadel served the Interrogatory Response. D.I. 176-1, Ex. A; D.I. 160. Jazz moved to strike Avadel's Interrogatory Response on September 20, 2022, D.I. 175, contending that Avadel's second supplementation "adds many new substantive arguments that could and should have been included in its final contentions." D.I. 176. While Jazz's Motion remained pending, fact discovery closed on October 21, 2022. D.I. 72. On November 28, 2022, the Court entered a stipulated Order extending certain deadlines related to expert discovery because "the parties are still working towards completing fact depositions in these cases." D.I. 240.

II. LEGAL STANDARD

The parties disagree on the applicable legal standard. Jazz argues that, because Avadel purportedly seeks to introduce new invalidity theories in violation of the Scheduling Order (D.I. 31) and its operative amendments (D.I. 65, 72, 97), Avadel must show good cause under Federal Rule of Civil Procedure 16. D.I. 176. Avadel responds that a motion to strike is evaluated under the *Pennypack* factors pursuant to Federal Rule of Civil Procedure 37. D.I. 189.

Courts in this district have applied both Rule 16 and the *Pennypack* factors in analogous situations involving belatedly-raised theories that should have been disclosed by a specific deadline in a scheduling order. *See In re ChanBond, LLC Pat. Litig.*, C.A. No. 15-842-RGA, 2019 WL 2098316, at *2 (D. Del. May 14, 2019) (applying good cause and *Pennypack* when considering whether to permit new invalidity combination raised in reply expert report when scheduling order required parties to reduce number of invalidity combinations by a certain date); *St. Clair Intellectual Property Consultants, Inc. v. Matsushita Electric Industrial Co.*, C.A. Nos. 04-1436-LPS, 06-404-LPS, 08-371-LPS, 2012 WL 1015993, at *5-7 (D. Del. Mar. 26, 2012), *aff'd*, 522

F. App'x 915 (Fed. Cir. 2013) (applying good cause and *Pennypack* when evaluating motion to supplement expert reports adding infringement theories when scheduling order set forth deadline for serving infringement contentions).² Thus, this Court will apply both standards here.

III. DISCUSSION

Jazz argues that Avadel lacked good cause to raise new invalidity theories after final contentions were due and that Avadel's belated disclosure prejudiced Jazz. D.I. 176 & 191. Avadel avers that its Interrogatory Response raised no new theories and, in any event, Jazz has incurred no prejudice. D.I. 189.

A. Avadel's Interrogatory Response Asserts a New Non-Enablement Theory Against the '079 and '782 Patents Based on Resinate Forms of GHB

While Jazz argues that Avadel's Interrogatory Response raises three "new contentions", D.I. 176 at 2, Avadel explains that its Interrogatory Response merely contains "elaborations" of invalidity theories previously disclosed. D.I. 189 at 1. The Court agrees with Avadel on the first two issues, and with Jazz on the third.

² While this Court issued a deadline for the parties to exchange final contentions (D.I. 65) neither that Order, the parties' Scheduling Order (D.I. 31), nor subsequent amendments thereto (D.I. 72, 97) established a good cause requirement governing modifications of the final contentions deadline. Under these unique circumstances, the parties' cited authority is not on all fours. While the court in *First Quality Tissue, LLC v. Irving Consumer Prods.*, C.A. No. 19-428, D.I. 149 (D. Del. Oct. 27, 2020) and *Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, C.A. No. 14-1268, 2018 WL 3369215 (D. Del. July 10, 2018) applied solely the *Pennypack* factors to a motion to strike, the operative schedule in *First Quality* "did not set a deadline for final invalidity contentions" and *Takeda* involved a supplemental interrogatory response raising a damages claim, not contentions. While the court in *Brit. Telecommunications PLC v. IAC/InterActiveCorp*, C.A. No. 18-366-WCB, 2020 WL 3047989 (D. Del. June 8, 2020) evaluated a motion to amend invalidity contentions solely under good cause, good cause was specifically adopted by the court in that action. *Id.* at *1 (warning defendant it "would permit [defendant] to amend its contentions and exceed those limits upon a showing of good cause"). Similarly, the court in *Fraunhofer-Gesellschaft Zur Forderung Der Angewandten Forschung e.V. v. Sirius XM Radio Inc.*, C.A. No. 17-184-JFB-SRF, 2022 WL 608143 (D. Del. Jan. 27, 2022) used only good cause to evaluate a motion for leave to amend invalidity contentions when a case-narrowing Order established relevant deadlines modifiable only upon a showing of good cause. D.I. 427 ¶ 15, 17-184-JFB-SRF.

First, Jazz seeks to strike Avadel's assertions related to a "new" enablement defense arising from Jazz's construction of "sustained release," arguing that Avadel "now contends for the first time in its Interrogatory Response that, '[i]f Jazz prevails on its construction of sustained release,' the specifications fail to enable the full scope of the claims of the Sustained Release³ patents." D.I. 176 at 2. Avadel's Interrogatory Response states, "The specification does not provide sufficient information to enable a skilled artisan to make and use the full scope of the claimed invention, especially under Jazz's construction of "sustained release" . . ."). D.I. 176-1, Ex. A at 15. This non-enablement theory is rooted in Avadel's Final Invalidity Contentions where Avadel cites the failure of "the specification [to] provide a POSA with any guidance how one would achieve the claimed GHB release profiles across the entire range of formulations claimed by the Jazz Sustained Release Patents" and explained that "[i]n view of the breadth of the functional claims of the Jazz Sustained Release Patents, the unpredictability in the art, and the limited disclosures in the specification, a POSA would not believe the inventors were in possession of the full range of possible formulations that met the recited drug release profile." D.I. 189-1, Ex. A at 112. Thus, Avadel's contentions broadly suggest the claims of the Sustained Release Patents are not enabled under *any* construction, which would include Jazz's proposed construction of "sustained release." While Jazz complains that Avadel raised non-enablement "in general terms and divorced from the context of any proposed claim construction," D.I. 191 at 1, the Court cannot conclude that Avadel's supplemental interrogatory response contains a new theory. Rather, Avadel's Interrogatory Response elaborates on the position it previously disclosed. Thus, the Court denies Jazz's motion

³ Because the parties previously agreed to refer to U.S. Patent Nos. 10,758,488 ("the '488 patent"), 10,813,885 ("the '885 patent"), 10,959,956 ("the '956 patent"), 10,966,931 ("the '931 patent") as the "Sustained Release Patents," D.I. 132 at xii, the Court uses that language here.

to strike portions of Avadel's Interrogatory Response discussing Avadel's enablement defense as to the Sustained Release Patents.

Second, Jazz seeks to strike Avadel's assertions related to a "new" written description defense, arguing Avadel inappropriately relies "on Jazz documents produced in October 2021" to invalidate the '079 patent.⁴ D.I. 176 at 2. In its Interrogatory Response, Avadel states, [REDACTED]

[REDACTED] D.I. 176-1, Ex. A at 45. This argument finds support in Avadel's Final Invalidity Contentions, which also questioned whether the inventors possessed a formulation permitting once-daily dosing: "a POSA would not have believed that the inventors were in possession of any controlled release component that could be administered as a single daily dose absent some disclosure of a means of achieving once-nightly dosing or data demonstrating the inventors had achieved once-daily dosing with a particular controlled release component." D.I. 189-1, Ex. A at 244; *see also id.* ("Given the foregoing, a POSA would need data to believe that the inventors were in possession of a controlled release portion that would permit single daily dosing."). While Jazz maintains that Avadel's contention is "much different" than Avadel's Interrogatory Response, both speak to whether the inventors possessed or developed a formulation that would allow once-nightly dosing. Thus, the Court denies Jazz's motion to strike portions of Avadel's Interrogatory Response discussing Avadel's written description defense as to the '079 patent.

Third, Jazz seeks to strike Avadel's assertions related to "new enablement arguments against the '079 and '782 patents⁵" that "rely[] upon Jazz's documents produced in October 2021."

⁴ "'079 Patent" refers to U.S. Patent No. 11,077,079.

⁵ "'782 Patent" refers to U.S. Patent No. 11,147,782.

D.I. 176 at 2. When comparing Avadel's Interrogatory Response with its Final Invalidity Contentions, Avadel's basis for this enablement defense changed. Avadel's Interrogatory Response argues for lack of enablement based on resinate forms, explaining that, "The '079 patent fails to enable the claimed method because resinate forms of GHB are inoperable," D.I. 176-1, Ex. A at 53; *see also id.* at 73 ("The '782 patent fails to enable the full scope of the claimed invention because resinate forms are inoperable."). However, in its Final Invalidity Contentions, Avadel argued lack of enablement based on "not GHB-resinate forms."⁶ *See* D.I. 189-1, Ex. A at 238-39; 264 (contending the '079 and '782 patents fail for lack of enablement because "the specification's disclosure of [a controlled release component in the '079 patent and modified release particles in the '782 patent] is limited to GHB-resinate forms . . . It would require undue experimentation to make and use controlled release components that are not GHB-resinate forms, [REDACTED] [REDACTED] Thus, Avadel's Interrogatory Response raises a new basis for its non-enablement theory.

Avadel argues that its Final Invalidity Contentions put Jazz on notice that Avadel would rely on Jazz's documents to prove non-enablement and, as a result, Avadel's use of those documents in its Interrogatory Response was not a surprise. Tr. 11:15-25; *see also* D.I. 189-1 at 264 (arguing lack of enablement [REDACTED]

[REDACTED] Even so, those statements do not excuse Avadel from changing the basis of its non-enablement theory from non-resinate forms to resinate forms via an Interrogatory Response served after final contentions were due.

⁶ Avadel's letter opposing Jazz's motion to strike does not dispute that its contentions are directed to "not GBH-resinate forms." D.I. 189 at 2.

Thus, the Court finds that Avadel's Interrogatory Response contains a new theory of non-enablement against the '079 and '782 patents based on resinate forms of GBH—a theory not rooted in Avadel's Final Invalidity Contentions. Accordingly, the Court turns to Rule 16 and the *Pennypack* factors.

B. Avadel Lacked Good Cause Under Rule 16 to Raise New Non-Enablement Theory After the Deadline for Final Invalidity Contentions

Under Rule 16(b)(4), “A schedule may be modified only for good cause and with the judge’s consent.” Fed. R. Civ. P. 16(b)(4). “Good cause is present when the schedule cannot be met despite the moving party’s diligence.” *Meda Pharm. Inc. v. Teva Pharm. USA, Inc.*, C.A. No. 15-785-LPS, 2016 WL 6693113, at *1 (D. Del. Nov. 14, 2016).

Avadel argues that Jazz “invited” the supplementation about which it now complains. D.I. 189. But Jazz served Interrogatory No. 8 on August 25, 2021, near the outset of this litigation. While Avadel had an obligation to supplement its response consistent with its general discovery obligations under the Federal Rules (*see, e.g.*, Rule 26(e)), Avadel does not argue that Jazz specifically invited supplementation after the May 6, 2022 deadline for final contentions. And even if Avadel had an obligation to supplement, “parties may not use their obligation to supplement as an excuse to violate the clear terms of a Scheduling Order, unilaterally buying themselves additional time to make disclosures, thereby unduly prejudicing other parties and potentially delaying the progress of a case.” *Abbott Lab’ys v. Lupin Ltd.*, C.A. No. 09-152-LPS, 2011 WL 1897322, at *3 (D. Del. May 19, 2011). Thus, Avadel’s obligation to supplement its interrogatory response does not amount to good cause.

Avadel also argues that, because Jazz’s claim construction briefing was submitted after the May 6 due date for final contentions, “[s]tatements from that briefing constitute a subsequent event that Courts recognize as good cause for a party to rely on.” D.I. 189 at 2 (citing *Amgen Inc. v.*

Kashiv Biosciences, LLC, C.A. No. 18-3347, 2019 WL 5445974, at *2 (D.N.J. Oct. 24, 2019)). But here, the Court specifically contemplated the circumstances of which Avadel complains—that is, the parties were ordered to serve final contentions “at least three weeks before Plaintiff serves its opening claim construction brief.” D.I. 65. Thus, Avadel was on notice that it must serve its final contentions before receiving Jazz’s opening claim construction brief.

Avadel advances no other arguments to demonstrate it acted with the requisite diligence in raising its new non-enablement theory. *cf. ChanBond*, 2019 WL 2098316, at *2 (finding good cause satisfied where defendant raised combination at issue “at the first available opportunity”). Also, Avadel’s delay in raising this theory six months after receiving all predicate documents from Jazz, and four months after the deadline for final contentions is suspect.⁷ *See, e.g., BioDelivery Sci. Int’l. v. Chemo Res., S.L.*, C.A. No. 19-444, D.I. 183 at 5 (D. Del. Feb. 20, 2020) (collecting cases noting that absent mitigating circumstances, three-, four- and five-month delays may amount to lack of diligence).

As a result, the Court will turn to whether Avadel’s untimely disclosure should be excluded under *Pennypack*. *See St. Clair*, 2012 WL 1015993, at *7 (considering *Pennypack* even after finding no good cause); *BioDelivery Sci. Int’l., Inc. v. Alvogen PB Research & Development LLC*, C.A. No. 18-1395, D.I. 143 (D. Del. Apr. 17, 2020) (considering *Pennypack* after concluding invalidity contentions supplementation was not timely and operative scheduling order did not contain good cause requirement).

⁷ Avadel does not dispute that it was in possession of the documents upon which it relied by March 2022 at the latest—before claim construction briefing, before final contentions were due in May 2022, and six months before it served its Interrogatory Response. D.I. 176 at 2, 3 n.4.

C. The *Pennypack* Factors Do Not Support Exclusion

Rule 37(c)(1) provides, “If a party fails to provide information . . . as required by Rule 26(a) or (e), the party is not allowed to use that information . . . to supply evidence on a motion, at a hearing, or at trial, unless the failure was substantially justified or is harmless.” To determine whether a failure to disclose was harmless, courts in the Third Circuit consider the *Pennypack* factors: (1) the prejudice or surprise to the party against whom the evidence is offered; (2) the possibility of curing the prejudice; (3) the potential disruption of an orderly and efficient trial; (4) the presence of bad faith or willfulness in failing to disclose the evidence; and (5) the importance of the information withheld. *Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710, 719 (3d Cir. 1997) (citing *Meyers v. Pennypack Woods Home Ownership Ass’n*, 559 F.2d 894, 904-05 (3d Cir. 1977)). “[T]he exclusion of critical evidence is an ‘extreme’ sanction, not normally to be imposed absent a showing of willful deception or ‘flagrant disregard’ of a court order by the proponent of the evidence.” *Id.* The determination of whether to exclude evidence is within the discretion of the district court. *Id.*

The first and second *Pennypack* factors (“the prejudice or surprise to the party against whom the evidence is offered” and “the possibility of curing the prejudice”) do not weigh in favor of exclusion. Jazz claims prejudice by arguing that Avadel’s belated supplementation was not fair.⁸ See D.I. 191 at 2; Tr. 7:11-16 (“If you have an order in place that requires contentions to be looked [sic] in as of a certain date, it’s not fair for a party to refuse to amend those contentions, try to introduce new theories through a separate discovery vehicle and then say gotcha; you have to

⁸ For example, Jazz argues that Avadel “deprived Jazz of the ability to adjust its claim construction positions based on the contentions,” D.I. 176 at 3, but does not explain any adjustments it would have purportedly made. Nor did Jazz raise any such adjustments during the Court’s October 25, 2022 claim construction hearing.

move under *Pennypack*.”). But unfairness alone does not rise to prejudice favoring exclusion. *See ChanBond*, 2019 WL 2098316, at *3 (explaining that movant’s mere identification of “fundamental unfair[ness]” as prejudice weighed against exclusion). While Jazz contends that the Scheduling Order does not afford Jazz enough time to address Avadel’s Interrogatory Response, including by obtaining discovery from third-parties, serving additional written discovery, and preparing for fact depositions, D.I. 176 at 3; D.I. 191 at 2, Avadel served its Interrogatory Response nearly two months before the close of fact discovery, and any lingering prejudice could be cured by a modest extension of the fact discovery deadline in the Scheduling Order. *cf. WebXchange Inc. v. FedEx Corp.*, C.A. No. 08-133-JJF, 2010 WL 299240, at *3 (D. Del. Jan. 20, 2010) (“In this case discovery has not yet closed and there is substantial time for investigation, eliminating prejudice.”). Indeed, while fact discovery closed while Jazz’s Motion remained pending, the parties signaled that, at least as of November 28, 2022, “the parties are still working towards completing fact depositions.” D.I. 240. Also, opening, responsive, and reply expert reports are not due until January 17, 2023, March 17, 2023, and May 15, 2023, respectively. D.I. 240.

The third *Pennypack* factor (“the potential disruption of an orderly and efficient trial”) weighs against exclusion as trial is scheduled for October 30, 2023—approximately eleven months away.

The fourth *Pennypack* factor (“the presence of bad faith or willfulness in failing to disclose the evidence”), is, on balance, neutral. While Avadel’s Interrogatory Response bypassed the final contentions deadline, Jazz does not adduce any evidence to suggest that Avadel acted in bad faith. Also, Avadel’s Interrogatory Response was served two months before fact discovery closed. *See Konstantopoulos*, 112 F.3d at 719 (“[T]he exclusion of critical evidence is an ‘extreme’ sanction,

not normally to be imposed absent a showing of willful deception or ‘flagrant disregard’ of a court order by the proponent of the evidence.”).

The fifth *Pennypack* factor (“the importance of the information withheld”) weighs against exclusion. Avadel has indicated that its enablement and written description invalidity positions are critical to its case. D.I. 189 at 5. See *EMC Corp. v. Pure Storage, Inc.*, 154 F. Supp. 3d 81, 93 (D. Del. 2016) (“Courts in the Third Circuit favor resolution of disputes on their merits, particularly with respect to patent validity issues, which raise public interest concerns extending beyond the immediate dispute between the parties.”).

Therefore, on balance, the *Pennypack* factors do not support striking Avadel’s Interrogatory Response. Any prejudice to Jazz can be cured with modest extensions to deadlines in the Scheduling Order.

IV. CONCLUSION

For the foregoing reasons, the Motion is **GRANTED-IN-PART AND DENIED-IN-PART**.

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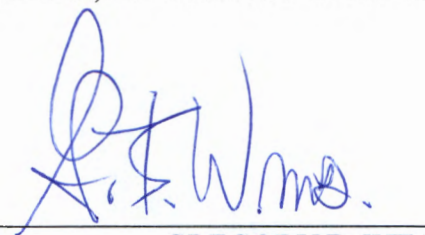
WHEREFORE, this 8th day of December, 2022, **IT IS HEREBY ORDERED** that:

1. Plaintiff Jazz Pharmaceuticals, Inc.'s Motion to Strike Defendant Avadel CNS Pharmaceuticals LLC's Second Supplemental Response to Interrogatory No. 8 (the "Motion") (D.I. 175) is **GRANTED-IN-PART** and **DENIED-IN-PART** as follows:

- a. Jazz's Motion related to Avadel's Second Supplemental Response to Interrogatory No. 8 discussing Avadel's enablement defense as to the Sustained Release Patents is **DENIED**.
- b. Jazz's Motion related to Avadel's Second Supplemental Response to Interrogatory No. 8 discussing Avadel's written description defense as to the '079 patent is **DENIED**.
- c. Jazz's Motion related to Avadel's Second Supplemental Response to Interrogatory No. 8 asserting a non-enablement theory against the '079 and '782 patents based on resinate forms of GHB is **GRANTED-IN-PART**. The parties shall meet and confer and, on or before December 14, 2022, submit to the Court a stipulated amended Scheduling Order that sets forth a plan to permit Jazz to conduct the supplemental discovery necessary, if any, to address Avadel's non-enablement theory against the '079 and '782 patents based on resinate forms of GHB, which plan may (a) extend the deadline for fact discovery set forth in the Scheduling Order, (b) contemplate additional third-party discovery, written fact discovery, and fact depositions, and (c) address whether any modifications to the deadlines governing expert discovery are necessary commensurate with the extension to the fact discovery deadline. If the parties are unable to reach agreement on such stipulated amended Scheduling Order, then, on or before December 14, 2022, Jazz shall file a supplemental letter of no

more than two (2) pages identifying the supplemental discovery it seeks to obtain pursuant to the Court's Order and identify any dates in the Scheduling Order for which Jazz requests adjustment. Avadel shall file a responsive letter of no more than two (2) pages no later than December 19, 2022.

2. Because the Memorandum Order is filed under seal, the parties shall meet and confer and, no later than December 14, 2022, submit a joint proposed redacted version. In the absence of a timely request compliant with applicable standards, the Court will unseal the entire Order.



GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE