

**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

JAZZ PHARMACEUTICALS, INC., et al.,

Plaintiffs,

v.

AVADEL CNS PHARMACEUTICALS,  
LLC,

Defendant.

C.A. No. 21-1594-GBW

**JOINT STATUS REPORT**

Pursuant to the Court's Order (D.I. 731)<sup>1</sup> following the Federal Circuit's May 6, 2025 appellate decision, Plaintiffs Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited (together, "Jazz") and Defendant Avadel CNS Pharmaceuticals ("Avadel") hereby submit this Post-Appeal Status Report and proposed briefing schedule on how the case should proceed.

## **I. INJUNCTION REMAND**

The Federal Circuit's May 6, 2025 appellate decision vacated the portion of this Court's injunction (D.I. 666, 710) enjoining Avadel from applying for approval from the U.S. Food and Drug Administration for any indication for Avadel's LUMRYZ<sup>TM</sup> drug product that was not part of LUMRYZ<sup>TM</sup>'s label as of March 4, 2024, and remanded to this Court for reconsideration of that issue in light of the Federal Circuit's opinion. The Federal Circuit's decision reversed the portion of this Court's injunction (D.I. 666, 710) enjoining Avadel from initiating new clinical trials for LUMRYZ<sup>TM</sup> and from offering open-label extensions to clinical trial participants. The Federal Circuit's decision left in place the portion of this Court's injunction (D.I. 666, 710) permanently enjoining Avadel from infringing claim 24 of U.S. Patent No. 11,147,782 ("the '782 patent") by marketing, making, using, or selling LUMRYZ<sup>TM</sup> for indications other than for the treatment of narcolepsy through the expiration date of the '782 patent.

Therefore, on remand, the parties must address whether Avadel should and/or can be enjoined from seeking FDA approval for an idiopathic hypersomnia ("IH") indication for LUMRYZ<sup>TM</sup> prior to the expiration of the '782 patent in light of the Federal Circuit's decision. As neither party intends to seek rehearing of the Federal Circuit decision (and thus the mandate will issue on June 12, 2025), the parties propose the following schedule for the remanded portion of the Court's injunction decision:

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<sup>1</sup> All "D.I." cites are to C.A. No. 21-691 unless indicated otherwise.

- June 17, 2025 – Jazz’s opening brief and any supporting papers;
- July 29, 2025 – Avadel’s opposition brief and any supporting papers;
- August 19, 2025 – Jazz’s reply brief and any supporting papers.

The parties request an oral argument and/or an evidentiary hearing following briefing on the remanded portion of the injunction.

**Avadel’s Position:** Separately, Avadel reserves the right to seek to modify the injunction in the future as permitted by law.

## **II. ONGOING ROYALTY**

Following the Court’s entry of an injunction, the parties briefed what the rate should be for an ongoing royalty to Jazz due to Avadel’s post-trial infringement of the ’782 patent based on LUMRYZ<sup>TM</sup> sales for the treatment of narcolepsy. *See* D.I. 687, 690, 705, 707. The issue of the ongoing royalty rate remains pending before this Court.

## **III. ENTRY OF JUDGMENT & POST-TRIAL MOTIONS**

This Court has not yet entered judgment on the jury verdict. This Court previously ordered that “[w]ith respect to the post-trial motions, including but not limited to post-trial motions under Federal Rules of Civil Procedure 50 and 59, the following schedule shall apply”:

- Opening post-trial briefs due 28 days after the entry of judgment;
- Opposition briefs due 28 days after opening briefs; and
- Reply briefs due 14 days after opposition briefs.

D.I. 585 at 2-3. The Court set the page limits for briefing regarding the potential post-trial motions at 20 pages per side for opening briefs, 20 pages per side for opposition briefs, and 10 pages per side for reply briefs. *Id.* at 3.

**Jazz's Position:** As the Court previously Ordered, post-trial briefing should be conducted following the entry of judgment pursuant to the schedule set forth above. *See* D.I. 585. Further, during the permanent injunction hearing last year, the Court rejected Avadel's attempt to put post-trial briefing ahead of resolution of the post-trial equitable issues and recognized that post-trial briefing would be due following at least resolution of the injunction issue. *See* Ex. A, 6/4/24 Hearing Tr. at 125-126. There is no reason to deviate from this procedure now and there is no reason to change the page counts for post-trial briefs that the Court previously set, as Avadel advocates for below. Jazz further proposes that the entry of judgment should include the Court's resolution of the pending ongoing royalty issue discussed above. To the extent the Court is inclined to enter partial judgment now, Jazz respectfully requests time to review and respond to Avadel's proposed form of judgment, which Avadel sent to Jazz for the first time earlier today mere hours before this report is due on a holiday weekend and for which Jazz would need client approval. Jazz would suffer undue prejudice should it not have sufficient time to provide input into the entry of judgment.

In addition to this case, Jazz's proposal is how the parties proceeded in the similarly situated cases of *Natera, Inc. v. ArcherDX, Inc.*, No. 20-125 (GBW) (D. Del.), *EIS, Inc. v. IntiHealth Ger GmbH*, No. 19-1227 (GBW) (D. Del.), and *HID Global Corporation v. Vector Flow, Inc.*, No. 21-1769 (GBW) (D. Del.) where this Court ordered further post-jury trial proceedings towards resolution of outstanding equitable issues prior to entry of judgment. *See* Ex. B, No. 20-125, D.I. 618; Ex. C, No. 19-1227, D.I. 672; and Ex. D, No. 21-1769, D.I. 506. Though Avadel reraises the issues, as Jazz previously stated (D.I. 584 at 2-4) and the Court agreed (D.I. 585), Avadel's request for entry of partial judgment does not even address, let alone make a

showing to satisfy, the requirement for such judgment under Federal Rule of Civil Procedure 54(b).<sup>2</sup>

Judgment should not be entered at this time because Jazz's equitable claim seeking a permanent injunction with respect to IH has yet to be resolved on remand and the ongoing royalty issue remains pending. Indeed, at the very least, the resolution of those issues would be relevant to the parties' post-trial briefing regarding the jury's award for past damages. Judgment should, therefore, be entered after the remanded portion of Jazz's equitable claim for injunctive relief and the ongoing royalty issue have been decided by the Court. Federal Rule of Civil Procedure 54(b) governs entry of partial judgment. Under that Rule, partial judgment may be entered "only if the court expressly determines that there is no just reason for delay." As the Supreme Court has explained, "partial final judgment" is used only to prevent "the hardship and denial of justice through delay if each issue must await the determination of all issues as to all parties before a final judgment can be had." *Dickinson v. Petroleum Conversion Corp.*, 338 U.S. 507, 511 (1950). Avadel alleges unexplained prejudice below but has not identified any alleged "hardship and denial of justice through delay" that would take place if the Court entered a single, final judgment after resolution of the remanded portion of the injunction order versus entry of partial judgment now. Moreover, the term "judgment" in the Federal Rules refers to a "final decision," *Bankers Trust Co. v. Mallis*, 435 U.S. 381, 384 n.4 (1978); Fed. R. Civ. P. 54 ("Judgment' as used in these rules includes a decree and any order from which an appeal lies."), and there is no final and appealable judgment when equitable claims remain to be decided. *See Cordance Corp. v. Amazon.com, Inc.*,

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<sup>2</sup> Avadel's citation to cases below for its proposed procedure are inapposite because the parties agreed to the proposed procedure in those cases or the court entered an order *sua sponte*. *See* C.A. No. 21-1317, D.I. 498; C.A. No. 21-653, D.I. 313; C.A. No. 15-634, D.I. 498; C.A. No. 11-484 D.I. 285; C.A. No. 21-1238, D.I. 341.

696 F. Supp. 2d 445, 450 (D. Del. 2010). It would be improper, waste resources, and lead to a duplication of efforts (for both the Court and the parties) to start the appeal, post-trial briefing, and execution clocks by entering “partial” judgment on claims that have not been fully resolved. As such, Jazz respectfully submits that judgment should be entered after resolution of the remanded portion of the injunction and the pending ongoing royalty issue.

**Avadel’s Position:** The Court should promptly enter judgment on the jury verdict from March 4, 2024. Typically, some form of judgment to trigger JMOL briefing is entered within two weeks of a jury verdict. *See, e.g., Ex. E, Sight Scis., Inc. v. Ivantis, Inc.*, C.A. No. 21-1317-JLH, D.I. 509 (D. Del. May 21, 2024). This is true even when post-trial equitable issues, including a permanent injunction and ongoing reasonable royalty, remain to be briefed. *See, e.g., Ex. F 10X Genomics, Inc. v. Nanostring Techs. Inc.*, C.A. No. 21-653-MFK, D.I. 312 (D. Del. Nov. 22, 2023) (entering “non-final judgment following jury verdict” to trigger JMOL briefing simultaneously with injunction and reasonable royalty briefing); *Ex. G, Godo Kaisha IP Bridge 1 v. TCL Comm’n Techs. Holdings Ltd.*, C.A. No. 15-634-JFB, D.I. 512 (D. Del. Jan. 2, 2019) (entering “judgment following jury verdict” under similar circumstances); *Ex. H, Riverbed Tech. Inc. v. Silver Peak Sys. Inc.*, C.A. No. 11-484-RGA, D.I. 280 (D. Del. Apr. 8, 2014) (entering “judgment following a jury verdict” that was “subject to modification following the Court’s consideration of the parties’ post-trial motions,” which included a motion for a permanent injunction). This Court followed that very protocol in *Rockwell Automation, Inc. v. Parcop S.R.L.*, entering a “judgment following jury verdict” two weeks after the jury verdict, which triggered all post-trial motions, including an equitable motion for a permanent injunction. *Ex. I, C.A. No. 21-1238-GBW, D.I. 342 (D. Del. Aug. 14, 2023)*. This allowed the Court to issue a “final judgment” on the same day it issued the

permanent injunction order and all issues were appealed together. Ex. J, *Id.* at D.I. 368 (D. Del. June 18, 2024); Ex. K, *Id.* at D.I. 369 (D. Del. June 18, 2024).

Given that the parties will now be briefing injunction issues again following remand, Avadel believes this Court should enter judgment on the jury verdict and permit the parties to proceed with post-trial motions on all issues to avoid further delay, which is prejudicial to Avadel because it delays the Court's ability to rule on Avadel's JMOL motion(s) and further delays Avadel's appeal to the Federal Circuit. Moreover, consideration of post-trial motions in parallel with Jazz's renewed request for an injunction is more efficient for the Court (e.g., Jazz's injunction and royalty motions would be mooted should the Court declare the '782 patent invalid as a matter of law). While the Court's approach of proceeding stepwise initially made sense, now that we are nearly 15 months post-verdict, it is time take the steps necessary in parallel to conclude this action so that it can be appealed to the Federal Circuit, if necessary, in the most timely fashion practicable. As such, Avadel respectfully requests that the Court enter **Exhibit L**, Avadel's proposed order for judgment on the jury verdict.

Further, Jazz's improper request below seeking a stay in the antitrust case while also seeking to delay any JMOL briefing on the '782 patent validity reveals Jazz's litigation strategy of pursuing all of Jazz's affirmative claims while precluding Avadel from having its day in Court. Jazz's strategy should not be countenanced.

#### **IV. RELATED PROCEEDINGS**

##### **A. Antitrust Proceedings in C.A. No. 22-941**

**Jazz's Position:** The parties are litigating antitrust counterclaims brought by Avadel against Jazz in the matter *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, No. 22-941-GBW (D. Del.) ("the antitrust case"). Jazz moved to stay proceedings in the antitrust case pending the

resolution of Avadel's expected appeal of the jury's verdict finding the '782 patent valid. *See* No. 22-941, D.I. 80, 84. On October 4, 2024, the Court granted Jazz's request to file a supplemental brief in support of Jazz's pending motion for a stay. No. 22-941, D.I. 182. Jazz and Avadel subsequently filed supplemental briefs regarding Jazz's motion for a stay and that motion remains pending before this Court. *See* No. 22-941, D.I. 184, 189, 193. Avadel is incorrect that the Court has already rejected Jazz's arguments for a stay as they relate to the '782 patent given the Court's request for further briefing on this issue which remains pending. *See* No. 22-941, D.I. 182. Avadel's argument that it is procedurally improper for Jazz to raise the antitrust case here lacks merit given that the Court's Order for a joint status report did not forbid the parties from identifying how this case affects related proceedings. Avadel itself argued to the Federal Circuit in appealing the injunction that the antitrust case may "be affected by" the appeal decision. *See Jazz Pharmaceuticals, Inc. v. Avadel CNS Pharmaceuticals, LLC*, No. 24-2274 (Fed. Cir.), Document 29 at ix. Avadel has also argued that given the scope of the injunction, the antitrust case should not be dismissed or stayed, as Jazz has argued. *See* No. 22-941, D.I. 196 at 1.

It is Jazz's position that the recent Federal Circuit decision makes a stay of the antitrust case all the more necessary and appropriate. Given that the portion of injunction that prevents Avadel from making, using, or selling Lumryz for any indication other than narcolepsy remains in effect, the antitrust case should be stayed for the reasons provided in Jazz's prior briefing. *See* No. 22-941, D.I. 80, 84, 100, 114, 184, 193. Further, because Avadel injected the issue into the case, the parties' experts in the antitrust case have based portions of their opinions on this Court's injunction relating to the '782 patent and on the jury's royalty rate awarded for Avadel's infringement of the '782 patent. Now that portions of the injunction concerning the '782 patent have been reversed-in-part, vacated-in-part, and remanded, the parties' experts may need to



supplement their reports depending on how this Court resolves the remanded portion of the injunction. Again, Avadel, not Jazz, first put the injunction at issue in the antitrust case through its experts. For the same reasons, the Court’s ruling on an ongoing royalty in the patent case may also require supplemental reports in the antitrust case. For these reasons, and those set forth in Jazz’s motion to stay (No. 22-941, D.I. 80, 84; *see also* D.I. 100, 114) and supplemental briefs (No. 22-941, D.I. 184, 193), Jazz respectfully requests that the Court stay the antitrust case. To the extent that Avadel disagrees, Jazz requests oral argument on this issue at the May 29, 2025 status conference.

**Avadel’s Position:** Jazz insists on leveraging the Court’s requested status report in these patent cases to force a discussion about a *different case*. This is improper—a fact that Avadel raised with Jazz multiple times. But it is also telling. The parties are less than six months from trial in an antitrust case where Jazz faces substantial liability. Jazz has filed one unavailing motion after another in that case in an increasingly desperate effort to escape accountability. The Court has properly declined to accommodate those efforts.

Procedural impropriety aside, Jazz’s most recent stay request fails on the merits. The antitrust case is about competition in the narcolepsy space—it has nothing to do with idiopathic hypersomnia. Jazz did not appeal this Court’s denial of a permanent injunction as to narcolepsy, as the Federal Circuit noted. *See Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, No. 2024-2274, 2025 WL 1298920, at \*3 n.5 (Fed. Cir. May 6, 2025). As the IH aspect of the injunction on remand has no bearing whatsoever on the antitrust case, there is no basis for a stay.<sup>3</sup>

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<sup>3</sup> Jazz asserts that “Avadel itself argued ... that the antitrust case may ‘be affected by’ the appeal decision.” Jazz is quoting the standard “statement of related cases” section in which Avadel identified all potentially related cases—i.e., ones that “may affect or be affected by” the appeal. *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, No. 2024-2274 (Fed. Cir. Sept. 30, 2024),

Jazz's renewed stay request is premised on arguments regarding the '782 patent that the Court has considered and properly rejected. The parties' positions on these issues are the subject of ongoing dispositive motion briefing in the antitrust case, which will be complete by June 13, 2025. Given that the parties are a few weeks away from completing briefing on dispositive motions and *Daubert* motions, it is unclear what Jazz seeks to stay—nearly everything the parties need to do is done, and the parties will have the benefit of the Court's ruling on the pending motions before trial, so there is no simplification or efficiencies gained by a stay at such a late stage of the case.<sup>4</sup> Instead, a stay at this juncture would only serve to prejudice Avadel by denying it its day in Court at the upcoming jury trial. Each of Jazz's arguments can and should be addressed in the context of summary judgment so that the case can be resolved expeditiously on the merits, not left in limbo for an indefinite duration under the guise of a stay.

To be sure, Jazz's purported justification for needing a stay—claiming that the parties' damages experts will have to update their reports to reflect the ongoing royalty for sales of LUMRYZ<sup>TM</sup>—is the same argument Jazz made last year, and that parade of horrors has not come to pass. Damages experts routinely supplement their reports shortly prior to trial. Indeed, these same parties supplemented their damages expert reports immediately before trial in the patent cases and again after the trial without any need for a stay. *See* D.I. 538 (Jazz's Notice of Service of the Supplemental Expert Report of [its damages expert] two weeks prior to trial); D.I. 585. In

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Document 29 at ix. Jazz is incorrect in contending that Avadel's required disclosure of a related case supports Jazz's attempt (yet again) to stay the antitrust action.

<sup>4</sup> This Court considers three factors in whether to grant a stay: (1) whether granting the stay will simplify the issues for trial; (2) the status of the litigation, particularly whether discovery is complete and a trial date has been set; and (3) whether a stay would cause the non-movant to suffer undue prejudice from any delay or allow the movant to gain a clear tactical advantage. *See Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, No. 15-1168-LPS, 2021 WL 616992, at \*2 (D. Del. Feb. 17, 2021). None could possibly justify a stay of the antitrust case at this point.

the antitrust case, the parties will update their damages reports shortly before trial to account for any developments such as the availability of new sales figures. This is routine supplementation that regularly occurs before any trial and has never been a basis for a stay.

Avadel respectfully requests this Court reject Jazz's attempt to inject the antitrust case issues into the patent case status report and conference, and accordingly, formally deny Jazz's motion to stay and request for oral argument on same. *See* No. 22-941 at D.I. 82, 83, 108, 189, 190. Avadel respectfully requests the Court issue an oral order (as it did previously) confirming it will not take up the antitrust issue at the May 29, 2025 in-person status conference as it impacts who will need to be present at the hearing. *See* D.I. 626.

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