IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	**REDACTED PUBLIC VERION FILED DECEMBER 19, 2023** C.A. No. 21-691-GBW [redacted]
JAZZ PHARMACEUTICALS, INC., et al., Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-1138-GBW [redacted]
JAZZ PHARMACEUTICALS, INC., et al., Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-1594-GBW [redacted]

DEFENDANT AVADEL CNS PHARMACEUTICALS, LLC'S CONCISE STATEMENT OF FACTS IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT NO. 3

CONCISE STATEMENT OF FACTS

C-1. Jazz is currently asserting claims 1-12 of U.S. Patent No 10,758,488 (the "'488 patent"); claims 1-15 of U.S. Patent 10,813,885 (the "'885 patent"); claims 1-20 and 23-35 of U.S. Patent No. 10,959,956 (the "'956 patent"); claims 1-15 of U.S. Patent No. 10,966,931 (the "'931 patent"); claims 1-3, 5-12, and 14-18 of U.S. Patent No. 11,077,079 (the "'079 patent"); and claims 1-24 of U.S. Patent No. 11,147,782 (the "'782 patent") (collectively the "Asserted Claims"). Ex. 23, Jazz's Final Infringement Contentions at 43, 83, 107, 177, 204, and 222.

C-2. The Asserted Claims all relate to either a pharmaceutical formulation or a method of using a pharmaceutical formulation. *See* Exs. 1-6, Asserted Claims.

C-3. Every Asserted Claim requires that the formulation either comprise or release gamma-hydroxybutyrate. *See* Exs. 1-6, Asserted Claims.

C-4. The accused product is Avadel's Lumryz™ product, a solid formulation that contains sodium gamma-hydroxybutyrate as its active ingredient. Ex. 24, AVDL_01395721 (Lumryz™ Package Insert) at AVDL_01395721.

C-5. The parties disputed the meaning of the claim terms "gamma-hydroxybutyrate" and "oxybate." The key dispute was whether the terms encompassed salts of gamma-hydroxybutyric acid or were limited to the "gamma-hydroxybutyrate"/"oxybate" anion itself. D.I. 310 at 1; Ex. 25 (Klibanov Decl.) at ⁋ 7; Ex. 26 (Little Decl.) at ⁋⁋ 25 & 34.

C-6. Avadel's proposed construction of "gamma-hydroxybutyrate"/"oxybate" limited the terms to the "negatively charged or anionic form (conjugate base) of gamma-hydroxybutyric

acid," which both parties agreed had the effect of "excluding [the anionic form] when ionically bound (e.g., in the form of sodium oxybate)." D.I. 310 at 1.

C-7. Jazz has taken the position that the gamma-hydroxybutyrate anion cannot exist in solid form. D.I 310 at 18 (Jazz explaining that "[b]oth [parties'] experts agree that the unbound anion (i.e., Avadel's proposed construction) cannot exist as a solid."); Ex. 26 (Little Decl.) at ⁋⁋ 25 & 34; Ex. 27, 11/01/23 Hrg. at 13:25-14:4 ("Because, as Dr. Klibanov admits, as everybody agrees, Jazz's experts, [Avadel's expert] Dr. Klibanov, the unbound or unbound negatively charged or anion form conjugate base of gamma-hydroxybutyrate acid [sic] cannot exist in solid form.").

C-8. Salts are meaningfully different from anions because a salt is a compound formed by the interaction of a cation and an anion, binding their changes together, while anions are negatively charged particles. Ex. 25 (Klibanov Decl.) at ¶¶ 9-13; Ex. 26 (Little Decl.) at ¶¶ 21-25.

C-9. Jazz's counsel admitted that "for the '079 and '782, we don't have an infringement theory if [Avadel's] construction gets adopted for the sustained release." Ex. 27, 11/01/23 Hrg. at 52:19-21.

C-10. Jazz indicated during the November 1, 2023 *Markman* hearing that it may choose to maintain an infringement position regarding the sustained release patents "because [Avadel's expert] said sodium oxybate releases gamma-hydroxybutyrate." Ex. 27, 11/01/23 Hrg. at 52:24-25

C-11. Claim 1 "recites a formulation that 'releases at least about 30% of its gamma-hydroxybutyrate,'" while claim 12 "recites a formulation that 'releases at least about 30% of its gamma-hydroxybutyrate or salt thereof by one hour.'" Ex. 25 (Klibanov Decl.) at ¶ 22.

C-12. "Its" is defined as "belonging to or relating to something that has already been mentioned." Ex. 28, "Its", *Cambridge* Dictionary, available at https://dictionary.cambridge.org/us/dictionary/english/its.

C-13. Dr. Little opined that the "release" limitations refer to the release from the formulation into the media. *See* Ex. 17, Little Dep. at 22:23-23:3 ("Q. Okay. And by release in all of those descriptions, you mean release from the formulation, the active being released from the formulation? Is that what you're referring to? A. I think that's a common way to say it, yes."); Ex. 29, Little Infringement Rpt. at ¶¶ 76-77 ("Given all of this, a POSA would understand that the full dose of active ingredient [sodium gamma-hydroxybutyrate] in the IR portion of Avadel's NDA Product has fully released by one hour and, therefore, that Avadel's NDA Product releases at least about 30% of its gamma-hydroxybutyrate by one hour.")

C-14. Dr. Klibanov opined that the "release" limitations refer to the release from the formulation into the media. Ex 14, Responsive Klibanov Rpt. at ¶¶ 99 ("In my review of the portions of Avadel's NDA that describe the dissolution testing performed on LUMRYZ and of the '062 Patent, I have seen no evidence that shows release of anything other than the API sodium oxybate from the controlled release pellets."), 102 ("Thus, regardless of whether some gamma-hydroxybutyrate is present in the dissolution medium, it would not satisfy the claim limitations at issue—particularly the 'its gamma-hydroxybutyrate' claim limitations. Those claim limitations do not merely recite that gamma-hydroxybutyrate is released in the testing, it specifies that (for instance) 'the sustained release portion releases greater than about 40% of its gamma-hydroxybutyrate by about 4 to about 6 hours' under certain conditions.").

C-15. Dr. Klibanov opined that "the express and repeatedly used claim term "its," [] specifies that the immediate or sustained release portion has to include gamma-hydroxybutyrate

in the first instance (and outside of the testing conditions) to be able to release it." Ex. 14, Responsive Klibanov Rpt. at ¶ 102.

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