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 **PUBLIC VERSION**
JAZZ PHARMACEUTICALS, INC., et al., Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-1138-GBW **PUBLIC VERSION**
JAZZ PHARMACEUTICALS, INC., et al., Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-1594-GBW **PUBLIC VERSION**

OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT NO. 3

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I. NATURE AND STAGE OF THE PROCEEDINGS

Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Ltd. ("Plaintiffs" or "Jazz") assert that Avadel infringes U.S. Patent Nos. 10,758,488; 10,813,885; 10,959,956; 10,966,931 ("the Sustained Release Patents"); 11,077,079; and 11,147,782 (the "'079/'782 Patents"). CoF No. 1. The parties dispute the construction of "gamma-hydroxybutyrate" from the Sustained Release Patents and "gamma-hydroxybutyrate" / "oxybate" from the '079/'782 Patents. *See* Avadel Statement of Facts ("SMF") ¶ C-5. The Court held a *Markman* hearing on November 1, 2023 but has not yet ruled. Avadel moves for summary judgment of non-infringement in the event the Court adopts its proposed construction. D.I. 399. Jazz opposes.

II. SUMMARY OF ARGUMENT

Summary judgment should be denied because a genuine material factual dispute exists regarding whether Avadel's accused product, LUMRYZ™, releases "gamma-hydroxybutyrate" under Avadel's proposed construction.

Avadel alleges that summary judgment of non-infringement is warranted for the Sustained Release Patents if Avadel's proposed construction of "gamma-hydroxybutyrate" is adopted because LUMRYZ™ releases sodium gamma-hydroxybutyrate rather than the stand-alone gamma-hydroxybutyrate anion (the "GHB Anion"). *See* Br. at 31.[1] Avadel misstates Jazz's expert's position and glosses over its own expert admitting that, should the Court adopt Avadel's proposal, then LUMRYZ™ necessarily releases the GHB Anion. In fact, Jazz's expert (Dr. Steven Little) explained how LUMRYZ™ releases the GHB Anion under Avadel's proposed construction and Avadel's expert's (Dr. Alexander Klibanov's) testimony stating as

[1] As used herein, "Br." refers to Avadel's "Brief in Support of Defendant's Summary Judgment and Daubert Motions" (C.A. No. 21-691, D.I. 407).

much. Here, Avadel and its own expert disagree on what is released from Avadel's accused product. If a "battle of the experts" is not amenable to resolution on summary judgment prior to the presentation of evidence at trial, *Transcenic, Inc. v. Google, Inc.*, No. 11-582, 2014 WL 7275835, at *2 (D. Del. Dec. 22, 2014), certainly a battle between both parties' experts and Avadel's attorney argument is not amendable to resolution on summary judgment.[2] At the very least, a disputed material fact remains.

III. FACTUAL BACKGROUND

A. The Sustained Release Patents' Asserted Claims And The Parties' Claim Construction Arguments For "Gamma-Hydroxybutyrate"

All asserted claims of the Sustained Release Patents require that the formulation contain "at least one pharmaceutically active ingredient selected from gamma-hydroxybutyrate and pharmaceutically acceptable salts of gamma-hydroxybutyrate." CoF No. 4. The claims further require that the formulation release certain percentages of "its gamma-hydroxybutyrate" at certain time periods when tested in deionized water. *Id.* In claim construction proceedings, Avadel argued that "gamma-hydroxybutyrate" is limited to the GHB Anion, excluding when ionically bound (e.g., in the form of sodium oxybate). SMF ¶ C-6. Jazz, on the other hand, argued that "gamma-hydroxybutyrate" includes: (1) gamma-hydroxybutyric acid or (2) the negatively charged or anionic form (conjugate base) of gamma-hydroxybutyric acid, including when ionically bound (e.g., in the form of sodium oxybate). CoF No. 5.

[2] With respect to the '079/'782 Patents, if the court adopts Avadel's proposed construction of "gamma-hydroxybutyrate" / "oxybate," then Jazz does not oppose summary judgment of non-infringement for the asserted claims of those patents. The Court should reject Avadel's proposed construction for the reasons described in Jazz's briefing and at oral argument. *See* D.I. 310.

B. The Sustained Release Patents' Asserted Claims Do Not Require That The Sustained Release Portion Contain Gamma-Hydroxybutyrate

Both parties' experts agree that the GHB Anion (i.e., Avadel's proposed construction) cannot exist as a solid. CoF No. 6. But as noted above, the asserted claims are not limited to containing the GHB Anion even under Avadel's proposed construction. Instead, if Avadel's proposed construction were to be adopted, the claims would require: "at least one pharmaceutically active ingredient selected from [the GHB Anion] and pharmaceutically acceptable salts of gamma-hydroxybutyrate." Therefore, if an accused product contains sodium gamma-hydroxybutyrate, it would meet this claim limitation. It need not contain the GHB Anion. And it is undisputed that LUMRYZ™ contains sodium gamma-hydroxybutyrate, which is the pharmaceutically acceptable sodium salt of gamma-hydroxybutyrate. SMF ¶ C-4.

C. LUMRYZ™ Releases The GHB Anion Under Avadel's Construction

If the Court adopts Avadel's proposal for "gamma-hydroxybutyrate," then it has adopted Avadel's expert's (Dr. Klibanov's) opinions in support of that construction. Dr. Klibanov testified that sodium gamma-hydroxybutyrate dissolves into the sodium cation and the GHB Anion *before* both are released from LUMRYZ™: "dissolution is the initial step of the process. When there is a molecule that is surrounded – the molecule of the API, which is surrounded by some molecules of water, it leaves other API molecules, *the dissolution takes place, and then after that*, diffusion takes place, and that results in *release*." CoF No. 8 (emphasis added). When asked "where does the 'gamma-hydroxybutyrate' as you've defined it come from," Dr. Klibanov admitted: "It comes from sodium gamma-hydroxybutyrate." CoF No. 9.

Jazz's expert, Dr. Little, opined that Avadel would infringe under Avadel's proposed construction and Dr. Klibanov's testimony. Dr. Little explained that, in the context of the Sustained Release Patents, "release" is measured when the drug is dissolved in the deionized

water testing media around the dosage form and that the drug must be dissolved in order to be measurable. CoF No. 10. In other words, the GHB Anion from LUMRYZ™ is "released" after it dissolves in deionized water, as stated by Dr. Klibanov. CoF No. 10. For a highly soluble drug such as gamma-hydroxybutyrate, dissolution happens essentially at the same time as water penetration/hydration of the dosage form. CoF No. 10. Thus, based on Dr. Klibanov's opinions, the parties' experts agree that the sodium gamma-hydroxybutyrate in LUMRYZ™ will dissolve and release the GHB Anion when the dosage form is added to water. The position Avadel now advances in its brief is contrary to the testimony of both parties' experts, and, at a minimum, is the subject of a genuine dispute of material fact.

IV. ARGUMENT

A. Legal Standards

"Infringement is a question of fact." *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1374 (Fed. Cir. 2009). Because infringement is a fact issue, courts should approach a motion for summary judgment of non-infringement with great care. *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 528 (Fed. Cir. 1996).

Pursuant to Rule 56(a) of the Federal Rules of Civil Procedure, "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." As the moving party, Avadel bears the burden of demonstrating the absence of a genuine issue of material fact. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 585-86 (1986). The court is to "draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." *Reeves v. Sanderson Plumbing Prods., Inc*., 530 U.S. 133, 150 (2000). There is a "genuine" issue of material fact if the "evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby,*

Inc., 477 U.S. 242, 248 (1986). The central issue under Rule 56 is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Id.* at 251-52.

B. A Genuine Material Factual Dispute Precludes Summary Judgment For the Sustained Release Patents

Avadel argues that "Lumryz™ cannot infringe as a matter of law if Avadel's construction is adopted, because it does not release any gamma-hydroxybutyrate anion, it releases the salt, sodium gamma-hydroxybutyrate." Br. at 31. But, as described above, Jazz's expert opined that the sodium gamma-hydroxybutyrate salt in LUMRYZ™ dissolves when it is placed in the deionized water dissolution media. CoF No. 10. And Avadel's expert agreed at deposition that this is what happens when the active ingredient in LUMRYZ™ is placed in water. CoF Nos. 7-8. Avadel's position contrary to its own expert's testimony establishes that there is at least a disputed material fact regarding whether LUMRYZ™ releases the GHB Anion when placed in deionized water as the Sustained Release Patents' claims require. Avadel attempts to avoid Dr. Klibanov's testimony by pointing to portions of his expert reports to argue that it is the salt that is released in deionized water, and not the GHB Anion. Br. 31 (citing SMF ¶ C-14). That is not enough, however, to warrant summary judgment. *See Transcenic*, 2014 WL 7275835, at *2 (denying summary judgment of noninfringement that presented "a 'battle of the experts' that is not amenable to resolution prior to the presentation of evidence, including testimony").

Further, Avadel's attempt to define "its" (Br. 31), does not remedy its motion's deficiencies. The Sustained Release Patents' asserted claims all refer to "gamma-hydroxybutyrate and pharmaceutically acceptable salts of gamma-hydroxybutyrate." CoF No. 4. Avadel's expert agreed that the GHB Anion released by LUMRYZ™ "comes from sodium gamma-hydroxybutyrate." CoF No. 9. Further, Avadel's one quote from Dr. Little's deposition

does not establish the lack of any genuine dispute of material fact where he stated that a "common" way to describe release would be "the active being released from the formulation." SMF ¶ C-13. Dr. Little has made clear that, using Avadel's expert's opinion, the GHB Anion is released when LUMRYZ™ is placed in deionized water. CoF No. 10. Further, Avadel's cite to Dr. Little's expert report does not concern his opinions regarding infringement under Avadel's proposed construction. In fact, Avadel did not ask Dr. Little any questions about his infringement opinions under Avadel's proposed construction at deposition. The one-sentence sound bite cited in its briefing does not establish the lack of a genuine dispute of material fact.

V. CONCLUSION

For the foregoing reasons, Avadel's motion for summary judgment of non-infringement with respect to the Sustained Release Patents should be denied.

Dated: December 15, 2023

Respectfully submitted,

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

Jack B. Blumenfeld (#1014)
Jeremy A. Tigan (#5239)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
jtigan@morrisnichols.com

Attorneys for Plaintiffs
Jazz Pharmaceuticals, Inc. and
Jazz Pharmaceuticals Ireland Limited

OF COUNSEL:

F. Dominic Cerrito
Eric C. Stops
Evangeline Shih
Andrew S. Chalson
Gabriel P. Brier
Frank C. Calvosa
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, NY 10010
(212) 849-7000

CERTIFICATE OF SERVICE

I hereby certify that on December 15, 2023, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on December 15, 2023, upon the following in the manner indicated:

Daniel M. Silver, Esquire — *VIA ELECTRONIC MAIL*
Alexandra M. Joyce, Esquire
McCARTER & ENGLISH, LLP
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, DE 19801
Attorneys for Defendant

Kenneth G. Schuler, Esquire — *VIA ELECTRONIC MAIL*
Marc N. Zubick, Esquire
Alex Grabowski, Esquire
Sarah W. Wang, Esquire
LATHAM & WATKINS LLP
330 North Wabash Avenue, Suite 2800
Chicago, IL 60611
Attorneys for Defendant

Herman H. Yue, Esquire — *VIA ELECTRONIC MAIL*
Franco Benyamin, Esquire
LATHAM & WATKINS LLP
1271 Avenue of the Americas
New York, NY 10020
Attorneys for Defendant

Audra Sawyer, Esquire — *VIA ELECTRONIC MAIL*
Alan J. Devlin, Esquire
Ian Conner, Esquire
Denise Laspina, Esquire
LATHAM & WATKINS LLP
555 Eleventh Street, NW, Suite 1000
Washington, D.C. 20004-1304
Attorneys for Defendant

Daralyn J. Durie, Esquire
Eric P. Berger, Esquire
Rebecca E. Weires, Esquire
Adam R. Brausa, Esquire
Tannyr Pasvantis, Esquire
MORRISON & FOERSTER LLP
425 Market Street
San Francisco, CA 94105
Attorneys for Defendant

VIA ELECTRONIC MAIL

Kira A. Davis, Esquire
Henry Huttinger, Esquire
Katherine E. McNutt, Esquire
Rose S. Lee, Esquire
MORRISON & FOERSTER LLP
707 Wilshire Boulevard
Los Angeles, CA 90017
Attorneys for Defendant

VIA ELECTRONIC MAIL

David F. McGowan, Esquire
David F. Kowalski, Esquire
MORRISON & FOERSTER LLP
12531 High Bluff Drive, Suite 100
San Diego, CA 92130
Attorneys for Defendant

VIA ELECTRONIC MAIL

Andrew T. Jones, Esquire
MORRISON & FOERSTER LLP
2100 L Street, NW, Suite 900
Washington, D.C. 20037
Attorneys for Defendant

VIA ELECTRONIC MAIL

/s/ Jeremy A. Tigan

Jeremy A. Tigan (#5239)