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

OPENING BRIEF IN SUPPORT OF PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT NO. 1 OF INFRINGEMENT OF THE SUSTAINED RELEASE PATENTS

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I. NATURE AND STAGE OF THE PROCEEDINGS

Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Ltd. ("Plaintiffs" or "Jazz") allege that Avadel CNS Pharmaceuticals, LLC ("Defendant" or "Avadel") infringes six patents, including U.S. Patent Nos. 10,758,488, 10,813,885, 10,959,956, and 10,966,931 (collectively, "the Sustained Release Patents"). C.A. No. 21-691, D.I. 325, ¶¶ 9-12, 24-75 (Counts I-IV). Avadel asserts an affirmative defense and counterclaims of non-infringement. C.A. No. 21-691, D.I. 336 at 21 (First Affirmative Defense), 28, 30, 32, 34 (Counterclaim Counts I, III, V, VII). Fact and expert discovery are closed and the parties are proceeding to a five-day jury trial beginning on February 26, 2024. Jazz moves herein for partial summary judgment against one of Avadel's five non-infringement defense theories: that Avadel's accused LUMRYZ™ product fails to meet the Sustained Release Patents' sustained release portion "core" claim element. In particular, Jazz moves for summary judgment that the core of LUMRYZ™'s controlled release ("CR") coated pellets comprises sodium gamma-hydroxybutyrate (a/k/a sodium oxybate).[1]

II. SUMMARY OF ARGUMENT

The Court should grant Jazz summary judgment because binding Fed. R. Civ. P. 36 judicial admissions, testimony of both parties' experts, and testimony of Avadel's lead of formulation development and listed inventor on Avadel's LUMRYZ™ patents (Dr. Herve Guillard) all demonstrate that there is no genuine dispute that "core" claim element is met.

[1] Avadel separately disputes whether LUMRYZ™'s CR coated pellets meet the "sustained release portion" of the Sustained Release Patents' claims. This motion is focused solely on whether the core of LUMRYZ™'s CR coated pellets comprises sodium gamma-hydroxybutyrate regardless of whether the CR coated pellets meet the overall "sustained release portion" claim element (they do).

Avadel admitted in its Responses to Jazz's Requests for Admission ("RFA Responses") that:

- LUMRYZ™ is an embodiment of Example 1 in Avadel's '062 Patent[2];
- Avadel's '062 Patent's Table 1b provides the "composition" for "the modified release ['MR'] portion of Example 1"; and
- That MR portion "corresponds to the controlled release portion of [LUMRYZ™]."

Further, both parties' experts, along with Dr. Guillard, agree that:

- Table 1b identifies LUMRYZ™'s immediate release pellets as the "core" of Avadel's CR coated pellets; and
- Those immediate release pellets comprise sodium gamma-hydroxybutyrate.

Accordingly, there can be no genuine dispute that the core of LUMRYZ™'s CR coated pellets comprises sodium gamma-hydroxybutyrate. Binding judicial admissions demonstrate that LUMRYZ™'s IR pellets are the core of LUMRYZ™'s CR coated pellets, and it is undisputed that those core pellets comprise sodium gamma-hydroxybutyrate. Summary judgment is therefore warranted.

III. THE CORE OF LUMRYZ™'S CR COATED PELLETS MEETS THE SUSTAINED RELEASE PATENTS' "CORE" CLAIM ELEMENT

To prove infringement, Jazz must show by a preponderance of the evidence that the accused product embodies all claim elements either literally or under the doctrine of equivalents. *Amgen, Inc. v. F. Hoffmann-LA Roche Ltd.*, 580 F.3d 1340, 1374 (Fed. Cir. 2009). Jazz asserts that LUMRYZ™ literally meets the Sustained Release Patents' "core" claim element.

[2] U.S. Patent No. 10,272,062.

A. The Sustained Release Patents' Asserted Claims All Share A Common "Core" Claim Element

Each asserted claim of the Sustained Release Patents requires, among other elements, that the "sustained release portion" comprises a functional coating and a core. SOF 3. Further, the "core" must comprise at least one pharmaceutically active ingredient selected from gamma-hydroxybutyrate and pharmaceutically acceptable salts of gamma-hydroxybutyrate. SOF 3-4.

B. There Is No Genuine Dispute That The Core Of LUMRYZ™'s CR Coated Pellets Comprises Sodium Gamma-Hydroxybutyrate

The accused product in this case, Avadel's LUMRYZ™, is comprised of both immediate release "IR" pellets (a/k/a IR microparticles) and controlled release "CR" coated pellets (a/k/a CR or MR microparticles). SOF 5, 9. LUMRYZ™'s IR pellets and CR coated pellets each represent 50% of the sodium gamma-hydroxybutyrate active ingredient dose in LUMRYZ™. SOF 9. As part of LUMRYZ™'s approval process, Avadel submitted for listing in the U.S. Food and Drug Administration's ("FDA") Orange Book Avadel's '062 Patent. SOF 6-7. Avadel represented to the FDA that Avadel's '062 Patent "claim[s] the drug product, as defined in 21 CFR 314.3, in the pending NDA" No. 214755, which is Avadel's New Drug Application for LUMRYZ™. SOF 7.

When responding to Jazz's Requests for Admission in this case, Avadel admitted that LUMRYZ™ is an embodiment of the formulation described in Example 1 of Avadel's '062 Patent. SOF 8. Avadel further admitted that "the *modified release portion* of Example 1 of [Avadel's '062 Patent] (the *composition of which is provided in Table 1b* of said patent) *corresponds to the controlled release portion* of [LUMRYZ™]." SOF 10.

Table 1b of Avadel's '062 Patent unequivocally states that the IR microparticles in LUMRYZ™ are the "core of MR microparticles" (SOF 11):

TABLE 1b

Composition of MR Microparticles

Component	Function	Quantity per 4.5 g dose (g)
IR Microparticles	Core of MR microparticles	2.786
Hydrogenated Vegetable Oil	Coating excipient	0.716
Methacrylic acid Copolymer Type C	Coating excipient	0.159
Methacrylic acid Copolymer Type B	Coating excipient	0.318
Isopropyl alcohol	Solvent	Eliminated during processing
Total		3.981

Both sides' experts agree with this, as does Avadel's lead of formulation development, Dr. Herve Guillard (who is also listed as an inventor on Avadel's '062 Patent). SOF 11-12, 15.[3]

Therefore, if LUMRYZ™'s IR pellets comprise the pharmaceutically active ingredient sodium gamma-hydroxybutyrate, then the core of LUMRYZ™'s CR coated pellets comprises the pharmaceutically active ingredient sodium gamma-hydroxybutyrate. That is because the core of LUMRYZ™'s CR coated pellets *is* LUMRYZ™'s IR pellets. SOF 11.

There is no dispute between the parties that LUMRYZ™'s IR pellets comprise the pharmaceutically active ingredient sodium gamma-hydroxybutyrate. SOF 9, 13. Table 1a in Avadel's '062 Patent provides the composition of LUMRYZ™'s IR pellets. Table 1a unequivocally states that the IR pellets comprise the pharmaceutically active ingredient sodium gamma-hydroxybutyrate (SOF 13):

[3] Avadel's 30(b)(6) witness on LUMRYZ™'s formulation and its development, Dr. Jason Vaughn, did not speak with Dr. Guillard or review Dr. Guillard's deposition transcript in preparation for his deposition, but confirmed he had no reason to believe that Dr. Guillard was untruthful at his deposition. SOF 14; *see also* SOF 9, n.1

TABLE 1a

Composition of IR Microparticles

Component	Function	Quantity per 2.25 g dose (g)
Sodium oxybate	Drug substance	2.25
Microcrystalline cellulose spheres	Core	0.418
Povidone K30	Binder and excipient in diffusion coating	0.118
Ethyl alcohol	Solvent	Eliminated during processing
Purified water	Solvent	Eliminated during processing
Total		2.786

Once again, both sides' experts agree with this, as does Avadel's lead of formulation development/listed inventor Dr. Guillard. *Id.*

Notwithstanding the above, Avadel and its expert, Dr. Klibanov, would have the Court disregard the record, including Avadel's binding judicial admissions, and find that the core of LUMRYZ™'s CR coated pellets is only a portion of, not LUMRYZ™'s entire, IR pellet. In particular, Avadel contends that only the non-pharmaceutically active microcrystalline cellulose sphere portion of LUMRYZ™'s IR pellet is the "core" of LUMRYZ™'s CR coated pellets. SOF 15. Controlling precedent, however, precludes that position.

The Third Circuit and this District have repeatedly held that an expert cannot contradict a party's Fed. R. Civ. P. 36 admission to survive summary judgment. *See, e.g., Langer v. Monarch Life Ins. Co.*, 966 F2d 786, 803 (3d Cir. 1992) (holding that Rule 36 admissions are an "unassailable statement of fact" and "sufficient to support summary judgment."); *Evonik Degussa GmbH v. Materia Inc.*, No. 09-636, 2015 U.S. Dist. LEXIS 175296, *8-12 (D. Del. Dec. 21, 2015) (granting summary judgment based solely on patentee's admission in response to Rule 36 request for admission that accused device does not literally infringe over patentee's expert's opinion to the contrary). Here, in its RFA Responses, Avadel did not identify anything other than Table 1b in Avadel's '062 Patent as providing the "composition" of LUMRYZ™'s

CR coated pellets. It cannot now walk away from its binding judicial admission; instead, Avadel's binding judicial admission controls. *See id.*; *see also Scott v. Harris*, 550 U.S. 372, 380 (2007) ("When opposing parties tell two different stories, one of which is blatantly contradicted by the record, . . . a court should not adopt that version of the facts for purposes of ruling on a motion for summary judgment."); *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1366-67 (Fed. Cir. 1999) ("MEHL/Biophile's expert testimony contradicting the plain language of the reference does not create a genuine issue of fact.").

Accordingly, there can be no genuine dispute that the "core" of LUMRYZ™'s CR coated pellets comprises sodium gamma-hydroxybutyrate. The "core" claim element of the Sustained Release Patents is therefore met, and Jazz is entitled to summary judgment on this issue.

IV. CONCLUSION

For the foregoing reasons, the Court should grant Jazz partial summary judgment in favor of Jazz's Counts I-IV, and against Avadel's First Affirmative Defense and Counterclaim Counts I, III, V, and VII, that Avadel's accused LUMRYZ™ product meets the "core" claim element of the asserted claims of the Sustained Release Patents.

Dated: November 30, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 30, 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 November 30, 2023, upon the following in the manner indicated:

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