IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	**REDACTED PUBLIC VERSION FILED JANUARY 10, 2024** 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'S OPPOSITION TO PLAINTIFFS' SUMMARY JUDGMENT AND DAUBERT MOTIONS

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AVADEL'S SUMMARY JUDGMENT OPPOSITIONS

I. AVADEL'S SUMMARY JUDGMENT OPPOSITION NO. 1 – THERE IS A MATERIAL DISPUTE OF FACT REGARDING INFRINGEMENT OF THE "CORE" LIMITATION

Jazz's Summary Judgment Motion No. 1 should be denied because it turns on a disputed question of fact: whether Avadel's product, LUMRYZ, contains microparticles with a controlled release ("CR") core that "comprises at least one pharmaceutically active ingredient selected from gamma-hydroxybutyrate and pharmaceutically acceptable salts of gamma-hydroxybutyrate" ("GHB").[1] Jazz SOF 3. The parties' disagree about what makes up LUMRYZ's CR "core" and whether it includes GHB; that factual dispute requires denial of summary judgment.

A. Factual Background

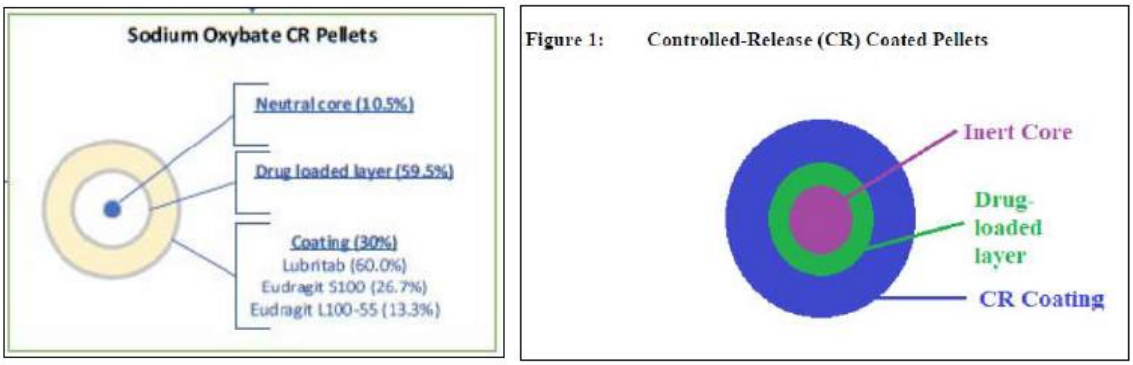
1. LUMRYZ

LUMRYZ contains a novel blend of two different microparticles. Avadel Counter SMF at ¶ A-1. Fifty percent of the sodium oxybate dose is in the form of immediate release (IR) microparticles. *Id.* The other fifty percent of the sodium oxybate dose is contained in CR microparticles. *Id.* The CR microparticles create a delayed release; their sodium oxybate is released immediately (within 15-30 minutes) while the patient is sleeping when the microparticles reach a particular trigger pH in the intestinal tract. *Id.*

Both microparticles are created using the same basic manufacturing process. The starting material is a small, inert microcrystalline cellulose ("MCC") core, sometimes referred to by Avadel as a "neutral core." *Id.* at ¶ A-2-4. The drug coating is sprayed onto that core to make the IR

[1] The parties disagree about the meaning of the terminology in the patents as it relates to sodium gamma-hydroxybutyrate; that dispute is not relevant to this motion, and Avadel adopts the terminology in Jazz's motion for simplicity.

microparticles.[2] *Id.* The CR microparticles are formed by "coating immediate release particles of gamma-hydroxybutyrate with a coating (or coating film)." *Id.* at ¶ A-2-4. Because the CR microparticles start out as IR microparticles, they too have an MCC neutral core, as shown in the excerpt from LUMRYZ's NDA submission:



Id. at ¶ A-1. As discussed in greater detail below, Avadel has been granted patents on LUMRYZ, including U.S. Patent No. 10,272,062 (the "'062 patent"). *Id.* at ¶ A-2; Jazz SOF 6.

2. Jazz's Sustained Release Patents

Despite decades of experience with sodium oxybate, Jazz has not been able to develop an FDA-approved once-nightly oxybate formulation for narcolepsy. Avadel Counter SMF at ¶ A-8. More importantly, Jazz's failed development efforts were focused on tablets, rather than microparticles. Thus, the shared specification of Jazz's Sustained Release patents discusses "a coated tablet composition having a controlled release core coated by a functional overcoat" where "the CR core includes at least one drug substance." *Id.*

The parties agree that each asserted claim of the Sustained Release patents requires, among other elements, a core "wherein the core comprises at least one pharmaceutically active ingredient

[2] As Avadel's expert Dr. Klibanov explained, "[t]ablets and capsules are generally not made this way and, therefore, have no need for neutral core. Instead, the innermost layer of tablets and capsules comprises the drug product." Avadel Counter SMF at ¶ A-6.

selected from gamma-hydroxybutyrate and pharmaceutically acceptable salts of gamma-hydroxybutyrate." Jazz SOF 3-4; Avadel Responsive SOF 3-4. Jazz did not seek claim construction as to what "core" means and therefore never argued that both the Sustained Release patents and Avadel's '062 patent use the term "core" in the same way.

3. Avadel's '062 Patent

The '062 patent was awarded to Avadel's predecessor Flamel. Jazz SOF 6. The specification begins by noting the substantial inconvenience for patients taking a twice-nightly oxybate and explains the failed efforts by others to create a once-nightly formulation. Avadel Counter SMF at ¶ A-9. Avadel's solution was a combination of immediate release and modified release portions, particularly microparticles. *Id.* at ¶ A-1. Example 1, which discloses LUMRYZ, is described in Tables 1a-1d, with the "physical structure of the microparticles" depicted in Figure 1. *Id.* at ¶ A-2-3. Figure 1 labels the cellulose bead as the "core" of both the IR microparticles and the MR microparticles:

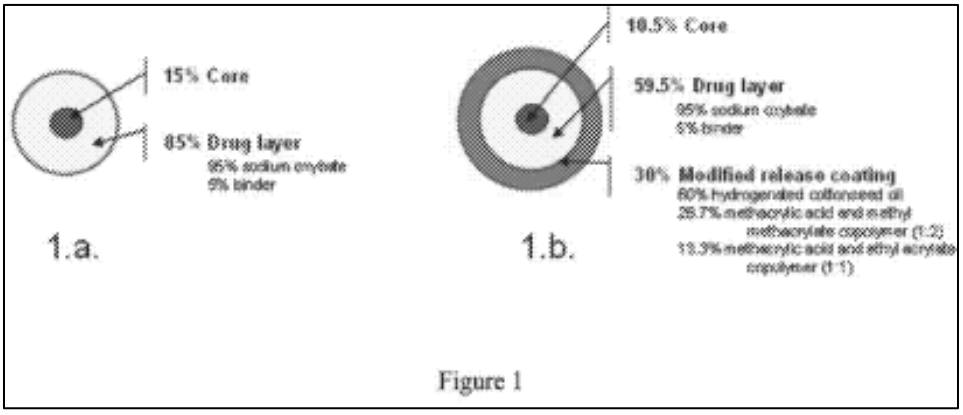


Figure 1

Id. at ¶ A-3. As Example 1 explains, to form the IR microparticles, a solution including sodium oxybate was sprayed onto "microcrystalline cellulose spheres (Cellets™ 127) in a fluid bed spray coater apparatus." *Id.* at ¶ A-4. The specification describes those MCC spheres as the core of the resulting formulation. *Id.* The MR microparticles are obtained by further coating the IR particles, resulting in a particle with the same cellulose sphere core, a specialized outer coating, and a drug

layer in between as depicted in Fig. 1.b. *Id.* at ¶ A-3-4.

Jazz ignores these disclosures, and focuses heavily on Table 1b. Table 1a lists the "microcrystalline cellulose spheres" as serving the function of "core" in the IR microparticles. *Id.* at ¶ A-3. Table 1b does not mention the cellulose spheres at all and lists the IR microparticles as serving the function of "core of MR microparticles." *Id.* Table 1c provides the total weights of components in the finished dose, which includes both the IR and MR microparticles and identifies the microcrystalline cellulose spheres alone as serving the function of "core." *Id.*

The remainder of the '062 patent specification consistently and repeatedly distinguishes between the core, which does not have drug substance and is preferably a cellulose sphere, and drug layers and coatings that are deposited over the core. *Id.* For example, "[t]he layer deposited onto the core comprises the immediate release gamma-hydroxybutyrate." *Id.*

4. Discovery in the Litigation

In its initial infringement contentions, Jazz asserted that the "core" limitations of the Sustained Release patents were met and pointed as it does now to the '062 patent, arguing that the IR pellet is the core in the CR pellet. *Id.* at ¶ A-5. In its responsive non-infringement contentions, Avadel specifically disputed that contention, explaining that "the immediate release pellets are not themselves the recited 'core.'" *Id.* "With respect to the core, the immediate release pellets themselves comprise 'neutral cores' with a 'drug layer' sprayed over the top of them. Thus, . . . [LUMRYZ's] controlled release pellets are not made up of a core of drug substance with a functional coating around them, but rather comprise a neutral core with two layers of coating, one containing the API and the other containing additional excipients. The core does not change between the IR and CR pellets merely because another coating is applied over the top of the IR pellets." *Id.*

During expert discovery, Avadel's expert Dr. Klibanov rejected Jazz's "core" theory and

explained in detail why he disagreed with the infringement opinion of Jazz's expert, Dr. Little. *Id.* at ¶ A-6. At his deposition, Dr. Klibanov again rejected the theory Jazz advocates here—that Table 1b is the only relevant disclosure in the '062 patent: "[Table 1b] has to be taken in the context of the entire patent, and at least of Example 1 where in Table 1A that we discussed previously, it specifically said that the core was microcrystalline cellulose spheres." *Id.* at A-7.

Jazz's RFA No. 48 asked Avadel to admit that LUMRYZ is an embodiment of the formulation described in "Example 1 of [the '062 patent] (the composition of which is provided in Table 1d of said patent)." *Id.* at ¶ A-10. Avadel lodged several objections, including that the RFA mischaracterized the '062 patent, because the composition of LUMRYZ is provided not only in Table 1d but also elsewhere in the patent. *Id.*

RFA No. 49 then asked Avadel to admit that "the modified release portion of Example 1 of [the '062 patent] (the composition of which is provided in Table 1b of said patent) corresponds to the controlled release portion of [LUMRYZ]." *Id.* at ¶ A-11. Again, Avadel lodged objections, including that Jazz was mischaracterizing the '062 patent in light of the patent's other descriptions of MR microparticles. *Id.* Avadel made no admissions about whether LUMRYZ satisfies the requirement of a "core" that includes the drug, as required by the Sustained Release patents.

B. Argument

1. Legal Standards

Summary judgment is not appropriate where there exists a genuine dispute as to a material fact, which is "one that could lead a reasonable jury to find in favor of the nonmoving party." *Persawvere, Inc. v. Milwaukee Elec. Tool Corp.*, No. CV 21-400-GBW, 2023 WL 8019085, at *1 (D. Del. Nov. 20, 2023) (quoting *Bletz v. Corrie*, 974 F.3d 306, 308 (3d Cir. 2020)). As the movant, Jazz is not entitled to have any inferences drawn in its favor, nor may it ask the Court to weigh evidence. *Id.* Instead, all reasonable inferences should be drawn in Avadel's favor. *Id.*

Regarding Rule 36 admissions, while admissions that are unqualified and precisely addressed to a particular subject will be conclusive on that subject, where there is a dispute as to meaning of an admission, courts "will not contort the plain wording of the admission to favor" a party's interpretation. *Evonik Degussa GmbH v. Materia Inc.*, No. 09-CV-636 (NLH/JS), 2016 WL 337378, at *4 (D. Del. Jan. 26, 2016); *see also Airco Indus. Gases, Inc. Div. of the BOC Grp., Inc. v. Teamsters Health & Welfare Pension Fund of Phila. & Vicinity*, 850 F.2d 1028, 1036 (3d Cir. 1988).

2. Avadel Did Not Admit That LUMRYZ Meets the "Core" Claim Element

Contrary to Jazz's representations in its motion, what Avadel admitted in RFA Nos. 48 and 49 was that Example 1 of the '062 patent was about LUMRYZ. Avadel Counter SMF ¶ A-10-11. Nothing more. Avadel thus agrees that its admissions are conclusive on the fact admitted—that Example 1 of the '062 patent is about LUMRYZ, but ***not*** on other facts neither asked nor admitted. *Id.* at ¶ A-2.

i. *Jazz misreads its RFA and Avadel's response*

Jazz's motion pretends that RFA No. 49 asked Avadel to admit that Table 1b alone conclusively defines the core of the CR microparticles. That is simply false. There is one place where Jazz *did* ask Avadel to agree to Jazz's current theory: in the parties' infringement/non-infringement contentions. There, as noted above, Avadel explicitly rejected Jazz's theory of what constitutes the "core" of LUMRYZ's CR microparticles. *Id.* at ¶ A-5. Thus, Jazz's summary judgment motion is based on the notion that Avadel (a) hotly contested Jazz's infringement theory in its contentions, but (b) conclusively admitted the opposite during discovery. That makes no sense.

First, Avadel objected to RFA No. 49, including the parenthetical and the extent that it

suggested that Table 1b was the only relevant part of the specification. *Id.* at ¶ A-11. Without the parenthetical, RFA No. 49 asks Avadel to "Admit that the modified release portion of Example 1 of U.S. patent No. 10,272,062 . . . corresponds to the controlled release portion of Defendant's NDA Product [i.e., LUMRYZ]." *Id.* Subject to its objections, that is what Avadel admitted, nothing more.

Second, if parentheticals were dispositive, Avadel would have admitted two contradictory things. RFA Nos. 48 and 49 shared the same odd structure, with a parenthetical in the middle, but the parenthetical for RFA No. 48 linked the entirety of Avadel's NDA product LUMRYZ, including both IR and CR microparticles, to ***Table 1d*** of the '062 patent (not Table 1b). *Id.* at ¶ A-10. As shown above, ***Table 1d*** identifies the core as the inert microcrystalline cellulose spheres for both IR and CR. *Id.* at ¶ A-3. Sodium oxybate is also listed in Table 1d and is not identified as part of the core. *Id.* Avadel admitted this RFA as well and therefore, according to Jazz's logic, would have admitted two contradictory things.

To be clear, Avadel did not read RFA No. 48 as asking Avadel to admit that Table 1d alone was relevant to what constitutes the core, just as Avadel did not read RFA No. 49 as asking Avadel to admit that Table 1b alone was relevant. To the contrary, in response to both RFAs, Avadel objected to the notion that either Table 1d or 1b alone describes LUMRYZ or the MR microparticles. *Id.* at ¶ A-10-11. But the fact that Avadel admitted to both RFA Nos. 48 and 49 confirms that Avadel was not admitting that Table 1b was the only portion of the patent describing the core.

Third, neither Avadel's actual admission (Example 1 is about LUMRYZ) nor Jazz's pretend version is an admission by Avadel that no other evidence is relevant to what the "core" is for purposes of the CR particles. The RFA does not even mention the core. *Id.* at ¶ A-11. Had

Jazz crafted an RFA that asked Avadel to admit no other evidence in the case was relevant to an infringement question, Avadel would have denied that RFA as both improperly seeking a legal conclusion and factually wrong. *See Medigus Ltd. v. Endochoice, Inc.*, No. CV 15-505-LPS-CJB, 2016 WL 5791409, at *3 (D. Del. July 19, 2016); *see also* Ex. 30 (explaining evidence showing that the cellulose sphere is the core). In any event, Jazz did not pose that question. Nor did Avadel consider how Jazz might misuse Avadel's answer in the future and include in its response a prebuttal refuting Jazz's unstated theories.

Fourth, Jazz has at the very most identified a way in which its RFA, and Avadel's response, are ambiguous. Ambiguous RFA responses do not get construed in favor of one party or the other, as the case on which Jazz relies confirms. *See Evonik Degussa GmbH*, 2016 WL 337378, at *4. This is particularly true for this summary judgment motion where Avadel is entitled to have all inferences drawn in its favor.

This case is similar to *Coca-Cola Bottling Co. of Shreveport v. Coca-Cola Co.*, 988 F.2d 414 (3d Cir. 1993). There, the Coca-Cola Company and some of its bottlers disputed whether the bottlers had the right to bottle diet Coke. *Id.* at 417. The admissions in question gave the bottlers the right to bottle some syrups but were silent about both diet Coke and the artificially sweetened syrups. *Id.* at 426. Because the admissions did not address either diet Coke or the issue of whether the syrup to which the bottlers had rights had to be sweetened in a particular way, the admissions were not conclusive on whether the bottlers had rights to diet Coke. *Id.* at 427.

To be sure, Avadel does not think its RFA responses are ambiguous. But any perceived ambiguity in Avadel's responses leads to the same conclusion: summary judgment should be denied, because the RFA responses are not conclusive on the issue of the composition of the CR microparticles. *See Coca-Cola Co.*, 988 F.2d at 427; *see also PharmaStem Therapeutics, Inc. v.*

ViaCell, Inc., 491 F.3d 1342, 1351 (Fed. Cir. 2007) (giving little weight to admissions that did not establish the fact the party offered them for); *Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd.*, 888 F. Supp. 2d 637, 643 (W.D. Pa. 2012) (similar). The weighing of evidence is for the jury.

Fifth, if the Court were nevertheless to determine that Jazz had succeeded in trapping Avadel with a tricky RFA that Avadel misinterpreted, then the Court can and should permit Avadel to amend its RFA answer to explicitly recite that Example 1, in full, is relevant to the composition of the MR microparticles. *See* Fed. R. Civ. P. 36(b) (explaining that the court may permit an admission to be withdrawn or amended "if it would promote the presentation of the merits of the action and if the court is not persuaded that it would prejudice the requesting party in maintaining or defending the action on the merits").

ii. *Example 1 as a whole supports Avadel, not Jazz*

Turning to what Avadel actually admitted—that Example 1 is about LUMRYZ—that admission supports Avadel. Avadel Counter SMF at ¶ A-2. As explained above, Example 1 refers to Figure 1 and Table 1a through Table 1d. *Id*. at ¶ A-3. Thus, Figure 1 and Tables 1a and 1d are at least as relevant as Table 1b, and in each of those, the inert MCC sphere ***alone*** is identified as the core. *Id.* Jazz tries to distinguish Table 1a as relating only to the IR microparticles, but Jazz wholly ignores Figure 1 and Table 1d, which describe IR and MR microparticles both and unequivocally identify only the inert MCC sphere as the core. *Id.* Sodium oxybate is not identified as being included in the core even though both Figure 1 and Table 1d include the MR microparticles. *Id.*

A factfinder weighing that evidence could easily conclude that the inert MCC spheres are the core and so find no infringement of the Sustained Release patents. That is particularly true because Jazz's only infringement theory is literal infringement—Jazz concedes that it has not asserted infringement under the Doctrine of Equivalents. *See* Jazz Br. at 2 (Jazz explaining that it

is asserting a literal infringement theory). "To establish literal infringement, every limitation set forth in a claim must be found in an accused product, exactly. The patentee has the burden of proving infringement by a preponderance of the evidence." *Duncan Parking Techs., Inc. v. IPS Grp., Inc.*, 914 F.3d 1347, 1360 (Fed. Cir. 2019) (quotation omitted). Jazz thus may not merely point to an active pharmaceutical ingredient somewhere in the MR microparticles of LUMRYZ that functions ***like*** a core. Jazz must in fact establish that the core of the MR microparticles of LUMRYZ comprises an active pharmaceutical ingredient. That is a question for the jury.

II. AVADEL'S SUMMARY JUDGMENT OPPOSITION NO. 2 – THERE IS A MATERIAL DISPUTE OF FACT REGARDING THE NONOBVIOUSNESS OF U.S. PATENT NOS. 11,077,079 AND 11,147,782

Jazz's motion for summary judgment of nonobviousness ignores the inconsistent positions Jazz has taken with respect to obviousness and written description. When defending the written description of the '079/'782 patents, Jazz argues that a POSA would have come equipped with significant knowledge about formulating sodium oxybate to compensate for the specification's lack of express written description support. But when it comes to obviousness, Jazz argues that the lack of express teachings in the prior art are, in fact a problem, and a POSA would have been unable to fill any gaps in the prior art. Jazz cannot have it both ways, as Avadel's experts, including Dr. Klibanov, point out. At a minimum, Dr. Klibanov's opinions demonstrate that there are material factual disputes between the parties about the sufficiency of the prior art disclosures if Jazz's written description arguments are accepted. Therefore, Jazz's motion for summary judgment of non-obviousness should be denied.

C. Jazz's Inconsistent Approach to Written Description and Obviousness

The inconsistent approach taken by Jazz and its experts for written description and obviousness is a product of Jazz's decision to copy Avadel's own claims. As a result of this copying, Jazz has been forced to argue that the scant disclosures of certain claim elements in the

'079/'782 patents (which are directed to different formulation technology) are sufficient to meet the written description requirement. Dr. Klibanov has merely taken the same standard applied by Jazz in evaluating written description support and applied them to evaluating the disclosures in the prior art. If Jazz is correct that the '079/'782 patents are sufficiently described (which Avadel contests), then the prior art disclosures are also sufficient to render the claims obvious.

1. The '079 Patent

The '079 patent claims recite methods of administering "a single daily dose to the patient" of a formulation that includes both immediate release and controlled release components by "opening a sachet containing a solid oxybate formulation, [and] mixing the formulation with water." *See, e.g.*, '079 patent at claim 1. Avadel's experts have opined that the asserted claims of the '079 patent lack sufficient written description support. Avadel Counter SMF at ¶ B-1. The few examples disclosed in the shared specification of the '079/'782 patents are almost entirely prophetic. '079 patent at 23:20-24:55. None demonstrates any formulation controlling the release of oxybate in any manner. *Id.* at 22:25-24:55. None involves a formulation dosed from a sachet. *Id.* The two prophetic examples that even mention a dosage form involve an "oral gavage" (*id.* at 23:32), or "tablets" containing not oxybate, but "soy protein." *Id.* at 24:38-39. Neither example recites—let alone demonstrates possession of—a "single daily dose." *Id.* at 23:32-54, 24:38-55. Nor does the specification contain any data indicating formulations that could be dosed from a sachet and include the claimed immediate release and controlled release portions.

Indeed, the word "sachet" appears only a single time in the specification, in a wholly aspirational statement that "it would be *desirable* to provide oxybate . . . in an extended release, oral liquid dosage form (including suspensions of oxybate-containing particles as described herein, which in some embodiments can be supplied as a sachet which can be suspended in e.g., tap water by the end user)." *Id.* at 6:4-10. Jazz's expert, Dr. Little, asserts that this single sentence is adequate

written description support for the claimed sachet containing a solid oxybate formulation with an immediate release component and a controlled release component, opining that "the '079 patent's specification teaches that the claimed inventions solve a problem of GHB administrability that the inventors had recognized" and that they had done so "through the development of GHB formulated in 'an extended release, oral liquid dosage form (including suspensions of oxybate-containing particles as described herein, which in some embodiments can be supplied as a sachet which can be suspended in e.g., tap water by the end user), using simply, readily controlled processing methods.'" Avadel Counter SMF at ¶ B-2. Notably, neither the '079 patent, nor Dr. Little, elaborate on what those processing methods are for sachets or how they would solve the problems associated with developing controlled release oxybate formulations.

2. The '782 Patent

The '782 patent claims recite "a formulation of gamma-hydroxybutyrate comprising: a plurality of immediate release particles[;] . . . a plurality of modified release particles[;] a viscosity enhancing agent; and an acid," and further require that "the viscosity enhancing agent and the acid are separate from the immediate release particles and the modified release particles." *See, e.g.*, '782 patent at claim 1. The '782 patent's description of acids and viscosity enhancing agents separate from the immediate release and modified release particles is lacking. The original parent application for the '782 patent does not reference viscosity enhancing agents. *See generally* '079 priority appl. (Ex. 40) at *passim*. Even after Jazz amended the specification to include a paragraph from a different application, the '782 patent's specification is still silent on having the viscosity enhancing agent and acid being separate from the immediate release particles and the modified release particles. None of the examples mention the use of acids or viscosity enhancing agents at all—let alone separately from the particles. Given the absence of any supporting disclosure, Jazz's experts have taken the position a POSA would have extrapolated from a generic disclosure of the

excipient categories on the ostensible basis that a POSA would have thereby understood that the most logical place to put these excipients is "external to the particles." Avadel Counter SMF at ¶ B-3.

3. The Disconnect between Jazz's Claims and Its Specification Is a Result of Jazz Copying Avadel's Claims

Jazz's extreme positions on written description are the result of its decision to copy Avadel's patent claims into its own patents. The asserted claims of the '782/'079 patents were only introduced by Jazz ***after*** Avadel's own patents published and Jazz reviewed them. This can be seen clearly by comparing claim 1 of the applications leading to the '079/'782 patents to claim 1 of the Avadel patent application and patent that published prior to Jazz amending its claims. Avadel Counter SMF at ¶ B-7. [redacted]

This left Jazz's specification divorced from the claims it ultimately obtained. Accordingly, to defend the written description for the '079/'782 patents, Jazz must rely exclusively on passing references to critical claim elements and the knowledge of a POSA. But this approach comes with a price. If the mere reference to an "acid" or "sachet" shows possession of the claimed formulations based on a POSA's ability to extrapolate from these limited teachings, then a POSA would also have been able to extrapolate in a similar fashion from the more detailed teachings of the prior art. Jazz's position cannot be "heads I win, tails you lose": lowering the bar for written description support, but not for obviousness.

D. Jazz Mischaracterizes Dr. Klibanov's Opinions to Obscure the Disputed Facts

Jazz contends that "Avadel has no evidence of obviousness under the correct legal standard" for two reasons: (1) Avadel's expert, Dr. Alexander Klibanov, supposedly considered

the '079/'782 patents in forming his obviousness opinions regarding them; and (2) because certain statements Avadel made before the Patent Office in pursuing its own patents allegedly contradict its arguments here. Neither argument justifies summary judgment of non-obviousness.

5. Dr. Klibanov's Obviousness Opinions Do Not Improperly Rely on the Disclosures of the Jazz Patents

Dr. Klibanov conducted a proper obviousness analysis premised on accepting Jazz's written description arguments at face value and applying the same disclosure standard to the prior art. Avadel Counter SMF at ¶ B-7. The Supreme Court articulated that in a proper obviousness analysis "differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved." *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). In determining differences between the prior art and the claims, Dr. Klibanov applied Jazz's contentions as to how a POSA would have allegedly interpreted and extrapolate from certain words in the specification. This is eminently reasonable, as Jazz should not be permitted to take inconsistent positions with regard to obviousness and written description/enablement. Indeed, the Federal Circuit has recognized that how a POSA would have understood the level of disclosure of the patent-in-suit is relevant to how a POSA would have understood similar disclosures in the prior art. *See In re Stauffer*, 290 F. App'x 327, 333 (Fed. Cir. 2008) (finding that a reference had "the requisite specificity to render the invention in the '882 Application obvious" where the application's "disclosure of decoding caller ID information is effectively identical to" the reference's). It was that standard of disclosure adopted by Jazz that Dr. Klibanov considered in forming his opinions. Avadel Counter SMF at ¶ B-8.

Put simply, Dr. Klibanov did not, as Jazz contends, "use[] an assumption that a POSA would have had access to and knowledge of the specification and claims of the '079/'782 Patents." Br. at 3. Jazz's supposed support for that assertion comes from ¶ 8 of its Statement of Facts, which

cites to Klibanov Tr. 19:15-20:11. Yet the cited testimony, which does not even correspond to a complete set of questions and answers, is nothing more than Dr. Klibanov identifying the '079/'782 patents and explaining that "You cannot judge the—whether the claims in question are obvious or not unless you have at the very least reviewed these claims, because otherwise what are you opining on?" Dr. Klibanov is not opining that the POSA would have had the disclosures of the '079/'782 patents, merely that he himself had to understand the claims in order to determine whether they were obvious—just as the *Deere* standard recites. *See* disc. s*upra* at II.B.1.

Jazz's case law addresses entirely different situations. Jazz cites two cases for the premise that "a finding of obviousness cannot be founded on the knowledge or teaching provided by the patentee's invention itself" or, similarly that "it is error to use the teachings in the challenged patent for the purpose of finding obviousness." Br. at 4 (citing *Procter & Gamble Co. v. Paragon Trade Brands, Inc.*, 989 F. Supp. 547, 592 (D. Del. 1997) and *Univ. of Strathclyde v. Clear-Vu Lighting LLC*, 17 F.4th 155, 165 (Fed. Cir. 2021)). But Dr. Klibanov does not rely on the teachings of the patent to demonstrate that the claimed limitations are obvious. Nor do Dr. Klibanov's obviousness opinions rely on any disclosures from the Jazz patents as part of the identified obviousness combinations. Instead, his obviousness analysis incorporates Jazz's position on how a POSA would have understood the level of detail in the '079/'782 patents' disclosures, and applies that same standard in considering how a POSA would have understood similarly detailed disclosures found in the prior art.

Jazz also argues that Dr. Klibanov improperly relied on hindsight by considering the '079/'782 patents, but Jazz again mischaracterizes the relevant case law. For instance, Jazz relies on *Janssen Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc.* to argue that it is "impermissible hindsight" to form opinions on obviousness by looking first at the patent's claims.

Br. at 5 (citing 571 F. Supp. 3d 281, 302 n.25 (D.N.J. 2021)). However, an expert necessarily must ascertain "differences between the prior art and the claims at issue" in order to conduct an appropriate analysis, which necessarily means that the expert has to look at the scope of the claimed subject matter and compare that to the prior art. *Graham*, 383 U.S. at 17 ("Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved."). The problem in *Janssen*, which is not at issue here, is that the expert in *Janssen* looked "'at the '906 Patent claims first' and then 'went back to see if [he] could find the elements that are in the '906 Patent claims in these other references next.'" *Janssen Pharms., Inc.*, 571 F. Supp. 3d at 302 n.25. Jazz does not, and cannot, argue that Dr. Klibanov used the claims as a hindsight guide to cherrypick prior art disclosures in the same way. Jazz's other cited authority, *Cheese Systems, Inc.* and *Orthopedic Equipment Co.*, focused similarly on using knowledge from the patent to find that same patent obvious. *See Cheese Sys, Inc. v. Tetra Pak Cheese & Powder Sys, Inc.* 725 F.3d 1341, 1352 (Fed. Cir. 2013) (expert engaged in improper hindsight where elements were "selectively culled from the prior art to fit the parameters of the patented invention"); *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1012 (Fed. Cir. 1983) (expert improperly used "the patent in suit as a guide through the maze of prior art references"). Thus, they are distinguishable for similar reasons as *Janssen.*

Indeed, *Janssen* and *Orthopedic Equipment Co.* also illustrate why summary judgment is inappropriate here. In *Janssen*, the Court did not rely on the expert's hindsight to grant summary judgment, but rather raised it in finding "credibility issues" after trial. *Janssen Pharms., Inc.*, 571 F. Supp. 3d at 302 n.25. Similarly, the trial court in *Orthopedic Equipment* made extensive factual findings *at trial* and held the patent obvious, an outcome the Federal Circuit affirmed. *Orthopedic*

Equip. Co. v. United States, 702 F.2d at 1012.

As the Federal Circuit has recognized, where "there is a material dispute as to the credibility and weight that should be afforded to conflicting expert reports, summary judgment is usually inappropriate." *Crown Packaging Tech., Inc. v. Ball Metal Beverage Container Corp.*, 635 F.3d 1373, 1384 (Fed. Cir. 2011). Jazz, at best, has raised credibility and weight issues regarding Dr. Klibanov's obviousness opinions. Those are issues for the jury, not summary adjudication.

6. Jazz's Estoppel Argument Does Not Warrant Summary Judgment

Jazz's remaining argument appears to be that Avadel is estopped from arguing the obviousness of the '079/'782 patents because of statements Avadel made during prosecution of its own patents. Jazz's position fails for two reasons. First, Jazz's motion is premised on the wrong standard for judicial estoppel. Second, Jazz cannot meet either its own standard or the proper standard because Avadel's obviousness positions in this litigation do not contradict its statements before the Patent Office.

With respect to the legal standard, Jazz argues that "where a party assumes a certain position in a legal proceeding, and succeeds in maintaining that position, he may not thereafter, simply because his interests have changed, assume a contrary position . . . ." Br. at 6 (quoting *New Hampshire v. Maine*, 532 U.S. 742, 749 (2001)). But that statement is mere dicta, as *Maine* goes on to list a variety of other potential factors before explaining that it is not meant to establish "an exhaustive formula for determining the applicability of judicial estoppel." 532 U.S. at 750-51. The test for such estoppel enunciated by the Third Circuit has three elements: "(1) the party to be estopped is asserting a position that is irreconcilably inconsistent with one he or she asserted in a prior proceeding; (2) the party changed his or her position in bad faith, i.e., in a culpable manner threatening to the court's authority or integrity; and (3) the use of judicial estoppel is tailored to

address the affront to the court's authority or integrity." *Dam Things from Denmark v. Russ Berrie & Co., Inc.*, 290 F.3d 548, 559 (3d Cir. 2002).

Jazz has not even attempted to meet this standard because it cannot do so. Even with respect to the first prong, Jazz failed to demonstrate that Avadel's arguments are "irreconcilably inconsistent" with its positions before the Patent Office, or are they "contrary position[s]" taken "simply because [its] interests have changed." Rather, the statements that Avadel made to the Patent Office were in the context of prosecuting its own patents with their own factual records, which are distinct from the facts in this litigation. Indeed, Jazz cites no case estopping a party from making arguments about one patent based on statements made during prosecution of an unrelated patent with a different factual record.

The different factual records have a clear impact on the parties' obviousness disputes. The two examples of Avadel's statements Jazz identified related to whether "the prior art 'teaches away from a sachet'" and whether the prior art discloses or suggests "a formulation having a suspending/viscosifying agent and an acidifying agent that are separate and distinct from the immediate release component and delayed/controlled release component of the formulation." Br. at 7. Yet, Dr. Klibanov formed his opinion on the obviousness of both of those elements, in part, by accounting for ***Jazz's position*** regarding the level of detail necessary to adequately teach the use of a sachet or the use of separate viscosity enhancing agents and acids. *See supra* at § II.B.1. Jazz's position was not part of the record in Avadel's prosecution of its own patents and Avadel disagrees with Jazz's approach to written description in this case. As a result, it would have made little sense for Avadel to employ such an approach to the prior art in prosecuting its own patents. This difference in circumstances demonstrates that Dr. Klibanov's current (and contingent) obviousness opinions are not irreconcilably inconsistent with Avadel's prior statements to the

Patent Office.

As to the remaining prongs, Jazz makes no argument that Avadel acted in bad faith or that blocking Avadel's entire obviousness defense is "tailored to address" any alleged affront to the court. And it cannot. All Jazz points to are Avadel's allegedly inconsistent statements, but those are explained by the different factual record. Even if they were not, the Third Circuit is clear that inconsistent statements alone do not show bad faith. *Montrose Med. Grp. Participating Sav. Plan v. Bulger*, 243 F.3d 773, 777-78 (3d Cir. 2001) ("A finding of bad faith must be based on more than the existence of an inconsistency."). Jazz's failure to address (let alone meet) the remaining prongs is another reason to reject Jazz's estoppel argument and deny summary judgment.

III. AVADEL'S SUMMARY JUDGMENT OPPOSITION NO. 3 – THERE IS A MATERIAL DISPUTE OF FACT REGARDING THE NONOBVIOUSNESS OF THE SUSTAINED RELEASE PATENTS

Jazz's 3rd summary judgment motion is predicated on its assertion that Avadel's experts agree that the prior art lacks a disclosure of the claimed dissolution profiles. Not so. Avadel's expert, Ms. Vivian Gray, has offered the opinion that that if Jazz's approach to written description is adopted with respect to the prior art, then the claimed dissolution profiles are taught by the prior art. At a minimum, her analysis is sufficient to create a genuine issue of material fact. Jazz makes two arguments to discount Ms. Gray's opinion: (1) that she agrees with Jazz's experts that the profiles are not disclosed; and (2) that she improperly relied on the teachings of the Sustained Release patents in offering the opinion that they were disclosed. Both arguments omit or mischaracterize key portions of Ms. Gray's opinions.

With respect to the argument that Ms. Gray agrees with Jazz's experts, Jazz omits that Ms. Gray's opinions are not limited to obviousness. She also opines that the patents are invalid for lack of written description. Jazz's experts disputed Ms. Gray's opinion by offering opinions that a POSA would have had sufficient skill to interpret the limited disclosure of the Sustained Release

patents to preserve its validity. Ms. Gray does not agree with Jazz's experts, but offered her obviousness opinion *on the express assumption* that the Court accepts the view of Jazz's expert on written description.

As to the argument that Ms. Gray relied on the teachings of the Sustained Release patents to inform her obviousness analysis, Jazz is just wrong. Ms. Gray considered the opinions Jazz's experts offered regarding how a POSA would have understood, and extrapolated from, the disclosures of the Sustained Release patents, and applied that same standard to her analysis of the prior art. Jazz may disagree with Ms. Gray's resulting opinions, but that is a dispute for the jury, not legal error warranting summary judgment. Jazz's motion should therefore be denied.

A. Ms. Gray's Obviousness Opinion is Conditioned on Acceptance of Jazz's Written Description Argument

The Sustained Release patent claims all require a formulation with a "sustained release portion" containing a "functional coating" comprising 20-50% of one or more methacrylic acid-methyl methacrylate co-polymers, and that the said sustained release portion release a certain percentage of "its gamma-hydroxybutyrate" by a certain time period "when tested in a dissolution apparatus 2 in deionized water at a temperature of 37° C. and a paddle speed of 50 rpm." '885 patent at claim 1. The specification for the Sustained Release patents does not, however, disclose any data for any formulation that contains any amount of methacrylic acid-methyl methacrylate co-polymer, let alone the requisite 20-50%. As a result, the specification does not demonstrate that the named inventors possessed any claimed formulation that did, in fact, exhibit the claimed dissolution profile "when tested in a dissolution apparatus 2 in deionized water at a temperature of 37° C. and a paddle speed of 50 rpm." *Id*.

The reason for the lack of guidance in the specification is straightforward—Jazz's inventors never had possession of any such formulation, so they were unable to demonstrate

possession to a POSA by way of information in the specification. The genesis of the claimed subject matter is instead data generated by Avadel's inventors and published in January 2018. This can be seen most clearly in the way Jazz amended its claims just months later to match the structure of Avadel's earlier publication. Avadel Counter SMF at ¶ C-1.

As a result of this approach to claim drafting, there is a disconnect between the specification of the Sustained Release patents, and the claims. This has forced Jazz and its experts to argue that a POSA would have somehow "extrapolate[d]" from data generated in experiments that involved coating materials far different from methacrylic acid-methyl methacrylate co-polymers and conclude that the Jazz inventors "possessed" dissolution profiles that they simply never even tested—let alone presented to the public in their specification. Avadel Counter SMF at ¶ C-2. It is this approach by Jazz regarding the POSA's abilities to extrapolate from limited disclosures of a patent that is relevant to Ms. Gray's opinion on the prior art.

Against that backdrop, Ms. Gray—a dissolution scientist with over 40 years of experience—opines that Jazz cannot have it both ways. As Ms. Gray makes clear in her report, she offers two separate opinions: (1) that the Sustained Release patents are invalid for lack of written description; or (2) that, if the trier of fact accepts Jazz's arguments that a POSA would have been able to find sufficient written description in the specification of the Sustained Release patents, then the claimed dissolution profiles would have thereby been taught by the prior art. Avadel Counter SMF at ¶ C-3. Ms. Gray's opinion regarding the prior art is conditional and requires assuming that Jazz's approach to written description is endorsed by the jury. As she explains:

> [I]f the reasons Jazz and Dr. Myers provide for why the Sustained Release Specification does provide sufficient written description, the same rationale must be applied to the prior art. In short, Dr. Myers and Jazz are taking positions with regard to how much "gap

> filling" a POSA would do with respect to the Sustained Release Specification that are inconsistent with Dr. Myers and Dr. Little's opinions on how a POSA would read the prior art.

Avadel Counter SMF at ¶ C-4. Ms. Gray identifies the following four assumptions made by Jazz and its experts regarding the POSA's abilities:

- "A POSA could draw conclusions regarding the dissolution profiles of the claimed [] formulations based on formulations that used other polymers, including pH-independent polymers." Avadel Counter SMF at ¶ C-5.
- "A POSA could draw conclusions regarding the dissolution profiles of the claimed formulations based on formulations that do not contain GHB." *Id.*
- "A POSA could draw conclusions regarding the dissolution profiles of the claimed formulations in USP Apparatus 2 based on dissolution testing conducted in different apparatus." *Id.*
- "A POSA could draw conclusions regarding the dissolution profiles of the claimed formulations in deionized water based on dissolution testing conducted in physiological media." *Id.*

Ms. Gray does not "agree" that these assumptions are correct, but if they are adopted to avoid invalidating the patent for lack of written description, then they must apply equally when considering the prior art for obviousness. Avadel Counter SMF at ¶ C-6.

B. Ms. Gray Does Not Rely on the Teachings of the Sustained Release Patents in Offering her Opinion That the Dissolution Profile Limitations are in the Prior Art

Jazz's assertion that Ms. Gray's analysis incorrectly allows a POSA to rely on the disclosures of the Sustained Release patents misrepresents her opinions. Ms. Gray does not assume that a POSA would have had access to the Sustained Release patents. Instead, as discussed above, Jazz's experts made certain assumptions about the skills a POSA would have had in

interpreting the Sustained Release patents, and Ms. Gray considered the prior art through the same lens. *Biogen Int'l GmbH v. Mylan Pharm., Inc.*, 18 F.4th 1333, 1344-45 (Fed. Cir. 2021) (affirming finding of no written description based on expert's "inconsistent statements" that "a skilled artisan would be drawn to the purported DMF480 efficacy upon reading the patent specification" but "would not have reasonably expected DMF480 to provide the therapeutic efficacy claimed in the patent during the IPR proceeding" on obviousness.).

Jazz argues that Ms. Gray's obviousness opinion is flawed because it is premised on the "assum[ption] that the Sustained Release Patents' description of different formulations tested under different dissolution conditions would reasonably convey to a POSA that the inventors were in possession of the claimed subject matter." Br. at 3. Jazz argues that this means that "Ms. Gray's POSA would necessarily have to have had access to, and to have relied upon, the disclosures in the specification and claims of the patents-in-suit." *Id.* But Jazz misses the point. Ms. Gray's opinion does not rely on a POSA having had access to the Sustained Release patents. Rather, she assumes that a POSA reviewing the prior art would have had the same level of skill and been able to perform the same type of extrapolations that Jazz's experts asserted a POSA would have displayed when reviewing the Sustained Release patents. Avadel Counter SMF at ¶ C-7.

Jazz's case law is unavailing, as it relates to entirely different situations where experts used the novel disclosures in the patents-in-suit to invalidate those patents. Jazz cites three cases for the established law that "a finding of obviousness cannot be founded on the knowledge or teaching provided by the patentee's invention itself." Br. at 3-4 (citing *Procter & Gamble Co.*, 989 F. Supp. At 592); *see also id.* (citing *Univ. of Strathclyde*, 17 F.4th at 165 ("it is error to use the teachings in the challenged patent for the purpose of finding obviousne[ss]") and *Orthopedic Equip. Co.*, 702 F.2d at 1012 ("It is wrong to use the patent in suit as a guide through the maze of prior art

references, combining the right references in the right way so as to achieve the result of the claims in suit."). Here, Ms. Gray did no such thing. Ms. Gray is not using the teachings of the patent against itself; her approach instead goes to the scope and content of the prior art when viewed through the lens of the POSA that Jazz itself relies on and argues is appropriate. *See* disc. *supra* at §II.B.1 (citing *Graham*). Thus, she merely points out that if a POSA would have found that the inventors conveyed "possession" of the claimed subject matter based on data involving formulations that lack the required polymer, active ingredient, and/or dissolution test/profile (as Jazz contends), then it also would have been obvious for the POSA to extrapolate the claimed subject matter from disclosures of the prior art. Jazz may disagree, but that merely raises a factual dispute between the parties about "the scope and content of the prior art to be determined [and the] differences between the prior art and the claims at issue." *Graham*, 383 U.S. at 17. Jazz's motion for summary judgment should therefore be denied.

IV. AVADEL'S SUMMARY JUDGMENT OPPOSITION NO. 4 – THERE IS A MATERIAL DISPUTE OF FACT REGARDING THE NON-ANTICIPATION OF U.S. PATENT NOS. 11,077,079

Jazz's Motion for Summary Judgment of No Anticipation of the '079 Patent misstates the record to avoid addressing the dispute between the parties. Jazz argues that Avadel and the parties' experts agree that Liang lacks a disclosure of each element of the asserted claims of the '079 patent. Not so. Avadel's expert, Dr. Charman, analyzed in detail the manner in which Liang discloses all of the limitations of the asserted claims of the '079 patent based on Jazz's own admissions in the context of its written description arguments. Like its prior summary judgment motion with respect to the '079 patent (discussed *supra* at § II), Jazz is simply trying to avoid the consequences of copying its claims from Avadel's patent publications by applying a different disclosure standard to its own patents than to the prior art.

Jazz contends that "both parties' experts agree, as did Avadel," that Liang 2006 ("Liang")

does not anticipate the asserted claims of the '079 patent. Jazz is incorrect. Dr. Charman has consistently maintained that if there is adequate written description for Jazz's '079 patent (as Jazz contends), then the '079 patent is anticipated by Liang. Avadel's statements about Liang during prosecution of its own patents were made in a different context, and one that did not involve accepting Jazz's arguments how much gap-filling a POSA would have been able to do when confronted with a limited disclosure like the '079 patent. Because Dr. Charman's opinions on the disclosures of Liang create a genuine dispute of material fact, summary judgment for Jazz should be denied.

A. Dr. Charman Concluded That Jazz's '079 Patent Is Anticipated Based on Jazz's Positions Regarding a POSA's Level of Skill and Understanding

Jazz mischaracterizes Dr. Charman's opinions in an attempt to obfuscate the factual disputes between the parties. Dr. Charman offered his anticipation opinion in the context of Jazz's contention that the '079 patent sufficiently describes and enables the full scope of the claimed invention in spite of the '079 patent's limited disclosures on certain claim elements. Avadel Counter SMF at ¶ D-1. In making these arguments, Jazz took a position regarding how a POSA, as of the '079 patent's alleged priority date, would have understood such sparse disclosures, and Dr. Charman applied the same approach as Jazz in forming his anticipation opinion. Dr. Charman explained as much in his report:

> As I previously explained, the disclosures in the '079 patent fail to provide sufficient written description support for a number of limitations of the Asserted Claims. The prior art references, however, provide disclosures that are essentially identical (or even more fulsome) than the disclosures of the '079 patent.… In my opinion, if the Court construes the term "oxybate" such that the claims encompass methods of treating with oxybate salts and the '079 patent disclosures are deemed to meet the written description and enablement requirements, then Liang 2006 and Lebon 2013 (with their corresponding disclosures) would each anticipate the '079 patent claims, as discussed below.

Avadel Counter SMF at ¶ D-1.

Dr. Charman did not, as Jazz contends, agree in isolation "that Liang does not disclose, expressly or inherently, the '079 Patents' [sic] common claim elements of 'opening a sachet containing a solid oxybate formulation,' 'mixing the formulation with water,' and 'orally administering the mixture to the patient.'" Br. at 3-4. Rather, Dr. Charman explained in his reports and confirmed in his testimony that he "rel[ied] on Liang for an anticipation opinion for the '079 patent." Avadel Counter SMF at ¶ D-2.

Jazz next argues that Dr. Charman "wants to change his opinions in order to opine on anticipation" if unsuccessful on written description. Br. at 4. Jazz claims that such "a contrary position" would violate the principle that "in order to demonstrate anticipation, the proponent must show that ***the four corners of a single, prior art document*** describe every element of the claimed invention." Br. at 4 (quoting *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (emphasis by Jazz). Dr. Charman is not changing his opinion, or improperly relying on evidence outside the four corners of the specification of the '079 patent. He is simply accepting Jazz's litigation position at face value and applying Jazz's views about how a POSA would have understood and interpreted a patent disclosure to the prior art. And to the extent that a POSA would have understood Jazz's '079 patent to disclose a sachet formulation (as Jazz contends), Dr. Charman opines that a POSA would have understood the "essentially identical (or even more fulsome)" disclosures of Liang in the same way. Avadel Counter SMF at ¶ D-1; *see In re Stauffer*, 290 F. App'x at 333 (finding that the way a POSA would have understood a prior art reference was informed by the way a POSA would have understood the "effectively identical" disclosures of the application-in-suit). Thus, Dr. Charman properly considered Jazz's written description position in forming his opinions about the disclosures in the "four corners" of Liang.

B. Jazz Has Not and Cannot Show Estoppel Forecloses Avadel or Dr. Charman from Arguing Anticipation of the '079 Patent over Liang

Jazz argues that Avadel should be estopped from arguing that Liang discloses "'opening a sachet containing a solid oxybate formulation,' 'mixing the formulation with water,' and 'orally administering the mixture to the patient.'" Br. at 2. But Jazz fails to apply the proper standard for judicial estoppel and cannot show that Avadel's conduct meets that standard.

Jazz argues that "where a party assumes a certain position in a legal proceeding, and succeeds in maintaining that position, he may not thereafter, simply because his interests have changed, assume a contrary position . . . ." Br. at 2-3 (quoting *Maine*, 532 U.S. at 749). But again, the language Jazz quotes from *Maine* is dicta and does not provide the applicable standard for judicial estoppel. *See* 532 U.S. at 750-51 (continuing to list various considerations for judicial estoppel and declining to establish an "exhaustive formula.") In the Third Circuit, judicial estoppel has three elements: "(1) the party to be estopped is asserting a position that is irreconcilably inconsistent with one he or she asserted in a prior proceeding; (2) the party changed his or her position in bad faith, i.e., in a culpable manner threatening to the court's authority or integrity; and (3) the use of judicial estoppel is tailored to address the affront to the court's authority or integrity." *Dam Things from Denmark*, 290 F.3d at 559.

Jazz fails each prong of the correct standard. Under the first prong, Avadel's arguments here are not "irreconcilably inconsistent" with its positions before the Patent Office because Avadel's statements about the '321 Application were made in the context of the '321 Application's factual record. That record did not contain Jazz's position that the '079 patent's disclosures meet written description and are enabling a part of the record. This difference is significant because Dr. Charman formed his opinion on anticipation by accepting Jazz's position that the scant level of detail in its '079 patent adequately describes the claim limitations that Jazz contends are missing

from the "essentially identical (or even more fulsome)" disclosures of Liang. Avadel Counter SMF at ¶ D-1. Thus, the positions regarding the disclosures of Liang and the '079 specification are not irreconcilably inconsistent with statements made outside the context of Jazz's position.

As to the remaining prongs, Jazz makes no argument that Avadel acted in bad faith or that blocking Avadel's entire obviousness defense is "tailored to address" any alleged affront to the court. And it cannot. All Jazz points to are Avadel's allegedly inconsistent statements, but those are explained by the different factual record. Even if they were not, the Third Circuit is clear that inconsistent statements alone do not show bad faith. *Bulger*, 243 F.3d at 777-78 ("A finding of bad faith must be based on more than the existence of an inconsistency."). Jazz's failure to meet these prongs is another reason to reject Jazz's estoppel argument and deny summary judgment.

AVADEL'S *DAUBERT* MOTIONS

V. AVADEL'S OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE EXPERT TESTIMONY OF DR. CORY J. BERKLAND AND DR. ROBERT S. LANGER

Jazz seeks to exclude evidence on an issue for which it has no response. As Avadel's expert, Dr. Langer, has opined, U.S. Patent Publication No. 2006/0210630 ("Liang"), discloses all of the limitations of Jazz's Sustained Release patents other than the requirement that the sustained release portion "releases greater than about 40% of its gamma-hydroxybutyrate by about 4 to about 6 hours when tested in a dissolution apparatus 2 in deionized water at a temperature of 37 ^{o}C and a paddle speed of 50 rpm." Dr. Berkland, who tested a formulation disclosed in Liang (the "Liang Formulation"), demonstrated that the formulation inherently has the required drug release profile, and that Liang therefore anticipates Jazz's patents.

Instead of substantively responding to Dr. Berkland's testing of the Liang Formulation, Jazz moves to keep this evidence from the jury by offering a parade of criticisms of Dr. Berkland's

methods for reproducing the Liang Formulation.[3] Jazz's criticisms are meritless. Dr. Berkland faithfully reproduced a formulation disclosed in Liang, including based on choices that a POSA would have made. Tellingly, Jazz has not explained how Dr. Berkland's choices in making the Liang Formulation depart from the formulations disclosed in Liang or its dissolution testing behavior. Jazz and its expert have also had samples of the formulations that Dr. Berkland made and tested since February 2023. But neither Jazz nor its experts have offered the results of any testing they performed on those—or any other—samples, though they could have.

Dr. Berkland's testing evidence is highly relevant to the validity of four of the six patents in this case. Any criticisms of Dr. Berkland's formulation and testing decisions are properly the subject of cross-examination at trial, not grounds for exclusion under *Daubert*.

A. Legal Standards

FEDERAL RULE OF EVIDENCE 702 "embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit." *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003). Rule 702 "has a liberal policy of admissibility." *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008).

"[A]n expert's testimony is admissible so long as the process or technique the expert used in formulating the opinion is reliable." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994) (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 590 (1993)). Additionally, FEDERAL RULE OF EVIDENCE 703 permits an expert to rely on facts or data, including those of

[3] Jazz's motion is based only on the reproduction of the Liang Formulation, and not any dissolution testing of the formulation. Jazz is therefore precluded from raising any criticisms of Dr. Berkland's dissolution testing on reply in support of its motion to exclude Dr. Berkland's testimony. *See In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, 751 F.3d 150, 157 (3d Cir. 2014) ("We have consistently held that '[a]n issue is waived unless a party raises it in its opening brief . . .' ").

another expert, "[i]f experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject." FED. R. EVID. 703. The Third Circuit has "emphasize[d] that the standard is not that high." *In re Paoli*, 35 F.3d at 745. "The evidentiary requirement of reliability is lower than the merits standard of correctness . . . . A judge will often think that an expert has good grounds to hold the opinion that he or she does even though the judge thinks that the opinion is incorrect." *Id.* at 744. Courts prefer "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof" to exclusion of expert testimony. *Daubert*, 509 U.S. at 596.

B. Argument

Jazz alleges that Dr. Berkland's testing failed to "reliably" reproduce the formulations in Liang. Jazz's attempt to exclude Dr. Berkland's testimony because he purportedly "deviated from Liang's procedure at every step" is both legally and factually incorrect. D.I. 388 at 1.

1. Jazz's Arguments Go to the Weight, and Not Admissibility, of Dr. Berkland's Testimony

Jazz's challenge to Dr. Berkland's testing is wrong as a matter of law. "Experimental evidence may be admitted even if conditions do not perfectly correspond to the conditions at issue in litigation; dissimilarities may affect the ***weight*** of the evidence, but not its ***admissibility***." *Stecyk v. Bell Helicopter Textron, Inc.*, 295 F.3d 408, 412 (3d Cir. 2002) (emphasis added). Indeed, the Federal Circuit has affirmed the denial of *Daubert* motions even when an expert admittedly "did not follow all the testing parameters set forth in the [relevant] patent." *MeadWestVaco Corp. v. Rexam Beauty & Closures, Inc.*, 731 F.3d 1258, 1268-69 (Fed. Cir. 2013).

Jazz's motion offers nothing more than a series of theoretical criticisms that Dr. Berkland failed to follow Liang's process for making the formulations. But Jazz does not explain how Dr. Berkland's purported "deviations" from Liang are scientifically unsound or undermine his

conclusion that the Liang Formulation disclosed in the prior art meets the claimed dissolution testing limitation. Berkland Reply Rpt. ¶¶ 15, 16, 20, 22, 24, 35 ("Dr. Little has not offered an empirical basis for why [the alleged testing] difference[s] would have mattered."). Despite having Dr. Berkland's formulations for months, Jazz has provided no empirical evidence that those formulations failed to accurately reproduce the formulation disclosed in Liang. Berkland Reply Rpt. ¶¶ 15, 32, 33. Nor did Jazz proffer its own evidence—it could have had an expert follow its view of how the Liang Formulation should have been made, but did not. That speaks volumes. Jazz's armchair criticisms cannot justify the exclusion of Dr. Berkland's testimony.

Jazz's cases do not support the exclusion of Dr. Berkland's testing evidence. None concern *Daubert* challenges, and are therefore irrelevant to Jazz's present challenge. *See, e.g.*, *Pfizer Inc. v. Teva Pharm. U.S.A., Inc.*, 882 F. Supp. 2d 643, 768-80 (D. Del. 2012), *aff'd sub nom.* 555 Fed. App'x 961 (Fed. Cir. 2014); *Valeant Int'l (Barbados) SRL v. Watson Pharms., Inc.*, No. 10-20526, 2011 WL 6792653 (S.D. Fla. Nov. 8, 2011), *aff'd sub nom.*, 534 Fed. App'x 999 (Fed. Cir. 2013). For example, in *Pfizer*, the Court did not credit the testimony of defendant's expert's *after* trial, and even then, based on *plaintiff's* testing—testing which is absent here. Similarly, in *Valeant*, the Court never excluded defendant's expert's testimony.

2. Dr. Berkland Reliably Reproduced the Liang Formulation

Equally important, Jazz's motion to exclude Dr. Berkland's testing should be denied because Dr. Berkland's reproduction of the formulations in Liang was scientifically reliable.

Any "[m]inor deviations from the strict disclosure of the prior art are accepted, as long as one of skill in the art would understand those minor deviations are consistent with the prior art's teachings." *Howmedica Osteonics Corp. v. Zimmer, Inc.*, 640 F. App'x 951, 959 (Fed. Cir. 2016) (citing *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047 n.4 (Fed. Cir. 1995)). Jazz does not contend that any of Dr. Berkland's alleged deviations from Liang were outside of what a POSA

would have done in making the Liang Formulation.

Nor does Jazz explain why any alleged deviations from Liang are legally significant. For inherent anticipation, the "critical question" is "whether the [prior art] sufficiently describes and enables one or more embodiments—whatever the settings of their operational features—that necessarily include or result in the subject matter of [the] limitation . . . ." *Arbutus Biopharma Corp. v. ModernaTX, Inc.*, 65 F.4th 656, 664 (Fed. Cir. 2023) (citation omitted) (finding that a POSA would have followed the disclosures in the prior art to arrive at a composition with the claimed morphological property). Jazz does not explain how any alleged deviations from Liang would have affected the dissolution testing results.

i. *Dr. Berkland's reproduced Liang Formulation was based on the express teachings of Liang*

Jazz attempts to argue that Dr. Berkland's formulation is unreliable because it does not follow the express disclosures in the examples of Liang. D.I. 388 at 4-5. But the law does not limit Dr. Berkland to reproducing Liang's examples so long as his formulation was based on Liang's teachings. Berkland Reply Rpt. ¶¶ 3, 6; *see also Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1344 (Fed. Cir. 2016) ("[A] reference need not always include an express discussion of the actual combination to anticipate. Instead, a reference may still anticipate if that reference teaches that the disclosed components or functionalities may be combined and one of skill in the art would be able to implement the combination.") (internal citations omitted). Dr. Berkland arrived at the Liang Formulation by using the express teachings of Liang as a whole as would have been implemented by a POSA. Berkland Reply Rpt. ¶¶ 3, 6; Berkland Tr. 106:6-8, 111:3-5, 112:15-17, 116:5-6, 116:10-13, 118:16-18, 118:25-119:1, 131:11-14 (discussing how choices Dr. Berkland made were "within the teachings of Liang").

ii. *Dr. Berkland followed the express teachings of Liang consistent with Examples 1 and 2 and Liang as a whole*

Jazz first asserts that Dr. Berkland's substitution of sodium acetate in place of sodium gamma-hydroxybutyrate "alone warrants exclusion of [his] alleged inherent anticipation testimony"[4] because the immediate release cores of the Liang Formulation do not "compris[e] the active pharmaceutical ingredient ('API') sodium gamma-hydroxybutyrate." D.I. 388 at 5-6. Jazz's reliance on *Valeant*, 2011 WL 6792653, however, is misplaced. In *Valeant*, a claim element was entirely absent from the prior art reference. That is not the case here: Jazz does not dispute that Liang discloses formulations with sodium oxybate. Dr. Berkland's use of sodium *acetate* (a commonly used substitute for sodium oxybate in dissolution testing) did not substitute for a missing claim element; it was simply a practical concession to the fact that sodium gamma-hydroxybutyrate is a controlled substance that is difficult to obtain and use. Berkland Tr. 116:16-19. Dr. Berkland thus relied on his experience as a formulator to determine that the use of sodium acetate is a "reasonable thing to do" for purposes of dissolution testing since "[t]he ultimate purpose of using sodium acetate as a substitute for sodium oxybate is to determine the rate the acetate (or oxybate) released during a dissolution testing." Berkland Tr. 116:23-25; *see also id.* 136:5-12; Berkland Reply Rpt. ¶ 10. Indeed, as Dr. Berkland points out, Clark Allphin, the lead inventor of Jazz's patents, submitted a declaration to the USPTO during the prosecution of Jazz's patents testifying that he performed *exactly the same substitution* when performing his testing. But contrary to Jazz's complaint now, Dr. Berkland was not relying on a post-priority date teaching as the basis for his substitution; he was simply pointing out that the actions of Jazz's own scientists

[4] As discussed in Section V.B.3. *infra*, this is another example of Jazz conflating Dr. Langer and Dr. Berkland's opinions. Dr. Berkland does not provide any inherent anticipation testimony; rather, he was instructed to make and carry out testing of formulations following Liang.

demonstrated the scientific reliability of using sodium acetate as a proxy for sodium oxybate in these tests. Berkland Tr. 136:5-11 ("It's ***supported*** by the Allphin declaration and supported by my scientific understanding.") (emphasis added).

iii. *Dr. Berkland followed the express teachings of Liang consistent with Example 4 and Liang as a whole*

Jazz next argues that Dr. Berkland "made several modifications" to Example 4 of Liang that are "sufficient to exclude [his] testimony." D.I. 388 at 7. These include exchanging ethyl alcohol with water to create the EC barrier coating solvents, raising the EC coating product temperature above 35 ºC, changing the EC coating weight, and having an EC coating weight loss instead of weight gain. D.I. 388 at 7-9. Again, Jazz attempts to improperly limit the disclosure of Liang to just its Examples. As explained by Dr. Berkland, each of these "modifications" are disclosed in Liang. Jazz's attempt to again paint these differences as outside "Liang's explicit disclosure," and therefore unreliable, lack merit. D.I. 388 at 9.

First, Jazz asserts that the substitution of water for ethyl alcohol has "nothing to do with the explicit disclosures in Liang" and should therefore be excluded. D.I. 388 at 7. However, Jazz ignores that "Liang [] contemplates the use of different solvents for the enteric coating." Berkland Reply Rpt. ¶ 34 (citing Liang ¶¶ 83, 85). Thus, Dr. Berkland's use of water to comply with the safety requirements of his university did not depart from the teachings of Liang. Jazz also does not present any explanation for why the difference matters to the Liang Formulation or its drug release characteristics.

Second, Jazz argues that Dr. Berkland's change in the EC coating product temperature to above 35 ºC is not explicitly disclosed in Liang. D.I. 388 at 7-8. Again, Dr. Berkland explained that the change in temperature was "a typical adjustment" and "very much within the teachings of Liang to operate a flow coater under appropriate conditions" in light of his substitution of water

for ethyl alcohol. Berkland Tr. 146:17-25; 147:13-19. Jazz again does not present any explanation for why the difference matters to the Liang Formulation or its drug release characteristics.

Third, Jazz argues that Dr. Berkland's EC coating weight gain of 4.31% was not one of the required weight gains of 3%, 6%, or 9.2% of Example 2. D.I. 388 at 8. However, Jazz's argument is again premised on the faulty belief that a POSA creating the Liang Formulation is limited to Liang's Examples. A POSA would have recognized that the exemplary weight gains disclosed in Example 2 represent a range of different potential weight gains. Indeed Dr. Berkland says as much. Berkland Tr. 111:3-5 ("In this case, to be consistent with Liang, the – approximately 4 percent is well within the teachings."); 113:13-15: ("4 percent is – in what is disclosed there, it's between 3 and 6. It's also between 3 and 9.2 percent weight gain."). Instead of presenting any evidence to refute Dr. Berkland decisions, Jazz simply brushes it aside and continues to incorrectly assert that a POSA would have been limited to the explicit disclosures of Liang's Examples. More importantly, Jazz again fails to present any explanation for why the difference would be material to the Liang Formulation or its drug release characteristics.

Fourth, Jazz asserts that the observable "weight loss" from the addition of a barrier coating in Dr. Berkland's formulation is contrary to the weight gain disclosed in Example 2 of Liang. D.I. 388 at 8. For support, Jazz relies on Dr. Berkland's statement that Liang is "silent" on a weight loss, and that the lab notebook shows "weight gain" crossed out. *Id.* First, this ignores the actual calculations. Dr. Berkland already opined on the issue and showed that there was a weight loss based on the data collected. Berkland Reply ¶ 27 (discussing that there was a calculated weight loss based on the mass recorded at 980 g, mass collected at 766 g, and mass of the fluid spray recorded at 33 g, resulting in 766 g – 33 g = 733 g). Second, the fact that Liang is "silent" about an observable weight loss, or that the lab notebook shows "weight gain" crossed out does not mean

it is outside the teachings of Liang or would affect the reliability of Dr. Berkland's testing. Jazz again makes no attempt at any explanation for why the difference matters to the Liang Formulation or its drug release characteristics.

iv. *Dr. Berkland followed the express teachings of Liang consistent with Example 6(b) and Liang as a whole*

Jazz next argues that Dr. Berkland did not follow the disclosure of Liang's Example 6(b). D.I. 388 at 9-10. These include not using the weight gain percentages disclosed in Liang's Example 6(b), removing acetone from the enteric coating solvents, and changing the Eudragit L100:talc ratio in the enteric coating solution. D.I. 388 at 9-10. However, Dr. Berkland's Liang Formulation is based on the express teachings of Liang.

First, Jazz argues that Dr. Berkland did not follow Liang's Example 6(b) because he did not coat the Liang Formulation with an enteric coating solution to 40%, 45%, 50%, or 60% weight gain. D.I. 388 at 9. However, Jazz is again improperly limiting a POSA's actions to the explicit disclosures of Liang's Example 6(b). As stated in Dr. Berkland's Reports, "Example 6(b), along with paragraph 85, discloses an enteric coating with a weight gain 'from about 10% to about 70% of the final enteric-coated particle weight.'" Berkland Reply Rpt. ¶ 36; *see also* Berkland Op. Rpt. ¶¶ 26-40; Liang ¶¶ 85, 95, 100, 108. Jazz's argument fails in light of the express disclosures in Liang.

Second, Jazz argues that Dr. Berkland's removal of acetone as the enteric coating solvents had nothing to do with the explicit disclosures in Liang. D.I. 388 at 9-10. Again, Jazz does not discuss how the change in solvents to accommodate safety concerns at Dr. Berkland's university would result in a deviation from formulations disclosed in Liang or their dissolution behavior.

Third, Jazz attempts to paint Dr. Berkland's decision to change the Eudragit L100:talc ratio in the enteric coating solution from 390g:24g (or 16.25:1) to 75g:37.5g (or 2:1) as a concerted

effort by him and Avadel to "target and force the alleged inherent anticipation analysis into the claims of the Sustained Release Patents." D.I. 388 at 10. This is a red herring. Dr. Berkland states that he was following counsel's instruction to "make a formulation in accordance with the teachings of the Liang reference ('Liang Formulation'), that has 'one or more methacrylic acid-methyl methacrylate copolymers that are from about 20% to about 50% by weight of the functional coating.'" D.I. 388 at 4; Berkland Op. Rpt. ¶ 21; Berkland Reply Rpt. ¶ 7. As Jazz acknowledged, Dr. Langer (not Dr. Berkland) has offered the opinion that Liang inherently discloses a formulation that has one or more methacrylic acid-methyl methacrylate copolymers that are from about 20% to about 50% by weight of the functional coating. D.I. 388 at 4, 10. Making such a formulation simply follows the import of Dr. Langer's opinions. Moreover, Dr. Berkland made clear that while there were discussions with counsel as to the formulation to target, the resulting formulations were "within the teachings of Liang." Berkland Tr. 118:25-119:1.

3. Dr. Langer's Expert Report Should Not be Excluded Based on Dr. Berkland's Testing

For the same reasons that Dr. Berkland's testing should not be excluded, neither should Dr. Langer's anticipation opinion that relies in part on Dr. Berkland's testing.

VI. AVADEL'S OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE EXPERT TESTIMONY OF ALEXANDER KLIBANOV AND CARLO GIOVANNI TRAVERSO

Avadel's experts have applied the Court's construction of "sustained release portion," which the Court explicitly held was "the plain and ordinary meaning," which is to say a release "that is not immediate and that releases over a period of time." Jazz did not ask the Court to include any particular testing methodology to determine whether a release is "not immediate" or happens "over a period of time," and the Court did not do so. To the contrary, the Court adopted the plain and ordinary meaning, which does not require any particular testing methodology. The

dictionary definition cited by the Court in its *Markman* opinion (reflecting the plain and ordinary meaning that the Court adopted) says that a "sustained release" is one that is designed to slowly release a drug ***in the body*** over an extended time. The Court's construction leaves open what testing methodology is most appropriate to make that determination in a particular case.

Avadel is in no way trying to reargue claim construction. During the claim construction proceedings, Avadel asked the Court to specify in the construction of "sustained release portion" that the *only* appropriate dissolution testing is in physiologic media of a certain pH. The Court declined to include that requirement in the definition, pointing to the separate requirement in the claim requiring that at least 40% of the drug be released within about 4 to about 6 hours when tested in deionized ("DI") water. The Court concluded that testing in DI water must be an appropriate testing methodology, but the Court did not conclude that testing in DI water is the ***only*** such methodology. That conclusion would be inconsistent with the dictionary definition the Court cited in its claim construction order. It would also be inconsistent with the specification of Jazz's Sustained Release patents, which disclose a variety of different testing conditions, including "purified water, 0.1 N HCl, simulated intestinal fluid, and others," such as "vodka" and "95/5 alcohol/water." Ex. 1, '488 patent at 8:1-4, 23:17, 24:23. Consistent with the specification and the plain meaning of the term "sustained release," the Court's construction does not specify any testing conditions, leaving it to the experts to opine as to which testing method is most appropriate to assess whether LUMRYZ infringes the claims of the Sustained Release patents. It will be for the jury to assess the credibility of the experts and determine who is correct.

To the extent that Jazz is suggesting that a sustained release formulation is defined in the claim to be one that releases at least 40% of its oxybate within about 4 to about 6 hours when tested in DI water, that cannot be correct. An immediate release formulation would meet that requirement

(it would release 100% of its oxybate within that timeframe). It makes no sense to say that a sustained release formulation is defined in a way that would on its face include immediate release. And, as a general proposition, a sustained release formulation might release less than 40% of its oxybate within about 4 to about 6 hours. That is why the claims also require that the formulation release at least 40% of its oxybate within about 4 to about 6 hours when tested in DI water.

Moreover, even if the Court were to adopt Jazz's proposed testing method into the definition of sustained release (as opposed to just recognizing the DI water testing as a separate limitation), Jazz's request for relief still over-reaches because it seeks to strike portions of the reports that apply to testing in DI water. DI water has a range of pHs; how Avadel's formulation behaves in DI water of the relevant pH would still be a question for the experts and the jury.

Finally, Jazz asserts that Dr. Klibanov improperly relies on the prosecution history of Jazz's patents in his analysis. Avadel will not present testimony from Dr. Klibanov regarding the prosecution history in connection with his infringement opinion. Jazz's motion should be denied.

B. Legal Standards

The FEDERAL RULES OF EVIDENCE establish a "strong and undeniable preference for admitting any evidence having some potential for assisting the trier of fact." *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 780 (3d Cir. 1996) (citation omitted). "While an expert witness is not allowed to deviate from the Court's claim construction, that expert is allowed to provide opinions reflecting the application of the Court's claim construction to the facts of [the] case." *Cirba Inc. v. VMware, Inc.*, No. CV 19-742-GBW, 2023 WL 3151853, at *8 (D. Del. Apr. 18, 2023). Thus, courts have admitted expert testimony to assist a jury with understanding how a POSA would have applied a Court's "plain and ordinary meaning" of a claim term. *See e.g., EMC Corp. v. Pure Storage, Inc.*, 154 F. Supp. 3d 81, 109–10 (D. Del. 2016) ("Expert testimony regarding whether an accused device falls within the scope of a court's claim construction is appropriate and raises a

factual issue for the jury to resolve.") (citation omitted) ; *Avid Tech., Inc. v. Harmonic Inc.*, No. CV 11-1040-GMS, 2014 WL 7206301, at *4 (D. Del. Dec. 17, 2014) (holding that "[i]t was not improper for [defendant] to offer its view of the plain and ordinary meaning to the jury" and that plaintiff could have challenged defendant's expert's "interpretation of the plain and ordinary meaning . . . on cross-examination, as is the usual practice"). Moreover, whether a particular product falls within the scope of a court's construction is properly the subject of expert testimony to assist a jury with resolving questions of infringement. *See, e.g., Bio-Rad Lab'ys, Inc. v. 10X Genomics, Inc.*, No. CV 15-152-RGA, 2018 WL 4691047, at *2 (D. Del. Sept. 28, 2018).

C. Argument

1. Background

The Asserted Claims of the Sustained Release patents are directed to, *inter alia*, formulations containing a "sustained release portion." The claims separately recite that the sustained release portion "releases greater than about 40% of its gamma-hydroxybutyrate by about 4 to about 6 hours when tested in a dissolution apparatus 2 in deionized water at a temperature of 37 ºC and a paddle speed of 50 rpm." *See, e.g.*, Ex. 1, '488 patent at claim 1.

Avadel's experts, Drs. Klibanov and Traverso, offer opinions pertinent to whether or not Jazz can establish that LUMRYZ has the claimed "sustained release portion." Collectively, their opinions are that LUMRYZ lacks a "sustained release portion" because there is no portion that releases over a period of time in the body—instead, all portions release their oxybate all at once. Ex. 30, Klibanov Reb. Rpt. at ¶¶ 33-34, 43-44, 60, 62-63, 65, 67, 70, 73-74, 78-79. Drs. Klibanov and Traverso offer their opinion that a POSA undertaking testing to ascertain whether a formulation component meets the "sustained release portion" limitation would have utilized conditions that best mimic physiological conditions in the intestine, *i.e.*, media buffered at pH 6.8. *Id.* at ¶¶ 53, 56-57, 60; Ex. 59, Traverso Reb. Rpt. ¶¶ 18, 20, 47-55, 59, 61, 65, 68, 69. They

further explain what happens to the microparticles in LUMRYZ at various pH levels that reflect the pH values of DI water. Ex. 30, Klibanov Reb. Rpt. ¶¶ 58, 59; Ex. 59, Traverso Reb. Rpt. ¶ 78. They further opine that upon exposure to those conditions, LUMRYZ provides an immediate release, rather than releasing drug over a period of time, and therefore does not meet the "sustained release portion" limitation under the Court's plain and ordinary construction. Ex. 30, Klibanov Reb. Rpt. ¶¶ 43-44, 60-63, 65, 67, 70, 73-74, 78-79; Ex. 59, Traverso Reb. Rpt. ¶¶ 18, 35-47.

These expert opinions properly apply the Court's claim construction. Notably, these opinions will be heard by the jury in any event, as they are pertinent to whether Jazz can establish that LUMRYZ has a "controlled release portion" for purposes of the '079 patent.[5] As set forth below, Jazz has no basis to seek to exclude such opinions, as they are consistent with the Court's claim construction ruling. Jazz did not ask for the construction to include specific testing methodology, and Avadel thus had no opportunity to explain why such a construction would be in error. Avadel should not be precluded from applying the Court's construction and presenting evidence of the appropriate testing methodology to the jury.

2. Jazz's Attempt to Exclude Avadel's Experts' Testimony Is Legally Flawed

Jazz's sole basis for its *Daubert* challenge is its contention that Avadel's experts' opinions "directly contradict the Court's claim constructions." Br. at 3. Jazz is incorrect.

i. *Jazz offers no basis to exclude paragraphs 42-44, 53-54, 59-66, 68-74 of Dr. Klibanov's opinions*

First, much of Jazz's motion is an effort in distraction. Jazz's introduction indicates that it moves to exclude "¶¶ 42-84" of Dr. Klibanov's Responsive Expert Report (Br. at 1), but only

[5] The '079 specification indicates that a POSA can evaluate release characteristics "using in vitro dissolution assays known to those of skill in the art," which can encompass physiologic media like pH 6.5 or 6.8. '079 patent at 6:63-64.

references a subset of those paragraphs in its actual argument. *See* Br. at 4 (citing "¶¶ 56-57"); *id*. at 5 (citing "¶¶ 48-52" and "¶¶ 75-84"); *id*. at 6 (citing "¶ 58").

Jazz does not cite the remaining paragraphs because they are not objectionable. Thus, amongst the opinions Jazz does not mention in its argument are the following:

- Dr. Klibanov's opinion that a POSA would have evaluated whether a formulation comprised a "sustained release portion" by characterizing the release of the drug from that portion under conditions that best represent in vivo conditions. *See* Ex. 30, Klibanov Reb. Rpt. At ¶¶ 53-54.
- Dr. Klibanov's opinion that deionized water is unbuffered and can have a range of pH values, which can affect dissolution. *See id*. at ¶ 59.
- Dr. Klibanov's opinion that when tested under the relevant conditions, LUMRYZ does not meet the Court's construction of "sustained release portion," because it releases immediately, and not over time. *See id*. at ¶¶ 60-74.

Jazz also mischaracterizes an entire section of Dr. Klibanov's expert report by asserting that his opinions were limited to evaluations of the prosecution history of the Sustained Release patents. *See, e.g.*, Br. at 5 (citing Klibanov Reb. Rpt. ¶¶ 75-84). In fact, the cited paragraphs primarily discuss arguments Jazz made in its validity contentions in this case distinguishing the Sustained Release patents' claims from "delayed release" formulations. Such party admissions are highly relevant to the infringement inquiry and Jazz offers no reason why they should be excluded.[6] And as to the few paragraphs of Dr. Klibanov's expert report addressing the

[6] As the experts acknowledge, given that the Court's construction is the plain and ordinary meaning of "sustained release," those in the field would have been aware of that meaning. *See, e.g.*, Little Dep. at 35:6-37:8. As such, the manner in which those in the field characterize LUMRYZ likewise is pertinent to whether or not it satisfies that plain meaning construction.

prosecution history itself, Avadel agrees that Dr. Klibanov will not present those opinions at trial.

ii. *Jazz's objections to the remaining opinions of Drs. Klibanov and Traverso are unwarranted*

Jazz's assertions as to the remaining sections of Dr. Klibanov's report (¶¶ 45-52, 55-58, 67 and 75-84) and Dr. Traverso's report cited in its argument are ill-founded. The Court's claim construction decision held that "sustained release portion" should be given its "plain and ordinary meaning." D.I. 229 at 9. The Court further explained that the "plain and ordinary" meaning includes two requirements: (1) that the release of the drug not be "immediate"; and (2) that the drug "releases over a period of time." *Id.* The Court's construction was silent as to the specific testing conditions to be employed to evaluate the drug release. Jazz did not propose any testing conditions, and waived any contention that they should be included in the construction. *See Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1345-46 (Fed. Cir. 2001) (presentation of the adopted construction to the district court constituted a waiver and precluded the party from proposing a new construction either on JMOL or on appeal). The Court construed the term "sustained release portion" to permit testing in DI water to evaluate whether a particular formulation had sustained release, but not to require it.

Dr. Klibanov applied the Court's claim construction and explained that in this circumstance, where the release of the active ingredient in LUMRYZ is triggered by hitting a certain pH, a POSA seeking to assess whether LUMRYZ contains a "sustained release portion" would rely on testing that mimics physiological conditions. Ex. 30, Klibanov Reb. Rpt. ¶ 56. Dr. Traverso further explained that a POSA would have determined whether LUMRYZ comprised a "sustained release portion" using a pH of 6.8 because the targeted *in vivo* drug release is the middle and distal regions of the small intestine, which have a pH of approximately 6.5 to 6.8. Ex. 30, Traverso Reb. Rpt. ¶¶ 41, 65. This would be the best test to determine whether LUMRYZ is

"designed to slowly release a drug ***in the body*** over an extended period of time," consistent with the ordinary meaning of sustained release. D.I. 229 at 9. A test that does not approximate conditions in the body would not test if the release in the body happens over a period of time.

In seeking to preclude Avadel's experts from applying the Court's claim construction to the facts of the case, Jazz improperly conflates claim construction with infringement. "An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). Jazz's suggestion that the Court effectively conducted step two of this analysis during claim construction is manifest error. *See EMC*, 154 F. Supp. 3d at 109–10 (permitting defendant's expert to opine on noninfringement based on how a POSA would have interpreted "memory" in the claim terms "memory system" and "memory board" following the court's construction of those terms as having their plain and ordinary meaning).

Jazz makes much of the fact that the Court's claim construction decision referenced the ***separate*** claim limitation requiring that the sustained release portion ***also*** demonstrate release "greater than about 40% of its gamma-hydroxybutyrate by about 4 to about 6 hours when tested in a dissolution apparatus 2 in deionized water." Br. at 3-4. In particular, Jazz contends that the Court's "plain and ordinary meaning" for the "sustained release portion" incorporates the separate DI water dissolution testing limitation and therefore precludes a POSA from considering any other testing conditions when determining whether a formulation provides a "sustained release portion." *Id.* That is wrong for multiple reasons.

First, Jazz's attempt to add language plainly *not* found in the Court's construction of "sustained release portion" should be rejected. *See Deere & Co. v. AGCO Corp.*, No. CV 18-827-

CFC, 2023 WL 2662778, at *16 (D. Del. March 28, 2023) (rejecting plaintiff's attempt to add language from the court's claim construction decision to the court's construction of "seed delivery system"). The testing conditions that Jazz is attempting to graft onto the Court's construction are not found in any cited dictionary definition or any other source for the plain and ordinary meaning of "sustained release portion." To the contrary, the dictionary definition cited by the Court for "sustained release portion" specifically referenced "*release in the body*," mandating an inquiry into which testing conditions would best approximate that release. D.I. 229 at 9. And Jazz's Sustained Release patents disclose a variety of different testing conditions, including "purified water, 0.1 N HCl, simulated intestinal fluid, and others." '488 patent at 8:1-4.

Tellingly, Jazz never proposed a "plain and ordinary meaning" construction for "sustained release" that specified the testing conditions a POSA would use. D.I. 229 at 4. Having failed to do so during claim construction, it waived its right to now ask the Court rewrite its construction. *See supra* at §IV.B.2.ii; *Rsch. Found. of State Univ. of N.Y. v. Mylan Pharms., Inc.*, No. CV 09-184-GMS-LPS, 2010 WL 11475865, at *6 (D. Del. June 28, 2010) ("[I]f Mylan wanted 'sub-antibacterial amount' construed to mean 'an amount that does not substantially inhibit the grown of microorganisms ***in vitro***,' it should have requested that construction during the *Markman* proceedings. But it did not.") (emphasis in original).

Second, Jazz's belated attempt to incorporate the deionized water testing limitation into the definition of "sustained release portion" limitation is wrong as a matter of law. Doing so would improperly collapse two claim terms—the "sustained release portion" and the deionized water testing—into one. This violates fundamental canons of claim construction that separate limitations have independent meaning. *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1119 (Fed. Cir. 2004) ("[A]ll claim terms are presumed to have meaning in a claim.").

Moreover, Jazz's formulation expert, Dr. Little, acknowledged that a POSA would understood the "sustained release portion" limitation to be separate from the deionized water limitation Jazz now seeks to incorporate. *See* Ex. 46, Little Dep. at 52:2-10 ("Q: Okay, that's what I was getting to. So it has to both be sustained release and satisfy the release requirements of the claim? A: Yes.").

Third, that the "sustained release" and "release" limitations are separate and distinct is further confirmed with the claims' use of the adjunctive "and" between the pertinent limitations. Thus, for instance, the '885 patent claim 1 recites in relevant part:

> the sustained release portion comprises a functional coating and a core, the functional coating is deposited over the core; . . .
> ***and*** the sustained release portion releases greater than about 40% of its gamma-hydroxybutyrate by about 4 to about 6 hours when tested in a dissolution apparatus 2 in deionized water at a temperature of 37° C. and a paddle speed of 50 rpm.

'885 patent at claim 1. The structure of the claim establishes that "sustained release portion" and the dissolution testing limitation must be treated as separate and distinct claim elements. *See Becton, Dickinson & Co. v. Tyco Healthcare Grp.*, LP, 616 F.3d 1249, 1254 (Fed. Cir. 2010) ("Where a claim lists elements separately, the clear implication of the claim language is that those elements are distinct components.") (internal citations omitted).

Fourth, the deionized water testing conditions recited in the claims cannot be the basis for determining whether a formulation meets the "sustained release portion" limitation because they cannot reliably make this determination. For example, an *immediate release* formulation that released *all* of its GHB in DI water within 5 minutes (or 30 minutes or even 60 minutes) would meet the deionized water limitation Jazz seeks to incorporate into the Court's "plain and ordinary meaning" of "sustained release portion" because it would release "more than 40% of its gamma-hydroxybutyrate by about 4 to about 6 hours." Ex. 30, Klibanov Reb. Rpt. ¶¶ 46-47. But this immediate release formulation cannot show a sustained release under the Court's construction

which expressly requires that a "sustained release portion" not provide immediate release. *Id.*

In addition, it is undisputed that DI water can have a wide variety of pH values. *See* Ex. 46, Little Dep. 168:21-22 ("[D]epending upon the level of carbon dioxide in the [DI] water, [the pH] could be between 5.5 and 7.5."); Ex. 59, Traverso Reb. Rpt. ¶ 78 ("[T]he pH of deionized water is not uniform" and can vary "from day to day," "depending on the source of the water," and can even "change during the [testing] run."). This variation in pH values presents issues when testing a formulation where the release is triggered by pH. As Dr. Klibanov explained, differences in pH values "will necessarily have a significant effect on the dissolution profile . . . . For example, the controlled release pellets will behave differently in water with a pH of 6.2 than in water with a pH of 6.6, let alone at wider pH variations." Ex. 30, Klibanov Reb. Rpt. ¶ 58. Thus, a formulation that provides immediate release when in deionized water under one set of pH conditions may instead display "release[] over a period of time" under different pH conditions in deionized water.

For all of these reasons, as Avadel's experts have explained, the most appropriate way to assess whether LUMRYZ has a sustained release is under physiologically relevant conditions.

3. Appropriate Testing Conditions to Determine "Sustained Release" Remains an Issue for Trial

Even if Jazz's contention that the Court's claim construction order incorporates the separate deionized water testing limitation were correct, whether LUMRYZ infringes remains subject to dispute. Drs. Klibanov and Traverso's testimony therefore remains relevant and should be admitted. *Virnetx, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1321 (Fed. Cir. 2014) (affirming that expert testimony about how a POSA would have applied the court's construction to determine if the accused product infringes was properly presented to the jury).

For example, as noted above, the deionized water's pH ranges from pH 5.5, below the "trigger pH" where LUMRYZ would release drug, to pH 7.5, well above the "trigger pH," where

drug release from LUMRYZ is rapid and immediate. *Supra* at §VI.B.2.ii. Avadel's experts explain that LUMRYZ does not exhibit a sustained release under some of these conditions. Their testimony therefore remains relevant and admissible, even under Jazz's interpretation of the Court's construction.[7]

Jazz further alleges that Drs. Klibanov and Traverso are "chang[ing] the testing requirements explicitly set forth in the asserted claims, which is also consistent with the Court's construction of those claims." Br. at 6. Avadel's experts are doing nothing of the sort. Avadel's experts are evaluating both whether LUMRYZ exhibits a sustained release and whether it releases 40% of its active ingredient within 4 hours when tested in DI water. A failure to meet either criteria means that LUMRYZ does not infringe.

VII. AVADEL'S OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE EXPERT TESTIMONY OF BRUCE CORSER, M.D. REGARDING U.S. PATENT NO. 11,077,079

Dr. Corser is a board-certified physician in sleep medicine and his opinions about what is and is not disclosed in the '079 patent provide facts relevant to other expert opinions regarding the ultimate legal issues. Jazz acknowledges that he is not offering any opinion that the asserted claims of the '079 patent are invalid for lack of written description or enablement. *See* Jazz Op. Br. at 1. Yet, Jazz still seeks to preclude Dr. Corser from offering testimony about the extent of the

[7] In addition, Jazz itself has argued that testing that mimics physiological conditions is relevant to testing using deionized water: during prosecution of the '488 patent, Jazz's lead formulation scientist, Clark Allphin, submitted a declaration to the USPTO asserting that testing of a controlled release formulations of sodium oxybate using physiologically relevant media produced results that were "substantially similar" to testing performed in deionized water. Ex. 60, Allphin Aff. Apr. 20, 2020 at 1-2 & n.1). Having relied on the alleged equivalency between testing in physiologically relevant conditions and testing in deionized water to obtain its patents, Jazz cannot now be heard to contend testing under physiological relevant conditions has no relevance to the infringement analysis, even if the plain and ordinary meaning of "sustained release" requires deionized water testing.

disclosures in the '079 patent, because he was unfamiliar with the governing legal standards for § 112. But familiarity with that legal standard is not required for Dr. Corser to opine on what a POSA would have taken away from the disclosures of the '079 patent. If Jazz disagrees with Dr. Corser's opinions, that goes to weight, not admissibility. Jazz's motion to exclude Dr. Corser's testimony regarding the disclosures of the '079 patent should therefore be denied.

Dr. Corser's opinions are relevant because he offers the perspective of one member of the POSA team. The parties agree that the relevant person of ordinary skill in the art in this case would "be a member of an inter-disciplinary team of scientists involved in drug research and development" and that "[t]he team would also have included or had access to an individual with a medical degree with experience in treating sleep disorders, and particularly of narcolepsy." Greenblatt Reb. Rpt. ¶ 15 (citing to the definition set forth in Dr. Scharf's Op. Rpt. ¶ 17). As a board-certified physician in sleep medicine with more than thirty years' experience, Dr. Corser is the exact team member that Dr. Charman, Dr. Klibanov, and the other experts in this case agree would be consulted by the person of ordinary skill in the art. *See* Corser CV.

Dr. Corser opines that the '079 patent does not include the type of data that a ***physician*** would expect to see, in order to conclude that the inventors had a drug product that could either effectively treat narcolepsy with a single daily dose or promote a patient to sleep for 6-8 hours as recited in the claims of the '079 patent. In particular, Dr. Corser opines, *inter alia*: "I see no information in the '079 patent that would lead me to believe that the inventors behind that patent had a drug product that enables the effective treatment of narcolepsy with a single daily dose or promotes the patient to sleep for 6 to 8 hours" and "[t]he '079 patent lacks any meaningful data pertinent to that issue." *See* Op. Rpt. ¶ 96.

Jazz attacks Dr. Corser's opinions, because he was not familiar with the legal standards for

written description or enablement. But Jazz cites no law to suggest that an expert ***must*** be familiar with written description and enablement ***law*** to provide testimony about how a POSA would have interpreted data from a ***factual*** standpoint, which other Avadel experts may rely on for their opinions about written description and enablement. *See Shire Viropharma Inc. v. CSL Behring LLC*, 2021 U.S. Dist. LEXIS 61551, at *45 (D. Del. Mar. 31, 2021) ("[I]t is common in technical fields for an expert to base an opinion in part on what a different expert believes on the basis of expert knowledge not possessed by the first expert.") (internal citations omitted, citing to *Dura Auto. Sys. of Indiana, Inc. v. CTS Corp.*, 285 F.3d 609, 613 (7th Cir. 2002); *see also Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1363 (Fed. Cir. 2006) ("Written description is a question of fact, judged from the perspective of one of ordinary skill in the art," and "enablement is a question of law involving underlying factual inquiries.") (internal citations omitted). Dr. Corser is well qualified to give his perspective as a physician and researcher as to what a POSA would have understood is disclosed (or not) in the '079 patent. Evaluating the extent of the disclosure in the '079 patent simply requires reading it, not any complex "methodology," as Jazz contends. Dr. Corser is familiar with the skill set of the POSA in this case, read the patent, and offered an opinion on what the patent discloses. Jazz argues that his opinion is "cursory," but the brevity of Dr. Corser's opinion simply reflects the lack of any significant data in the '079 patent.

If Jazz disagrees with Dr. Corser's views on how a POSA would read and interpret the '079 patent, the solution is cross examination, not preclusion. *Masimo Corp. v. Philips Elec. N. Am. Corp.*, 62 F. Supp. 3d 368, 388 (D. Del. 2014) ("The weight and credibility of an expert's testimony may be challenged through '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'") (citing to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 596 (1993)).

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