IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiff, v. AVADEL CNS PHARMACEUTICALS LLC and AVADEL PHARMACEUTICALS PLC, Defendants.	C.A. No. 21-691-GBW [redacted] REDACTED- PUBLIC VERSION
JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiff, v. AVADEL CNS PHARMACEUTICALS LLC and AVADEL PHARMACEUTICALS PLC, Defendants.	C.A. No. 21-1138-GBW [redacted] REDACTED - PUBLIC VERSION
JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiff, v. AVADEL CNS PHARMACEUTICALS LLC and AVADEL PHARMACEUTICALS PLC, Defendants.	C.A. No. 21-1594-GBW [redacted] REDACTED - PUBLIC VERSION

ORDER

Having reviewed the proposed joint pretrial order (D.I. 419) submitted by Plaintiff Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited ("Jazz") and Defendants Avadel CNS Pharmaceuticals LLC and Avadel Pharmaceuticals PLC ("Avadel") regarding the jury trial scheduled to begin on February 26, 2024, **IT IS HEREBY ORDERED** that:

1. With respect to Jazz's motion *in limine* number 1, Jazz requests that the Court preclude Avadel from introducing evidence and argument related to any safety or efficacy requirements or limitations for Jazz's non-method-of-treatment asserted claims. D.I. 419-1 at 112. Jazz's motion *in limine* number 1 is **GRANTED**. Avadel's expert, Dr. Charman, opined in his expert report that U.S. Patent Nos. 10,758,488 ("the '488 patent") and 11,147,782 ("the '782 patent") (collectively, the "Asserted Patents") are invalid for lack of enablement and written description support. *Id.* In support, Dr. Charman explained that the specifications of the Asserted Patents do not describe modified release particles that can help a patient stay asleep throughout the night. *Id.* Jazz seeks to preclude Dr. Charman from offering these opinions, and contends that Dr. Charman's opinions improperly import unrecited safety and efficacy requirements into Claims 7 and 11 of the '488 patent, and Claim 24 of the '782 patent, (collectively, the "Asserted Claims"). *Id.* The Court agrees. Those claims recite formulations that comprise, *inter alia*, "modified release particles." *Id.* The Court construed "modified release particles" and gave that term its plain and ordinary meaning—i.e., "particles containing an active pharmaceutical ingredient with a release profile that is different from that of an immediate release particle." *See* D.I. 229. Thus, the term has a structural requirement (the "active pharmaceutical ingredient") and a

functional requirement (that the particle possess "a release profile that is different from that of an immediate release profile"). *Id.* The Asserted Claims do not recite a separate limitation that requires the modified release particles to help a patient stay asleep throughout the night. *Id.*

Avadel contends that the specification of the '782 patent teaches that the full scope of "modified release" includes "a controlled release profile suitable for once-a-day dosing." *See* D.I. 419-1 at 252 (citing '782 patent at 6:44-46). The specification of the '782 patent explains that a "controlled release" is a release wherein "at least one of the active components having a release over a period of at least about 2 to at least about 8 hours," inclusive of all release-profile ranges there between. '782 patent at 6:56-60, 63-64. Thus, Avadel contends that the patent must enable and describe that "attribute of the formulation." *Id.* (citing *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1256 (Fed. Cir. 2004)).[1] The Court is not persuaded by Avadel's argument, however, because the Court has not construed any term of the Asserted Claims to require "suitab[ility] for once-a-day dosing" or "achiev[ing] and maintain[ing] therapeutic levels of a drug over a sustained period of time." *Id.* Thus, those requirements are not limitations of the Asserted Claims. *See Nuvo Pharm. (Ireland) Designated Activity Co. v. Dr. Reddy's Labs. Inc.*, 923 F.3d 1368, 1384 (Fed. Cir. 2019) (explaining that "[Federal Circuit] case law provides that [a claimed] result must be supported by adequate disclosure in the specification" "when the inventor *expressly claims* that result") (emphasis added).

[1] Similarly, Avadel contends that an "attribute of the formulation" that must be enabled with respect to the'488 patent is a formulation that "allow[s] patients to quickly achieve and maintain therapeutic levels of a drug over a sustained period of time, while reducing the frequency with which the drug must be dosed." D.I. 419-1 at 252; '488 patent at 4:35-38.

Bial-Portela & CA. S.A. v. Alkem Labs. Ltd., is illustrative. 2022 WL 4244989 (D. Del. Sept. 15, 2022). There, the patent-at-issue was directed to the use of a drug to treat a patient that had previously been treated unsuccessfully with a different drug. *Id.* at 5-6. The asserted method of treatment claim of that patent recited, *inter alia*, "administering to a subject in need thereof a therapeutically effective amount of [the drug]" as a "monotherapy for treating [the] condition." *Id.* at 5-6. The court found that the asserted claim was invalid for lack of written description because the patentee "claim[ed] treatment of [the condition] with [the drug] in patients intractable to [the other drug]" but "no data in the patent suggest[ed] that [the drug] could be used to effectively treat a patient intractable to [the other drug]." Here, unlike *Bial-Portela*, the Asserted Claims do not recite "a controlled release profile suitable for once-a-day dosing" or "achiev[ing] and maintain[ing] therapeutic levels of a drug over a sustained period of time." *See* '782 patent (controlled release); '488 patent (achieving and maintaining). Thus, there is no requirement that the Asserted Patents enable those unclaimed limitations. *See Nuvo Pharm.*, 923 F.3d at 1384. Accordingly, the Court grants Jazz's motion to preclude Dr. Charman from testifying that the Asserted Claims are invalid for lack of enablement or written description as a result of the Asserted Patents' failure to enable or describe "modified release particles" with a "controlled release profile that is suitable for once-a-day dosing" or "sustained release particles" that "allow[] patients to quickly achieve and maintain therapeutic levels of a drug over a sustained period of time." *See* '782 patent; '488 patent.

2. With respect to Jazz's motion *in limine* number 2, Jazz requests that the Court preclude Avadel from offering argument on its anticipation and inventorship defenses, including any evidence of Jazz's purported copying of Avadel's patents. D.I. 419-1 at 366. Jazz's

motion *in limine* number 2 is **DENIED**. Jazz contends that those defenses are wholly dependent on Avadel's written description defense. *Id.* Avadel's anticipation and inventorship defenses are premised on the theory that the Asserted Claims lack written description support and were, instead, copied from Avadel's later-in-time patent filings. *Id.* at 366-367. Thus, Avadel argues that its patent filings anticipate Jazz's claims and that its former employees are the true inventors. *Id.* Jazz argues that Avadel's inventorship and anticipation defenses, along with any evidence of copying, should be excluded because those defenses merely suggest to the jury an improper basis for reaching a conclusion on invalidity—i.e., that because "Avadel did it first, Avadel should win." *Id.* (citing *Webasto Thermo & Comfort North America v. BesTop Incorporated*, No. 16-13456, 2019 WL 4892417, at *5 (E.D. Mich. July 29, 2019)).

However, the elimination of a legal issue is the proper function of a summary judgment motion—not a motion *in limine*. *Johns Hopkins Univ. v. Alcon Labs. Inc.*, 2018 WL 4178159, at *21 (D. Del. Aug. 30, 2018). The Court finds *CardioVention v. Medtronic* and *Woods v. Szakacs* distinguishable. In those cases, the court struck one claim as duplicative of another when the proof of one claim would require proving the same legal elements as the other. *See CardioVention v. Medtronic*, 483 F. Supp. 2d 830, 834 (D. Minn. 2007); *Woods v. Szakacs*, No. 15-027, 2017 WL 11567918, at *2 (N.D.N.Y. May 25, 2017). Avadel's anticipation, inventorship, and written description defenses may rely on the same facts, but the legal standards for each defense are different. Thus, the Court denies Jazz's motion to preclude Avadel from offering argument on its anticipation and inventorship defenses. *See, e.g., Bradley v. Pittsburgh Board of Ed.*, 913 F.2d 1064, 1069 (3d Cir. 1990) ("Unlike a summary judgment motion, which is designed to eliminate a trial

in cases where there are no genuine issues of fact, a motion *in limine* is designed to narrow the evidentiary issues for trial and to eliminate unnecessary trial interruptions.").

The Court also denies Jazz's motion to preclude Avadel from offering evidence of Jazz's purported copying. D.I. 419-1 at 367-368. Avadel contends that Jazz cancelled its pending claims and replaced those claims with new claims that copied substantial portions of Avadel's patents. *Id.* at 397-398. Avadel argues that Jazz's actions show that Jazz was not in possession of the invention described by the Asserted Patents. *Id.* The Court finds that such evidence is relevant to Avadel's written description defense and is not substantially outweighed by the risk of undue prejudice. *See Idenix Pharm. LLC v. Gilead Scis., Inc.*, 2016 WL 6901742, at *3 (D. Del. Nov. 22, 2016) (explaining that evidence that a patentee "cancelled all pending original claims and added broader claims" after certain disclosures were made to the patentee's patent attorney may be "probative of [the patentee's] inventors not being in possession of the full scope of the ultimately-claimed inventions at the time they filed the original patent application"); *see also Boston Sci. Corp. v. Cook Med. LLC*, 2023 WL 2411277, at *2 (S.D. Ind. Feb. 2, 2023) (permitting argument that plaintiff did not possess its invention because plaintiff tried to "copy" defendant's products through plaintiff's newly-issued patents drafted specifically to encompass defendant's product).

3. With respect to Jazz's motion *in limine* number 3, Jazz requests that the Court preclude Avadel from introducing evidence and argument on topics that are not properly before the jury in this case. D.I. 419-1 at 427. Those topics include: (1) Jazz's request for injunctive relief, (2) U.S. Patent No. 8,731,963 (the "'963 patent"), which is no longer in this case, (3) inequitable conduct, and (4) other litigation between the parties. *Id.* Jazz notes that "these are only examples," and that "Avadel might raise [other topics] that should not be

considered by the jury." *Id.* Jazz's motion *in limine* number 3 is **GRANTED-IN-PART** and **DENIED-IN-PART-AS-PREMATURE**. The Court denies-as-premature Jazz's motion to the extent that Jazz seeks to preclude evidence on "other topics" that should not be considered by the jury. *See id.* The Court is unaware of what these other topics are and, thus, cannot determine whether they are relevant or unfairly prejudicial at this time. With respect to the defined categories of evidence that Jazz seeks to exclude, Avadel contends that it does not intend to present to the jury evidence or argument related solely to those topics unless Jazz opens the door to that evidence. *See id.* at 432-434. However, Avadel argues that the Court should deny-as-premature Jazz's motion because those evidentiary issues can be decided on an issue-by-issue basis at trial. *Id.* Avadel also contends that Jazz's motion is overly broad because it seeks to exclude evidence or argument on the "subject matter" of other litigation between the parties when that subject matter could also be relevant to this action. *Id.* The Court grants-in-part Jazz's motion to the extent that Jazz seeks to preclude Avadel from offering evidence or argument that is not relevant to this case on the grounds that it is solely relevant to Jazz's request for injunctive relief, the '963 patent, inequitable conduct, or other litigation between the parties. The Court finds that such evidence is properly excluded at this time because Avadel has not shown how that evidence would be relevant absent Jazz opening the door. The Court also finds that this category is sufficiently definite such that the parties, and the Court can determine what is, or is not, excluded by the Court's order. Thus, if Avadel believes that Jazz's arguments at trial have opened the door, Avadel may request permission from the Court to admit testimony on those topics for which Jazz has opened the door. *See Power Integrations, Inc. v. Fairchild Semiconductor Int'l Inc.*, 2018 WL 5292544, at *1 (D. Del. Oct. 25, 2018)

("Both sides should understand that the Court's pretrial rulings are subject to reevaluation should a party open the door and materially alter the considerations the Court had before it prior to trial.").

4. With respect to Avadel's motion *in limine* number 1, Avadel requests that the Court preclude Jazz from offering at trial any evidence, testimony, or argument relating to drug pricing at KV Pharmaceuticals Co. ("KV"), including the media's response to that pricing. D.I. 419-1 at 518. Avadel's motion *in limine* number 1 is **GRANTED-IN-PART** and **DENIED-IN-PART**. Prior to joining Avadel, Mr. Davis was the CEO of KV. *Id.* Other witnesses on Jazz's witness list were also employees of KV. *Id.* at 520. During Mr. Davis's tenure at KV, the company was involved in a pricing controversy regarding a drug used to prevent premature birth, hydroxyprogesterone caproate. *Id.* at 518. The FDA granted orphan drug approval for that drug in 2011, thus granting to KV the exclusive right to sell that drug under the trade name Makena. *Id.* KV then priced Makena higher than off-label hydroxyprogesterone caproate. *Id.* In response, members of the public launched a social media campaign that criticized KV, along with Mr. Davis personally. *Id.* As a result, the FDA ultimately declined to enforce Makena's orphan drug exclusivity. *Id.* Avadel argues that the pricing of Makena is not relevant to any issue at trial because, *inter alia*, LUMRYZ (Avadel's product) is unrelated to Makena and the pricing of those drugs is not related. *Id.* at 519. Jazz responds that KV's pricing is relevant to its rebuttal of Avadel's damages theory [redacted] *Id.* at 536-538. Jazz argues that Mr. Davis, and other witnesses', experiences at KV are an example of the FDA not enforcing orphan drug exclusivity in all instances. *Id.* Thus, Jazz argues that this evidence is relevant to rebut Avadel's damages expert, who intends to opine that Avadel's orphan drug

exclusivity confers value to Avadel and, thus, decreases the royalty rate the parties would reach in a hypothetical negotiation. *Id.* Jazz also contends that this evidence is relevant to its rebuttal of [redacted] *Id.* Jazz contends that such evidence [redacted] *Id.*

The Court grants Avadel's motion to exclude evidence and argument on the specifics of Avadel's employees' experiences with KV and Makena as those experiences relate to Makena's pricing and the surrounding controversy. The Court properly excludes evidence under Rule 403 when its "admission would lead to litigation of collateral issues, thereby creating a side issue which might distract the jury from the main issue." *Blancha v. Raymark Indus.*, 972 F.2d 507, 516 (3d Cir. 1992). Whether, and to what extent, Avadel is a "innovative" and "patient-focused" business is a "side issue" to the "main issue[s]," namely whether the Asserted Claims are valid and infringed. *See* D.I. 1. While the Court tends to allow some inquiry into a parties' "themes" at trial, Jazz's proffered evidence regarding KV and Makena is "collateral to the overall issue of liability." *See Reynolds v. Univ. of Pa.*, 684 F. Supp. 2d 621, 632 (E.D. Pa. 2010). Further, to the extent that Jazz intends to argue that [redacted] *See* Fed. R. Evid. 404.

However, the Court finds that Avadel's high-level employees' knowledge of the FDA's discretion in enforcing orphan drug exclusivity is relevant and not outweighed by the risk of undue prejudice. *See id.*; Fed. R. Evid. 402. Thus, subject to any other applicable objections, the Court will permit Jazz to ask Avadel's witnesses whether (1) they were previously employed at another company that sold orphan drugs, (2) they possess knowledge that the FDA does not always enforce orphan drug exclusivity, and (3) their knowledge of what is required for a drug to receive orphan drug exclusivity. If Jazz believes that Avadel's arguments at trial, or its witnesses' responses to the topics recited above, have opened the door to other related evidence, Jazz may request permission from the Court to admit testimony on those topics for which Avadel has opened the door. *See Power Integrations*, 2018 WL 5292544 at *1.

5. With respect to Avadel's motion *in limine* number 2, Avadel requests that the Court preclude Jazz from offering any testimony by its inequitable conduct expert, Mr. Stoll. D.I. 419-1 at 624. Inequitable conduct has been bifurcated from this trial. *Id.* Thus, because Avadel contends that Mr. Stoll's opinions relate solely to inequitable conduct, Avadel asks the Court to exclude those opinions from this trial. *Id.* Avadel's motion *in limine* number 2 is **DENIED-AS-PREMATURE**. Jazz contends that the scope of Mr. Stoll's opinions are not limited to inequitable conduct. *Id.* at 713. Rather, Jazz contends that Mr. Stoll is an expert on "patent office practices and procedures" and that Mr. Stoll will testify at trial about those procedures in so far as they relate to Avadel's invalidity defenses of improper inventorship and lack of written description. *Id.* at 714. In his expert report, Mr. Stoll opined—in response to the contrary opinion of Mr. Matal (Avadel's expert on inequitable conduct)—that no authority requires a patentee to disclose alleged copying of claims to an

examiner during prosecution. *See id.* at 672-673. Mr. Stoll also explained that he disagreed with Mr. Matal's opinion that the examiner should have notice of allegedly copied claims because that notice would trigger a more stringent inquiry into whether the application provides sufficient written description support for the claimed subject matter. *Id.* Conversely, Mr. Stoll opined that such notice would not trigger a more stringent inquiry because the "written description analysis is conducted by an examiner irrespective of the source of the pending claims and irrespective of having knowledge of the source of the claims." *Id.* Stated another way, Mr. Stoll opined that "knowledge of copying claims would not influence or trigger a further written description analysis by an examiner because that analysis takes place as part of the normal examination process anyway." *Id.*

The Court finds that Mr. Stoll's opinions are relevant to Jazz's rebuttal of Avadel's invalidity defenses and that Mr. Stoll did not exceed the proper scope of rebuttal testimony by offering those opinions. The Court finds that Mr. Stoll's opinions are relevant to invalidity because "if the PTO did not have all material facts before it, its considered judgment may lose significant force." *Microsoft Corp. v. I4I Ltd. P'ship*, 131 S. Ct. 2238, 2241 (2011). Mr. Stoll opined that the PTO analyzes patent applications for written description support regardless of whether the PTO has notice that claims from the patent application have been copied from other patent applications. *See* D.I. 419-1 at 672-673. Thus, Mr. Stoll's opinions are relevant to the weight that the fact-finder should give the PTO's judgment in its determination of whether the Asserted Claims are valid. *See Microsoft Corp*, 131 S. Ct. at 2241. The Court also finds that Mr. Stoll's opinions did not exceed the scope of rebuttal. Mr. Stoll's opinions rebut Mr. Matal's opinions regarding whether, and why, a patentee must provide evidence of claim copying to the PTO. D.I.

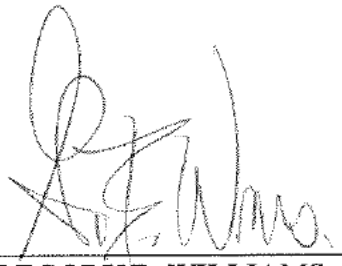
419-1 at 672-673; *see* Fed. R. Civ. P. 26(a)(2)(D)(ii) (rebuttal evidence is "intended solely to contradict or rebut evidence on the same subject matter identified by another party"). Thus, the Court finds that Mr. Stoll's opinions were proper rebuttal opinions as they contradict the opinions of Mr. Matal and are on the same "subject matter." *See id.* Accordingly, the Court finds that Mr. Stoll's testimony would provide useful background on the procedures at the PTO to the fact-finder, and declines to exclude his testimony at this time. *See, e.g.*, *Shire Viropharma Inc. v. CSL Behring LLC*, 2021 WL 1227097, at *18 (D. Del. Mar. 31, 2021) (admitting testimony from an expert on PTO practices and procedures when such testimony would be useful to the fact-finder). Avadel may re-raise its objection if Mr. Stoll testifies outside the bounds of his expert reports or on issues that are not relevant to this trial.

6. With respect to Avadel's motion *in limine* number 3, Avadel requests that the Court preclude Jazz from offering argument or testimony related to its alleged copying of Avadel's earlier-filed patent applications and Jazz's suppression of its own patent applications. D.I. 419-1 at 752. Defendants' motion *in limine* number 3 is **GRANTED-IN-PART** and **DENIED-IN-PART**. Avadel contends that Jazz is attempting to use privilege as a "sword and shield" because Jazz's witnesses invoked the attorney/client and attorney work-product privileges when asked about actions Jazz took during patent prosecution. *Id.*; *see, e.g.*, *Persawvere, Inc. v. Milwaukee Electric Tool Corp.*, C.A. No. 21-400-GBW, 2023 WL 8094642 at *2 (D. Del. Nov. 21, 2023) ("Milwaukee may not rely on the advice its counsel provided on the center of gravity of the Accused Products because Milwaukee asserted privilege with respect to that advice."). Avadel deposed Jazz's in-house patent counsel (Mr. McGarrigle) and Jazz's outside prosecution counsel (Mr.

Valentine) and contends that the only explanation those witness provided regarding the similarity of Jazz's patent claims to Avadel's published patent applications was that Mr. Valentine "refer[red] to" Avadel's publications when drafting Jazz's claims. *Id.* at 753. Thus, Avadel seeks to preclude Jazz from offering "any additional or contradictory explanation of the similarity between Jazz and Avadel's patent claims beyond the fact that Mr. Valentine "referred" to Avadel's patent applications. *Id.* Jazz contends that, with respect to that issue, Mr. Valentine and Mr. McGarrigle will only testify at trial that Mr. Valentine "referred to" Avadel's publicly-available patent filings. *Id.* at 804. Avadel, however, contends that Jazz's representation is insufficient to moot its motion *in limine* because Avadel *also* seeks to preclude Jazz from offering any other evidence or argument that explains the similarity of Jazz and Avadel's patent claims and applications. *Id.* at 811. The Court finds that Avadel's request goes too far. Avadel's request captures evidence that is relevant, non-privileged, and not directed towards the topics for which Jazz sought privilege. Both parties, for example, are pharmaceutical companies who sought to develop a sodium oxybate pharmaceutical product—i.e., evidence that could explain the similarity of the parties' claims and applications. *Compare, e.g.*, Xyrem (Jazz's product) *with* LUMRYZ (Avadel's product).

Accordingly, the Court grants-in-part Avadel's motion to the extent that Avadel seeks to preclude Mr. Valentine and Mr. McGarrigle from offering testimony, beyond what was provided at their depositions, on matters for which they sought privilege. The Court denies-in-part Avadel's motion to the extent that it seeks to exclude all other argument and testimony that tends to explain that similarity between Jazz and Avadel's patent claims and applications.

Date: February 14, 2024



GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE