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

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MEMORANDUM OPINION[1]

Pending before the Court are Avadel CNS Pharmaceuticals LLC and Avadel Pharmaceuticals PLC's ("Avadel") motions for partial summary judgment (D.I. 399) and Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited's ("Jazz") motions for partial summary judgment (D.I. 393; D.I. 395; D.I. 397; D.I. 400). Also pending before the Court are Avadel's motions to exclude the testimony of Dr. Mark Rainey, Dr. Cristian Moreton, and Dr. Steven Little (D.I. 285) and Jazz's motions to exclude the expert testimony of Dr. Cory Berkland, Dr. Robert Langer, Mr. Alexander Klibanov, Mr. Carlo Giovanni Traverso, and Dr. Bruce Corser (D.I. 387; D.I. 389; D.I. 391).

This is a consolidated action for patent infringement brought by Jazz against Avadel, arising from Avadel's filing of a New Drug Application ("NDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a sodium oxybate ("oxybate" or "GHB") drug product prior to the expiration of U.S. Patent Nos. 10,758,488, 10,813,885, 10,959,956, and 10,966,931 (collectively, the "Sustained Release Patents" or "SR

[1] The Court writes for the benefit of the parties and assumes their familiarity with this action.

Patents") and U.S. Patent Nos. 11,077,079 (the "'079 patent"); and 11,147,782 (the "'782 patent"). *See* D.I. 394 at 1. Jazz alleges that Avadel's product, LUMRYZ, infringes those six (6) patents. Avadel asserts that the SR Patents are invalid and that LUMRYZ does not infringe. *Id.* The parties informed the Court, in the proposed pre-trial order, that Jazz has narrowed its asserted patents to the '488 and '782 patents (the "Asserted Patents") and has narrowed its asserted claims to claims 7 and 11 of the '488 patent and claim 24 of the '782 patent (collectively, the "Asserted Claims").[2] D.I. 421.

I. LEGAL STANDARDS

i. Summary Judgment

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "A genuine issue of material fact is one that could lead a reasonable jury to find in favor of the nonmoving party." *Bletz v. Corrie*, 974 F.3d 306, 308 (3d Cir. 2020) (citation omitted). "The court must review the record as a whole, draw all reasonable inferences in favor of the nonmoving party, and must not 'weigh the evidence or make credibility determinations.'" *Id.* (citation omitted). The Court must enter summary judgment if the non-moving party "fails to make a showing sufficient to establish the existence of an element essential to [its] case, and on which [the non-moving] party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *see also SodexoMAGIC, LLC v. Drexel Univ.*, 24 F.4th 183, 204 (3d Cir. 2022) (quoting *Celotex*, 477 U.S. at 322). The Federal Circuit "reviews a district court's grant of

[2] Thus, considering that the parties have narrowed the issues that will be presented at trial to those asserted patents and claims, the Court will consider only those patents and claims for the purpose of this Opinion and Order. Accordingly, the Court addresses only the '488 patent with respect to Avadel's motion for partial summary judgment no. 1 and addresses only the '782 patent with respect to Avadel's motion for partial summary judgment no. 2 and Jazz's motion for partial summary judgment no. 2.

summary judgment under the law of the regional circuit, here the Third Circuit." *Acceleration Bay LLC v. 2K Sports, Inc.*, 15 F.4th 1069, 1075 (Fed. Cir. 2021) (citation omitted).

ii. Expert Witness Testimony

Federal Rule of Evidence 702 sets out the requirements for expert witness testimony and states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. The Third Circuit has explained:

> [T]he district court acts as a gatekeeper, preventing opinion testimony that does not meet the requirements of qualification, reliability and fit from reaching the jury. *See Daubert* ("Faced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset, pursuant to Rule 104(a) [of the Federal Rules of Evidence] whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.").

Schneider ex rel. Estate of Schneider v. Fried, 320 F.3d 396, 404 05 (3d Cir. 2003) (footnote and internal citations omitted). Qualification examines the expert's specialized knowledge, reliability examines the grounds for the expert's opinion, and fit examines whether the testimony is relevant and will "assist the trier of fact." *Id.* at 404.

II. DISCUSSION

i. The Court Denies Jazz's Motion for Partial Summary Judgment No. 1.

Jazz asks the Court to enter partial summary judgment in its favor and find that the core of LUMRYZ's controlled release coated pellets (the "CR pellets") comprise sodium oxybate. *See* D.I. 394. For the reasons stated below, the Court denies Jazz's motion.

The parties dispute the make-up of LUMRYZ's "core" and whether that core includes sodium gamma-hydroxybutyrate ("GHB"). LUMRYZ contains two types of pellets: immediate

release pellets ("IR pellets") and controlled release pellets ("CR pellets"). *Id.* at 3. The CR pellets contain the IR pellets. *Id.* Thus, Jazz contends that the IR pellets are the "core" of the CR pellets. *Id.* However, the IR pellets contain a microcrystalline crystal sphere ("MCC sphere") that is coated with GHB. D.I. 418 at 1-2. Thus, Avadel contends that the MCC spheres are the "core" of the CR pellets. *Id.* Accordingly, the CR pellet contains a core that comprises GHB if the IR pellet is the core of the CR pellet but, conversely, does not contain a core that comprises GHB if the core of the CR pellet is the MCC sphere. *See* D.I. 394 at 5; D.I. 418 at 1-2.

Table 1b of U.S. Patent No. 10,272,062 (the "'062 patent") states that "IR microparticles" function as the "core of MR microparticles." *See* '062 patent, table 1b. [redacted] D.I. 394 at 2.

Jazz argues that [redacted] Table 1b, show that the IR pellets function as the core of the CR pellets. *Id.* at 3-6. [redacted] *Id.* Table 1b shows that the MR microparticles have an IR "core". *Id.* Thus because the CR pellets are the MR microparticles the CR pellets must have an IR core. *Id.* Conversely, Avadel argues that Table 1a, and Example 1 as a whole, shows that the core of the CR pellets are the MMC spheres because Table 1a states that "microcrystalline cellulose spheres" function as the "core" of the IR microparticles. D.I. 419 at 3-5, 9. Jazz, however, contends that this argument is foreclosed by [redacted]

Table 1b. D.I. 394 at 4-6. Accordingly, Jazz contends that the only relevant inquiry is how Table 1b characterizes the MR microparticles. *Id.*

The Court finds that Avadel's response to Jazz's request for admission was not an admission that [redacted] *See Evonik Degussa GmbH v. Materia Inc.*, No. 09-CV-636 (NLH/JS), 2016 WL 337378, at *4 (D. Del. Jan. 26, 2016). Importantly, Jazz's request for admission did not ask Avadel to admit that [redacted] *See* D.I. 418 at 4. Thus, the Court finds that Avadel's admission [redacted] does not mean that [redacted] *See 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) (explaining that courts do not "contort the plain wording of the admission to favor either party's interpretation" where there is a dispute as to the meaning of an admission).

Accordingly, the Court finds it proper to consider the rest of the '062 patent to determine if the parties genuinely dispute whether the core of LUMRYZ comprises GHB. Considering the rest of the '062 patent, the specification shows that Avadel used the term "core" to refer to both IR microparticles and MCC spheres. *See* '062 patent. Table 1d, for example, refers to the "quantitative finished composition" (which includes the MR and IR microparticles; *see*, *e.g.*, Table 1c) and states that the "core" of the finished composition are "microcrystalline cellulose spheres." *Id.* Thus, the Court finds that the '062 patent does not conclusively establish that the core of the CR pellets are the IR microparticles.

Jazz also argues that the Court should find that the Sustained Release Patents and the '062 patent both use "core" in the same way (and thus, presumably, that the IR microparticles are the

core of the CR pellets as core is defined by the SR patents). D.I. 462 at 5-6. Jazz contends that the plain and ordinary meaning of "core" applies to both patents as neither party has sought claim construction for that term in the SR patents. *Id.* Thus, as Avadel has not argued that the '062 patent lexicographically defined "core," Jazz contends that the Court should give "core" its plain and ordinary meaning in the '062 patent as well. *Id.*

However, the Court does not find Jazz's argument persuasive because constructions need not be consistent across patents. *See Trustees of Columbia Univ. in City of New York v. Symantec Corp.*, 811 F.3d 1359, 1369 (Fed. Cir. 2016). Further, the '062 patent uses "core" to refer to both the IR microparticles and the MCC spheres. *See* '062 patent, Example 1. Thus, even were the Court to assume that "core"—as defined by the SR patents—refers to the IR microparticles, the Court would decline to ascribe the same meaning to "core" in the '062 patent because the '062 patent uses the term to refer to both the IR microparticles and the MCC spheres. *Id.* The Court sees no basis on which it could find at this time that only one use of "core" in the '062 patent comports with the term's plain and ordinary meaning as that term is used in the '062 patent.

Accordingly, the Court finds that there is a genuine dispute of material fact regarding whether the core of the CR pellets are IR pellets (which contain GHB) or MCC spheres (which do not contain GHB). Thus, the Court denies Jazz's motion for partial summary judgment that LUMRYZ's core comprises GHB.

ii. The Court Denies Jazz's Motion for Partial Summary Judgment No. 2.

Jazz asks the Court to enter partial summary judgment in its favor and find that Avadel has presented no evidence of obviousness under the correct legal standard regarding the '782 patent. *See* D.I. 285 at 1-5. Alternatively, Jazz asks the Court to judicially estop Avadel from arguing that

the asserted claim of the '782 patent is invalid as obvious. *See id.* at 5-8. For the reasons stated below, the Court denies Jazz's motion.

Jazz's motion is effectively a motion to exclude Dr. Klibanov's expert opinions regarding obviousness. *See id.* Thus, because Jazz contends that Avadel has no other evidence of obviousness, Jazz asks the Court to grant its motion for partial summary judgment against Avadel's obviousness defense as well. *Id.* Avadel's counsel asked Dr. Klibanov to assume, for the purpose of his obviousness analysis, that the asserted claim of the '782 patent possessed adequate written description support and was enabled. *Id.* at 2. Jazz contends that Dr. Klibanov's assumption renders his opinions inadmissible because that assumption requires a person of ordinary skill in the art to review and consider the '782 patent. *Id.* at 3-5; *see Procter & Gamble Co. v. Paragon Trade Brands, Inc.*, 989 F. Supp. 547, 592 (D. Del. 1997) ("[O]bviousness cannot be founded on knowledge or teaching provided by the patentee's invention itself."). Conversely, Avadel contends that Dr. Klibanov properly (1) considered Jazz's admissions about the level of detail that a person of ordinary skill in the art would require to believe that the inventors of the '782 patent were in possession of the claimed invention and (2) applied that same level of detail in his consideration of the disclosures in the prior art. D.I. 309 at 14.

The Court finds that Dr. Klibanov's testimony is sufficiently reliable. One of the factors that the Court considers when determining if a patent is invalid for obviousness is the level of ordinary skill in the art at the time of the invention. *Procter & Gamble Co. v. Paragon Trade Brands, Inc.*, 989 F. Supp. 547, 588 (D. Del. 1997). While the relevant period of time is "the time of the invention," the Court is unaware of any authority that prevents the fact-finder from relying on evidence that *post-dates* the invention in its determination of the level of ordinary skill in the art *at the time* of the invention. *See, e.g., OrthoPediatrics Corp. v. Wishbone Med., Inc.*, 2022 WL

4978169, at *3 (N.D. Ind. Oct. 4, 2022) (noting that "[b]oth parties relied on expert opinions in arguing for their POSITA definition" and that "the Court can rely on those expert opinions"). Moreover, to determine the level of ordinary skill in the art, courts consider evidence that is contemporaneous with the patent whose validity is being challenged. *See, e.g., Daiichi Sankyo Co., Ltd. v. Apotex, Inc.*, 501 F.3d 1254, 1256-1257 (Fed. Cir. 2007) (considering the "art involved in the [] patent" and the "problem the invention of the [] patent" was trying to solve in its determination of the level of ordinary skill in the art at the time of the invention). Further, the language the inventors of the '782 patent chose to use (and the level of detail the inventors thought necessary) to describe the asserted claim, is relevant to, at least, the "sophistication of the technology" and the "educational level of active workers in the field." *See id.* Thus, the Court is not convinced that Dr. Klibanov's review of the '782 patent and his assumption that the specification described, and informed a person of ordinary skill in the art how to 'make and use,' the invention renders his opinions unreliable. Accordingly, the Court finds that Dr. Klibanov's opinions regarding obviousness are sufficiently reliable.

Jazz also seeks to exclude Dr. Klibanov's opinions on obviousness under the doctrine of judicial estoppel. D.I. 285 at 5-8. Dr. Klibanov opined that February 18, 2016 is the effective filing date of the '782 patent. D.I. 352 at 3. Avadel's patents have a later-effective filing date of July 22, 2016. *Id.* Avadel alleges that Jazz "cop[ied] Avadel's patent claims into its own patents." *Id.* As a result, Jazz contends that—if Dr. Klibanov's obviousness opinions render Jazz's patent obvious those opinions must necessarily render Avadel's patents obvious as well. *Id.* Accordingly, because Avadel successfully argued to the PTO that its patents are not obvious, Jazz contends that Avadel is estopped from asserting a contradictory theory in this case. *Id.*; *see New Hampshire v. Maine*, 532 U.S. 742, 749 (2001) ("[W]here 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."). Specifically, Jazz points to statements Avadel made to the PTO contending that the prior art does not disclose a formulation with a "viscosifying agent" and an "acid" where those components are "separate and distinct" from immediate and delayed-release compounds elements i.e., the limitations of the asserted claim of the '782 patent. D.I. 285 at 7; *see* '782 patent claim 14.

In response, Avadel contends that the language Jazz quotes from *New Hampshire* was dicta and did not establish an "exhaustive formula for determining the applicability of judicial estoppel." D.I. 309 at 17 (quoting *New Hampshire*, 532 U.S. 742 at 749). Thus, Avadel argues that the proper test is the test established by the Third Circuit in *Dam Things from Denmark v. Russ Berrie & Co., Inc.*, namely:

> (1) [T]he 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

290 F.3d 548, 559 (3d Cir. 2002). The Court finds that it need not determine which test controls because the doctrine of judicial estoppel does not preclude Avadel from offering its position on obviousness under either test. Dr. Klibanov's opinions on obviousness are contingent on Jazz's position regarding the level of detail necessary to teach the contents of the '782 patent. *See* D.I. 309 at 18. Thus, Avadel's position is based on the level of ordinary skill in the art necessary to interpret Jazz's patent not Avadel's. *See id.* Accordingly, the Court finds that Avadel's position is not "contrary" to the position it argued at the PTO because the PTO considered the validity of Avadel's patents based on how a person of ordinary skill in the art would interpret Avadel's patent.

As a result, given that Dr. Klibanov's opinions on obviousness are sufficiently reliable and that Avadel is not estopped from arguing that the asserted claim of the '782 patent is invalid as obvious, the Court denies Jazz's motion for partial summary judgment no. 2.

iii. The Court Denies Avadel's Motion for Partial Summary Judgment No. 1.

Avadel asks the Court to enter partial summary judgment in its favor and find that the Sustained Release Patents (which include the asserted '488 patent) are invalid. *See* D.I. 407 at 1-2. Avadel contends that the SR Patents lack sufficient written description because the SR Specifications, while broad, lack "blaze marks" leading to the specific claimed formulations. *Id.* Avadel also argues that the SR Patents lack written description support because the SR Specifications do not disclose a formulation that meets both the MAMM structural limitations and the GHB release profile functional limitations. *Id.* Thus, Avadel contends that the SR Specifications do not disclose a representative number of species within the claimed sub-genus. *Id.* For the reasons stated below, the Court denies Avadel's motion.

A. The Court Finds That There is a Genuine Dispute of Material Fact Regarding Whether the SR Specification Possesses Sufficient "Blaze Marks" Leading a Person of Ordinary Skill in the Art to the Claimed Formulations.

The claims of the SR Patents recite a "sustained release portion" that "comprises a functional coating and a core." D.I. 407 at 6-7. The functional coating "comprises one or more methacrylic acid-methyl methacrylate co-polymers ("MAMM") that are from about 20% to about 50% by weight of the functional coating." *Id.* The SR Specifications disclose that these claimed formulations include a drug-containing core and a functional coating. *Id.* at 5-6. The core can also include the active ingredient, along with excipients "such as binders, fillers, diluents, disintegrants, colorants, buffering agents, coatings, surfactants, wetting agents, lubricants, glidants, or other suitable excipients." *Id.* The functional coating surrounding the drug-containing

core can include "one or more" base polymers, pore formers, plasticizers, and/or anti-tack agents. *Id.*

MAMM, an enteric pore-former, is an excipient that can be included in the functional coating. *Id.* Pore formers "can be selected to modify the permeability of the coating composition provided over the CR core" and the "amount and nature" of the pore former "can be adjusted to obtain desired release rate characteristics for a given drug substance". *See, e.g.*, '956 patent at 13:23-26, 13:44-50. The SR Specifications further explain that "incorporating enteric components in the film may result in delivery characteristics that exhibit some level of sensitivity to gastric and intestinal transit times." *Id.* at 13:41-43.

Further, the "integrated dosage form" can be formulated such that the "controlled release formulation" either (A) "begins release of drug substantially simultaneously with delivery of the drug from the [immediate release] component" or (B) "exhibits a start-up time lag." *Id.* at 18:50-56. A start-up lag can be imparted to the controlled release formulation through inclusion of either an enteric coating or an enteric pore-former. *Id.* at 18-59:67. However, enteric coatings limit the start-up lag to "gastric residence and its associated variability" and enteric pore-formers result in embodiments that are "more sensitive to food effects and gastric motility." *Id.*

Avadel argues that the SR Specifications lack "blaze marks" that guide attention to the claimed MAMM copolymers. D.I. 407 at 4. Stated another way, Avadel contends that a person of ordinary skill in the art would not have a reason to select the claimed MAMM copolymers from the "multitude of other potential excipients in the claimed formulation." *Id.* at 8. In support, Avadel notes that pore formers are merely an optional class of excipients described in the SR Specifications. *Id.* at 8-9. Moreover, the SR Specifications recite four (4) categories of pore formers, list multiple examples of specific pore formers within each category, and do not express

a preference for a specific category of pore former. *Id.* Indeed, Avadel contends that the SR Specifications in fact counsel *against* selection of an enteric pore-former because the SR Specifications explain that "enteric components in the firm may result in delivery characteristics that exhibit some level of sensitivity to gastric and intestinal transit times." *Id.*

Jazz responds that the SR Specifications direct a person of ordinary skill in the art to use polymers to control the release profile of a drug. D.I. 416 at 2. Jazz contends that the claimed invention is a "sustained release" formulation where a "functional coating" over a core works to deliver a sustained release of the drug within that core. *Id.* Jazz further argues that the SR Specifications focus on the polymers to describe the inventive functional coating used to control the release of GHB. Therein, the SR Specifications state that the "functional coating compositions" "may include one or more base polymer and at least one pore-former" and include examples of "sustained release formulations" that use polymeric functional coatings, including those with pore formers. *Id.* Accordingly, Jazz argues that the SR Specifications disclose the inventive feature of the claims—namely, "the use of a polymeric functional coating, and in particular pore formers within that coating." *Id.* at 4.

In addition, Jazz argues that MAMM copolymers are part of a limited universe that the SR Specifications teach to use to achieve a pH-sensitive start-up lag time. *Id.* at 4-5. The SR Specifications state that a controlled release formulation can be formulated to have a start-up lag time and that the start-up lag time will be more-or-less pH sensitive based on what excipients are used to achieve that start-up lag time. *See, e.g.*, '956 patent at 19:3-7. Three (3) enteric materials impart a start-up lag time that is more sensitive to pH: cellulose acetate phthalate, polyvinyl acetate phthalate, and MAMM co-polymers. D.I. 416 at 5. Thus, Jazz contends that the SR Specifications

direct a person of ordinary skill in the art who "desires" a formulation with a pH-sensitive start-up lag time to use one of those three (3) options (including the claimed MAMM copolymers). *Id.*

The Court finds that there is a genuine dispute of material fact regarding whether the SR Specifications provide adequate written description support for the claimed polymers. Viewing the facts in the light most favorable to Jazz, the SR Specifications direct a person of ordinary skill in the art to select an enteric pore-former (of which MAMM is one) when that person desires a pH sensitive time lag. *See id.* at 4-5. However, the specification does not explain why a person of ordinary skill in the art would want a start-up time lag. *See, e.g., generally*, '956 patent. Indeed, Jazz's expert, Dr. Moreton, conceded that the specification does not direct a person of ordinary skill in the art to a formulation with any lag time. D.I. 473 at 4-5. Accordingly, Avadel contends that there are no "blaze marks" directing a person of ordinary skill in the art to formulations with a pH sensitive start-up lag time in the first instance.

But, Dr. Moreton stated that the "clinical development side of things" could provide a reason for why a person of ordinary skill in the art would desire a lag time. *Id.* Thus, there is at least some evidence that the desirability of a pH-sensitive start-up time lag was well-known in the art as of the filing date of the SR Applications. Accordingly, the Court finds that Dr. Moreton's statement sufficiently establishes a genuine dispute of material fact regarding whether the specification provides a person of ordinary skill in the art with sufficient blaze marks to pursue formulations with a pH sensitive start-up lag time. "Because the specification is viewed from the perspective of one of skill, in some circumstances, a patentee may rely on information that is "well-known in the art" for purposes of meeting the written description requirement." *Boston Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353,1366 (Fed. Cir. 2011). Accordingly, the Federal Circuit, in *Falkner v. Inglis*, held that a disclosure in an application of vaccinia, a type of poxvirus, provided

sufficient written description for a claim requiring that a mutation in the vaccinia was to an "essential gene." 448 F.3d 1357, 1367–66 (Fed. Cir. 2006). In *Rivera v. Int'l Trade Comm'n*, the Federal Circuit explained that while "the patent [at issue in *Falkner*] did not teach the gene sequence of the essential gene," the specification provided adequate written description support "because the sequence of the essential gene was well-known in the art." 857 F.3d 1315, 1322 (Fed. Cir. 2017).

Similarly, the SR Specifications may provide adequate written description support for the claimed MAMM polymers if a person of ordinary skill in the art would know why a start up lag time is desirable. *See id.* Dr. Moreton testified that the "clinical development side of things" informs a person of ordinary skill in the art as to the desirability of a start-up lag time. D.I. 473 at 4-5. Accordingly, the Court finds that there is a genuine dispute of material fact regarding whether the specification provides a person of ordinary skill in the art with a blaze mark to pursue formulations with a pH-sensitive start-up lag time.

Avadel's expert, Dr. Charman's, opinion that the SR Specification "teach[es] away from the use of enteric polymers" because it "highlight[s] the downside of using enteric polymers" does not compel a different result. D.I. 416 at 8-9. Dr. Moreton opined that a person of ordinary skill in the art would not see the SR Specifications as having any "warning or 'caution' against using [MAMM] copolymers" and testified that "if you want a lag time, [MAMM] is the way to go." *Id.* Accordingly, Avadel's motion merely presents a battle of the experts that is not amenable to resolution on a motion for summary judgment. *See Transcenic, Inc. v. Google, Inc.*, No. 11-582, 2014 WL 7275835, at *2 (D. Del. Dec. 22, 2014).

Thus, viewing the facts in the light most favorable to Jazz, the Court credits Dr. Moreton's testimony and finds that a person of ordinary skill in the art would know why a formulation with

a pH-sensitive start-up time lag is desirable. As a result, the Court must then consider whether there is a genuine issue of material fact regarding whether the SR Specifications provide blaze marks directing a person of ordinary skill in the art to select the claimed MAMM co-polymers. The Court finds that there is.

The SR Specifications direct a person of ordinary skill in the art who desires a formulation with a start-up lag time that is more sensitive to pH to select an "enteric component" or an "enteric pore former." *See, e.g.*, '956 patent at 18:59-19:3. The SR Specifications disclose only four (4) such enterics –cellulose acetate phthalate, polyvinyl acetate phthalate, and the claimed MAMM co-polymers. *Id.* at 13:35-41. Thus, the Court finds that a reasonable factfinder could find that the SR Specifications provide sufficient blaze marks directing a person of ordinary skill in the art to select the claimed MAMM. *See Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1069 (Fed. Cir. 2020) (affirming a district court's finding that a priority application for the patents-in-suit disclosed possession of the claimed invention where the specification identified four preferred fusion proteins, including the claimed fusion protein, and provided the steps required to make those fusion proteins).

B. The Court Finds that There is a Genuine Dispute of Material Fact Regarding Whether the Specification Discloses Structural Features Sufficient to "Visualize or Recognize" the Claimed Formulations.

Avadel contends that the functional limitations of the claims of the SR Patents lack written description support because the claims recite formulations with specific GHB release profiles under particular *in vitro* testing conditions but the SR Specifications do not disclose any examples of formulations that meet the MAMM copolymer limitation and exhibit the claimed release profiles. D.I. 473 at 8-10.

Jazz responds that the SR Specifications include sufficient data to inform a person of ordinary skill in the art that the claimed release profiles could be achieved by using water-soluble pore-formers, including the claimed MAMM copolymers. D.I. 416 at 11-14. The pore former used in Examples 1-3 of the SR Specifications is hydroxypropyl cellulose. *Id.* at 5. Hydroxypropyl cellulose and MAMM co-polymers are both water-soluble pore formers. *Id.* Jazz's expert, Dr. Moreton, opined that a person of ordinary skill in the art would expect a MAMM co-polymer to behave similarly to the hydroxypropyl cellulose coating described in Example 2 of the SR Specifications, with the only exception being that the MAMM formulation would include a start-up lag. *Id.* at 5-6.

The Court finds that there is a genuine dispute of material fact regarding whether the SR Specifications disclose sufficient structural features common to the claimed formulations such that a person of ordinary skill in the art could 'visualize or recognize' the members of the genus. Jazz has introduced evidence from which a reasonable juror could find that the Examples in the SR Specifications provide support for the dissolution release profiles. *See* D.I. 416. Further, Jazz has also introduced evidence from which a reasonable juror could find that non-enteric water-soluble polymers function in the same manner as enteric polymers for purposes of the claimed release profiles. *Id.* Thus, Dr. Moreton's opinion that a person of ordinary skill in the art could 'visualize or recognize' the claimed formulations based on (1) the SR Specifications' description of formulations that meet the claimed release profile through use of non-enteric water-soluble pore-formers and (2) a person of ordinary skill in the art's knowledge that enteric pore-formers behave in a similar fashion to non-enteric pore-formers "at least raises a genuine issue of material fact." *See id.*; *10x Genomics, Inc. v. NanoString Techs., Inc.*, 2023 WL 5805585, at *6 (D. Del. Sept. 7, 2023) (citing *Vasudevan Software, Inc. v. MicroStrategy, Inc.*, 782 F.3d 671, 683 (Fed. Cir. 2015).

Accordingly, given that there is a genuine dispute of material fact regarding whether the SR Specifications provide sufficient written description for the claims of the SR patents, the Court denies Avadel's motion for summary judgment.

iv. The Court Denies Avadel's Motion for Partial Summary Judgment No. 2.

Avadel asks the Court to enter partial summary judgement in its favor, and find that the asserted claim of the '782 patent is invalid for lack of enablement. *See* D.I. 297 at 14. For the reasons stated below, the Court denies Avadel's motion.

The asserted claim of the '782 patent is directed to a formulation that provides modified release of oxybate. *See* '782 patent claim 14. Claim 14 recites, *inter alia*, a formulation comprising "immediate" and "modified" "release particles" that comprise GHB, along with a separate "viscosity enhancing agent" and an "acid." *Id.* The Court construed "modified release particles" and gave that term its plain and ordinary meaning, namely "particles containing an active pharmaceutical ingredient with a release profile that is different from that of an immediate release particle." *See* D.I. 151. The Court further construed "modified release particles" to include both resinate and non-resinate compositions. *Id.*

Avadel contends that the specification of the '782 patent fails to teach a person of ordinary skill in the art how to make and use both resinate and non resinate embodiments of the claimed invention. *See* D.I. 297 at 15. Specifically, Avadel contends that "modified release particles" encompasses an extensive array of formulations and that a person of ordinary skill in the art would need to perform undue testing to determine whether an oxybate formulation exhibits a "modified release." *Id.*

The Court agrees with Avadel that claim 14 of the '782 patent is broad and covers a variety of formulations. *See id.* at 17. Specifically, the "modified release particle" limitation has a

structural requirement (the "active pharmaceutical ingredient") and a functional requirement (the "release profile that is different from that of an immediate release particle"). *See* '782 patent at claim 14. The functional requirement encompasses a broad number of formulations because the only requirement imposed by that limitation is that the release profile be "different" from the release profile of an immediate release particle. *Id.*; *see* D.I. 151 at 12-13; *Perring B.V. v. Mylan Pharms., Inc.*, C.A. No. 13-5909, 2014 WL 6676670, at *3 (E.D. Pa. Nov. 25, 2014) (concluding that the "plain meaning of the phrase 'modified release material' as used in the asserted claims means 'a material that modifies the release of the active pharmaceutical ingredient.'").

Accordingly, the Court agrees with Avadel that the asserted claim of the '782 patent is similar to the claims-at-issue in *Amgen Inc. v. Sanofi*, 143 S. Ct. 1243, 1256 (2023). In *Amgen*, the plaintiff sought "to monopolize an entire class of things defined by their function," namely "every antibody that both binds to particular areas of the sweet spot of PCSK9 and blocks PCSK9 from binding to LDL receptors." *Id.* Similarly, the asserted claim of the '782 patent seeks "to monopolize an entire class of things defined by their function"—namely every material that modifies the release of the active pharmaceutical ingredient recited by the structural requirement, i.e., GHB. *See* '782 patent claim 14. Thus, the functional requirement of the asserted claim's "modified release particle" limitation covers the full "genus" of materials that modify the release of an active pharmaceutical ingredient. *See id.*

As a result, this case is distinguishable from *Janssen Pharm., Inc. v. Mylan Labs. Ltd.* and *Orexo AB v. Sun Pharm. Indus. Ltd.* The claims-at-issue in *Janssen and Orexo* were directed to compositions of a specific drug with defined structural features. *See Orexo AB v. Sun Pharm. Indus. Ltd.*, 2023 WL 4492095, *24 (D.N.J. June 30, 2023) ("This case involves a patent for a single composition of an opioid dependence drug, not an entire "genus" ... Orexo's invention is a

narrow composition covering a sublingual tablet containing separate microparticles of buprenorphine and weak acid."); *Janssen Pharm., Inc. v. Mylan Labs. Ltd.*, 2023 WL 3605733, *36 (D.N.J. May 23, 2023) (explaining that the claimed prodrugs-at-issue were not "unduly broad, because a POSA would understand the '693 Patent to limit [] formulations to the specific ingredients, concentrations, and particle sizes (or ranges) in the Patent").

However, the breadth of the asserted claim of the '782 patent does not mean that the claim necessarily fails for lack of enablement. A patent need not describe with particularity how to make and use every single embodiment within a claimed class. *Amgen*, 143 S. Ct. 1243 at 1254. Instead, examples disclosing "some general quality running through the class that gives it a peculiar fitness for the particular purpose" may be sufficient to enable a person skilled in the art to make and use all of what is claimed. *Id.*

The functional requirement of the asserted claim of the '782 patent recites a "release profile" that is "different" from that of an "immediate release particle." *See* D.I. 151; '782 patent claim 14. Unlike the Sustained Release Patents, which recite, *inter alia*, formulations with specific GHB release profiles under particular *in vitro* testing conditions, the '782 patent requires only that the release profile be "different" from the immediate release profile. *Compare*, *e.g.*, '488 patent claim 11 ("[T]he sustained release portion releases about 10% or less of its gamma-hydroxybutyrate by about 1 hour when tested in a dissolution apparatus 2 in deionized water at a temperature of 37° C and a paddle speed of 50 rpm.") *with* '782 patent claim 14. Indeed, Dr. Little opined that the inventive concept of the '782 patent does not focus on modifying oxybate release rates but, instead, focuses on the administrability of the modified release oxybate through the use of a specific dosing form. In support, Dr. Little explained that the asserted claim of the '782 patent separately recites a "viscosity enhancing agent" and an "acid" and that those limitations allowed

Jazz to overcome prior-art administrability issues with modified release oxybate dosage forms. *See* D.I. 310 at 4-5. Thus, the Court finds that the '782 patent enables the asserted claim if the '782 patent teaches a person of ordinary skill in the art how to "modify" the release profile of both resinate and non-resinate compositions that contain an active pharmaceutical ingredient (i.e., GHB). *See* D.I. 151; '782 patent claim 14.

The Court addresses resinate and non-resinate-based formulations in turn and finds that there is a genuine dispute of material fact with respect to enablement for each formulation.

The specification raises a genuine issue of material fact with respect to whether the '782 patent enables resinate modified release particles. *See* '782 patent 15:27-30 ("The sustained release profiles of drug can be obtained by using a mix of uncoated and semipermeable coated resinates and by selecting the degree of cross-linking and particle size of the resins without a coating process"). The specification explains that "the release of GHB can be tailored by changing the bead size and/or degree of crosslinking of the beads to provide additional resistance to diffusion" and that increased bead size, increased crosslinking, or both, would decrease the rate at which GHB releases. *Id.* at 17:50-65. The Court finds this discussion in the specification of the '782 patent is sufficient to show that the parties genuinely dispute whether the '782 patent identifies a "general quality" running through the class of substances used to modify the release of GHB that gives those substances "a peculiar fitness for the particular purpose [of modifying GHB's release]." *See Amgen*, 143 S. Ct. 1243 at 1254.

The parties also genuinely dispute whether the '782 patent enables *non-resinate* modified release particles. Dr. Moreton, Jazz's expert on validity, opined that the Sustained Release Patents—which are prior art to the '782 patent and pre-date the '782 patent by five (5) years explain how to overcome the difficulties attendant to modifying the release of oxybate. *See* D.I.

310 at 3-4. Dr. Little opined that the specification of the '782 patent incorporates by reference U.S. Patent Publication No. 2012/0078865 ("Allphin") and that Allphin discloses non-resinate multi-particulate formulations of oxybate. *See id.* at 11. Dr. Little also explained that the '782 patent itself (without reference to Allphin) discloses the use of non-resinate microparticles. *Id.* Discussed, *infra* at § 2(ix), the Court finds Dr. Little's opinions on those issues reliable. Thus, a reasonable juror could credit Dr. Little's opinions and find that how to 'make and use' non-resinate oxybate formulations was incorporated by reference into the '782 patent, well-known in the art, or both. *See id.* Accordingly, the Court finds that there is a genuine dispute of material fact regarding whether the '782 patent enables non-resinate oxybate formulations.

The parties' dispute regarding the amount of testing necessary to determine whether a given formulation exhibits a modified release profile does not compel a different result. Jazz contends that the testing necessary, if any, to determine whether a formulation exhibits modified release is "common" formulation work. *Id.* at 8-10. Avadel disagrees, and contends instead that the asserted claim is not enabled because "trial-and-error experimentation" is necessary to determine whether any given formulation falls within the scope of the claim. D.I. 297 at 24-26; *see Baxalta Inc. v. Genentech, Inc.*, 81 F.4th 1362, 1367 (Fed. Cir. 2023) ("Under *Amgen*, such random trial-and-error discovery, without more, constitutes unreasonable experimentation that falls outside the bounds required by § 112(a).") (citing 143 S.Ct. at 1243).

The Court, however, finds that *Baxalta* and *Amgen* are distinguishable. In those cases, the patent lacked any disclosures that would allow an "a skilled artisan to predict which antibodies [would] perform the claimed functions" and merely guided a person of skill in the art to "create a wide range of candidate antibodies and then screen each to see which happen to bind." *Baxalta Inc. v. Genentech, Inc.*, 81 F.4th 1362, 1366-1367 (Fed. Cir. 2023) (citing *Amgen*, 143 S.Ct. at

1243). Conversely, the Court has found that there is a genuine issue of material fact regarding whether the '782 patent identifies a "general quality" that runs through the class of substances that the '782 patent identifies as modifiers of oxybate-release. *See supra*. Thus, a person of ordinary skill in the art may be able to predict what substances modify the release of oxybate if the '782 patent identifies such a "general quality" common to those substances. Accordingly, the parties' dispute merely presents a battle of the experts that is not amenable to resolution on a motion for summary judgment. *See Transcenic*, 2014 WL 7275835 at *2. As a result, the Court denies Avadel's motion for partial summary judgment no. 2 of lack of enablement.

v. The Court Denies Jazz's Motion to Exclude the Expert Testimony of Dr. Cory Berkland and Dr. Robert Langer and Jazz's Motion to Exclude the Expert Testimony of Dr. Bruce Corser.

Avadel has confirmed that it does not plan to introduce any expert testimony that is the subject of Jazz's *Daubert* motions regarding Dr. Cory Berkland, Dr. Robert Langer and Dr. Bruce Corser. D.I. 537. Thus, the parties agree that Jazz's motions to exclude the testimony of those witnesses is moot. *Id.* Accordingly, the Court denies-as-moot Jazz's motions.

vi. The Court Grants-In-Part and Denies-In-Part Jazz's Motion to Exclude the Expert Testimony of Mr. Alexander Klibanov and Mr. Carlo Giovanni Traverso.

Jazz asks the Court to exclude certain expert opinions of Mr. Klibanov and Mr. Traverso that relate to the testing of LUMRYZ's release profile in buffered simulated intestinal fluid. *See* D.I. 390. For the reasons stated below, the Court grants-in-part and denies-in-part Jazz's motion.

The claims of the Sustained Release Patents are directed to, *inter alia*, formulations containing a "sustained release portion." *See, e.g.*, '956 patent claim 1. The parties dispute how to determine whether this limitation is met. *See* D.I. 390; D.I. 418. The Court previously construed "sustained release portion" to have its "[p]lain and ordinary meaning, i.e., the portion

of the formulation that is not immediate release and that releases over a period of time." D.I. 229 at 4-9.

Jazz contends that the "period of time" implicit in the Court's construction requires that the sustained release portion "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 at a temperature of 37 C and a paddle speed of 50 rpm" (the "Claimed Release Profile"). D.I. 390 at 1-2. Avadel contends that Jazz is improperly reading into the "sustained release portion" limitation a separate limitation of the claims of the SR Patents. D.I. 418 at 37-38, 41-43. Stated another way, Avadel argues that a "sustained release portion" is "the portion of the formulation that is not immediate release and that releases over a period of time" and that, separately, a sustained release portion infringes only if, *inter alia*, it also meets the Claimed Release Profile limitation. *Id.* Accordingly, Avadel contends that the Court's construction does not specify what media a person of ordinary skill in the art must use to determine whether the sustained release portion "releases [its GHB] over time." *Id.* Thus, Avadel argues that a person of ordinary skill in the art would use simulated intestinal media because such media mimics physiological conditions. *Id.* Indeed, Avadel's experts opined that [redacted]. *Id.* at 43-44.

The Court previously explained that the period of time implicit in Jazz's proposed construction (which the Court adopted) is not "unbounded" because the "relevant time period is expressly set forth in the claims." D.I. 229 at 6. The Court also explained that the Claimed Release Profile defines the period of time over which a sustained release portion releases its GHB. *Id.* Accordingly, the Court construed "sustained release portion" as "[p]lain and ordinary

meaning, i.e., the portion of the formulation that is not immediate release and that releases over a period of time." *Id.* at 4. Stated another way, the Court's construction was equivalent to "[p]lain and ordinary meaning, i.e., the portion of the formulation that is not immediate release and that 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]."[3] *See id.* at 4-9.

The Court is not convinced that the "sustained release" limitation is a separate and distinct limitation from the Claimed Release Profile. Avadel contends that the claims of the SR Patents' use of "and" between those two (2) requirements renders them separate limitations. D.I. 418 at 40. However, the Court instead agrees with Jazz that there are two necessary requirements for the "sustained release portion" limitation one structural and the other functional. D.I. 461 at 4-5. Structurally, the "sustained release portion" must comprise a "functional coating" deposited over a "core." *See id.* Functionally, the "sustained release portion" must possess the Claimed Release Profile. *See id.* Thus, the use of "and" ties together the structural and functional requirements of the "sustained release profile." *See id.*

Accordingly, the Court grants Jazz's motion to the extent that Jazz seeks to exclude testimony by Avadel's experts that the proper testing medium to determine whether a formulation meets the "sustained release profile" limitation is buffered simulated intestinal fluid. *See* D.I. 390. However, Avadel's experts also opined that D.I. water does not possess a uniform pH and that [redacted] *See* D.I. 418 at 42. The Court does not find, at this time,

[3] Nothing in this Opinion should be construed as altering the Court's prior construction of "sustained release portion" or as a construction of a term that the Court did not construe in its November 18, 2022 Opinion and Order regarding claim construction. *See* D.I. 229; D.I. 230.

that those opinions are the result of an improper application of the Court's claim construction. Thus, the Court declines to exclude those opinions and denies-in-part Jazz's motion accordingly.

vii. The Court Denies Avadel's Motion to Exclude the Expert Testimony of Dr. Mark Rainey.

Avadel asks the court to exclude certain expert opinion of Jazz's damages expert, Dr. Mark Rainey. *See* D.I. 407 at 32. For the reasons stated below, the Court denies Avadel's motion.

Jazz seeks to introduce Dr. Rainey's opinion on a reasonable royalty for the '079 patent based on a hypothetical negotiation between the parties. *Id.* at 32-33. [redacted] *Id.* Avadel objects to the [redacted] royalty rates and contends that those royalty rates are based on a coercive hypothetical negotiation wherein Jazz threatens to exclude Avadel's product from the market if Avadel does not meet Jazz's demands. *Id.* at 33-35.

The Court disagrees with Avadel's characterization of Dr. Rainey's opinions. Dr. Rainey opined that [redacted] D.I. 473 at 19. Thus, Dr. Rainey explains, [redacted] *Id.* [redacted] *Id.* Accordingly, Dr. Rainey opined that [redacted] *Id.* Using that framework, Dr. Rainey then explained that [redacted]

[redacted] for the months of May 2023 and June 2023 i.e., the months after LUMRYZ received final FDA approval on May 1, 2023. *Id.*

The Court finds that Dr. Rainey's opinions do not reflect a coercive hypothetical negotiation wherein Jazz acts as a unwilling licensor. The law does not require that a hypothetical licensor make a profit under the hypothetical negotiation. *TRUSTID, Inc. v. Next Caller Inc.*, 2020 WL 5016924, at *3 (D. Del. Apr. 21, 2020) ("[A]n infringer's net profit margin is not the ceiling by which a reasonable royalty rate is capped."); *Monsanto Co. v. Ralph*, 382 F.3d 1374, 1384 (Fed. Cir. 2004) ("[A]lthough an infringer's anticipated profit from use of the patented invention is among the factors to be considered in determining a reasonable royalty, the law does not require that an infringer be permitted to make a profit.") (internal citation omitted). Thus, Dr. Rainey's opinion that Avadel would benefit from a deal where its profit is at least zero is not *prima facie* unreasonable or contrary to law. *See id.*; D.I. 473 at 19. Further, the Court finds that Dr. Rainey reasonably opined on the value Avadel would assign to Jazz's patented technology considering "the benefits it would expect to receive from using the technology" and the "alternatives that it might have pursued." *Carnegie Mellon Univ. v. Marvell Tech. Group, Ltd.*, 807 F.3d 1283, 1304 (Fed. Cir. 2015). Specifically, Dr. Rainey opined that [redacted] *See* D.I. 425 at 4; *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1135 (Fed. Cir. 2015) ("[I]f avoiding the patent would be difficult, expensive, and time-consuming, the amount the infringer would be willing to pay for a license is likely to be greater.") [redacted]

[redacted] *Id.*; *see Monsanto Co.*, 382 F.3d at 1385.

Avadel also argues that Dr. Rainey did not assume that Jazz would act as an unwilling licensor at the hypothetical negotiation because he stated that "Jazz would not have been a willing licensor unless it earned a royalty rate sufficient to recoup the value of what was taken due to Avadel's use of the Patents-in-Suit." D.I. 473 at 19. The Court does not find that this statement shows that Dr. Rainey assumed Jazz would be an unwilling licensor. Rather, the Court finds that statement stands merely for the unremarkable proposition that Dr. Rainey's opinion is that Jazz would not agree to a royalty rate that was "[in]sufficient to recoup the value of what was taken due to Avadel's use of the Patents-in-Suit." *See Asetek Danmark A/S v. CMI USA Inc.*, 852 F.3d 1352, 1362-1363 (Fed. Cir. 2017) ("[A] patent owner would be unlikely to be interested in accepting a royalty rate lower than its profit margin on the patented products.") (internal citations omitted).

The parties dispute only whether Dr. Rainey's [redacted] royalty rates were based on a coercive hypothetical negotiation. *See* D.I. 407 at 33. Thus, giving that Dr. Rainey's analysis was not based on a coercive hypothetical negotiation, the Court denies Avadel's motion.

viii. The Court Denies Avadel's Motion to Exclude the Expert Testimony of Dr. Cristian Moreton.

Avadel seeks to exclude Dr. Christian Moreton's opinions on written description support for the claims of the Sustained Release Patents. D.I. 407 at 35. Avadel contends that Dr. Moreton improperly relied on the claims of the SR Patents for written description support because those claims post-date the priority date of the SR Patents. *Id.* at 35-37.

Jazz filed the '369 application (to which the Sustained Release Patents claim priority) on March 24, 2011, but ultimately abandoned that application. *Id.* After the publication of Avadel's

'062 patent application on January 25, 2018 (Pub No. 2018/0021284 A1), Jazz filed U.S. Application No. 16/025,487 on July 2, 2018. *Id.* Subsequently, Jazz cancelled all of its original claims of the '369 application and replaced the original claims with different claims. *Id.* Avadel contends that Dr. Moreton impermissibly considered the later-added issued claims as support for his written description analysis because those claims did not exist as of the date of the invention. *Id.*; *see Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1329 (Fed. Cir. 2000).

The relevant portion of Dr. Moreton's expert report states:

> Dr. Charman's position appears to overlook a key aspect of the claims and the teachings of the Sustained Release Specification, and one that greatly supports the disclosure of microparticles. In particular, each of Sustained Release Asserted Claims requires not only the functional coating to which Dr. Charman refers (see, e.g., Charman at ¶¶ 203-204), but also that the functional coating is in the sustained release portion of the formulation with a core, and deposited over that core. See, e.g., Ex. 5, '488 patent at Claim 1. In my opinion, the claimed core requirement, along with the teachings in the Sustained Release Specification, would clearly convey to a POSA that the inventors had arrived at the film coatings described therein, and that such film coatings could be applicable in a variety of formulations.

D.I. 433 at A2252, ¶ 44. In response to Avadel's argument that Dr. Moreton relied on the claims for written description support, Jazz contends that Dr. Moreton merely referred to the claims to "define the invention" and, subsequently, looked to the specification to see if sufficient support was present for the defined invention. D.I. 427 at 3. Stated another way, Jazz contends Dr. Moreton relied on the claims to "define the invention" but found "the support for the invention . . . in the specification as filed." *Id.* (citing *Purdue Pharma*, 230 F.3d at 1329).

The Court finds that Dr. Moreton's statement that "[T]he claimed core requirement, along with the teachings in the Sustained Release Specification, would clearly convey to a POSA that the inventors had arrived at the film coatings described therein" could fairly be interpreted in accordance with either of the parties' positions. *See* D.I. 433 at A2252, ¶ 44.

Accordingly, the Court declines to strike it at this time. The Court cautions the parties, however, that it will not permit Dr. Moreton to testify that the later-added claims provide written description support for the SR patents. *See Purdue Pharma*, 230 F.3d at 1329. Thus, the Court denies-as-premature Jazz's motion, but notes that Jazz may re-raise its objection at trial if Dr. Moreton testifies that the claims provide written description support.

ix. The Court Denies Avadel's Motion to Exclude the Expert Testimony of Dr. Steven Little.

Avadel asks the Court to exclude certain expert testimony from Dr. Steven Little regarding whether the '079 patent enables non-resinate oxybate formulations. D.I. 407 at 37-38. Avadel contends that Dr. Little offered only a single paragraph of opinion on this issue and that within that paragraph—Dr. Little offered but a single conclusory sentence laying out his analysis. *Id.* at 39. For the reasons stated below, the Court denies Avadel's motion.

Jazz contends that Dr. Little provided a detailed analysis of whether the '079 patent enables non-resinate oxybate formulations. D.I. 430 at 1. In support, Jazz points to sections of Dr. Little's report wherein Dr. Little responded to Dr. Charman's written description opinions and concluded that the '079 patent contains adequate written description for non-resinate forms. *Id.* Avadel contends that Dr. Little's written description opinions do not support his enablement opinion because the written description opinions are based on a prior art disclosure. D.I. 473 at 23-24. Thus, Avadel argues that Dr. Little cannot rely on those opinions to show that the '079 patent enables non-resinate oxybate formulations because prior art, by definition, cannot enable an invention's novel aspects. D.I. 470; see *Creative Kingdoms, LLC v. ITC*, 588 Fed. App'x. 993, 995 (Fed. Cir. 2014). Avadel also argues that Dr. Charman's opinions on written description cannot render his opinions on enablement reliable because the written description requirement is

different from the enablement requirement. D.I. 473 at 23-24; *see Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1340 (Fed. Cir. 2010) (en banc).

Conversely, Jazz contends that the formulation of non-resinate oxybate was known in the art and that the novel portion of the '079 patent is its teachings regarding the administrability of oxybate formulations through use of a claimed sachet. D.I. 430 at 4-5. Accordingly, Jazz argues that Dr. Little properly considered the prior art (and thus, his written description opinions) in forming his opinions on enablement because prior art can enable the non-novel aspects of the '079 patent – namely, the use of non-resinate oxybate. *Id.*

The Court finds that Dr. Little's opinions on written enablement are sufficient to render reliable Dr. Little's opinions on enablement. The enablement requirement asks whether "the specification teach[es] those in the art to make and use the invention without undue experimentation." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Dr. Little, in his opinions on written description, provided support for his opinions that the '079 patent discloses how to 'make and use' non-resinate oxybate formulations. In Dr. Little's discussion of written description, Dr. Little concluded that the '079 specification describes both non-resinate and resinate formulations. *See* D.I. 433 at A2508. In support, Dr. Little, *inter alia*, explained that he disagrees with Dr. Charman's opinion that the specification of the '079 patent disparages non-resinate forms of controlled release (such as enteric forms). *See id.* at A2509-A2510. Dr. Little explains that Dr. Charman's opinion on disparagement was based on the specification's discussion of the buffering effect of GHB. *See id.* at A2513. Contrary to Dr. Charman, Dr. Little concluded that the buffering effect of GHB would not direct a person of ordinary skill in the art

away from using enteric-coated microparticles because other disclosures in the '079 patent teach the use of an acid to further control the release of GHB. *See id.*

Dr. Little reached that conclusion by, *inter alia*, considering "background information on GHB and its method of manufacture," including the patent publication Allphin. *See id.* at A2510-A2511. Dr. Little found that Allphin was incorporated by reference into the '079 patent for its discussion of how to make and use film-coated formulations of GHB, including non-resinate compositions. *See id.* at A2515-A2517. Dr. Little also explained that he agrees with, and relied upon, Dr. Moreton's discussion of Allphin. *Id.* Dr. Moreton's expert report discusses Allphin and provides support for Dr. Moreton's opinion that a person of ordinary skill in the art could make and use the non-resinate formulations of GHB described therein. *See id.* at A2252-A2256, A2260.

Accordingly, the Court finds that Dr. Little discussed why, and how, he reached his conclusion that the claimed non-resinate formulations are enabled by the '079 patent. Thus, the Court disagrees with Avadel's position that Dr. Little's opinions were merely conclusory. As a result, the Court finds that Avadel's objections go to the weight of Dr. Little's testimony, not its admissibility, and denies Avadel's motion.

III. CONCLUSION

For the foregoing reasons, this 13th day of February, **IT IS HEREBY ORDERED** as follows:

1. Jazz's Motion for Partial Summary Judgment No. 1. is **DENIED**. *See* D.I. 282.
2. Jazz's Motion for Partial Summary Judgment No. 2. is **DENIED**. *See* D.I. 284.
3. Jazz's Motion for Partial Summary Judgment No. 3 is **DENIED-AS-MOOT**. *See* D.I. 423.
4. Jazz's Motion for Partial Summary Judgment No. 4 is **DENIED-AS-MOOT**. *See id.*
5. Avadel's Motion for Partial Summary Judgment No. 1. is **DENIED**. *See* D.I. 288.

6. Avadel's Motion for Partial Summary Judgment No. 2. is **DENIED**. *See id.*
7. Jazz's Motion to Exclude the Expert Testimony of Dr. Cory Berkland and Dr. Robert Langer is **DENIED-AS-MOOT**. *See* D.I. 276.
8. Jazz's Motion to Exclude the Expert Testimony of Dr. Bruce Corser is **DENIED-AS-MOOT**. *See* D.I. 280.
9. Jazz's Motion to Exclude the Expert Testimony of Mr. Alexander Klibanov and Mr. Carlo Giovanni Traverso is **GRANTED-IN-PART** and **DENIED-IN-PART**. *See* D.I. 278.
10. Avadel's Motion to Exclude the Expert Testimony of Dr. Mark Rainey is **DENIED**. *See* D.I. 288.
11. Avadel's Motion to Exclude the Expert Testimony of Dr. Cristian Moreton is **DENIED-AS-PREMATURE**. *Id.*
12. Avadel's Motion to Exclude the Expert Testimony of Dr. Steven Little is **DENIED**. *Id.*

Date: February 14, 2024

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE