IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	**REDACTED PUBLIC VERISON** **FILED DECEMBER 19, 2023** 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]

BRIEF IN SUPPORT OF DEFENDANT'S
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I. INTRODUCTION

In these actions, Plaintiff Jazz Pharmaceuticals, Inc. ("Plaintiff" or "Jazz") asserts six patents across two families against Defendant Avadel CNS Pharmaceuticals, LLC's ("Defendant" or "Avadel") game-changing, once-nightly LUMRYZ™ sodium oxybate-containing drug product. For the reasons set forth below, none of Jazz's claims warrant a trial, as this case can be disposed of entirely on summary judgment. Moreover, Jazz cannot carry its burden to establish that certain of its experts' opinions are admissible.

First, although Jazz lays claim to the world when it comes to oxybate, it is now clear—after extensive fact and expert discovery—that Jazz's patent claims are invalid. Specifically, the claims of four of six of the patents[1] (the "Sustained Release Patents") lack sufficient written description demonstrating Jazz possessed the *claimed invention*; the very broad, generic disclosure in the specification lacks the requisite "blaze marks" to the very the specific formulation components that are required by the claims. That is undisputed, and it is fatal under controlling Federal Circuit precedent.

Second, the remaining two patents (the "'079/782 Patents") suffer from a different but equally fatal defect: they do not enable a person of skill in the art to practice the full scope of their claims. Jazz successfully argued at *Markman* for a broad interpretation of these claims to encompass both resinate and non-resinate formulations. Having gotten its wish, Jazz must now contend with the fact that there are no enabling disclosures teaching a POSA how to practice the full scope of the claims. It is undisputed that the '079/782 Patents provide a POSA with nothing more than a roadmap to conduct trial and error testing to see if they can practice the claimed invention, particularly with regard to non-resinate formulations. That is the antithesis of

[1] U.S. Patent Nos. 10,758,488; 10,813,885; 10,959,956; and 10,966,931.

enablement. Jazz tries to fill the gap with *ipse dixit* expert testimony, but that is insufficient to create a genuine issue of material fact.

Third, although the Court likely need not reach the infringement question due to the invalidity of all asserted claims, Avadel is entitled to summary judgment of no infringement should the pending claim construction dispute regarding "gamma hydroxybutyrate" be resolved in its favor. Jazz has admitted as much with regard to the '079/782 Patents, and the Sustained Release Patents fare no better because each of the asserted claims require the release of something not found in the accused LUMRYZ™ product.

Finally, although not necessary for the grant of summary judgment, in the unlikely event that this case proceeds to trial, Avadel respectfully submits that Jazz has failed to carry its burden of establishing the admissibility of certain opinions of its experts, Dr. Mark Rainey, Dr. Christian Moreton, and Dr. Steven Little. As set forth below, certain opinions of each of those experts fail the *Daubert* gate-keeping standard and should never be presented a jury.

For the reasons set forth herein, Avadel respectfully requests summary judgment in its favor, and that Jazz's improper expert opinions be excluded from trial.

II. STANDARDS

A. 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 non-moving 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 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)."

B. *Daubert*

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 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 trial court is tasked with ensuring that an expert's testimony "both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993). The Third Circuit has explained that, "[b]y means of a so-called '*Daubert* hearing,' the district court acts as a gatekeeper, preventing opinion testimony that does not meet the requirements of qualification, reliability and fit from reaching the jury." *APEX Fin. Options v. Gilbertson*, Civil Action 19-046-WCB-SRF, 4 (D. Del. Jan. 31, 2022) citing to *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404-05 (3d Cir. 2003).

AVADEL'S SUMMARY JUDGMENT MOTIONS

III. AVADEL'S SUMMARY JUDGMENT MOTION NO. 1 – INVALIDITY OF ASSERTED CLAIMS OF SUSTAINED RELEASE PATENTS FOR LACK OF WRITTEN DESCRIPTION

The asserted claims of Jazz's Sustained Release Patents are invalid for lack of written description for two independent reasons. *First,* the specification, as drafted in 2011, lists many dozens of potential ingredients, which can be combined in many dozens of ways, to make an unfathomably large number of potential formulations. It includes examples of particular formulations. Over 7 years later, Jazz submitted claims that were specifically tailored to try to cover the Avadel product. Those new claims do not cover any of the examples in the patent specification. Instead, they pick out one ingredient used in the Avadel formulation—methacrylic acid-methyl-methacrylate—and call out the inclusion of that particular ingredient as a feature of Jazz's invention. In that circumstance, where a patentee initially files a broad disclosure and later tries to get narrower claims, the specification must include "blaze marks" leading a POSA to the narrowed claims. Jazz's specification lacks those blaze marks, and thus the Court should grant summary judgment for lack of written description.

Second, each of the asserted claims requires a certain release profile for gamma hydroxybutyrate, i.e., the release of specific amounts of gamma hydroxybutyrate by certain times. The specification, however, does not disclose a representative number of species within the claimed sub-genus of formulations that provide the desired release profile, nor does it disclose "structural features," i.e., formulation excipients, common to the claimed sub-genus of formulations. Thus, summary judgment for lack of written description is also warranted under *Ariad* and its progeny.

A. Factual Background

1. The specification's enormous genus of potential formulations

The specification of the Sustained Release Patents discloses that the formulations at issue (which are described as being tablets) include a drug-containing core and a functional coating. (SMF ¶ A-5). Within these basic structural limits, however, the specification discloses a vast universe of possible formulations.

As to the core, the specification discloses that it may include the active ingredient. (SMF ¶ A-5) (Moreton Dep. Tr. 67:6-13 ("[T]he only thing it says [] is that the core includes at least one drug substance.")). But the core can also include things "such as binders, fillers, diluents, disintegrants, colorants, buffering agents, coatings, surfactants, wetting agents, lubricants, glidants, or other suitable excipients." (*Id.*)

Looking at just one category of excipients—binders—the specification provides 22 options. (SMF ¶ A-6). The specification does not state any preference for any one of those binders over any other. (*Id.*). And Jazz's expert asserts that the list in the specification is not even limiting, so it poses no restrictions at all on what the binder might be. (*Id.*). Moreover, whether to use a binder in the first place is optional. (*Id.*). If a binder is used, it can be from 1 to 10% of the total weight of the core. (SMF ¶ A-7). And more than one binder may be used in combination with another. (SMF ¶ A-6).

Similarly, the specification lists 12 potential lubricants (which is to say essentially all of those approved for pharmaceutical use). (SMF ¶ A-8). Again, the inclusion of a lubricant is optional and there is no preference expressed for any one lubricant over another. (*Id.*). The specification goes on to list various surfactants, fillers, and other materials, any of which can be included (or not included) in the core. (SMF ¶ A-9). Beyond the formulations set forth in the examples, none of which correspond to the claimed formulations, Jazz has identified nothing in

the specification that would indicate a preference for any particular excipients, combination of excipients, or quantity of excipients.

As to the functional coating surrounding the drug-containing core, it may include one or more base polymers, one or more pore formers, one or more plasticizers, and/or one or more anti-tack agents. (SMF ¶ A-10). For each of these four categories of excipients, the specification provides a laundry list of options. (*Id.*). Again, the text of the specification does not express a preference for any of them. (*Id.*). While some of the examples do describe formulations including a functional coating, none of the examples describe a formulation with a coating as claimed. (SMF ¶ A-11).

The specification does not place any limitations on the polymers that could be used as part of a functional coating. (SMF ¶ A-12). Indeed, when Jazz's expert was asked "do you understand there to be any restrictions that are being placed in the specification of the '488 patent on the polymers that could be included within a functional coat?" he answered "no, only that they must be approved for . . . pharmaceutical use." (SMF ¶ A-13). Nor does it place any limitation on the amount of base polymer that may be present. (SMF ¶ A-12). The specification describes the pore former as optional and, if used, expresses no preference for the use of anything in particular as a pore former. (*Id.*). In fact, Jazz's expert testified that in its description of the functional coating, the specification was merely "listing different materials that can be used, no preference." (*Id.*).

2. Jazz claimed a specific sub-genus of formulations with specific release characteristics after reviewing Avadel's published claims

The issued claims of the Sustained Release Patents are directed to a sub-genus of the wide array of potential sustained release formulations described in the specification. All require, *inter alia*:

- A sustained release portion, including a core and functional coating;

- A core containing at least one pharmaceutically active ingredient selected from gamma-hydroxybutyrate and pharmaceutically acceptable salts of gamma-hydroxybutyrate;

- A functional coating including one or more methacrylic acid-methyl methacrylate (MAMM) co-polymers that are about 20-50% by weight of the functional coating;

- Certain release profiles for gamma-hydroxybutyrate under particular conditions; and

- Certain *in vitro* testing conditions, including testing in deionized water using USP apparatus 2.

Many of these claim limitations did not appear in the original claims of the priority patent application for the Sustained Release Patents, U.S. Patent Application No. 13,071,369, filed on March 24, 2011. (SMF ¶ A-14). Of the 108 claims filed alongside the '369 Application, not a single one mentions methacrylic acid-methyl methacrylate (MAMM), USP apparatus 2, or deionized water. (*Id.*). Indeed, from March 2011 to July 2018, Jazz pursued claims directed to "*controlled* release" formulations, none of which made mention of any enteric pore formers (of which MAMM is one) or any *in vitro* testing conditions whatsoever. (SMF ¶ A-15). In July 2018, however, Jazz abandoned its pending claims and introduced a new set of claims requiring "one or more methacrylic acid-methyl methacrylate co-polymers that are from about 20% to about 50% by weight of the functional coating," and certain dissolution characteristics measured using USP apparatus 2. (SMF ¶ A-16). Both of these requirements are present in the specification and claims of Avadel's '284 application, which published in January 2018. (SMF ¶ A-17). [redacted]

[2] In March 2020, Jazz further modified the claims to replace "controlled release" with "sustained release," which Jazz argued made its invention "distinct from the delayed release formulations of Liang." (SMF ¶ A-18).

B. Argument

1. The specification lacks sufficient blaze marks

"Evaluating whether the written description requirement is satisfied involves an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. For genus claims, which are present here, [the Federal Circuit has] looked for blaze marks within the disclosure that guide attention to the claimed species or subgenus." *Regents of the Univ. of Minn. v. Gilead Scis., Inc.*, 61 F.4th 1350, 1356 (Fed. Cir. 2023) (quotation and citation omitted).

There is no dispute that the specification of the Sustained Release Patents discloses laundry lists of potential core and functional coating excipients that can be combined in various ways and amounts to create a large genus of potential formulations. (SMF ¶¶ A-5 – A-12). But the claims are directed to a specific sub-genus of formulations, with no guidance provided in the specification of how to identify the specifically claimed trees from the forest of possibilities set forth in the specification.

In particular, a POSA reading the as-filed specification would have no reason to select the claimed 20-50% MAMM copolymers from the multitude of other potential excipients in the claimed formulation. (SMF ¶ A-19). The claimed MAMM co-polymers are mentioned by name once in the specification as one of numerous potential "pore formers"—an optional class of materials which the specification explains can be used to modify the permeability of the base polymer. (*Id.*). The as-filed specification lists four categories of pore formers and several, non-limiting examples of such pore formers within each category:

1. Polymeric pore formers, "such as hydroxyalkyl cellulose, hydroxypropyl methylcellulose, hydroxypropyl cellulose, polyethylene glycols, polyvinyl alcohol, povidone, copovidone, and poloxamers, such as 188 or 407."

2. Small-molecule pore formers, "such as water soluble sugar or organic acid, including, for example, citric acid or sorbitol," as well as "a pharmaceutically acceptable salt of GHB."

3. Expanding/swelling pore formers, which "comprise a polymer that expands in the presence of the drug" included in the core, and may include a "suitable carbomer."

4. Enteric components, which may be used as "part or all of the pore former in the composition," including "cellulose acetate phthalate, methacrylic acid-methyl methacrylate copolymers, and polyvinyl acetate phthalate."

(SMF ¶ A-19).

As these disclosures show, MAMM is one potential pore former disclosed, but it is only one of many, even within the "enteric component" category. (*Id.*). The specification also discloses that cellulose acetate phthalate and polyvinyl acetate phthalate may be used. (*Id.*). And Dr. Moreton testified that there are another two enteric coating polymers not mentioned in the specification. (*Id.*). The specification states that the use of enteric components is "possible," but then goes on to caution that incorporating any "enteric components in the firm may result in delivery characteristics that exhibit some level of sensitivity to gastric and intestinal transit times." (*Id.*). And more generally, Jazz's expert confirm that there is nothing "in the specification that directs the person of skill in the art to use one pore former versus another." (SMF ¶ A-20). Indeed, the use of *any* pore former is entirely optional (*id.*), and of the 13 working examples provided, *none* contain any enteric pore former, much less MAMM. (SMF ¶ A-10).

In such circumstances, where the specification discloses laundry lists of excipients, but does not provide blaze marks to steer the POSA toward the claimed combination, the Federal Circuit and courts in this District have held the claims must be found to be invalid for lack of written description.

In a recent decision, for instance, the Federal Circuit considered a set of claims directed to a genus of chemical compounds. *Gilead*, 61 F.4th at 1353. There was no dispute that the

specification provided a literal disclosure of each limitation of the claims-at-issue. *Id.* at 1357. To arrive at the claimed sub-genus, however, required making a particular series of selections from the many options presented in the specification. *Id.* "Following this maze-like path, each step providing multiple alternative paths, is not a written description of what might have been described if each of the optional steps had been set forth as the only option." *Id.* The Court ultimately concluded that "the structures here are so extensive and varied that that the structures of [the disclosure], which through its multiple dependencies, encompasses a significantly larger genus than is claimed . . . are not sufficiently common to that of claim 1 of the '830 patent to provide written description support." *Id.* at 1358.

In another Federal Circuit decision, *Purdue Pharma L.P. v. Iancu*, the Court invalidated a patent claiming a formulation comprising two particular gelling agents, PEO and HPMC. 767 F. App'x 918, 920 (Fed. Cir. 2019). While the specification disclosed both recited gelling agents, they were "merely two of many undifferentiated compounds that fall within the genus of gelling agents" and the specification "fail[ed] to highlight any preference for how many and which gelling agents to combine." *Id.* at 924. Similarly, in *Fujikawa v. Wattanasin*, the Court considered a specification that disclosed a large genus of chemical compounds defined by a core chemical structure with various combinations of chemical groups appended to the core structure. 93 F.3d 1559, 1570 (Fed. Cir. 1996). The specification provided a number of options for each possible chemical group, some of which were "preferred," whereas the challenged claim was to a subgenus that included chemical groups that were disclosed, but not "preferred." *Id.* at 1570-71. Because the specification did not express any preference or "special interest" in the claimed subgenus, the Federal Circuit affirmed the PTAB's determination that the claim lacked written description support. *Id.* at 1571. And in *FWP IP ApS v. Biogen MA, Inc.*, the Federal Circuit affirmed the

PTAB's determination that a claim added to cover a competitor's product which recited a method of treating multiple sclerosis by administering one of two specific fumarate compounds at a specific dosage of 480 mg per day lacked adequate written description support where the specification simply listed 20 different diseases and conditions, an entire class of active pharmaceutical compounds (fumarates), and a long list of possible dosages. 749 F. App'x 969, 971, 974 (Fed. Cir. 2018).

Jazz's Sustained Release Patents fail this blaze marks requirement. Jazz claimed specific formulations in later-added claims, but the specification does not direct the POSA to those specific formulations. Instead, the specification lists formulation ingredients, like MAMM co-polymers in a laundry list of potential, *and entirely optional*, excipients, that may or may not be combined with one another in the claimed fashion. As Jazz's expert confirmed, nothing in the specification would direct a POSA towards using MAMM as opposed to any other coating material, nor does it even direct a POSA to the use of a pore former. (SMF ¶ A-20).

Thus, a POSA would search Jazz's Sustained Release patent specifications "in vain for the disclosure of even a single species that falls within the claims or for any 'blaze marks' that would lead an ordinarily skilled investigator toward such a species among a slew of competing possibilities." *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013) (quoting *In re Ruschig*, 379 F.2d 990, 995 (C.C.P.A. 1967)). It is not enough for Jazz's specification to provide "formal textual support for each individual limitation recited in the claims." *Id.* The claims are still invalid for lack of written description support, because the specification "nowhere describes the actual functioning [] variant[] that those limitations together define." *Id.*

2. The specification fails to sufficiently describe the functional requirements of the asserted claims of the sustained release patents

The asserted claims of Sustained Release Patents are also invalid for lack of written description because their functional limitations—how gamma hydroxybutyrate must release—lack written description support. For genus claims with such functional language, "a sufficient description of a genus . . . requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010). Jazz's Sustained Release Patents do neither.

First, as discussed above, none of the exemplary formulations include a MAMM co-polymer as required by the claims. (SMF ¶ A-11). Thus, there can be no dispute that the specification does not disclose a representative number of species that exhibit the claimed release profile, because *no* such species are disclosed. *See Allergan USA, Inc. v. MSN Lab'ys Priv. Ltd.*, No. CV 19-1727-RGA, 2023 WL 6295496, at *16 (D. Del. Sept. 27, 2023) (finding no written description when the specification only disclosed formulations using certain excipients, including fillers and disintegrants, but failed to "inform a POSA what structural or chemical properties permits excipients to be viable fillers or disintegrants, let alone a viable combination of the two.").

Second, the specification does not describe any structural features of a formulation (i.e., specific excipients) sufficient to "visualize or recognize" all formulations within the scope of the asserted claims, because there is no description of any formulation that comprises the claimed amount of MAMM *and* that exhibits the claimed release profile. (SMF ¶ A-21).

The Federal Circuit's decision in *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc.* is instructive. There, the Federal Circuit considered a claim directed to the treatment of hepatitis C

by administering an "effective amount" of a compound with a particular structure. 941 F.3d 1149, 1164 (Fed. Cir. 2019), *cert. denied*, 141 S. Ct. 1234 (2021). There was no dispute that multiple compounds fell within the scope of the claims and that the specification provided eighteen formulas it described as "principal embodiments" effective at treating hepatitis C. *Id.* The Federal Circuit concluded that while the specification provided adequate written description for the ***compounds*** within the claimed formula, it "provide[d] no method of distinguishing effective from ineffective compounds." *Id.*

Judge Bryson, sitting by designation in this District, reached a similar conclusion in *Lopocine Inc. v. Clarus Therapeutics, Inc.*, 541 F. Supp. 3d 435 (D. Del. 2021). That case involved a claim that, as in *Idenix*, had both a structural component (the inclusion of a solubilizer and dispersant) and a functional component (providing a particular level of testosterone in the body). *Id.* at 466. Judge Bryson determined that the specification failed to adequately support these claims, concluding that:

> The underlying problem with the claims that require different combinations of excipients is that there is no basis from which to conclude that the functional limitations of any of those claims will be satisfied, except with respect to the few specific formulations that were the subjects of the clinical tests and simulations reported in the Data Examples.

Id. at 467.

The formulations claimed in the Sustained Release Patent suffer from a similar flaw. Even if the formulations were sufficiently described (they are not for the reasons discussed above), the specification does not explain which formulations within the scope of the claims will also satisfy the claimed release profiles. As Jazz's expert confirms, the specification places few restrictions on what can be included in the claimed formulations in addition to the claimed excipients. (SMF ¶ A-10). While certain examples are disclosed that exhibit the claimed release profile, none of

these examples used a formulation that included the claimed MAMM co-polymer (SMF ¶ A-11), nor does the specification explain what excipients should be included or omitted from the formulation to achieve the claimed release profiles. (SMF ¶ A-21).

Thus, as in *Idenix* and *Lipocine*, the POSA considering Jazz's Sustained Release Patents "is deprived of any meaningful guidance into what compounds beyond the examples and formulas, if any, would provide the same result." *Idenix*, 941 F.3d at 1164. The asserted claims of the Sustained Release Patents are invalid for lack of written description for this additional reason.

IV. AVADEL'S SUMMARY JUDGMENT MOTION NO. 2 – INVALIDITY OF ASSERTED CLAIMS FOR LACK OF ENABLEMENT

The asserted claims of the '079 and '782 patents are directed to formulations that provide controlled/modified release of oxybate. During claim construction, Jazz argued that the claimed dosage forms were not limited to formulations that rely on the use of ion-exchange resins ("or resinates") to control the release of oxybate. Instead, Jazz argued—successfully—that the claims should be broadly construed to encompass all types of controlled and modified release oxybate dosage forms. But as the Supreme Court emphasized in *Amgen Inc. v. Sanofi*, "[t]he more one claims, the more one must enable." 598 U.S. 594, 610 (2023) (citations omitted). As a result, Jazz sought "broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage." *MagSil Corp. v. Hitachi Glob. Storage Techs., Inc.*, 687 F.3d 1377, 1381 (Fed. Cir. 2012).

The Supreme Court in *Amgen* and the Federal Circuit in *Baxalta Inc. v. Genentech, Inc.* recently found claims invalid for lack of enablement as a matter of law. 598 U.S. 594 (2023); 81 F.4th 1362 (Fed. Cir. 2023). In both cases, the courts found that a POSA would have to engage in experimentation in order to identify the particular compounds of the invention. The same is true here. The specification of Jazz's patents focuses on how to make oxybate-loaded ion-exchange

resins. And, when Jazz filed the application that led to the '079 and '782 patents, it pursued claims directed specifically to resinate dosage forms. After learning of Avadel's once-nightly program and its success, Jazz abruptly changed course and began pursuing much broader claims. Jazz's patent specification, however, barely mentions "conventional," i.e., non-resinate forms of controlling oxybate release, and what little is there disparages such approaches and expressly cautions that "the high solubility and mobility of GHB would tend to *significantly reduce* the number of viable approaches using such conventional solubility and diffusivity control technologies." '079 patent at 5:54-60.[3]

Nothing in the specification teaches how to overcome those problems. As a result, Jazz is left to rely on the ability of a POSA to engage in iterative testing to identify formulations that might work. That is legally impermissible. Enablement requires more than an instruction that leaves to the POSA to engage in "random trial-and-error discovery." *Amgen*, 598 U.S. at 615. That is particularly true where, as here, it is undisputed that the compound at issue is particularly difficult to formulate and a POSA would have to test hundreds of thousands of formulations to figure out which ones might work.

Jazz's patents must enable the full scope of what has been claimed. *MagSil*, 687 F.3d at 1381. For the reasons discussed below, the undisputed factual record demonstrates that the specification of the '079 and '782 patents fails to teach a POSA how to make and use at least non-resinate embodiments of the claimed invention, and accordingly fails to enable the full scope of the claims.[4] *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1378 (Fed. Cir. 2007) (finding

[3] Emphasis added unless otherwise noted.

[4] To be clear, Avadel also believes that the specification of the '079 and '782 patents fails to enable the full scope of GHB resinate-based formulations.

claims invalid for lack of enablement for failing to enable syringes both with and without pressure jackets, consistent with the full scope of the claims).

If Jazz wanted to obtain a monopoly over an entire class of controlled/modified-release oxybate formulations, it was required to instruct a POSA how to make the full array of those formulations. Such is the *quid pro quo* of the patent system. It did not, and the Asserted Claims should accordingly be found invalid for lack of enablement.

A. Legal Standard

The enablement requirement of 35 U.S.C. § 112(a) mandates that the patent specification disclose the "manner and process of making and using [an invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use [it]." This reflects the fundamental bargain of patent law: the monopoly afforded by "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable." *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997).

The Supreme Court has affirmed that to satisfy the enablement requirement "the specification must enable the *full scope* of the invention as defined by its claims." *Amgen*, 598 U.S. at 610. Thus, where a patent claims "an entire class" of compositions or formulations, "the patent's specification must enable a person skilled in the art to make and use the entire class." *Id*. Further, disclosing a possible approach to discovering embodiments within the scope of the claimed invention is not enough: "random trial-and-error discovery, without more, constitutes unreasonable experimentation that falls outside the bounds required by § 112(a)." *Baxalta*, 81 F.4th at 1366 (citing *Amgen Inc. v. Sanofi*, 598 U.S. 594, 613–15).

Although the enablement requirement does not demand that that specification disclose what is well known in the art, "that rule is not a substitute for a basic enabling disclosure." *Enzo*

Life Scis., Inc. v. Roche Molecular Sys., Inc., 928 F.3d 1340, 1346 (Fed. Cir. 2019). A patentee "cannot simply rely on the knowledge of a person of ordinary skill to serve as a substitute for [] missing information in the specification." *ALZA Corp. v. Andrx Pharms., LLC*, 603 F.3d 935, 941 (Fed. Cir. 2010). Importantly, the *specification*, "not the knowledge of one skilled in the art, [] must supply the novel aspects of an invention." *Creative Kingdoms, LLC v. ITC*, 588 Fed. App'x. 993, 995 (Fed. Cir. 2014) (citations omitted).

B. Argument

The specification of the '079 and '782 patents do not enable a POSA to make and use the extensive array of formulations that are encompassed by the claimed "controlled release component" and "modified release particles."

It is undisputed that formulation science is generally unpredictable. (SMF ¶ B-1). Moreover, Jazz's experts agree that oxybate is a particularly challenging drug to formulate for controlled release. (SMF ¶ B-2) ("[B]ecause oxybate is a difficult drug to work with, the complexities associated with formulating oxybate into a finished dosage form only increase."); (SMF ¶ B-3) (acknowledging that a POSA at the time of the invention "would have found the creation of a controlled release GHB formulation to be both a complicated and unpredictable endeavor").[5] The specification likewise emphasizes that the inherent unpredictability of formulation science is magnified by various attributes of GHB:

> The solubility of sodium oxybate is unusually high. For example, a Xyrem solution is provided as 500 mg/mL concentration in water, or 42 wt %, and its solubility limit is considerably higher. Furthermore, due to the small size and ionic nature of GHB at physiological pH, the drug is unusually mobile in solution. Those skilled in the art will appreciate that these factors complicate and, in many cases, limit conventional approaches for modified

[5] Jazz's expert Dr. Little opines on the validity of the '079 and '782 patents under § 112, and the validity of the Sustained Release patents under §§ 102 and 103. Jazz's expert Dr. Moreton opines on the validity of the Sustained Release patents under § 112.

> release, such as core/shell or matrix formulations, as the high solubility and mobility of GHB would tend to significantly reduce the number of viable approaches using such conventional solubility and diffusivity control technologies.

'079 patent at 5:49-60.

> In addition, the sustained release matrix or coating compositions used to provide extended release are complex and expensive to produce.

Id. at 6:1-4.

Jazz's experts rely on the fact that the specification of the '079 and '782 patents incorporates by reference the specification of the Sustained Release patents, which is part of the prior art. SMF ¶¶ B-4, B-5. But that specification likewise emphasizes the difficulties of utilizing non-resinate technologies to attempt to control the release of sodium oxybate:

> in the context of a controlled release drug formulation produced as a unit dosage form for oral administration, drugs that must be administered at a high dose constrain the amount of rate controlling excipients that can be used in formulating a drug composition that is both capable of sustained delivery of therapeutic doses of the drug and exhibits a size and shape suited to oral administration. Low molecular weight and high-solubility drugs may also readily permeate films and matrices that might otherwise be used to control release, and high solubility drugs are not suited to some drug delivery approaches, particularly where zero-order release kinetics are desired. An example of a drug that is administered at a high dose, has a low molecular weight, and high water solubility, is gamma-hydroxy butyrate (GHB) . . . .

'488 patent at 1:26-40. In addition:

> Controlled release formulations typically require the addition of significant amounts of excipients or rate controlling materials to control the delivery of drug, and the presence and need for such materials often limits the drug loading available for a given controlled release technology. Additionally, low molecular weight drugs, such as GHB, typically exhibit high permeability through films and matrices. Even further, high water solubility increases drug mobility and may *preclude the use of some approaches utilized to achieved a controlled release dosage form*.

Id. at 5:5-15.

Against this complex and unpredictable backdrop, the shared specification of the '079 and '782 patents does not provide any instructions for how a POSA can make non-resinate controlled release oxybate formulations. (SMF ¶¶ B-6, B-7).

1. The asserted claims cover a broad functional genus

The asserted claims of the '079 and '782 Patents recite oxybate formulations that include a "controlled release component," and "modified release particles," respectively. The claimed formulations contain few additional requirements. The '079 patent claims methods of administering an oxybate formulation and require that the formulation be provided in a sachet prior to being added to water for administration. The '782 patent claims require that the formulation contain an acid and viscosity enhancing agent separate from the drug-containing particles. *See, e.g.*, '079 patent, claim 1; '782 patent, claim 1. As a result, the claims are defined primarily by functional requirements—namely, that they provided controlled or modified release of oxybate.

In addition, the '079 patent requires that the formulation be administered as a "single daily dose." To the extent that term means anything, it requires the administration of a single dose that has the requisite effect. That too is a functional limitation, requiring the formulation to have the release characteristics required for it to be administered as a single daily dose.

There is no dispute that the universe of materials that could be used in the claimed controlled/modified release oxybate formulations is extensive, as Dr. Charman opined. (SMF ¶ B-9). Dr. Little, Jazz's formulation expert, did not dispute that the structural requirements recited in the claims—sachet, acid, and viscosity enhancing agent—fail to limit the number or types of materials that could be used in the claimed formulation. (SMF ¶ B-10). And in his report on obviousness, Dr. Little repeatedly acknowledged that there are "far more than a finite number of options" for potential coating materials. (SMF ¶ B-11). Indeed, when asked to assess the breadth

of the possible formulations, Dr. Little admitted that because different percentages of excipients can be used, the number of options "would be infinity." (SMF ¶ B-12).

Jazz's other formulation expert, Dr. Moreton, similarly acknowledged that there are at least *hundreds of thousands* of formulations that could be made just based on the materials listed in the Sustained Release patents specification ("SR specification"). For example, the SR specification explains that functional coatings that can be used to control the release of oxybate from conventional dosage forms can comprise one or more base polymers and one or more "pore formers" that facilitate drug release. '488 patent at 12:40-42. Multiple pore formers and multiple base polymers can be used in combination in the claimed sustained release formulation, along with other excipients, such as plasticizers, fillers, lubricants, and surfactants, that can further impact drug release. '488 patent at 10:56-11:44; 13:48-14:4; (SMF ¶¶ B-14, B-5). Even assuming hypothetically that the universe of functional coatings is limited to those with two base polymers and two pore formers, and only taking into account the materials that Dr. Moreton agreed would be appropriate, a POSA would be facing over 300,000 possible formulations.[6]

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[6] Dr. Moreton explained that there are at least 16 pharmaceutically acceptable base polymers suitable for use in a functional coating: a dozen or more water soluble based polymers, and four to five water insoluble polymers. (SMF ¶¶ B-16, B-17); '488 patent at 12:13-39. In a combination of two base polymers, there are 16 options for the first polymer, and 15 options for the second polymer. Thus, the number of unique combinations of base polymers is 16 multiplied by 15, divided by 2 (to remove duplicates resulting from the same two polymers appearing in a different order), which equals 120. Dr. Moreton also admitted that there are 15 materials that can be used as pore formers in the claimed coating, (SMF ¶¶ B-18, B-19), and agreed that there is nothing in the specification "that expresses a preference for the use of anything in particular as a pore former," (SMF ¶ B-20). If two pore formers are used, there are 15 possible options for the first, 14 possible options for the second, divided by 2 to account for duplicates, which results in 105 possible combinations. Thus, the 120 base polymer combinations multiplied by the 105 pore formers results in 12,600 combinations of base polymers and pore formers. Dr. Moreton also agreed that a POSA would include a pore former as at least 20-50% of the functional coating. (SMF ¶ B-22), '488 Patent at 13:35-47. Using only integer values, there are at least 30 different variations of each pore former/base polymer combination resulting from the different percentages of pore former used.

2. The specification does not teach a POSA how to make and use the full scope of formulations encompassed by the claims

The specification of the '079 and '782 patents explains that the challenging attributes of GHB, discussed above, "complicate, and in many cases limit conventional approaches for modified release, such as core/shell or matrix formulations, as the high solubility and mobility of GHB would tend to significantly reduce the number of viable approaches using such conventional solubility and diffusivity control techniques." '079 patent at 5:54-60. The specification goes on to list numerous problems with known "extended release dosage forms" like those discussed in the Sustained Release patents. *Id*. at 5:61-6:4. It then offers drug-resin complexes as an alternative formulation approach that avoids the limitations with the conventional formulations disclosed in the prior art. *Id*. at 6:12-19.

Nothing in the specification of the '079 and '782 patents itself teaches a POSA how to address the problems it identifies with "conventional," non-resinate formulations or how to make a controlled release GHB formulation using conventional formulation approaches. (SMF ¶¶ B-6, B-7, B-36). Dr. Little concedes this point by relying *exclusively* on the specification's purported incorporation by reference of Allphin 2012—the published application that led to the Sustained Release patents—for the alleged disclosure of "non-resinate multiparticulate formulations of GHB." (SMF ¶¶ B-25, B-26). The only support Dr. Little offers for his opinion that non-resinate forms of controlled and modified release components are enabled is the SR specification, and Dr. Moreton's analysis thereof. *See* (SMF ¶¶ B-24, B-26).

The first problem with Dr. Little's theory is that the prior art cannot cure the deficiencies in the specification. The '079 and '782 patents repeatedly disparage the prior art and assert that

12,600 combinations multiplied by 30 coating weight variations results in at least 378,000 possible combinations of base polymers and pore formers in varying ratios.

the prior art fails to teach how to make controlled release formulations. '079 patent at 5:54-6:4; (SMF ¶ B-33). The Sustained Release patents were filed five years before the asserted priority date of the '079 and '782 patents. *Compare, e.g.*, '488 patent at cover *with* '782 patent at cover. The Sustained Release patents thus form part of the very prior art that the '079 and '782 patents disparage. Their disclosures cannot be both the problem and the solution. That is, it cannot be the case that the very problem that the '079 and '782 patents identified, and set out to solve, had already been solved five years earlier.

Moreover, controlling authority requires that the '079 and '782 patents themselves contain an enabling disclosure—it is not enough simply to gesture at the knowledge of a person of skill in the art. *ALZA Corp. v. Andrx Pharms., LLC*, 603 F.3d 935, 941 (Fed. Cir. 2010); *Creative Kingdoms, LLC v. ITC*, 588 Fed. App'x. 993, 995 (Fed. Cir. 2014). And even if one looks at the substantive teachings of the Sustained Release patents, they merely provide a laundry list of excipients, which Dr. Moreton admits were all known in the art, (SMF ¶ B-27). Notably absent from the SR specification is *any* meaningful guidance as to how those well-known excipients should be combined to achieve the claimed release profile. (SMF ¶¶ B-6, B-7, B-8, B-35). Nor does the SR specification provide any instructions on how to apply its teachings regarding *tablet* dosage forms to *microparticle* dosage forms, which are indisputably within the scope of the '079 and '782 patent claims. (SMF ¶ B-28) ("Q: But again, there's no explicit teaching in the '488 [sustained release] patent that tells a person of ordinary skill in the art how to make the translation from a tablet to a microparticle, right? A: Not in that detail, no."); *see also* (SMF ¶ B-29). Thus, the SR specification provides a POSA with nothing beyond generic statements that a functional coating "may include a polymer or blends of compatible polymers that are water soluble or that are water insoluble and selected to exhibit desired permeability characteristics." '488 patent at

12:13-17. That is nothing more than a statement of a desired functional result, *i.e.*, having a formulation that "exhibit[s the] desired permeability characteristics," without any explanation of how to achieve that result. Indeed, since polymers can *only* be water soluble or water insoluble, stating that the polymers in the functional coating can be "water soluble" or "water insoluble" tells a POSA nothing.

This leaves a POSA seeking to make and use the claimed formulation with no other choice but to engage in a "trial and error" effort to identify formulations with the desired drug release profile. *See* (SMF ¶ B-30) (Dr. Charman opining that "against the backdrop of teachings in the specification that explain why both resinate and non-resinate controlled release formulations face myriad problems and challenges . . . [t]here are no teachings or information in the specification that a POSA could use to achieve the full scope of the claims without undertaking undue and rote trial-and-error experimentation."). Indeed, Dr. Little admits that the way to determine whether a particular formulation creates a desired outcome is to "use an experiment that would show you the release behavior" in the relevant conditions. (SMF ¶ B-31).

The specifications at issue likewise indicate that a POSA must evaluate whether or not a coating mixture will or will not achieve the requisite controlled/modified release empirically. The SR specification states that "[d]rug delivery performance provided by the dosage forms described herein can be evaluated using a standard USP type 2 or USP type 7 dissolution apparatus set to 37° C.±2° C. under the conditions described, for example, in the experimental examples provided herein." '488 patent at 7:64-8:4. The '079 and '782 patents say the same: "[t]he release profile may be assessed using in vitro dissolution assays known to those of skill in the art, e.g., USP apparatus 2 (paddle) or, more preferably, apparatus 4," or by way of "pharmacokinetic studies

using plasma concentrations to assess maximum concentration *(*C_{max}*)* and area under the curve (AUC)." '079 patent at 7:3-8.

In short, a POSA would have to make *and* test individual formulations to determine whether or not they achieve the recited dissolution profile(s). But a teaching of how to test for the claimed dissolution limitations does not teach how to achieve them, (SMF ¶ B-32); '488 patent at 7:64-8:1, as the Supreme Court and Federal Circuit acknowledge, *see disc. infra* at 24-26.

Moreover, with respect to the '079 patent, to the extent that the "single daily dose" is a meaningful claim limitation, nothing in the specification of the '079 patent teaches how to achieve it. A POSA would have to first make the formulation and then test it to see whether it was suitable for that purpose. That would require yet more experimentation.

The Federal Circuit and Supreme Court have made clear that where claims encompass a broad genus of compositions, the need to make and test the thousands of compositions that may fall within the scope of the claims demonstrates lack of enablement as a matter of law.[7] In *Amgen*, the Supreme Court found Amgen's claims directed to antibodies capable of binding PSCK9 invalid for lack of enablement where the specification offered little more than a "roadmap" for how a POSA could engage in experimental testing to identify antibodies with the desired binding characteristics. 598 U.S. at 613-614. Such a "step-by-step" disclosure of a "trial-and-error method" for identifying the claims subject matter did not constitute an enabling disclosure. *Id.* at

[7] The Federal Circuit's decision in *Baxalta Inc. v. Genentech, Inc.* confirms that this issue is appropriate for adjudication on summary judgment. *See* 81 F.4th 1362, 1366–67 (Fed. Cir. 2023) (granting summary judgment of lack of enablement in light of the Supreme Court's decision in *Amgen* finding that "random trial-and-error discovery, without more, constitutes unreasonable experimentation that falls outside the bounds required by § 112(a)"). And the Supreme Court's decision in *Amgen Inc. v. Sanofi* affirmed the district court's grant of judgment as a matter of law of invalidity for lack of enablement after a jury initially found the claims enabled. *See* 598 U.S. 594, at 604, 616 (2023).

614. And in September of this year, the Federal Circuit in *Baxalta* affirmed summary judgment of invalidity for lack of enablement where the claims covered a large class of antibodies defined in functional terms. 81 F.4th at 1366. Relying on the Supreme Court's *Amgen* decision, the Federal Circuit found that an instruction in the specification to create a wide range of formulations and then test each one, without more, "is not enough to enable the broad functional genus at issue." *Id*.; *see also Enzo Life Scis., Inc., v. Roche Molecular Sys*., 928 F.3d 1340, 1348-49 (Fed. Cir. 2019) (finding lack of enablement where "the number of possible polynucleotides that would fit the limitations of claim 1 would be at least tens of thousands" and each "would need to be tested" to determine if it meets the claims).

Here, as in *Amgen* and *Baxalta*, the claims cover a large class of formulations defined by their function. *See supra* at §IV.A. *Amgen*, 598 U.S. at 613; *Baxalta*, 81 F.4th at 1366. And as with the patents in *Amgen* and *Baxalta*, "nothing in the specification teaches how to identify any [formulations] complying with the claim limitations," leaving a POSA to engage in iterative trial and error testing to identify embodiments falling within the scope of the claims. *Baxalta*, 81 F.4th at 1366; *see also Amgen*, 598 U.S. at 615 ("Amgen offers [POSAs] little more than advice to engage in 'trial and error.'"). Thus, a list of potential ingredients, devoid of any instruction of how or whether to combine them to achieve controlled release, cannot provide an enabling disclosure.

Further compounding the lack of guidance found in either specification for non-resinate formulations, the SR specification itself acknowledges that large swaths of non-resinate formulations *will not work* to control release: "low molecular weight drugs, such as GHB, typically exhibit high permeability through films and matrices" and "high water solubility increases drug mobility and may *preclude the use of some approaches utilized to achieved a controlled release*

dosage form." '488 patent at 5:5-15. Dr. Little further concedes that the specification of the '079 and '782 patents is entirely silent on how to discern which approaches will and will not work:

> Q In the context of the sentence that we just read, what does significantly reduce mean to you as a person of skill in this context?
> A That ***it would not allow you to use every formulation strategy*.**
> Q Does the specification of the '079 patent identify which conventional solubility and diffusivity control technologies do not work with gamma-hydroxybutyrate?
> **A** I don't think that it -- if I can remember correctly, ***I don't think that it goes through those specifics*.**

(SMF ¶ B-34). There is no dispute that the only option left to a POSA attempting to practice the full scope of the claimed subject matter would be rote trial-and-error experimentation:

> Q I guess I'm trying to understand how a [POSA] would determine which technologies would and would not work for GHB?
> A So I think, for instance, you could pick a particular class of formulations and you could -- ***you could prepare a formulation and observe*** given the principles of the materials and the methods to see, . . . you could observe it. And then you would get an idea in that category of what the limitations of that particular method would be.

Id. at 72:15-73:2; *see also* (SMF ¶ B-30) (Dr. Charman explaining "against the backdrop of teachings in the specification that explain why both resinate and non-resinate controlled release formulations face myriad problems and challenges . . .[t]here are no teachings or information in the specification that a POSA could use to achieve the full scope of the claims without undertaking undue and rote trial-and-error experimentation.").

C. Conclusion

The claims of the '079 and '782 patents cover a broad class of formulations, but specification offers no specific guidance to the POSA regarding which materials will work to control or modify the release of oxybate. Thus, the POSA has two options: rely on his or her own knowledge, or rely on testing to demonstrate that any particular material could control or modify release of oxybate. But neither the knowledge of a POSA nor reliance on testing the tens of

thousands of compositions encompassed by the claims can supply the requisite teachings to satisfy the enablement requirement. Accordingly, Jazz cannot raise a genuine dispute of material fact in response to Avadel's demonstration that the asserted claims of the '079 and '782 patents are invalid for lack of enablement.

V. AVADEL'S SUMMARY JUDGMENT MOTION NO. 3 – NON-INFRINGEMENT UNDER AVADEL'S PROPOSED CONSTRUCTION OF "GAMMA-HYDROXYBUTYRATE"/"OXYBATE"

A. Every Asserted Claim Requires a Formulation That Comprises or Releases Gamma-Hydroxybutyrate

Jazz has asserted two families of patents, the Sustained Release Patents and the '079/'782 patents. (SMF ¶ C-1). The Asserted Claims of both families relate to either a pharmaceutical formulation or a method of using a pharmaceutical formulation. (SMF ¶ C-2). Representative claims for the Sustained Release, '079, and '782 patents are shown below. There is no dispute that each and every Asserted Claim requires that the formulation comprise, or release, "oxybate"/"gamma-hydroxybutyrate."[8] (SMF ¶ C-3).

1. Exemplary sustained release patent limitations

> 1. A formulation comprising immediate release and sustained release portions, each portion comprising at least one pharmaceutically active ingredient selected from gamma-hydroxybutyrate and pharmaceutically acceptable salts of gamma-hydroxybutyrate, wherein:
>
> a. the sustained release portion comprises a functional coating and a core, wherein the functional coating is deposited over the core, wherein the core ***comprises at least one pharmaceutically active ingredient selected from gamma-hydroxybutyrate and pharmaceutically acceptable salts of gamma-hydroxybutyrate*** wherein the functional coating comprises one or more methacrylic acid-methyl methacrylate co-polymers that are from about 20% to

[8] Consistent with Avadel's position in the pending claim construction briefing, the Asserted Claims use the terms "gamma-hydroxybutyrate" and "oxybate" interchangeably, and the two terms have the same meaning. For clarity, Avadel will use the term "gamma-hydroxybutyrate" throughout this Motion unless referring to the term specifically used in a patent.

about 50% by weight of the functional coating; the sustained release portion comprises about 500 mg to 12 g of at least one pharmaceutically active ingredient selected from gamma-hydroxybutyrate and pharmaceutically acceptable salts of gamma-hydroxybutyrate; ***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;

b. the immediate release portion ***comprises about 75% and about 98% by weight of at least one pharmaceutically active ingredient selected from gamma-hydroxybutyrate and pharmaceutically acceptable salts of gamma-hydroxybutyrate,*** and the amount of gamma-hydroxybutyrate and pharmaceutically acceptable salts of gamma-hydroxybutyrate in the immediate release portion is about 10% to 50% by weight of the gamma-hydroxybutyrate and pharmaceutically acceptable salts of gamma-hydroxybutyrate in the formulation;

c. ***the formulation releases at least about 30% of its gamma-hydroxybutyrate*** by one hour when tested in a dissolution apparatus 2 in deionized water at a temperature of 37° C. and a paddle speed of 50 rpm; and

d. ***the formulation releases greater than about 90% of its gamma-hydroxybutyrate*** by 8 hours when tested in a dissolution apparatus 2 in deionized water at a temperature of 37° C. and a paddle speed of 50 rpm. ’488 patent at claim 1.

2. ’079 patent

1. A method of treating narcolepsy in a patient in need thereof, the method comprising:

administering a single daily dose to the patient, the single daily dose ***comprising an amount of oxybate*** equivalent to from 4.0 g to 12.0 g of sodium oxybate, wherein the administering comprises:

opening a sachet containing a solid oxybate formulation,

mixing the formulation with water, and

orally administering the mixture to the patient, wherein the oxybate formulation comprises an immediate release component and a controlled release component. ’079 patent at claim 1.

3. '782 patent

1. A formulation of gamma-hydroxybutyrate comprising:

a plurality of ***immediate release particles comprising gamma-hydroxybutyrate;***

a plurality of ***modified release particles comprising gamma-hydroxybutyrate;***

a viscosity enhancing agent; and

an acid;

wherein the viscosity enhancing agent and the acid are separate from the immediate release particles and the modified release particles. '782 patent at claim 1.

B. The Parties Agree That Avadel's Product Cannot Contain Gamma-Hydroxybutyrate under Avadel's Proposed Construction

Avadel's Lumryz™ product is a solid dosage form comprising the salt sodium gamma-hydroxybutyrate. (SMF ¶ C-4). Lumryz™ does not—and, as Jazz has insisted, cannot—contain any gamma-hydroxybutyrate anion. (SMF ¶ C-7). Salts are meaningfully different from anions because a salt is a compound formed by the interaction of a cation and an anion, binding their changes together, while anions are negatively charged particles. (SMF ¶ C-8). In a supplemental claim construction proceeding, the parties disputed whether "gamma-hydroxybutyrate" was limited to its anionic (i.e., negatively charged) form, which necessarily excluded sodium gamma-hydroxybutyrate and other salts of gamma-hydroxybutyric acid (as Avadel proposed), or whether it included sodium gamma-hydroxybutyrate (as Jazz proposed). (SMF ¶¶ C-5, C-6). In fact, Jazz took the position that "[b]oth [parties'] experts agree that the unbound anion (i.e., Avadel's proposed construction) ***cannot exist*** as a solid." (SMF ¶ C-7).

C. Jazz Concedes That Avadel Does Not Infringe the '079 and '782 Patents under Avadel's Proposed Construction

As shown above, both the '079 and '782 patents recite solid oral dosage forms that include gamma-hydroxybutyrate as the active ingredient. *See* disc. *supra* at V.A.2, V.A.3. In the event that the Court adopts Avadel's construction, there is no disputed issue of fact as to whether Avadel infringes the Asserted Claims, as LUMRYZ indisputably does not—and cannot—contain the gamma-hydroxybutyrate anion. Jazz has argued that the conjugate base (anionic form) of gamma-hydroxybutyrate cannot exist in solid form. (SMF ¶ C-7). Further, Jazz has admitted the same in Court, conceding that "for the '079 and '782, we don't have an infringement theory if [Avadel's] construction gets adopted. . . ." (SMF ¶ C-9).

D. No Disputed Issue of Fact Exists on Non-Infringement of the Sustained Release Patents under Avadel's Proposed Construction

Various limitations of the Sustained Release patents require that the immediate release or sustained release portions "release[] . . . its gamma-hydroxybutyrate" when tested in de-ionized water. *See* disc. *supra* at V.A.1. Yet, as discussed above Avadel's Lumryz™ product is a solid dosage form, which Jazz has asserted cannot contain any unbound gamma-hydroxybutyrate anion. (SMF ¶¶ C-4, C-7). Therefore, even if the controlled release particles in Lumryz™ are considered to be the claimed "sustained release portion" of the formulation, they do not contain—and thus cannot release—any gamma-hydroxybutyrate and cannot infringe the Asserted Claims of the Sustained Release Patents as a matter of law.

Jazz's suggestion that Avadel's expert indicated that Lumryz™ would still release gamma-hydroxybutyrate (SMF ¶ C-10) at some point does not raise any disputed issues of material fact. Jazz's theory is predicated on Dr. Klibanov's testimony that sodium gamma-hydroxybutyrate dissociates after being released from the solid dosage form, but that theory fails based on three undisputed facts.

First, Lumryz™ is a solid dosage form, which Jazz's counsel conceded could not contain "gamma-hydroxybutyrate," as construed by Avadel. (SMF ¶¶ C-4, C-7).

Second, the subject claim limitations require that the "sustained release portion [or formulation] release[]"certain percentages of "***its*** gamma-hydroxybutyrate" under the recited conditions. (SMF ¶ C-11). The plain meaning of "its" in the context of the pertinent claim limitations is "belonging to or relating to something that has already been mentioned." (SMF ¶ C-12). Thus, to release "its gamma-hydroxybutyrate," the formulation must release gamma-hydroxybutyrate contained within it, not simply release a salt that later forms gamma-hydroxybutyrate. (SMF ¶ C-15).

Third, both experts (Drs. Klibanov and Little) agree that the relevant release is the ***one from the formulation into the media***. (SMF ¶¶ C-13, C-14). But there is no dispute that Avadel's Lumryz™ formulation dissolves, it "releases" the salt, sodium gamma-hydroxybutyrate, not the gamma-hydroxybutyrate anion under the claimed testing conditions. (SMF ¶¶ C-10, C-13, C-14). In sum, there is no dispute that Lumryz™ is a solid dosage form containing sodium gamma-hydroxybutyrate, not the gamma-hydroxybutyrate anion. There is also no dispute that the claims require that gamma-hydroxybutyrate contained within the formulation be released from the formulation when it is placed in the dissolution media. Lumryz™ cannot infringe as a matter of law if Avadel's construction is adopted, because it does not release any gamma-hydroxybutyrate anion, it releases the salt, sodium gamma-hydroxybutyrate. Based on these facts, if Avadel's construction of "gamma-hydroxybutyrate" is adopted, Avadel respectfully submits that summary judgment of non-infringement of the Sustained Release patents should be granted.

AVADEL'S *DAUBERT* MOTIONS

VI. MOTION TO EXCLUDE EXPERT TESTIMONY OF MARK RAINEY, PH.D

Jazz's damages expert Dr. Mark Rainey engages in an improper reasonable royalty analysis

[redacted]

A. Factual Background

Dr. Rainey offers what he describes as a reasonable royalty opinion, and thus he ostensibly considered the *Georgia-Pacific* factors and the hypothetical negotiation. [redacted]

[redacted]

[redacted]

B. The Court Should Exclude Dr. Rainey's [redacted]

The hypothetical negotiation that Dr. Rainey claims to have considered "assumes a voluntary agreement will be reached between a willing licensor and a willing licensee, with validity and infringement of the patent not being disputed." *LaserDynamics, Inc. v. Quanta Computer, Inc.*, 694 F.3d 51, 77 (Fed. Cir. 2012). The voluntary nature of the hypothetical negotiation is important, and courts have repeatedly excluded expert testimony that relies too heavily on what might happen in a coercive situation, such as where an expert tries to rely on settlement agreements "that are tainted by the coercive environment of patent litigation are unsuitable to prove a reasonable royalty." *Id.*; *see also, e.g.*, *M2M Sols. LLC v. Enfora, Inc.*, 167 F. Supp. 3d 665, 678 (D. Del. 2016) (explaining that a coercive litigation settlement provides "a drastically different backdrop than the hypothetical negotiation involving two willing licensors"). As another example, courts will exclude opinions that start with a prior unaccepted offer made by

[9] [redacted]

the patentee in anticipation of litigation, because an offer made with the condition that the accused infringer accept it or face patent litigation is not tied to the value of the invention—it is tied to the threat of enforcement. *See MiiCs & Partners, Inc. v. Funai Elec. Co.*, No. CV 14-804-RGA, 2017 WL 6268072, at *4 (D. Del. Dec. 7, 2017) ("Litigation–influenced offers, like settlement agreements, are less likely to reflect the value of the claimed invention.").

Dr. Rainey's opinions suffer from the same flawed reasoning. [redacted] *In re Koninklijke Philips Pat. Litig.*, No. 18-CV-01885-HSG, 2020 WL 7398647, at *9 (N.D. Cal. Apr. 13, 2020) (excluding as too one-sided an opinion that relied on a licensing program with rates that the patentee had advertised but not successfully obtained).

[redacted] *Nordock Inc. v. Sys. Inc.*, No. 11-C-118, 2013 WL 989864 (E.D. Wis. Mar. 13, 2013). There, design patentee Nordock's expert Smith claimed that the defendant would pay Nordock 100% of its lost sales in part because the patentee "'*would never have been willing* to license its patents.'" *Id.* at *8. The court explained that "[a] reasonable royalty requires willing parties and a balancing of their interests. Smith's reliance on the 100% royalty figure does not reflect Nordock being a willing party or that he engaged in any balancing of the parties' interests." *Id.* [redacted]

[redacted]

[redacted]

C. Conclusion

Dr. Rainey's opinions [redacted] should be excluded.

VII. MOTION TO EXCLUDE EXPERT TESTIMONY OF CHRISTIAN MORETON PH.D

Jazz's expert Dr. Christian Moreton's opinions on written description support for the asserted claims of the Sustained Release Patents should be excluded at trial because they are based on flawed methodology. Specifically, Dr. Moreton improperly relied on the issued claims for written description support, even though those claims long post-date the priority date.

"To satisfy the written description requirement, a patent's specification must reasonably convey to those skilled in the art that the inventor had possession of the claimed subject matter *as of the filing date*." *Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, 38 F.4th 1013, 1016 (Fed. Cir. 2022) (emphasis added) (citations and quotations omitted). Claims filed with the original application are part of the specification and may provide written description support for later, amended claims. *See Crown Packaging Tech. v. Ball Metal Beverage*, 635 F.3d 1373, 1380 (Fed. Cir. 2011) ("Original claims are part of the specification."); *In re Downing*, 754 F. App'x 988, 994-95 (Fed. Cir. 2018) (emphasis in original) ("Because the adequacy of the written description is judged 'as of the filing date,' each claim limitation must be supported by the *originally* filed specification." (emphasis in original)). The same is not true, however, of later amended/issued claims, which did not exist as of the date of the invention and are not part of the specification and

what it discloses for written description purposes.[10] *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1329 (Fed. Cir. 2000) (affirming district court opinion as "articulating the correct legal principles that the amended claims define the invention, that the support for the invention must be found in the specification as filed, and that the amended claims could not be used to provide that [written description] support."). Such later-added claims shed no light on the critical question of whether the inventors had in possession as of the priority date the subject matter they would later claim, or whether, as Avadel alleges here, the inventors did not possess the subject matter on which Jazz's lawyers would later file claims.

Jazz filed the '369 application (to which the Sustained Release Patents claim priority) on March 24, 2011, but ultimately abandoned it. 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 (ultimately issued as the '488 patent) on July 2, 2018, and immediately cancelled all 108 original claims of the '369 application, replacing the original claims with different claims. Ex. 7 (JPION00000261) at -263-268. Dr. Moreton explicitly considered the later-added issued claims themselves as a basis for his opinion that the asserted claims of the Sustained Release patents are supported by sufficient written description. For example, in his expert report responding to the opinion of Avadel's expert, Dr. Charman's opinion that the Sustained Release Patent claims lack sufficient written description support, Dr. Moreton opined that "Dr. Charman's

[10] Here, the original claims of the priority application for the Sustained Release Patents differ considerably in scope from the issued claims. *Compare* claim 1 of Appl. No. 13/071,369 (the "'369 application") (requiring a "controlled release formulation comprising at least one drug selected from GHB and pharmaceutically acceptable salts, hydrates, tautomers, solvates and complexes of GHB") *with* claim 1 of '488 patent (requiring "a formulation comprising immediate release and sustained release portions . . . the sustained release portion comprises a functional coating and a core, wherein the functional coating is deposited over the core . . . and wherein the functional coating comprises one or more methacrylic acid-methylmethacrylate co-polymers that are from about 20% to about 50% by weight of the functional coating").

position appears to overlook ***a key aspect of the claims . . . and one that greatly supports the disclosure of microparticles.*** In particular, each of the Sustained Release Asserted Claims requires not only the functional coating to which Dr. Charman refers . . . 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***." Ex. 13 (May 2, 2023 Moreton Rebuttal Expert Report) ¶ 44 (first and second emphasis added) (citation omitted).) Dr. Moreton again relied on the issued claims as their own written description support, when he opined that "[a] POSA would understand that (in view of the ***claims'*** other compositional requirements (i.e., the functional coating and core)) if the immediate release portion is a powder, liquid, or suspension, then that immediate release portion comprises microparticles or microparticles that were then dissolved or suspended." *Id.* ¶ 47.

Because Dr. Moreton's opinions are based on a flawed application of the law of written description and improperly rely on the issued claims themselves for written description support, they should be excluded on *Daubert* grounds. *See, e.g., In re ChanBond, LLC Patent Litig.*, No. 15-842-RGA, 2019 WL 6910284, at *6 (D. Del. Dec. 19, 2019) ("exclud[ing] as unreliable Ms. Quigley's opinions regarding written description" because "she did not conduct a proper written description assessment").

VIII. MOTION TO EXCLUDE EXPERT TESTIMONY OF STEVEN LITTLE PH.D

The '079 patent claims require administration of an oxybate formulation having, *inter alia*, a "controlled release" portion, which the Court construed to mean "[c]ompositions characterized by having at least one of the active components having a release over a period of at least about 2 to about 8 hours." D.I. 229 at 9. The '782 claims recite a formulation with, *inter alia*, "modified release particles." *Id.* at 12. The Court construed "modified release particles" to mean "particles containing an active pharmaceutical ingredient with a release profile that is different from that of

an immediate release particle." *Id.* During claim construction, the parties disputed whether the claims at issue covered only resinate formulations or whether they ***also*** encompassed non-resinate formulations. D.I. 229 at 9, 12. Jazz prevailed. *Id*. That means that the claims of both patents encompass any formulation having a coating or other material that can control or modify release in the manner construed by the Court. Given the broad genus of materials and combinations thereof potentially encompassed by the claims, Avadel contends that the claims are invalid for lack of enablement.

Because the claims have been construed, at Jazz's insistence, to include both resinate and non-resinate formulations, the shared specification of the '782 and '079 patents must enable a POSA to control or modify oxybate release utilizing, *inter alia*, non-resinate techniques. Dr. Little offers a single paragraph enablement opinion on this issue (containing only a single conclusory sentence laying out his "analysis"):

> Dr. Charman opines that the asserted claims are not enabled because "[t]here is no information in the specification that could teach a POSA to make and use non-resinate controlled release components that could control release of oxybate over a period of about 2 to about 8 hours, and be administered as part of an oxybate formulation that could be administered in a single daily dose to a patient for treatment of narcolepsy." Charman ¶ 736. For this opinion, Dr. Charman refers to his written description analysis and states that, "[a]s explained above, every embodiment and description in the specification of the '079 patent is directed to resinates, and there are no detailed disclosures of non-resinate formulations of a controlled release component." Charman ¶ 736. As I explained above, the '079 patent contains a written description of nonresinate forms of a "controlled release component." *See supra* at ¶¶ 21-42. In my opinion, that written description would teach a POSA how to make and use the claimed inventions, including non-resinate controlled release components. Further, as described above, a POSA would understand that the oxybate anion would need to be bound to something and the '079 patent contains multiple disclosures of oxybate salts and oxybate ion exchange resins. *See supra* at ¶¶ 65-67. Consequently, in my opinion, the '079 patent specification describes formulations of the gamma-hydroxybutyrate anion bound to either a cation or an ion exchange resin.

Little Rebuttal Rpt. ¶ 79. Paragraphs 21-42 of Dr. Little's Report cite back to Allphin 2012 (which ultimately issued in the form of the Sustained Release patents) as support.[11] Dr. Little then incorporates Dr. Moreton's opinions on Allphin 2012 to conclude that the specification describes non-resinate forms of controlled/modified release oxybate formulations.

The newly amended Federal Rule of Evidence 702 (which will be in effect as of the completion of the briefing on this motion) sets out the requirements for expert witness testimony and states:

(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 expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

The Third Circuit has explained that under *Daubert*, "the district court acts as a gatekeeper, preventing opinion testimony that does not meet the requirements of qualification, reliability and fit from reaching the jury. *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404–05 (3d Cir. 2003) (footnote and internal citations omitted).

Dr. Little's enablement opinion does not come close to meeting this standard. The single paragraph cited above contains a single sentence of "analysis," which merely states Dr. Little's conclusory opinion. And even that wholly conclusory sentence does not address the "undue experimentation" aspect of the inquiry. Little Rebuttal Rpt. at ¶ 79 ("In my opinion, that written

[11] As explained above, paragraphs 21-28 of Dr. Little's written description analysis are dedicated to explaining that the claims encompass non-resinate controlled/modified release oxybate formulations, which is not in dispute. Paragraphs 29-42 allege that Allphin 2012 is incorporated by reference into the specification of the '079 and '782 patents, and relies exclusively on Allphin 2012 for the substantive written description of non-resinate controlled/modified release particles.

description would teach a POSA how to make and use the claimed inventions, including non-resinate controlled release components."). Nor does Dr. Little recite the facts he evaluated nor the methods he used that would allow a finder of fact to determine whether his analysis was based on "sufficient facts or data," is the "product of reliable principles and methods," or "reflects a reliable application of the principles and methods to the facts of the case." Such *ipse dixit* does not satisfy Rule 702 and should be excluded. *Adasa Inc. v. Avery Dennison Corp.*, 55 F.4th 900, 915 (Fed. Cir. 2022) (affirming district court decision to exclude "conclusory opinions" that "were inadequate to carry [the sponsoring party's] burden.").

In addition to failing to meet the Rule 702 standard, Dr. Little's opinions are also contrary to established Federal Circuit precedent. Section 112 mandates that the enabling disclosure of the novel aspects of the invention come from the specification, "not the knowledge of one skilled in the art." *Creative Kingdoms, LLC v. ITC*, 588 Fed. App'x. 993, 995 (Fed. Cir. 2014); *see also Enzo Life Scis., Inc. v. Roche Molecular Sys*., 928 F.3d 1340, 1346 (Fed. Cir. 2019) ("The deficiencies in the description as to enablement cannot be cured in this case by looking to the knowledge of those skilled in the art at the time of the invention…a patentee cannot simply rely on the knowledge of a [POSA] to serve as a substitute for the missing information in the specification."); *ALZA Corp. v. Andrx Pharms., LLC*, 603 F.3d 935, 941 (Fed. Cir. 2010). Dr. Little's single paragraph opinion ignores this black letter law and improperly relies on what was known in the art. Dr. Little's opinion regarding the enablement of non-resinate embodiments of the claimed inventions should therefore be excluded at trial. *Inline Connection Corp. v. AOL Time Warner Inc.*, No. CIVA 02-272MPT, 2007 WL 275928 at *5 (D. Del. Jan. 29, 2007) (excluding expert testimony as "not reliable" because the expert "did not conduct a proper enablement analysis.").

For these reasons, Dr. Little should not be able to testify to the jury that the non-resinate embodiments of the asserted claims are enabled.

Dated: November 30, 2023

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